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

**FORM 10-Q**

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

**For the quarterly period ended September 30, 2016**

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

**Commission file number: 000-51476**

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**20-2903526**  
(I.R.S. Employer  
Identification Number)

**248 Route 25A, No. 2**  
**East Setauket, New York 11733**  
(Address of principal executive offices)

**(631) 942-7959**  
(Registrant's telephone number, including area code)

**Not applicable**  
(Former name, former address and former fiscal year, if changed since last report)

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 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, or a non-accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Large accelerated filer   
Non-accelerated filer

Accelerated filer   
Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

As of November 1, 2016, the Company had 47,875,814 shares of common stock, \$0.0001 par value, issued and outstanding.

Documents incorporated by reference: None

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**LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
AND SUBSIDIARY**

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## Forward-Looking Statements

This Quarterly Report on Form 10-Q of Lixte Biotechnology Holdings, Inc. (the “Company”) contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, and Section 21E of the Securities Exchange Act of 1934. These might include statements regarding the Company’s financial position, business strategy and other plans and objectives for future operations, and assumptions and predictions about future product demand, supply, manufacturing, costs, marketing and pricing factors are all forward-looking statements. These statements are generally accompanied by words such as “intend,” “anticipate,” “believe,” “estimate,” “potential(ly),” “continue,” “forecast,” “predict,” “plan,” “may,” “will,” “could,” “would,” “should,” “expect” or the negative of such terms or other comparable terminology. The Company believes that the assumptions and expectations reflected in such forward-looking statements are reasonable, based on information available to it on the date hereof, but the Company cannot provide assurances that these assumptions and expectations will prove to have been correct or that the Company will take any action that the Company may presently be planning. These forward-looking statements are inherently subject to known and unknown risks and uncertainties. Actual results or experience may differ materially from those expected, anticipated or implied in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, regulatory policies or changes thereto, available cash, research and development results, competition from other similar businesses, and market and general economic factors. This discussion should be read in conjunction with the condensed consolidated financial statements and notes thereto included in Item 1 of this Quarterly Report on Form 10-Q and the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2015, including the section entitled “Item 1A. Risk Factors”. The Company does not intend to update or revise any forward-looking statements to reflect new information, future events or otherwise.

**PART I - FINANCIAL INFORMATION**

**ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
AND SUBSIDIARY**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

	<u>September 30, 2016</u>	<u>December 31, 2015</u>
	(Unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash	\$ 669,771	\$ 25,281
Money market funds	—	104,095
License fee receivable	—	200,000
Advances on research and development contract services, including \$181,510 and \$185,392 made to or through Theradex at September 30, 2016 and December 31, 2015, respectively	192,220	207,677
Prepaid expenses and other current assets	71,570	60,922
Total current assets	<u>933,561</u>	<u>597,975</u>
Total assets	<u>\$ 933,561</u>	<u>\$ 597,975</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 112,107	\$ 159,076
Research and development contract liabilities, including \$46,982 and \$88,162 to Theradex at September 30, 2016 and December 31, 2015, respectively	83,470	124,566
Dividend payable on Series A Convertible Preferred Stock	—	2,000
Total current liabilities	<u>195,577</u>	<u>285,642</u>
Commitments and contingencies		
Stockholders' equity:		
Series A Convertible Preferred Stock, \$0.0001 par value, \$10.00 per share stated value, \$50.00 per share redemption value; 350,000 shares and 175,000 shares authorized, issued and outstanding at September 30, 2016 and December 31, 2015, respectively; aggregate redemption values of \$17,500,000 and \$8,750,000 at September 30, 2016 and December 31, 2015, respectively; liquidation preference based on assumed conversion into common shares; 4,375,000 shares and 2,187,500 shares of common stock issuable upon conversion at September 30, 2016 and December 31, 2015, respectively	3,500,000	1,750,000
Common stock, \$0.0001 par value; authorized – 100,000,000 shares; issued and outstanding – 47,875,814 shares at September 30, 2016 and December 31, 2015	4,787	4,787
Additional paid-in capital	17,423,941	17,129,815
Accumulated deficit	(20,190,744)	(18,572,269)
Total stockholders' equity	<u>737,984</u>	<u>312,333</u>
Total liabilities and stockholders' equity	<u>\$ 933,561</u>	<u>\$ 597,975</u>

See accompanying notes to condensed consolidated financial statements (unaudited).

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
AND SUBSIDIARY**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
(Unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Licensing revenues	\$ —	\$ —	\$ —	\$ —
<b>Costs and expenses:</b>				
General and administrative costs, including \$6,250 and \$6,250 to related parties for the three months ended September 30, 2016 and 2015, respectively, and \$88,889 and \$93,651 to related parties for the nine months ended September 30, 2016 and 2015, respectively	170,272	155,307	560,399	615,615
Research and development costs, including \$130,820 and \$162,425 to Theradex for the three months ended September 30, 2016 and 2015, respectively, and \$340,746 and \$670,540 to Theradex for the nine months ended September 30, 2016 and 2015, respectively	476,805	624,405	1,058,248	1,416,940
Total costs and expenses	<u>647,077</u>	<u>779,712</u>	<u>1,618,647</u>	<u>2,032,555</u>
Loss from operations	(647,077)	(779,712)	(1,618,647)	(2,032,555)
Interest income	141	25	172	71
Fair value of warrant extensions	—	—	—	(34,016)
Fair value of warrant discount	—	—	—	(171,757)
Net loss	<u>(646,936)</u>	<u>(779,687)</u>	<u>(1,618,475)</u>	<u>(2,238,257)</u>
Dividend on Series A Convertible Preferred Stock	—	—	—	—
Net loss attributable to common stockholders	<u>\$ (646,936)</u>	<u>\$ (779,687)</u>	<u>\$ (1,618,475)</u>	<u>\$ (2,238,257)</u>
Net loss per common share – basic and diluted	<u>\$ (0.01)</u>	<u>\$ (0.02)</u>	<u>\$ (0.03)</u>	<u>\$ (0.05)</u>
Weighted average common shares outstanding – basic and diluted	<u>47,875,814</u>	<u>46,060,597</u>	<u>47,875,814</u>	<u>46,428,767</u>

See accompanying notes to condensed consolidated financial statements (unaudited).

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
AND SUBSIDIARY**

**CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY  
(Unaudited)**

Nine Months Ended September 30, 2016

	<b>Series A Convertible Preferred Stock</b>		<b>Common Stock</b>		<b>Additional Paid-in Capital</b>	<b>Accumulated Deficit</b>	<b>Total Stockholders' Equity</b>
	<b>Shares</b>	<b>Amount</b>	<b>Shares</b>	<b>Par Value</b>			
Balance, December 31, 2015	175,000	\$ 1,750,000	47,875,814	\$ 4,787	\$ 17,129,815	\$ (18,572,269)	\$ 312,333
Sale of Series A Convertible Preferred Stock	175,000	1,750,000	—	—	—	—	1,750,000
Stock-based compensation expense	—	—	—	—	294,126	—	294,126
Net loss	—	—	—	—	—	(1,618,475)	(1,618,475)
Balance, September 30, 2016	<u>350,000</u>	<u>\$ 3,500,000</u>	<u>47,875,814</u>	<u>\$ 4,787</u>	<u>\$ 17,423,941</u>	<u>\$ (20,190,744)</u>	<u>\$ 737,984</u>

See accompanying notes to condensed consolidated financial statements (unaudited).

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
AND SUBSIDIARY**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
(Unaudited)**

	<b>Nine Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (1,618,475)	\$ (2,238,257)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Stock-based compensation expense included in -		
General and administrative costs	105,334	157,370
Research and development costs	188,792	269,027
Fair value of warrant -		
Extensions	—	34,016
Discounts	—	171,757
<b>Changes in operating assets and liabilities:</b>		
<b>(Increase) decrease in -</b>		
Licensing fee receivable	200,000	—
Advances on research and development contract services	15,457	13,893
Prepaid expenses and other current assets	(10,648)	(18,126)
<b>Increase (decrease) in -</b>		
Accounts payable and accrued expenses	(46,969)	(1,350)
Research and development contract liabilities	(41,096)	42,812
<b>Net cash used in operating activities</b>	<b>(1,207,605)</b>	<b>(1,568,858)</b>
<b>Cash flows from investing activities:</b>		
<b>(Increase) decrease in money market funds</b>	104,095	(310,388)
<b>Net cash provided by (used in) investing activities</b>	<b>104,095</b>	<b>(310,388)</b>
<b>Cash flows from financing activities:</b>		
Proceeds from sale of Series A Convertible Preferred Stock	1,750,000	1,750,000
Payment of accrued dividend on Series A Convertible Preferred Stock	(2,000)	—
Cash payments made for costs incurred in connection with sale of Series A Convertible Preferred Stock	—	(12,608)
Proceeds from exercise of warrants	—	315,000
<b>Net cash provided by financing activities</b>	<b>1,748,000</b>	<b>2,052,392</b>
<b>Cash:</b>		
Net increase	644,490	173,146
Balance at beginning of period	25,281	44,411
<b>Balance at end of period</b>	<b>\$ 669,771</b>	<b>\$ 217,557</b>
<b>Supplemental disclosures of cash flow information:</b>		
<b>Cash paid for -</b>		
Interest	\$ —	\$ —
Income taxes	\$ —	\$ —
<b>Non-cash financing activities:</b>		
Conversion of advances due to Chairman and major stockholder into common stock	\$ —	\$ 92,717

See accompanying notes to condensed consolidated financial statements (unaudited).

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(Unaudited)**

**Three Months and Nine Months Ended September 30, 2016 and 2015**

**1. Organization and Basis of Presentation**

The condensed consolidated financial statements of the Lixte Biotechnology Holdings, Inc., a Delaware corporation (“Holdings”), including its wholly-owned Delaware subsidiary, Lixte Biotechnology, Inc. (“Lixte”) (collectively, the “Company”), at September 30, 2016, and for the three months and nine months ended September 30, 2016 and 2015, are unaudited. In the opinion of management of the Company, all adjustments (including normal recurring adjustments) have been made that are necessary to present fairly the financial position of the Company as of September 30, 2016, and the results of its operations for the three months and nine months ended September 30, 2016 and 2015, and its cash flows for the nine months ended September 30, 2016 and 2015. Operating results for the interim periods presented are not necessarily indicative of the results to be expected for a full fiscal year. The consolidated balance sheet at December 31, 2015 has been derived from the Company’s audited financial statements at such date.

The statements and related notes have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the “SEC”). Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been omitted pursuant to such rules and regulations. These financial statements should be read in conjunction with the financial statements and other information included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2015, as filed with the SEC.

**2. Business**

The Company is a drug discovery company that uses biomarker technology to identify enzyme targets associated with serious common diseases and then designs novel compounds to attack those targets. The Company’s product pipeline encompasses two major categories of compounds at various stages of pre-clinical and clinical development that the Company believes have broad therapeutic potential not only for cancer but also for other debilitating and life-threatening diseases.

The Company’s activities are subject to significant risks and uncertainties, including the need for additional capital, as described below. The Company has not yet commenced any sustainable revenue-generating operations, does not have any positive cash flows from operations, and is dependent on equity capital to fund its operating requirements.

The Company’s common stock is traded on the OTCQB operated by the OTC Markets under the symbol “LIXT”.

***Going Concern***

The Company’s condensed consolidated financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has not generated any sustainable revenues from operations to date, and does not expect to do so in the foreseeable future. The Company has experienced recurring operating losses and negative operating cash flows since inception, and has financed its working capital requirements during this period primarily through the recurring sale of its equity securities and the exercise of outstanding warrants. As a result, management has concluded that there is substantial doubt about the Company’s ability to continue as a going concern. In addition, the Company’s independent registered public accounting firm, in their report on the Company’s consolidated financial statements for the year ended December 31, 2015, has expressed substantial doubt about the Company’s ability to continue as a going concern.

The Company’s ability to continue as a going concern is dependent upon its ability to raise additional equity capital to fund its research and development activities and to ultimately achieve sustainable operating revenues and profits. The Company’s consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties.



Because the Company is currently engaged in research at a relatively early stage, it will likely take a significant amount of time to develop any product or intellectual property capable of generating sustainable revenues. Accordingly, the Company's business is unlikely to generate any sustainable operating revenues in the next several years, and may never do so. In addition, to the extent that the Company is able to generate revenues through licensing its technologies or through product sales, there can be no assurance that the Company will be able to achieve positive earnings and operating cash flows.

At September 30, 2016, the Company had cash and money market funds aggregating \$669,771. Subsequent to September 30, 2016, the Company expects to receive a refund of advances made to or through Theradex Systems, Inc. of \$181,510 upon the administrative closure of the Phase 1 clinical trial of LB-100 (which was closed to further patient enrollment in April 2016). Accordingly, at September 30, 2016, the Company believes that it has sufficient resources to complete the analysis of the clinical data, reconcile and pay the remaining costs owed to the participating clinical sites, and prepare and submit the required Clinical Study Report to the U.S. Food and Drug Administration ("FDA") on the completed Phase 1 clinical trial of LB-100, as well as to fund the Company's ongoing operating expenses, including maintaining its patent portfolio, through at least March 2017.

The amount and timing of future cash requirements will depend on the pace and design of the Company's clinical trial program. As market conditions present uncertainty as to the Company's ability to secure additional funds, there can be no assurances that the Company will be able to secure additional financing on acceptable terms, or at all, as and when necessary to continue to conduct operations. If cash resources are insufficient to satisfy the Company's ongoing cash requirements, the Company would be required to scale back or discontinue its technology and product development programs and/or clinical trials, or obtain funds, if available (although there can be no certainty), through strategic alliances that may require the Company to relinquish rights to certain of its compounds, or to discontinue its operations entirely.

### **3. Summary of Significant Accounting Policies**

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

The accompanying condensed consolidated financial statements of the Company are prepared in accordance with United States generally accepted accounting principles ("GAAP") and include the financial statements of Holdings and its wholly-owned subsidiary, Lixte. Intercompany balances and transactions have been eliminated in consolidation.

#### ***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Significant estimates include accounting for potential liabilities and the assumptions utilized in valuing stock-based compensation issued for services. Actual results could differ from those estimates.

#### ***Cash Concentrations***

The Company maintains cash balances with financial institutions in federally-insured accounts. The Company may periodically have cash balances in banks in excess of FDIC insurance limits. The Company maintains its accounts with financial institutions with high credit ratings. The Company has not experienced any losses to date resulting from this practice.

#### ***Research and Development***

Research and development costs consist primarily of fees paid to consultants and outside service providers, patent fees and costs, and other expenses relating to the acquisition, design, development and testing of the Company's treatments and product candidates.

Research and development costs are expensed ratably over the life of the underlying contracts, unless the achievement of milestones, the completion of contracted work, or other information indicates that a different expensing schedule is more appropriate.

The Company retained Theradex Systems, Inc. (“Theradex”), an international contract research organization (“CRO”) that provides professional services for the clinical research and development of pharmaceutical compounds, to be responsible for managing and administering the Company’s Phase 1 clinical trial of LB-100. The costs of the Phase 1 clinical trial of LB-100 that are being paid through Theradex are recorded and expensed based upon the documentation provided by the CRO.

Payments made pursuant to research and development contracts are initially recorded as advances on research and development contract services in the Company’s balance sheet and then charged to research and development costs in the Company’s statement of operations as those contract services are performed. Expenses incurred under research and development contracts in excess of amounts advanced are recorded as research and development contract liabilities in the Company’s balance sheet, with a corresponding charge to research and development costs in the Company’s statement of operations. The Company reviews the status of its research and development contracts on a quarterly basis.

At September 30, 2016, the Company had made advances to or through Theradex aggregating \$181,510, which are expected to be refunded to the Company upon completion of the Company’s Phase 1 clinical trial of LB-100.

#### ***Patent Costs***

Due to the significant uncertainty associated with the successful development of one or more commercially viable products based on the Company’s research efforts and any related patent applications, all patent costs, including patent-related legal and filing fees, are expensed as incurred. Patent costs were \$140,855 and \$139,485 for the three months ended September 30, 2016 and 2015, respectively, and \$338,938 and \$351,711 for the nine months ended September 30, 2016 and 2015, respectively. Patent costs are included in research and development costs in the Company’s condensed consolidated statements of operations.

#### ***Accounting for Preferred Stock***

The Company accounts for preferred stock as either equity or debt, depending on the specific characteristics of the security issued. The Series A Convertible Preferred Stock issued by the Company in January 2016 and March 2015 has been classified in stockholders’ equity, as described at Note 5.

#### ***Concentration of Risk***

The Company periodically contracts with directors, including companies controlled by or associated with directors, to provide consulting services related to the Company’s research and development and clinical trial activities. Agreements for these services can be for a specific time period (typically one year) or for a specific project or task, and can include both cash and non-cash compensation. The only such contract that represents 10% or more of general and administrative or research and development costs is described below.

On September 21, 2012, the Company entered into a work order agreement with Theradex, the CRO responsible for the clinical development of the Company’s lead anti-cancer compound LB-100, to manage and administer the Phase 1 clinical trial of LB-100. The Phase 1 clinical trial of LB-100, which began during April 2013 with the entry of patients into the clinical trial, was carried out by nationally recognized comprehensive cancer centers. As the patient accrual goal was reached in April 2016, the clinical trial was closed to further patient enrollment at that time. All patients completed treatment with LB-100 and were off study by the end of May 2016. The Company estimates that it will continue to incur costs through December 2016 to complete the analysis of the clinical data, reconcile and pay the remaining costs owed to the participating clinical sites, and prepare and submit the required Clinical Study Report to the FDA on the completed Phase 1 clinical trial of LB-100.

The Phase 1 clinical trial was estimated to cost a total of approximately \$2,200,000, with such payments expected to be allocated approximately 60% for services provided by Theradex and approximately 40% for pass-through costs for clinical center laboratory costs and investigator costs over the life of the clinical trial. Total costs charged to operations through September 30, 2016 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, aggregated \$2,040,867.

During the three months ended September 30, 2016 and 2015, \$130,820 and \$162,425, respectively, of such clinical trial costs were incurred, representing approximately 27% and 26% of research and development costs for such periods. During the nine months ended September 30, 2016 and 2015, the Company incurred \$340,746 and \$670,540, respectively, of such clinical trial costs, representing approximately 32% and 47% of research and development costs for such periods. Costs pursuant to this agreement are included in research and development costs in the Company’s condensed consolidated statements of operations.

## ***Income Taxes***

The Company accounts for income taxes under an asset and liability approach for financial accounting and reporting for income taxes. Accordingly, the Company recognizes deferred tax assets and liabilities for the expected impact of differences between the financial statements and the tax basis of assets and liabilities.

The Company has elected to deduct research and development costs on a current basis for federal income tax purposes. For federal tax purposes, start-up and organization costs were deferred until January 1, 2008 at which time the Company began to amortize such costs over a 180-month period.

The Company records a valuation allowance to reduce its deferred tax assets to the amount that is more likely than not to be realized. In the event the Company was to determine that it would be able to realize its deferred tax assets in the future in excess of its recorded amount, an adjustment to the deferred tax assets would be credited to operations in the period such determination was made. Likewise, should the Company determine that it would not be able to realize all or part of its deferred tax assets in the future, an adjustment to the deferred tax assets would be charged to operations in the period such determination was made.

The Company is subject to U.S. federal income taxes and income taxes of various state tax jurisdictions. As the Company's net operating losses have yet to be utilized, all previous tax years remain open to examination by Federal authorities and other jurisdictions in which the Company currently operates or has operated in the past. The Company had no unrecognized tax benefits as of September 30, 2016 and 2015 and does not anticipate any material amount of unrecognized tax benefits within the next 12 months.

The Company accounts for uncertainties in income tax law under a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns as prescribed by GAAP. The tax effects of a position are recognized only if it is "more-likely-than-not" to be sustained by the taxing authority as of the reporting date. If the tax position is not considered "more-likely-than-not" to be sustained, then no benefits of the position are recognized. As of September 30, 2016, the Company had not recorded any liability for uncertain tax positions. In subsequent periods, any interest and penalties related to uncertain tax positions will be recognized as a component of income tax expense.

## ***Stock-Based Compensation***

The Company periodically issues common stock and stock options to officers, directors, Scientific Advisory Committee members and consultants for services rendered. Options vest and expire according to terms established at the issuance date of each grant.

The Company accounts for stock-based payments to officers and directors by measuring the cost of services received in exchange for equity awards based on the grant date fair value of the awards, with the cost recognized as compensation expense on the straight-line basis in the Company's financial statements over the vesting period of the awards. The Company accounts for stock-based payments to Scientific Advisory Committee members and consultants by determining the value of the stock compensation based upon the measurement date at either (a) the date at which a performance commitment is reached or (b) at the date at which the necessary performance to earn the equity instruments is complete.

Stock grants, which are generally time vested, are measured at the grant date fair value and charged to operations ratably over the vesting period.

Stock options granted to members of the Company's Scientific Advisory Committee and to outside consultants are revalued each reporting period to determine the amount to be recorded as an expense in the respective period. As the stock options vest, they are valued on each vesting date and an adjustment is recorded for the difference between the value already recorded and the value on the date of vesting.

The fair value of common stock issued as stock-based compensation is determined by reference to the closing price of the Company's common stock on the date of issuance. The fair value of stock options granted as stock-based compensation is determined utilizing the Black-Scholes option-pricing model, and is affected by several variables, the most significant of which are the life of the equity award, the exercise price of the stock option as compared to the fair market value of the common stock on the grant date, and the estimated volatility of the common stock over the term of the equity award. Estimated volatility is based on the historical volatility of the Company's common stock. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. The fair market value of common stock is determined by reference to the quoted market price of the Company's common stock.

The Company recognizes the fair value of stock-based compensation awards in general and administrative costs and in research and development costs, as appropriate, in the Company's condensed consolidated statement of operations. The Company issues new shares of common stock to satisfy stock option exercises.

#### **Revenue Recognition**

The Company recognizes revenue when all four of the following criteria are met: (i) persuasive evidence that an arrangement exists; (ii) delivery of the products and/or services has occurred; (iii) the fees earned can be readily determined; and (iv) collectability of the fees is reasonably assured.

Revenues from milestone payments under license agreements are recognized when earned and the Company has no further performance obligations thereunder.

#### **Comprehensive Income (Loss)**

Components of comprehensive income or loss, including net income or loss, are reported in the financial statements in the period in which they are recognized. Comprehensive income or loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income (loss) and other comprehensive income (loss) are reported net of any related tax effect to arrive at comprehensive income (loss). The Company did not have any items of comprehensive income (loss) for the three months and nine months ended September 30, 2016 and 2015.

#### **Earnings (Loss) Per Share**

The Company's computation of earnings (loss) per share ("EPS") includes basic and diluted EPS. Basic EPS is measured as the income (loss) attributable to common stockholders divided by the weighted average common shares outstanding for the period. Diluted EPS is similar to basic EPS but presents the dilutive effect on a per share basis of potential common shares (e.g., preferred shares, warrants and stock options) as if they had been converted at the beginning of the periods presented, or issuance date, if later. Potential common shares that have an anti-dilutive effect (i.e., those that increase income per share or decrease loss per share) are excluded from the calculation of diluted EPS.

Net income (loss) attributable to common stockholders consists of net income or loss, as adjusted for preferred stock dividends declared, amortized or accumulated.

Loss per common share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the respective periods. Basic and diluted loss per common share is the same for all periods presented because all preferred shares, warrants and stock options outstanding are anti-dilutive.

At September 30, 2016 and 2015, the Company excluded the outstanding securities summarized below, which entitle the holders thereof to acquire shares of common stock, from its calculation of earnings per share, as their effect would have been anti-dilutive.

	<b>September 30,</b>	
	<b>2016</b>	<b>2015</b>
Series A Convertible Preferred Stock	4,375,000	2,187,500
Common stock options	9,100,000	8,250,000
Total	<u>13,475,000</u>	<u>10,437,500</u>

#### **Fair Value of Financial Instruments**

The authoritative guidance with respect to fair value established a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three levels, and requires that assets and liabilities carried at fair value be classified and disclosed in one of three categories, as presented below. Disclosure as to transfers in and out of Levels 1 and 2, and activity in Level 3 fair value measurements, is also required.

Level 1. Observable inputs such as quoted prices in active markets for an identical asset or liability that the Company has the ability to access as of the measurement date. Financial assets and liabilities utilizing Level 1 inputs include active-exchange traded securities and exchange-based derivatives.

Level 2. Inputs, other than quoted prices included within Level 1, which are directly observable for the asset or liability or indirectly observable through corroboration with observable market data. Financial assets and liabilities utilizing Level 2 inputs include fixed income securities, non-exchange based derivatives, mutual funds, and fair-value hedges.

Level 3. Unobservable inputs in which there is little or no market data for the asset or liability which requires the reporting entity to develop its own assumptions. Financial assets and liabilities utilizing Level 3 inputs include infrequently-traded non-exchange-based derivatives and commingled investment funds, and are measured using present value pricing models.

The Company determines the level in the fair value hierarchy within which each fair value measurement falls in its entirety, based on the lowest level input that is significant to the fair value measurement in its entirety. In determining the appropriate levels, the Company performs an analysis of the assets and liabilities at each reporting period end.

Money market funds are the only financial instrument that is measured and recorded at fair value on the Company's consolidated balance sheet on a recurring basis.

The carrying value of financial instruments (consisting of cash and accounts payable and accrued expenses) is considered to be representative of their respective fair values due to the short-term nature of those instruments.

#### ***Recent Accounting Pronouncements***

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2014-09 (ASU 2014-09), Revenue from Contracts with Customers. ASU 2014-09 will eliminate transaction- and industry-specific revenue recognition guidance under current GAAP and replace it with a principle based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for reporting periods beginning after December 15, 2017, with early adoption permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. Entities will be able to transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. The adoption of ASU 2014-09 is not expected to have any impact on the Company's financial statement presentation or disclosures.

In August 2014, the FASB issued Accounting Standards Update No. 2014-15 (ASU 2014-15), Presentation of Financial Statements – Going Concern (Subtopic 205-10). ASU 2014-15 provides guidance as to management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. In connection with preparing financial statements for each annual and interim reporting period, an entity's management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). Management's evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued (or at the date that the financial statements are available to be issued when applicable). Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or available to be issued). ASU 2014-15 is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The adoption of ASU 2014-15 is not expected to have any impact on the Company's financial statement presentation or disclosures.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02 (ASU 2016-02), Leases (Topic 842). ASU 2016-02 requires a lessee to record a right-of-use asset and a corresponding lease liability, initially measured at the present value of the lease payments, on the balance sheet for all leases with terms longer than 12 months, as well as the disclosure of key information about leasing arrangements. ASU 2016-02 requires recognition in the statement of operations of a single lease cost, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. ASU 2016-02 requires classification of all cash payments within operating activities in the statement of cash flows. Disclosures are required to provide the amount, timing and uncertainty of cash flows arising from leases. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. The Company has not yet evaluated the impact of the adoption of ASU 2016-02 on the Company's financial statement presentation and disclosures.

In March 2016, the FASB issued Accounting Standards Update No. 2016-09 (ASU 2016-09), Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. ASU 2016-09 requires, among other things, that all income tax effects of awards be recognized in the statement of operations when the awards vest or are settled. ASU 2016-09 also allows for an employer to repurchase more of an employee's shares than it can today for tax withholding purposes without triggering liability accounting and allows for a policy election to account for forfeitures as they occur. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early adoption is permitted for any entity in any interim or annual period. The adoption of ASU 2016-09 is not expected to have any impact on the Company's financial statement presentation or disclosures.

Management does not believe that any other recently issued, but not yet effective, authoritative guidance, if currently adopted, would have a material impact on the Company's financial statement presentation or disclosures.

#### **4. License Agreement**

Effective December 25, 2015, the Company entered into a License Agreement (the "TMU License Agreement") with Taipei Medical University ("TMU"), pursuant to which the Company granted to TMU an exclusive license of its lead anti-cancer compound LB-100 in the treatment of hepatocellular carcinoma ("HCC") in Asia. Under the TMU License Agreement, TMU will determine the effectiveness of LB-100 against HCC in clinical trials conducted in accordance with both Taiwan and United States regulatory requirements.

Under the TMU License Agreement, TMU is obligated to make non-refundable milestone payments to the Company of \$200,000 within ninety days from the effective date of December 25, 2015, \$50,000 upon the completion of the first Phase 1b/2 clinical trial, \$150,000 upon the completion of the first Phase 3 clinical trial, and \$200,000 upon the first filing of a New Drug Application ("NDA") with the FDA or a comparable non-United States regulatory authority. During the term of the TMU License Agreement, TMU will also pay earned royalties of 10% on cumulative net sales, and 10% to 15% on non-sale based sub-license income. A Phase 1b/2 clinical trial of LB-100 plus doxorubicin, to be managed and funded by TMU, is expected to commence during the first quarter of 2017.

The Company did not have any further performance obligations under the TMU License Agreement on the December 25, 2015 effective date. Accordingly, as the \$200,000 licensing fee was fully earned on the December 25, 2015 effective date, the Company recorded such amount as licensing revenues and license fee receivable at December 31, 2015. The Company received the \$200,000 milestone payment on March 18, 2016.

#### **5. Stockholders' Equity**

##### *Preferred Stock*

The Company has authorized a total of 10,000,000 shares of preferred stock, par value \$0.001 per share. On March 17, 2015, the Company filed a Certificate of Designations, Preferences, Rights and Limitations (the "Certificate of Designations") of its Series A Convertible Preferred Stock with the Delaware Secretary of State to amend the Company's certificate of incorporation. The Company designated 175,000 shares as Series A Convertible Preferred Stock, which are non-voting and are not subject to increase without the written consent of a majority of the holders of the Series A Convertible Preferred Stock or as otherwise set forth in the Certificate of Designations. The holders of each 175,000 share tranche of the Series A Convertible Preferred Stock are entitled to receive a per share dividend equal to 1% of the annual net revenue of the Company divided by 175,000, until converted or redeemed.

Effective January 28, 2016, the Series A Convertible Preferred Stock Certificate of Designations was amended to increase the authorized shares of Series A Convertible Preferred Stock from 175,000 shares to 350,000 shares. Accordingly, as of September 30, 2016, 9,650,000 shares of preferred stock were undesignated and may be issued with such rights and powers as the Board of Directors may designate.

Effective March 17, 2015, the Company entered into a Securities Purchase Agreement with a stockholder of the Company who owned 10.6% of the Company's issued and outstanding shares of common stock immediately prior to this transaction, pursuant to which such stockholder purchased 175,000 shares of the Company's Series A Convertible Preferred Stock at \$10.00 per share, representing an aggregate purchase price of \$1,750,000.

Effective January 21, 2016, the Company entered into a Securities Purchase Agreement with the holder of the Series A Convertible Preferred Stock previously sold on March 17, 2015, pursuant to which the Company sold an additional 175,000 shares of Series A Convertible Preferred Stock at \$10.00 per share, representing an aggregate purchase price of \$1,750,000.

Based on the Company's net revenues of \$200,000 for the year ended December 31, 2015, the Company recorded a dividend of \$2,000 on the shares of Series A Convertible Preferred Stock issued and outstanding at December 31, 2015. The dividend was recorded as of December 31, 2015 and was presented as a current liability in the Company's condensed consolidated balance sheet at such date. The dividend was paid in cash on May 1, 2016.

Each share of Series A Convertible Preferred Stock may be converted, at the option of the holder, into 12.5 shares of common stock (subject to customary anti-dilution provisions) and the Series A Convertible Preferred Stock is subject to mandatory conversion at the conversion rate in the event of a merger or sale transaction resulting in gross proceeds to the Company of at least \$21,875,000. The Series A Convertible Preferred Stock has a liquidation preference based on its assumed conversion into shares of common stock.

If fully converted, the Series A Convertible Preferred Stock sold in the March 17, 2015 closing would convert into 2,187,500 shares of common stock, representing an effective price per share of common stock of \$0.80. On March 17, 2015, the closing price of the Company's common stock was \$0.25 per share. If fully converted, the Series A Convertible Preferred Stock sold in the January 21, 2016 closing would also convert into 2,187,500 shares of common stock, representing an effective price per share of common stock of \$0.80. On January 21, 2016, the closing price of the Company's common stock was \$0.22 per share. The Company has the right to redeem the Series A Convertible Preferred Stock up to the fifth anniversary of the respective closing dates at a price per share equal to \$50.00. The Series A Convertible Preferred Stock has no right to cash, except for the payment of the aforementioned dividend based on the generation of revenues by the Company, and does not have any registration rights.

Based on the attributes of the Series A Convertible Preferred Stock described above, the Company has determined to account for the Series A Convertible Preferred Stock as a permanent component of stockholders' equity. Legal costs of \$12,608 incurred with respect to the issuance of the Series A Convertible Preferred Stock on March 17, 2015 were charged directly to additional paid-in capital. The Company did not incur any material costs with respect to the sale of the Convertible Preferred Stock on January 21, 2016.

#### ***Common Stock***

Effective March 17, 2015, the Company's Chairman and major stockholder converted advances due to him aggregating \$92,717 into 92,717 shares of the Company's common stock, reflecting an effective price of \$1.00 per share. On the effective date of the transaction, the closing price of the Company's common stock was \$0.25 per share. The Company accounted for this transaction as a capital transaction.

Information with respect to the issuance of common stock in connection with various stock-based compensation arrangements is provided at Note 8.

#### ***Common Stock Warrants***

On March 6, 2015, the Company's Board of Directors extended to April 15, 2015 the outstanding warrants to acquire 2,928,800 shares of the Company's common stock, which were then currently scheduled to expire on March 31, 2015, and discounted the cash exercise prices of the warrants by 50%. Warrants so extended and discounted consisted of 1,075,000 warrants currently exercisable at \$0.75 per share and 1,853,800 warrants currently exercisable at \$0.50 per share. The difference in the fair value of the warrants immediately before and after the grant of the extensions, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$34,016 (average of \$0.01 per share), and such amount was charged to operations on March 6, 2015. The fair value of the warrant extensions was calculated using the following input variables: stock price - \$0.30 per share; exercise price - \$0.50 and \$0.75 per share; expected life - 25 to 40 days; expected volatility - 199%; expected dividend yield - 0%; risk-free interest rate - 0.01%. The difference in the fair value of the warrants immediately before and after the grant of the discount, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$171,757 (an average of \$0.06 per share), and such amount was charged to operations on March 6, 2015. The fair value of the warrant discount was calculated using the following input variables: stock price - \$0.30 per share; exercise price - \$0.50 and \$0.75 per share to \$0.25 and \$0.375 per share, respectively; expected life - 15 days (the period during which the discount was available); expected volatility - 199%; expected dividend yield - 0%; risk-free interest rate - 0.01%.

As a result of the March 6, 2015 warrant extension and discount offers, warrants to acquire 1,050,000 shares of the Company's common stock were exercised in April 2015 (including warrants to acquire 500,000 shares of common stock by Dr. Debbie Schwartzberg, an affiliate of the Company, and 300,000 shares of common stock by Philip F. Palmedo, a director of the Company) at exercise prices ranging from \$0.25 to \$0.375 per share. The exercise of the warrants generated aggregate net proceeds to the Company of \$315,000 (average exercise price of \$0.30 per share).

As of September 30, 2016 and December 31, 2015, there were no warrants outstanding to purchase common stock.

## 6. Money Market Funds

Investments in money market funds at December 31, 2015 consisted of shares of Morgan Stanley New York Municipal Money Market Trust with a fair value of \$104,095.

The Morgan Stanley New York Municipal Money Market Trust is an open-end fund incorporated in the United States. The fund invests in high quality, short-term municipal obligations that pay interest exempt from federal and New York state income taxes.

The following table presents money market funds at their level within the fair value hierarchy at December 31, 2015.

	<u>Total</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Money market funds	\$ 104,095	\$ 104,095	\$ —	\$ —

The Company did not have any investments in money market funds at September 30, 2016.

## 7. Related Party Transactions

The Company had advances from its Chairman and major stockholder, Dr. John Kovach, aggregating \$92,717, which were non-interest bearing, due on demand, and included in current liabilities in the Company's consolidated balance sheets through December 31, 2014. Effective March 17, 2015, such advances were converted into 92,717 shares of the Company's common stock, reflecting an effective price of \$1.00 per share. On the effective date of the transaction, the closing price of the Company's common stock was \$0.25 per share.

Dr. Kovach was paid a salary of \$15,000 for the three months ended September 30, 2016 and 2015, and \$45,000 for the nine months ended September 30, 2016 and 2015, which amounts are included in general and administrative costs in the Company's condensed consolidated statements of operations.

Dr. Kovach is not involved in other business activities but could, in the future, become involved in other business opportunities that become available. Accordingly, Dr. Kovach may face a conflict in selecting between the Company and his other business interests. The Company has not yet formulated a policy for the resolution of such potential conflicts.

The Company's principal office facilities have been provided without charge by Dr. Kovach. Such costs were not material to the Company's consolidated financial statements and, accordingly, have not been reflected therein.

Legal and consulting fees charged to operations for services rendered by the Eric Forman Law Office were \$12,000 for the three months ended September 30, 2016 and 2015, and \$36,000 for the nine months ended September 30, 2016 and 2015. Eric J. Forman is the son-in-law of Gil Schwartzberg, a significant stockholder of and consultant to the Company, and is the son of Dr. Stephen J. Forman, who was elected to the Company's Board of Directors on May 13, 2016. Julie Forman, the wife of Eric Forman and the daughter of Gil Schwartzberg (a significant stockholder of and consultant to the Company, as described at Note 8), is Vice President of Morgan Stanley Wealth Management and has been involved with the Company's investment in money market funds as described at Note 6.

Effective January 1, 2014, the Company entered into an Advisory Agreement with Dr. Kathleen P. Mullinix, a member of the Board of Directors of the Company, effective for an initial term of one year through December 31, 2014 to advise on business development matters. The Advisory Agreement provided for annual cash compensation of \$25,000. The term of the Advisory Agreement is automatically extended for a term of one year annually unless a notice of intent to terminate is given by either party at least 90 days before the end of the applicable term. Accordingly, the Advisory Agreement was extended for additional terms of one year effective January 1, 2015 and 2016. The Company recognized a charge to operations of \$6,250 as consulting and advisory fees pursuant to this Advisory Agreement during the three months ended September 30, 2016 and 2015, and \$18,750 during the nine months ended September 30, 2016 and 2015, which were included in general and administrative costs in the Company's condensed consolidated statements of operations.



Stock-based compensation arrangements involving members of the Company's Board of Directors and affiliates are described at Note 8. Total stock-based compensation expense relating to directors, officers, affiliates and related parties was \$3,930 and \$0 for the three months ended September 30, 2016 and 2015, respectively. Total stock-based compensation expense relating to directors, officers, affiliates and related parties was \$105,334 and \$74,901 for the nine months ended September 30, 2016 and 2015, respectively.

## 8. Stock-Based Compensation

The Company issues common stock and stock options as incentive compensation to directors and as compensation for the services of independent contractors and consultants of the Company.

On June 20, 2007, the Board of Directors of the Company approved the 2007 Stock Compensation Plan (the "2007 Plan"), which provides for the granting of awards, consisting of stock options, stock appreciation rights, performance shares, or restricted shares of common stock, to employees and independent contractors, for up to 2,500,000 shares of the Company's common stock, under terms and condition, as determined by the Company's Board of Directors. As of September 30, 2016, unexpired stock options for 1,700,000 shares were issued and outstanding under the 2007 Plan, and stock options for 800,000 were available for issuance under the 2007 Plan.

The fair value of each stock option awarded is estimated on the date of grant and subsequent measurement dates using the Black-Scholes option-pricing model. The expected dividend yield assumption is based on the Company's expectation of dividend payouts. The expected volatilities are based on historical volatility of the Company's stock. The risk-free interest rate is based on the U.S. treasury yield curve in effect as of the grant date. The expected life of the stock options is the average of the vesting term and the full contractual term of the stock options.

For stock options requiring an assessment of value during the nine months ended September 30, 2016, the fair value of each stock option award was estimated using the Black-Scholes option-pricing model with the following assumptions:

Risk-free interest rate	0.60% to 1.31%
Expected dividend yield	0%
Expected volatility	196.75% to 226.44%
Expected life	2.25 to 5.0 years

For stock options requiring an assessment of value during the nine months ended September 30, 2015, the fair value of each stock option award was estimated using the Black-Scholes option-pricing model with the following assumptions:

Risk-free interest rate	0.68% to 1.66%
Expected dividend yield	0%
Expected volatility	243.00%
Expected life	3.5 to 4.3 years

On January 28, 2014, the Company approved a second amendment to the Company's consulting agreement with Gil Schwartzberg, a significant stockholder of and consultant to the Company, dated September 12, 2007 to extend it for an additional four years to January 28, 2019 and granted to Mr. Schwartzberg stock options to purchase an additional aggregate of 4,000,000 shares of common stock, exercisable for a period of the earlier of five years from the grant date or the termination of the consulting agreement at \$0.50 per share, with one-half of the stock options (2,000,000 shares) vesting immediately and one-half of the stock options (2,000,000 shares) vesting on January 28, 2015. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$596,400 (\$0.15 per share) on January 28, 2014, of which \$298,200 was attributable to the stock options that were fully vested on January 28, 2014 and was therefore charged to operations on that date. The remaining unvested portion of the fair value of the stock options was charged to operations ratably from January 28, 2014 through January 28, 2015. During the nine months ended September 30, 2015, the Company recorded a charge to operations of \$74,901 with respect to these stock options.

On December 24, 2013, the Company entered into an agreement with NDA Consulting Corp. (“NDA”) for consultation and advice in the field of oncology research and drug development. As part of the agreement, NDA also agreed to cause its president, Dr. Daniel D. Von Hoff, M.D., to become a member of the Company’s Scientific Advisory Committee. In connection with this agreement, NDA was granted stock options to purchase 100,000 shares of the Company’s common stock, vesting 25,000 shares on June 24, 2014, and thereafter 25,000 shares annually on June 24, 2015, 2016 and 2017, exercisable for a period of five years from the date of grant at \$0.13 per share, which was the fair market value of the Company’s common stock on the grant date. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be \$12,960 (\$0.13 per share), and is being charged to operations ratably from December 24, 2013 through June 24, 2017. During the three months ended September 30, 2016 and 2015, the Company recorded a charge (credit) to operations of \$1,494 and \$(4,056), respectively, with respect to these stock options. During the nine months ended September 30, 2016 and 2015, the Company recorded a (credit) charge to operations of \$(3,048) and \$(186), respectively, with respect to these stock options.

On October 7, 2014, the Company entered into an Advisory Agreement with Andrew Robell for consultation and advice with respect to identifying and assessing potential licensing and strategic opportunities through September 30, 2016. In connection with the agreement, the Company granted stock options to Mr. Robell to purchase 200,000 shares of the Company’s common stock, vesting 100,000 shares on October 7, 2014 and 100,000 shares on October 7, 2015, exercisable for a period of five years from the date of grant at \$0.50 per share. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$20,000 (\$0.10 per share), of which \$10,000 was attributable to the stock options fully-vested on October 7, 2014 and was therefore charged to operations on that date. The remaining unvested portion of the fair value of the stock options was charged to operations ratably from October 7, 2014 through October 7, 2015. During the three months and nine months ended September 30, 2015, the Company recorded a (credit) charge to operations of \$(3,341) and \$9,775, respectively, with respect to these stock options.

On October 7, 2014, the Company entered into an agreement with ProActive Capital Resources Group LLC (“ProActive”) for strategic advisory, investor relations and public relations services through October 6, 2015. In connection with the agreement, the Company agreed to pay ProActive a monthly fee of \$1,500 in cash and agreed to issue to ProActive 250,000 shares of the Company’s common stock, vesting 125,000 shares upon execution of the agreement on October 7, 2014 and 125,000 shares six months thereafter on April 7, 2015. Additionally, the Company issued a stock option in the form of a warrant to ProActive to purchase 500,000 shares of the Company’s common stock, vesting upon execution of the agreement on October 7, 2014, and exercisable for a period of one year from the date of grant at \$0.25 per share. The fair value of the warrant, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$33,000 (\$0.066 per share). The Company inadvertently neglected to timely record a charge to operations in 2014 of \$45,500 with respect to this transaction, as well as to record a portion of the fair value of the remaining unvested 125,000 shares in 2014 (which had a fair value on the grant date of \$12,500). The Company recorded a charge to operations for the aggregate fair value of these securities of \$76,750 during the nine months ended September 30, 2015. Management performed an evaluation with respect to this matter and determined that this correction was not qualitatively or quantitatively material to the Company’s financial statements for the years ended December 31, 2014 or 2015, and thus determined that no restatement of such prior periods was necessary or appropriate under the circumstances.

Effective September 14, 2015, the Company entered into a Collaboration Agreement with BioPharmaWorks LLC (“BioPharmaWorks”), pursuant to which the Company engaged BioPharmaWorks to perform certain services for the Company as described at Note 9. In connection with the Collaboration Agreement, the Company agreed to issue to BioPharmaWorks 1,000,000 fully-vested shares of the Company’s common stock, valued at \$260,000, based upon the closing price of the Company’s common stock of \$0.26 per share, on September 14, 2015. Additionally, the Company issued to BioPharmaWorks two options in the form of warrants to purchase 1,000,000 shares (500,000 shares per warrant) of the Company’s common stock. The first warrant will vest on September 14, 2016, and is exercisable for a period of five years from the date of grant at \$1.00 per share. The second warrant will vest on September 14, 2017, and is exercisable for a period of five years from the date of grant at \$2.00 per share. The fair value of the first and second warrants, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$128,400 (\$0.2568 per share) and \$127,850 (\$0.2557 per share), respectively. During the three months ended September 30, 2016 and 2015, the Company recorded a charge to operations of \$36,313 and \$265,157, respectively, with respect to these common shares and warrants. During the nine months ended September 30, 2016 and 2015, the Company recorded a charge to operations of \$79,337 and \$265,157, respectively, with respect to these common shares and warrants.

On November 28, 2015, the Company entered into a two-year advisory agreement with Dr. Fritz Henn, M.D., Ph.D., for consultation and advice on the development of certain of the Company's products for clinical neurological and neuropsychiatric applications. Dr. Henn is an internationally recognized investigative neuroscientist and psychiatrist. In connection with the advisory agreement, and as sole compensation, Dr. Henn was granted stock options to purchase 200,000 shares of the Company's common stock, with 100,000 shares vesting on November 28, 2015, and 100,000 shares vesting on November 28, 2016. The stock options are exercisable for a period of five years from the grant date at \$0.50 per share. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be \$103,360 (\$0.5168 per share), of which \$51,680 was attributable to the stock options fully-vested on November 28, 2015 and was therefore charged to operations on that date. The remaining unvested portion of the fair value of the stock options is being charged to operations ratably from November 28, 2015 through November 28, 2016. During the three months and nine months ended September 30, 2016, the Company recorded a charge to operations of \$5,163 and \$13,602, respectively, with respect to these stock options.

Effective April 25, 2016, in connection with her continuing role as a member of the Company's Board of Directors, Dr. Kathleen P. Mullinix was granted fully-vested stock options under the 2007 Plan to purchase 150,000 shares of the Company's common stock. The stock options are exercisable for a period of five years from the date of grant at \$0.12 per share, which was the fair market value of the Company's common stock on such date. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$17,535 (\$0.1169 per share), which was charged to operations on the date of grant.

Effective April 25, 2016, in connection with his continuing role as a member of the Company's Board of Directors, Dr. Philip F. Palmedo was granted fully-vested stock options under the 2007 Plan to purchase 450,000 shares of the Company's common stock. The stock options are exercisable for a period of five years from the date of grant at \$0.12 per share, which was the fair market value of the Company's common stock on such date. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$52,604 (\$0.1169 per share), which was charged to operations on the date of grant.

Effective May 13, 2016, in conjunction with his appointment as a director of the Company, the Company granted to Dr. Stephen J. Forman stock options to purchase an aggregate of 200,000 shares of common stock under the 2007 Plan, exercisable for a period of five years from vesting date at \$0.16 per share, which was the fair market value of the Company's common stock on such date. One-half (100,000 shares) vest annually on each of May 13, 2016 and 2017. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$31,180 (\$0.1559 per share), of which \$15,590 was attributable to the stock options fully-vested on May 13, 2016 and was therefore charged to operations on that date. The remaining unvested portion of the fair value of the stock options is being charged to operations ratably from May 13, 2016 through May 13, 2017. During the three months and nine months ended September 30, 2016, the Company recorded a charge to operations of \$3,930 and \$21,570, respectively, with respect to these stock options.

Effective June 7, 2016, in connection with his continuing role as a consultant to the Company, Eric Forman was granted fully-vested stock options under the 2007 Plan to purchase 100,000 shares of the Company's common stock. The stock options are exercisable for a period of five years from the date of grant at \$0.15 per share. The fair market value of the Company's common stock on the date of grant was \$0.14 per share. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$13,625 (\$0.1363 per share), which was charged to operations on the date of grant.

Effective September 12, 2016, in connection with his continuing role as a consultant to the Company, Francis Johnson was granted fully-vested stock options under the 2007 Plan to purchase 500,000 shares of the Company's common stock. The stock options are exercisable for a period of five years from the date of grant at \$0.25 per share. The fair market value of the Company's common stock on the date of grant was \$0.25 per share. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$98,901 (\$0.1978 per share), which was charged to operations on the date of grant.

Total stock-based compensation expense was \$145,801 and \$257,760 for the three months ended September 30, 2016 and 2015, respectively. Total stock-based compensation expense was \$294,126 and \$426,397 for the nine months ended September 30, 2016 and 2015, respectively.

A summary of stock option activity during the nine months ended September 30, 2016 is presented in the tables below.

	<u>Number Of Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Life (in Years)</u>
Options outstanding at December 31, 2015	7,950,000	\$ 0.697	
Granted	1,400,000	0.156	
Exercised	—	—	
Expired	(250,000)	0.980	
Options outstanding at September 30, 2016	<u>9,100,000</u>	<u>\$ 0.606</u>	<u>2.64</u>
Options exercisable at December 31, 2015	6,800,000	\$ 0.586	
Options exercisable at September 30, 2016	<u>8,375,000</u>	<u>\$ 0.530</u>	<u>2.53</u>

Total deferred compensation expense for the outstanding value of unvested stock options was approximately \$61,000 at September 30, 2016, which is being recognized subsequent to September 30, 2016 over a weighted-average period of approximately ten months.

The exercise prices of common stock options outstanding and exercisable are as follows at September 30, 2016:

<u>Exercise Prices</u>	<u>Options Outstanding (Shares)</u>	<u>Options Exercisable (Shares)</u>
\$ 0.120	600,000	600,000
\$ 0.130	100,000	75,000
\$ 0.150	100,000	100,000
\$ 0.160	200,000	100,000
\$ 0.200	500,000	500,000
\$ 0.250	500,000	500,000
\$ 0.500	4,400,000	4,300,000
\$ 0.650	700,000	700,000
\$ 1.000	1,500,000	1,500,000
\$ 2.000	500,000	—
	<u>9,100,000</u>	<u>8,375,000</u>

The intrinsic value of exercisable but unexercised in-the-money stock options at September 30, 2016 was approximately \$62,300, based on a fair market value of \$0.20 per share on September 30, 2016.

The intrinsic value of exercisable but unexercised in-the-money stock options at December 31, 2015 was approximately \$31,300, based on a fair market value of \$0.296 per share on December 31, 2015.

Outstanding options to acquire 725,000 shares of the Company's common stock had not vested at September 30, 2016.

The Company expects to satisfy such stock obligations through the issuance of authorized but unissued shares of common stock.

## 9. Commitments and Contingencies

The Company is not currently subject to any pending or threatened legal actions or claims.

Significant agreements and contracts are summarized as follows:

On September 21, 2012, the Company entered into a work order agreement with Theradex, the CRO responsible for the clinical development of the Company's lead anti-cancer compound LB-100, to manage and administer the Phase 1 clinical trial of LB-100. The Phase 1 clinical trial of LB-100, which began during April 2013 with the entry of patients into the clinical trial, was carried out by nationally recognized comprehensive cancer centers. As the patient accrual goal was reached in April 2016, the clinical trial was closed to further patient enrollment at that time. All patients completed treatment with LB-100 and were off study by the end of May 2016. The Company estimates that it will continue to incur costs through December 2016 to complete the analysis of the clinical data, reconcile and pay the remaining costs owed to the participating clinical sites, and prepare and submit the required Clinical Study Report to the FDA on the completed Phase 1 clinical trial of LB-100.

The Phase 1 clinical trial was estimated to cost a total of approximately \$2,200,000, with such payments expected to be allocated approximately 60% for services provided by Theradex and approximately 40% for pass-through costs for clinical center laboratory costs and investigator costs over the life of the clinical trial. Total costs charged to operations through September 30, 2016 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, aggregated \$2,040,867.

On December 24, 2013, the Company entered into an agreement with NDA Consulting Corp. (“NDA”) for consultation and advice in the field of oncology research and drug development. As part of the agreement, NDA also agreed to cause its president, Dr. Daniel D. Von Hoff, M.D., to become a member of the Company’s Scientific Advisory Committee. The term of the agreement was for one year and provided for a quarterly cash fee of \$4,000. The agreement was automatically renewed on its anniversary date for an additional one-year term. Consulting and advisory fees charged to operations pursuant to this agreement were \$4,000 during the three months ended September 30, 2016 and 2015, and \$12,000 during the nine months ended September 30, 2016 and 2015.

Effective January 1, 2014, the Company entered into an Advisory Agreement with Dr. Kathleen P. Mullinix, a member of the Board of Directors of the Company, effective for an initial term of one year through December 31, 2014 to advise on business development matters. The Advisory Agreement provided for annual cash compensation of \$25,000. The term of the Advisory Agreement was automatically extended for a term of one year annually unless a notice of intent to terminate was given by either party at least 90 days before the end of the applicable term. Accordingly, the Advisory Agreement was extended for additional terms of one year effective January 1, 2015 and 2016. The Company recognized a charge to operations of \$6,250 as consulting and advisory fees pursuant to this Advisory Agreement during the three months ended September 30, 2016 and 2015, and \$18,750 during the nine months ended September 30, 2016 and 2015.

On October 7, 2014, the Company entered into an agreement with ProActive Capital Resources Group LLC for strategic advisory, investor relations and public relations services through October 6, 2015. Among other things, the agreement provided for compensation in the form of a monthly cash fee of \$1,500. The Company recorded a charge to operations pursuant to this agreement of \$4,500 and \$13,500 for the three months and nine months ended September 30, 2015, respectively.

Effective September 14, 2015, the Company entered into a Collaboration Agreement with BioPharmaWorks, pursuant to which the Company engaged BioPharmaWorks to perform certain services for the Company. Those services include, among other things: (a) assisting the Company to (i) commercialize its products and strengthen its patent portfolio, (ii) identify large pharmaceutical companies with potential interest in the Company’s product pipeline, and (iii) prepare and deliver presentations concerning the Company’s products; (b) at the request of the Board of Directors, serving as backup management for up to three months should the Company’s Chief Executive Officer and scientific leader be temporarily unable to carry out his duties; (c) being available for consultation in drug discovery and development; and (d) identifying providers and overseeing tasks relating to clinical use and commercialization of new compounds. BioPharmaWorks was founded in 2015 by former Pfizer scientists with extensive multi-disciplinary research and development and drug development experience. The Collaboration Agreement is for an initial term of two years and automatically renews for subsequent annual periods unless terminated by a party not less than 60 days prior to the expiration of the applicable period. In connection with the Collaboration Agreement, the Company agreed to pay BioPharmaWorks a monthly fee of \$10,000, subject to the right of the Company to pay a negotiated hourly rate in lieu of the monthly payment, and agreed to issue to BioPharmaWorks certain equity-based compensation as described at Note 8. The Company recorded a charge to operations pursuant to this Collaboration Agreement of \$30,000 and \$90,000 during the three months and nine months ended September 30, 2016, respectively.

#### *Summary of Principal Cash Obligations and Commitments*

The following table sets forth the Company’s principal cash obligations and commitments for the next five fiscal years as of September 30, 2016 aggregating \$357,899, of which \$82,532 is included in current liabilities in the Company’s condensed consolidated balance sheet at September 30, 2016. Amounts included in the 2016 column represent amounts due at September 30, 2016 for the remainder of the 2016 fiscal year ending December 31, 2016.

	<u>Total</u>	<u>Payments Due By Year</u>				
		<u>2016</u>	<u>2017</u>	<u>2018</u>	<u>2019</u>	<u>2020</u>
Research and development contracts	\$ 38,870	\$ 38,870	\$ —	\$ —	\$ —	\$ —
Clinical trial agreements	190,029	190,029	—	—	—	—
Consulting agreements	129,000	39,000	90,000	—	—	—
Total	<u>\$ 357,899</u>	<u>\$ 267,899</u>	<u>\$ 90,000</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

#### **10. Subsequent Events**

The Company performed an evaluation of subsequent events through the date of filing of these financial statements with the SEC, noting no items requiring disclosure.

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

### Overview

Lixte Biotechnology Holdings, Inc., a Delaware corporation, including its wholly-owned Delaware subsidiary, Lixte Biotechnology, Inc. (collectively, the "Company"), is a drug discovery company that uses biomarker technology to identify enzyme targets associated with serious common diseases and then designs novel compounds to attack those targets. The Company's product pipeline encompasses two major categories of compounds at various stages of pre-clinical and clinical development that the Company believes have broad therapeutic potential not only for cancer but also for other debilitating and life-threatening diseases.

The Company's activities are subject to significant risks and uncertainties, including the need for additional capital, as described below. The Company has not yet commenced any sustainable revenue-generating operations, does not have any positive cash flows from operations, and is dependent on equity capital to fund its operating requirements.

The Company's common stock is traded on the OTCQB operated by the OTC Markets under the symbol "LIXT".

### Going Concern

The Company's condensed consolidated financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has not generated any sustainable revenues from operations to date, and does not expect to do so in the foreseeable future. The Company has experienced recurring operating losses and negative operating cash flows since inception, and has financed its working capital requirements during this period primarily through the recurring sale of its equity securities and the exercise of outstanding warrants. As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern. In addition, the Company's independent registered public accounting firm, in their report on the Company's consolidated financial statements for the year ended December 31, 2015, has expressed substantial doubt about the Company's ability to continue as a going concern.

The Company's ability to continue as a going concern is dependent upon its ability to raise additional equity capital to fund its research and development activities and to ultimately achieve sustainable operating revenues and profits. The Company's consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties.

Because the Company is currently engaged in research at a relatively early stage, it will likely take a significant amount of time to develop any product or intellectual property capable of generating sustainable revenues. Accordingly, the Company's business is unlikely to generate any sustainable operating revenues in the next several years, and may never do so. In addition, to the extent that the Company is able to generate revenues through licensing its technologies or through product sales, there can be no assurance that the Company will be able to achieve positive earnings and operating cash flows.

At September 30, 2016, the Company had cash and money market funds aggregating \$669,771. Subsequent to September 30, 2016, the Company expects to receive a refund of advances made to or through Theradex Systems, Inc. of \$181,510 upon the administrative closure of the Phase 1 clinical trial of LB-100 (which was closed to further patient enrollment in April 2016). Accordingly, at September 30, 2016, the Company believes that it has sufficient resources to complete the analysis of the clinical data, reconcile and pay the remaining costs owed to the participating clinical sites, and prepare and submit the required Clinical Study Report to the U.S. Food and Drug Administration ("FDA") on the completed Phase 1 clinical trial of LB-100, as well as to fund the Company's ongoing operating expenses, including maintaining its patent portfolio, through at least March 2017.

The amount and timing of future cash requirements will depend on the pace and design of the Company's clinical trial program. As market conditions present uncertainty as to the Company's ability to secure additional funds, there can be no assurances that the Company will be able to secure additional financing on acceptable terms, or at all, as and when necessary to continue to conduct operations. If cash resources are insufficient to satisfy the Company's ongoing cash requirements, the Company would be required to scale back or discontinue its technology and product development programs and/or clinical trials, or obtain funds, if available (although there can be no certainty), through strategic alliances that may require the Company to relinquish rights to certain of its compounds, or to discontinue its operations entirely.

## Recent Accounting Pronouncements

Information with respect to recently issued accounting standards is provided at Note 3 to the Company's condensed consolidated financial statements included elsewhere in this document.

## Concentration of Risk

The Company periodically contracts with directors, including companies controlled by or associated with directors, to provide consulting services related to the Company's research and development and clinical trial activities. Agreements for these services can be for a specific time period (typically one year) or for a specific project or task, and can include both cash and non-cash compensation. The only such contract that represents 10% or more of general and administrative or research and development costs is described below.

On September 21, 2012, the Company entered into a work order agreement with Theradex, the CRO responsible for the clinical development of the Company's lead anti-cancer compound LB-100, to manage and administer the Phase 1 clinical trial of LB-100. The Phase 1 clinical trial of LB-100, which began during April 2013 with the entry of patients into the clinical trial, was carried out by nationally recognized comprehensive cancer centers. As the patient accrual goal was reached in April 2016, the clinical trial was closed to further patient enrollment at that time. All patients completed treatment with LB-100 and were off study by the end of May 2016. The Company estimates that it will continue to incur costs through December 2016 to complete the analysis of the clinical data, reconcile and pay the remaining costs owed to the participating clinical sites, and prepare and submit the required Clinical Study Report to the FDA on the completed Phase 1 clinical trial of LB-100.

The Phase 1 clinical trial was estimated to cost a total of approximately \$2,200,000, with such payments expected to be allocated approximately 60% for services provided by Theradex and approximately 40% for pass-through costs for clinical center laboratory costs and investigator costs over the life of the clinical trial. Total costs charged to operations through September 30, 2016 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, aggregated \$2,040,867.

During the three months ended September 30, 2016 and 2015, \$130,820 and \$162,425, respectively, of such clinical trial costs were incurred, representing approximately 27% and 26% of research and development costs for such periods. During the nine months ended September 30, 2016 and 2015, the Company incurred \$340,746 and \$670,540, respectively, of such clinical trial costs, representing approximately 32% and 47% of research and development costs for such periods. Costs pursuant to this agreement are included in research and development costs in the Company's condensed consolidated statements of operations.

## Critical Accounting Policies and Estimates

The Company prepared its condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. Management periodically evaluates the estimates and judgments made. Management bases its estimates and judgments on historical experience and on various factors that are believed to be reasonable under the circumstances. Actual results may differ from these estimates as a result of different assumptions or conditions.

The following critical accounting policies affect the more significant judgments and estimates used in the preparation of the Company's condensed consolidated financial statements.

## Research and Development

Research and development costs consist primarily of fees paid to consultants and outside service providers, patent fees and costs, and other expenses relating to the acquisition, design, development and testing of the Company's treatments and product candidates.

Research and development costs are expensed ratably over the life of the underlying contracts, unless the achievement of milestones, the completion of contracted work, or other information indicates that a different expensing schedule is more appropriate.

The Company retained Theradex Systems, Inc. (“Theradex”), an international contract research organization (“CRO”) that provides professional services for the clinical research and development of pharmaceutical compounds, to be responsible for managing and administering the Company’s Phase 1 clinical trial of LB-100. The costs of the Phase 1 clinical trial of LB-100 that are being paid through Theradex are recorded and expensed based upon the documentation provided by the CRO.

Payments made pursuant to research and development contracts are initially recorded as advances on research and development contract services in the Company’s balance sheet and then charged to research and development costs in the Company’s statement of operations as those contract services are performed. Expenses incurred under research and development contracts in excess of amounts advanced are recorded as research and development contract liabilities in the Company’s balance sheet, with a corresponding charge to research and development costs in the Company’s statement of operations. The Company reviews the status of its research and development contracts on a quarterly basis.

#### **Patent Costs**

Due to the significant uncertainty associated with the successful development of one or more commercially viable products based on the Company’s research efforts and any related patent applications, all patent costs, including patent-related legal and filing fees, are expensed as incurred.

#### **Stock-Based Compensation**

The Company periodically issues common stock and stock options to officers, directors, Scientific Advisory Committee members and consultants for services rendered. Options vest and expire according to terms established at the issuance date of each grant.

The Company accounts for stock-based payments to officers and directors by measuring the cost of services received in exchange for equity awards based on the grant date fair value of the awards, with the cost recognized as compensation expense on the straight-line basis in the Company’s financial statements over the vesting period of the awards. The Company accounts for stock-based payments to Scientific Advisory Committee members and consultants by determining the value of the stock compensation based upon the measurement date at either (a) the date at which a performance commitment is reached or (b) at the date at which the necessary performance to earn the equity instruments is complete.

Stock grants, which are generally time vested, are measured at the grant date fair value and charged to operations ratably over the vesting period.

Stock options granted to members of the Company’s Scientific Advisory Committee and to outside consultants are revalued each reporting period to determine the amount to be recorded as an expense in the respective period. As the stock options vest, they are valued on each vesting date and an adjustment is recorded for the difference between the value already recorded and the value on the date of vesting.

The fair value of common stock issued as stock-based compensation is determined by reference to the closing price of the Company’s common stock on the date of issuance. The fair value of stock options granted as stock-based compensation is determined utilizing the Black-Scholes option-pricing model, and is affected by several variables, the most significant of which are the life of the equity award, the exercise price of the stock option as compared to the fair market value of the common stock on the grant date, and the estimated volatility of the common stock over the term of the equity award. Estimated volatility is based on the historical volatility of the Company’s common stock. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. The fair market value of common stock is determined by reference to the quoted market price of the Company’s common stock.

The Company recognizes the fair value of stock-based compensation awards in general and administrative costs and in research and development costs, as appropriate, in the Company’s statement of operations. The Company issues new shares of common stock to satisfy stock option exercises.

#### **Income Taxes**

The Company accounts for income taxes under an asset and liability approach for financial accounting and reporting for income taxes. Accordingly, the Company recognizes deferred tax assets and liabilities for the expected impact of differences between the financial statements and the tax basis of assets and liabilities.



The Company records a valuation allowance to reduce its deferred tax assets to the amount that is more likely than not to be realized. In the event the Company was to determine that it would be able to realize its deferred tax assets in the future in excess of its recorded amount, an adjustment to the deferred tax assets would be credited to operations in the period such determination was made. Likewise, should the Company determine that it would not be able to realize all or part of its deferred tax assets in the future, an adjustment to the deferred tax assets would be charged to operations in the period such determination was made.

## **Plan of Operation**

### **General Overview of Plans**

The Company's original focus was the development of new treatments for the most common and most aggressive type of brain cancer of adults, glioblastoma multiforme ("GBM"), and the most common cancer of children, neuroblastoma. The Company has expanded the scope of its anti-cancer investigational activities to include the most common brain tumor of children, medulloblastoma, and also to several other types of more common cancers. This expansion of activity is based on documentation that each of two distinct types of drugs being developed by the Company has activity against cell lines of breast, colon, lung, prostate, pancreas, ovary, stomach and liver cancer, as well as against the major types of leukemias. LB-100 has now been shown to have activity in animal models of brain tumors of adults and children, and also against melanomas and sarcomas. Studies in animal models of human melanoma, lymphoma, sarcoma, brain tumors, and the rare neuroendocrine cancer, pheochromocytoma, have demonstrated marked potentiation by LB-100 of the anti-tumor activity of the widely used standard chemotherapeutic drugs. These studies confirm that the LB-100 compounds, in combination with any of several standard anti-cancer drugs, have broad activity affecting many different cell types of cancer.

The Company's immediate focus has been to determine the safety and appropriate dose of LB-100 when used alone and in combination with widely used anti-cancer drugs in its Phase 1 clinical trial. The Company's longer-term objective is to secure one or more strategic partnerships with pharmaceutical companies with major programs in cancer, vascular disease and/or neurologic disease.

The significant diversity of the potential therapeutic value of the Company's Series 2 compounds (LB-201 and homologs) stems from the fact that these agents modify critical pathways in cancer cells and in microorganisms such as fungi, and appear to ameliorate pathologic processes that lead to brain injury caused by trauma or toxins or through as yet unknown mechanisms that underlie the major chronic neurologic diseases, including Alzheimer's disease, Parkinson's disease, and Amyotrophic Lateral Sclerosis (ALS, or Lou Gehrig's disease).

### **Operating Plans**

The Company's primary focus is developing new treatments for human cancers for which better therapies are urgently needed. The scope of potential applications of the Company's products has expanded to other common non-malignant diseases, including vascular diseases (heart attacks and stroke), diabetes, genetic diseases, such as Gaucher's disease, and recently to depression and potentially post-traumatic stress syndrome. This has occurred because the targets selected by the Company have multiple functions in the cell, which, when altered, result in different disorders that may benefit by treatment from the Company's products.

The Company's drug discovery process is based on discerning clues to potential new targets for disease treatments reported in the increasingly large body of literature identifying the molecular variants which characterize human cancers and other non-cancer disorders. The Company designs drugs for which there are existing data suggesting that they may affect the altered pathways of the cancer cell and may be given safely to humans. The Company seeks to rapidly arrive at patentable structures through analysis of the literature rather than screening of thousands of structures for activity against a particular biochemical pathway.

This approach has led to the development of two classes of drugs for the treatment of cancer, consisting of protein phosphatase inhibitors (PTase-i), designated by the Company as the LB-100 series of compounds, and histone deacetylase inhibitors (HDACi), designated by the Company as the LB-200 series of compounds. Compounds of both types also have potential use in the prevention and treatment of neurodegenerative diseases.

The LB-100 series consists of novel structures, which have the potential to be first in their class, and may be useful in the treatment of not only several types of cancer but also vascular and metabolic diseases. The LB-200 series contains compounds which have the potential to be the most effective in its class and may be useful for the treatment of chronic hereditary diseases, such as Gaucher's disease, in addition to cancer and neurodegenerative diseases.

The Company has demonstrated that lead compounds of both series of drugs are active against a broad spectrum of human cancers in cell culture and against several types of human cancers in animal models. The research on new drug treatment was initiated in 2006 with the National Institute of Neurological Disorders and Stroke (“NINDS”) of the National Institutes of Health (“NIH”) under a Cooperative Research and Development Agreement (“CRADA”) effective March 22, 2006. The research at NINDS was led by Dr. Zhengping Zhuang, an internationally recognized investigator in the molecular pathology of cancer. The initial focus of the CRADA was on the most common and uniformly fatal brain tumor of adults, GBM. The work at NIH was then extended to the most common brain tumor of children, medulloblastoma, and to the most common extracranial solid tumor of children, neuroblastoma. The CRADA was extended through a series of amendments and remained in effect until April 1, 2013, when it terminated as scheduled.

Effective October 18, 2013, the Company entered into a Materials Cooperative Research and Development Agreement (M-CRADA) with the National Institute of Neurological Disorders and Stroke of the National Institutes of Health (NINDS, NIH) for a term of four years. The Surgical Neurology Branch of NINDS, NIH will conduct research characterizing a variety of compounds proprietary to the Company, and will examine the compounds’ potential for anti-cancer activity, reducing neurological deficit due to ischemia and brain injury, and stabilizing catalytic function of misfolded proteins for inborn brain diseases. Under an M-CRADA, a party provides research material, in this case proprietary compounds from the Company’s pipeline, for study by scientists at NIH. The exchange of material is for research only and implies no endorsement of the material on the part of either party. Under the M-CRADA the NIH grants a collaborator an exclusive option to elect an exclusive or non-exclusive commercialization license. The M-CRADA does not generate any incremental cost to the Company.

Effective treatment of brain tumors depends upon the ability of compounds to penetrate a physiological barrier known as the “blood-brain barrier”, which protects the brain from exposure to potentially toxic substances in the blood. Because there is no certainty that the Company’s compounds will be active against tumors confined to the brain, the LB-100 compounds have been studied against a variety of common and rare cancer types and have been shown to potentiate the activity of standard anti-cancer drugs in animal models of breast and pancreatic cancer, melanoma, pheochromocytomas and sarcomas. Because the LB-100 compounds appear to exert their ability to improve the effectiveness of different forms of chemotherapy and radiation therapy by inhibiting a process upon which most, if not all, cancer cell types depend on to survive treatment, the Company believes the LB-100 series of compounds may be useful against most, if not all, cancer types.

The second class of drugs under development by the Company, referred to as LB-200, is the histone deacetylase inhibitors. Many pharmaceutical companies are also developing drugs of this type, and at least two companies have HDACi approved for clinical use, in both cases for the treatment of a type of lymphoma. Despite this significant competition, the Company has demonstrated that its HDACi has broad activity against many cancer types, has neuroprotective activity, and has anti-fungal activity. In addition, these compounds have low toxicity, making them attractive candidates for development. It appears that one type of molecule has diverse effects, affecting biochemical processes that are fundamental to the life of the cell, whether they are cancer cells, nerve cells, or even fungal cells. The neuroprotective activity of the Company’s HDACi has been demonstrated in the test tube in model systems that mimic injury to brain cells, such as occurs in stroke and Alzheimer’s disease. This type of protective activity may have potential application to a broad spectrum of other chronic neurodegenerative diseases, including Parkinson’s disease and Amyotrophic Lateral Sclerosis (ALS, or Lou Gehrig’s disease).

The Company’s primary objective has been to bring one lead compound of the LB-100 series to clinical trial. In 2012, the Company completed the pre-clinical studies required to prepare an Investigational New Drug (“IND”) application to the FDA to conduct a Phase 1 clinical trial of LB-100, and engaged Theradex Systems, Inc. (“Theradex”), an international contract research organization (“CRO”) that provides professional services for the clinical research and development of pharmaceutical compounds, to be responsible for the clinical development of the Company’s lead anti-cancer compound LB-100 and to prepare an IND application for filing with the FDA.

The Company filed an IND application with the FDA on April 30, 2012, and on July 24, 2012, the FDA notified the Company that it would allow initiation of a Phase 1 clinical trial of LB-100. The purpose of this clinical trial was to demonstrate that LB-100 can be administered safely to human beings at a dose and at a frequency that achieves the desired pharmacologic effect; in this case, inhibition of a specific enzyme, without being associated with toxicities considered unacceptable. The Phase 1 clinical trial of LB-100 was designed to be conducted in two parts. In Part 1, the maximum tolerable dose (“MTD”) of LB-100 was to be determined. In Part 2, the MTD of LB-100, in combination with the standard cytotoxic drug docetaxel (which is a well-established anti-mitotic chemotherapy medication approved by the FDA for the treatment of various cancers), was to be determined.

The Phase 1 clinical trial of LB-100 began in April 2013 with the entry of patients into the clinical trial initiated at the City of Hope National Medical Center in Duarte, California, and was extended in December 2013 to include the Mayo Clinic in Rochester, Minnesota, both of which are Comprehensive Cancer Centers designated by the National Cancer Institute. As the accrual of patients was slower than anticipated, in October 2014, the Company entered into a Clinical Research Agreement (“CRA”) with US Oncology Research, LLC, a large community-based research network based in Texas, to increase the rate of entry of patients into the clinical trial by adding four more active clinical oncologic research sites.

The costs of Part 1 of the Phase 1 clinical trial exceeded the Company’s original estimates, in part because patients were able to tolerate higher doses of LB-100 than originally expected, thus requiring more dose escalation steps to determine the MTD of LB-100 given alone. In addition, patients achieved stabilization without any dose-limiting toxicity (“DLT”) and remained on treatment with LB-100 for longer periods of time than was usual in a Phase 1 clinical trial of a new drug in patients failing all previous treatments, thus increasing the overall cost of the clinical trial. The Company’s interpretation of the clinical trial results to date is that LB-100 as a single agent has activity against several types of cancer, as evidenced by stabilization of progressive disease in the absence of DLT.

As a prelude to determining the therapeutic effectiveness of LB-100 in a subsequent Phase 2 clinical trial of common cancers, a key goal of Part 1 of the Phase 1 clinical trial was to demonstrate that the target enzyme of LB-100, protein phosphatase 2A (“PP2A”), can be inhibited in humans with readily tolerable toxicity. As the patient accrual goal was reached in April 2016, Part 1 of the Phase 1 clinical trial of LB-100 was closed to further patient enrollment at that time, and the MTD of LB-100 administered for three consecutive days every three weeks was determined. All patients completed treatment with LB-100 and were off study by the end of May 2016. The Company is now working with Theradex to complete the analysis of the clinical data, reconcile and pay the remaining costs owed to the participating clinical sites, and prepare and submit the required Clinical Study Report to the FDA on the completed Phase 1 clinical trial of LB-100.

As an anti-cancer drug, LB-100 is likely to be used at MTD in Phase 2 clinical trials. For the potential treatment of non-malignant diseases, such as acute vascular diseases and metabolic diseases, however, lower doses may achieve therapeutic benefit by inhibition of the target enzyme, PP2A, thus opening up the possibility of a host of therapeutic applications for LB-100 and related proprietary compounds.

The costs of the Phase 1 clinical trial of LB-100 are being paid to or through Theradex, the CRO responsible for the clinical development of LB-100. Total costs charged to operations through September 30, 2016 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, aggregated \$2,040,867.

The Company had planned to proceed with Part 2 of the Phase 1 clinical trial to determine the toxicity of LB-100 in combination with docetaxel against a specific solid tumor for which single agent docetaxel is indicated. However, two developments have altered this plan. First, LB-100 appears to have anti-cancer activity in its own right, and second, preclinical studies indicate that LB-100 in combination with cisplatin or doxorubicin (widely used cytotoxic drugs) is more active than LB-100 in combination with docetaxel. LB-100 significantly potentiates the standard anti-cancer drugs cisplatin and doxorubicin in animal models of several tumor types, including hepatocellular cancer and platinum-resistant ovarian cancer. It has also been reported that inhibition of the enzyme-target of LB-100, PP2A, inhibits certain variants of the hematologic disorder known as myelodysplastic syndrome (“MDS”). Accordingly, the Company decided not to proceed with Part 2 of the Phase 1 clinical trial, and has initiated preliminary planning for Phase 1b/2 clinical trials to evaluate the effectiveness of LB-100 alone for the treatment of MDS and in combination with doxorubicin for the treatment of advanced hepatocellular cancer. This clinical trial will be initiated in Taiwan under the December 2015 license agreement entered into with Taipei Medical University, and is expected to commence during the first quarter of 2017. In addition, subject to the availability of additional capital, the Company will consider conducting a Phase 1b/2 clinical trial of LB-100 in the hematologic disorder known as myelodysplastic syndrome and a Phase 1b/2 clinical trial of LB-100 in combination with a platinum compound in platinum-resistant ovarian cancer, in 2017.

The Company estimates that Part 1 of the Phase 1 clinical trial of LB-100, patient enrollment for which was closed in May 2016, will cost a total of approximately \$2,200,000. The following factors have contributed to the most recent revisions to the total cost and the delay in the completion date of this clinical trial: (1) some patients are continuing to receive the study compound longer than is usual for patients with treatment-refractory progressive disease in a Phase 1 clinical trial; (2) the establishment of the MTD required more subjects than the initially planned six patients; and (3) the planned pharmacokinetic studies required more than the initially planned three patients.

As a compound moves through the FDA approval process, it becomes an increasingly valuable property, but at a cost of additional investment at each stage. As the potential effectiveness of LB-100 has been documented at the clinical trial level, the Company has allocated resources to expand the depth and extent of its patent portfolio. The Company’s approach has been to operate with a minimum of overhead, moving compounds forward as efficiently and inexpensively as possible, and to raise funds to support each of these stages as certain milestones are reached.

## Results of Operations

At September 30, 2016, the Company had not yet commenced any sustainable revenue-generating operations, does not have any positive cash flows from operations, and is dependent on its ability to raise equity capital to fund its operating requirements.

The Company's condensed consolidated statements of operations as discussed herein are presented below.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Licensing revenues	\$ —	\$ —	\$ —	\$ —
Costs and expenses:				
General and administrative costs	170,272	155,307	560,399	615,615
Research and development costs	476,805	624,405	1,058,248	1,416,940
Total costs and expenses	647,077	779,712	1,618,647	2,032,555
Loss from operations	(647,077)	(779,712)	(1,618,647)	(2,032,555)
Interest income	141	25	172	71
Fair value of warrant extensions	—	—	—	(34,016)
Fair value of warrant discount	—	—	—	(171,757)
Net loss	(646,936)	(779,687)	(1,618,475)	(2,238,257)
Dividend on Series A Convertible Preferred Stock	—	—	—	—
Net loss attributable to common stockholders	\$ (646,936)	\$ (779,687)	\$ (1,618,475)	\$ (2,238,257)
Net loss per common share – basic and diluted	\$ (0.01)	\$ (0.02)	\$ (0.03)	\$ (0.05)
Weighted average common shares outstanding – basic and diluted	47,875,814	46,060,597	47,875,814	46,428,767

### Three Months Ended September 30, 2016 and 2015

**Licensing Revenues.** The Company did not have any licensing revenues for the three months ended September 30, 2016 and 2015.

**General and Administrative.** For the three months ended September 30, 2016, general and administrative costs were \$170,272, which consisted of the fair value of stock options issued to directors and consultants of \$3,930, consulting and professional fees of \$124,794, insurance expense of \$14,781, officer's salary and related costs of \$16,792, stock transfer fees of \$2,401, filing fees of \$0, travel and entertainment costs of \$764, listing fees of \$3,125 and other operating costs of \$3,685.

For the three months ended September 30, 2015, general and administrative costs were \$155,307, which consisted of a credit for the fair value of stock options issued to directors and consultants of \$3,341, consulting and professional fees of \$117,394, insurance expense of \$15,646, officer's salary and related costs of \$16,864, stock transfer fees of \$2,537, filing fees of \$1,389, travel and entertainment costs of \$2,326, listing fees of \$2,795 and other operating costs of \$4,885.

General and administrative costs increased by \$14,965 or 9.6% in 2016 as compared to 2015, primarily as a result of an increase of \$7,271 in stock-based compensation.

**Research and Development.** For the three months ended September 30, 2016, research and development costs were \$476,805, which consisted of the vested portion of the fair value of common stock options and warrants of \$141,871, patent costs of \$140,855, and contractor costs of \$194,079, including \$130,820 to Theradex in connection with the Phase 1 clinical trial of LB-100. Contractor costs during the three months ended September 30, 2016 also include \$63,259 incurred with other vendors, primarily in connection with the Company's pre-clinical research focused on the development of additional novel anti-cancer compounds to add to its clinical pipeline.

As the patient accrual goal was reached in April 2016, the Phase 1 clinical trial of LB-100 was closed to further patient enrollment at that time. All patients completed treatment with LB-100 and were off study by the end of May 2016. The Company estimates that it will continue to incur costs through December 2016 to complete the analysis of the clinical data, reconcile and pay the remaining costs owed to the participating clinical sites, and prepare and submit the required Clinical Study Report to the FDA on the completed Phase 1 clinical trial of LB-100.

For the three months ended September 30, 2015, research and development costs were \$624,405, which consisted of the vested portion of the fair value of stock options of \$261,101, patent costs of \$139,485, and contractor costs of \$223,819, including \$162,425 to Theradex in connection with the Phase 1 clinical trial of LB-100.

Research and development costs decreased by \$147,600 or 23.6% in 2016 as compared to 2015, primarily as a result of a decrease of \$119,230 for the vested portion of the fair value of stock options and a decrease of \$29,740 in contractor costs, attributable primarily to Theradex, reflecting the wind down of the Phase 1 clinical trial of LB-100.

A significant component of the fair value of stock options issued to directors and consultants of \$141,871 for the three months ended September 30, 2016 was \$98,901 charged to operations for the fair value of immediately vesting stock options to acquire 500,000 shares of the Company's common stock that were issued to Francis Johnson on September 12, 2016 for his on-going contributions to the Company.

A significant component of the fair value of stock options issued to directors and consultants of \$261,101 for the three months ended September 30, 2015 was \$260,000 charged to operations for the fair value of 1,000,000 shares of the Company's common stock that were issued to BioPharmaWorks on September 14, 2015, in connection with a Collaboration Agreement between BioPharmaWorks, and the Company.

Net Loss. For the three months ended September 30, 2016, the Company incurred a net loss of \$646,936, as compared to a net loss of \$779,687 for the three months ended September 30, 2015.

Dividends on Series A Convertible Preferred Stock. The Company did not recognize any dividends on its Series A Convertible Preferred Stock for the three months ended September 30, 2016 and 2015.

Net Loss Attributable to Common Stockholders. For the three months ended September 30, 2016, the Company incurred a net loss attributable to common stockholders of \$646,936, as compared to a net loss attributable to common stockholders of \$779,687 for the three months ended September 30, 2015.

#### **Nine Months Ended September 30, 2016 and 2015**

Licensing Revenues. The Company did not have any licensing revenues for the nine months ended September 30, 2016 and 2015.

General and Administrative. For the nine months ended September 30, 2016, general and administrative costs were \$560,399, which consisted of the fair value of stock options issued to directors and consultants of \$105,334, consulting and professional fees of \$318,687, insurance expense of \$44,742, officer's salary and related costs of \$50,525, stock transfer fees of \$7,005, filing fees of \$6,892, travel and entertainment costs of \$12,825, listing fees of \$5,625 and other operating costs of \$8,764.

For the nine months ended September 30, 2015, general and administrative costs were \$615,615, which consisted of the fair value of stock options issued to directors and consultants of \$161,426, consulting and professional fees of \$320,615, insurance expense of \$43,295, officer's salary and related costs of \$50,613, stock transfer fees of \$8,153, filing fees of \$7,245, travel and entertainment costs of \$9,827, listing fees of \$5,625 and other operating costs of \$8,816.

General and administrative costs decreased by \$55,216 or 9.0% in 2016 as compared to 2015, primarily as a result of a decrease of \$56,092 in stock-based compensation.

A significant component of the fair value of stock options issued to directors and consultants of \$105,334 for the nine months ended September 30, 2016 was \$87,779 charged to operations for the fair value of stock options granted to two continuing directors, as well as stock options issued to a new director.

A significant component of the fair value of stock options issued to directors and consultants of \$161,426 for the nine months ended September 30, 2015 was \$74,901 charged to operations for the fair value of stock options to acquire 4,000,000 shares of the Company's common stock that were issued to Gil Schwartzberg on January 28, 2014 for his continuing contributions to the Company's financial strategy, which were fully amortized as of March 31, 2015. The fair value of stock options issued to directors and consultants for the nine months ended September 30, 2015 also included \$76,750 charged to operations for the fair value of stock options issued to ProActive Capital Resources Group LLC as described at Note 8.

Research and Development. For the nine months ended September 30, 2016, research and development costs were \$1,058,248, which consisted of the vested portion of the fair value of common stock options and warrants of \$188,792, patent costs of \$338,938, and contractor costs of \$530,518, including \$340,746 to Theradex in connection with the Phase 1 clinical trial of LB-100. Contractor costs during the nine months ended September 30, 2016 also include \$189,772 incurred with other vendors, primarily in connection with the Company's pre-clinical research focused on the development of additional novel anti-cancer compounds to add to its clinical pipeline.

As the patient accrual goal was reached in April 2016, the Phase 1 clinical trial of LB-100 was closed to further patient enrollment at that time. All patients completed treatment with LB-100 and were off study by the end of May 2016. The Company estimates that it will continue to incur costs through December 2016 to complete the analysis of the clinical data, reconcile and pay the remaining costs owed to the participating clinical sites, and prepare and submit the required Clinical Study Report to the FDA on the completed Phase 1 clinical trial of LB-100.

For the nine months ended September 30, 2015, research and development costs were \$1,416,940, which consisted of the vested portion of the fair value of stock options of \$264,971, patent costs of \$351,711, and contractor costs of \$800,258, including \$670,540 to Theradex in connection with the Phase 1 clinical trial of LB-100. Contractor costs during the nine months ended September 30, 2015 also include \$129,718 incurred with other vendors, primarily in connection with the Company's pre-clinical research focused on the development of additional novel anti-cancer compounds to add to its clinical pipeline.

Research and development costs decreased by \$358,692 or 25.3% in 2016 as compared to 2015, primarily as a result of a decrease of \$76,199 in stock based compensation and a decrease of \$269,740 in contractor costs, attributable primarily to Theradex, reflecting the wind down of the Phase 1 clinical trial of LB-100.

Fair Value of Warrant Extensions. During the nine months ended September 30, 2015, the Company incurred an expense of \$34,016 for the fair value of extending the expiration dates of warrants to acquire 2,928,800 shares of common stock from March 31, 2015 to April 15, 2015. During the nine months ended September 30, 2016, the Company did not incur any warrant extension costs.

Fair Value of Warrant Discount. During the nine months ended September 30, 2015, the Company incurred an expense of \$171,757 for the fair value of discounts offered to warrant holders as an inducement for the early exercise of warrants to acquire 2,928,800 shares of common stock. The discounts ranged from \$0.25 to \$0.375 per share. The subsequent exercise of warrants resulted in the issuance of 1,050,000 shares of common stock and generated net proceeds to the Company of \$315,000 in April 2015. During the nine months ended September 30, 2016, the Company did not incur any warrant discount costs.

Net Loss. For the nine months ended September 30, 2016, the Company incurred a net loss of \$1,618,475, as compared to a net loss of \$2,238,257 for the nine months ended September 30, 2015.

Dividends on Series A Convertible Preferred Stock. The Company did not recognize any dividends on its Series A Convertible Preferred Stock for the nine months ended September 30, 2016 and 2015.

Net Loss Attributable to Common Stockholders. For the nine months ended September 30, 2016, the Company incurred a net loss attributable to common stockholders of \$1,618,475, as compared to a net loss attributable to common stockholders of \$2,238,257 for the nine months ended September 30, 2015.

#### **Liquidity and Capital Resources – September 30, 2016**

The Company's condensed consolidated financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has not generated any sustainable revenues from operations to date, and does not expect to do so in the foreseeable future. The Company has experienced recurring operating losses and negative operating cash flows since inception, and has financed its working capital requirements during this period primarily through the recurring sale of its equity securities and the exercise of outstanding warrants. As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern. In addition, the Company's independent registered public accounting firm, in their report on the Company's consolidated financial statements for the year ended December 31, 2015, has expressed substantial doubt about the Company's ability to continue as a going concern (see "Going Concern" above).

At September 30, 2016, the Company had working capital of \$737,984 (including advances on research and development contract services of \$192,220), as compared to working capital of \$312,333 at December 31, 2015 (including a licensing fee receivable of \$200,000 and advances on research and development contract services of \$207,677), an increase in working capital of \$425,651 for the nine months ended September 30, 2016. The increase in working capital during the nine months ended September 30, 2016 was primarily the result of the receipt of \$1,750,000 of proceeds from the sale of additional shares of Series A Convertible Preferred Stock.

At September 30, 2016, the Company had cash and money market funds aggregating \$669,771, as compared to \$129,376 at December 31, 2015, an increase of \$540,395 for the nine months ended September 30, 2016. Subsequent to September 30, 2016, the Company expects to receive a refund of advances made to or through Theradex Systems, Inc. of \$181,510 upon the administrative closure of the Phase 1 clinical trial of LB-100.

At September 30, 2016, the Company believes that it has sufficient resources to complete the analysis of the clinical data, reconcile and pay the remaining costs owed to the participating clinical sites, and prepare and submit the required Clinical Study Report to the FDA on the completed Phase 1 clinical trial of LB-100, as well as to fund the Company's ongoing operating expenses, including maintaining its patent portfolio, through at least March 2017.

The amount and timing of future cash requirements depend on the pace and design of the Company's clinical trial program. As market conditions present uncertainty as to the Company's ability to secure additional funds, there can be no assurances that the Company will be able to secure additional financing on acceptable terms, or at all, as and when necessary to continue to conduct operations. If cash resources are insufficient to satisfy the Company's ongoing cash requirements, the Company would be required to scale back or discontinue its technology and product development programs and/or clinical trials, or obtain funds, if available (although there can be no certainty), through strategic alliances that may require the Company to relinquish rights to certain of its compounds, or to discontinue its operations entirely.

Operating Activities. For the nine months ended September 30, 2016, operating activities utilized cash of \$1,207,605, as compared to utilizing cash of \$1,568,858 for the nine months ended September 30, 2015, to fund the Company's Phase 1 clinical trial of LB-100, to support its other ongoing research and development activities, and to fund its other ongoing operating expenses, including maintaining its patent portfolio.

Investing Activities. For the nine months ended September 30, 2016, investing activities consisted of a decrease in money market funds of \$104,095, due to the liquidation of such funds and the transfer of such amounts to cash. For the nine months ended September 30, 2015, investing activities consisted of an increase in money market funds of \$310,388, due primarily to the investment in money market funds of a portion of the proceeds from the sale of shares of the Company's Series A Convertible Preferred Stock in March 2015.

Financing Activities. For the nine months ended September 30, 2016, financing activities consisted of the receipt of \$1,750,000 of proceeds from the sale of 175,000 shares of the Company's Series A Convertible Preferred Stock at \$10.00 per share in January 2016, less a dividend paid on the Company's Series A Convertible Preferred Stock of \$2,000. For the nine months ended September 30, 2015, financing activities consisted of \$315,000 from the exercise of common stock warrants and \$1,750,000 of proceeds received from the sale of 175,000 shares of the Company's Series A Convertible Preferred Stock at \$10.00 per share in March 2015, less costs of \$12,608 associated with the sale of the Company's Series A Convertible Preferred Stock.

#### **Principal Commitments**

On September 21, 2012, the Company entered into a work order agreement with Theradex, the CRO responsible for the clinical development of the Company's lead anti-cancer compound LB-100, to manage and administer the Phase 1 clinical trial of LB-100. The Phase 1 clinical trial of LB-100, which began during April 2013 with the entry of patients into the clinical trial, was carried out by nationally recognized comprehensive cancer centers. As the patient accrual goal was reached in April 2016, the clinical trial was closed to further patient enrollment at that time. All patients completed treatment with LB-100 and were off study by the end of May 2016. The Company estimates that it will continue to incur costs through December 2016 to complete the analysis of the clinical data, reconcile and pay the remaining costs owed to the participating clinical sites, and prepare and submit the required Clinical Study Report to the FDA on the completed Phase 1 clinical trial of LB-100.

The Phase 1 clinical trial was estimated to cost a total of approximately \$2,200,000, with such payments expected to be allocated approximately 60% for services provided by Theradex and approximately 40% for pass-through costs for clinical center laboratory costs and investigator costs over the life of the clinical trial. Total costs charged to operations through September 30, 2016 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, aggregated \$2,040,867.

On December 24, 2013, the Company entered into an agreement with NDA Consulting Corp. (“NDA”) for consultation and advice in the field of oncology research and drug development. As part of the agreement, NDA also agreed to cause its president, Dr. Daniel D. Von Hoff, M.D., to become a member of the Company’s Scientific Advisory Committee. The term of the agreement was for one year and provided for a quarterly cash fee of \$4,000. The agreement was automatically renewed on its anniversary date for an additional one-year term. Consulting and advisory fees charged to operations pursuant to this agreement were \$4,000 during the three months ended September 30, 2016 and 2015, and \$12,000 during the nine months ended September 30, 2016 and 2015.

Effective January 1, 2014, the Company entered into an Advisory Agreement with Dr. Kathleen P. Mullinix, a member of the Board of Directors of the Company, effective for an initial term of one year through December 31, 2014 to advise on business development matters. The Advisory Agreement provided for annual cash compensation of \$25,000. The term of the Advisory Agreement was automatically extended for a term of one year annually unless a notice of intent to terminate was given by either party at least 90 days before the end of the applicable term. Accordingly, the Advisory Agreement was extended for additional terms of one year effective January 1, 2015 and 2016. The Company recognized a charge to operations of \$6,250 as consulting and advisory fees pursuant to this Advisory Agreement during the three months ended September 30, 2016 and 2015, and \$18,750 during the nine months ended September 30, 2016 and 2015.

On October 7, 2014, the Company entered into an agreement with ProActive Capital Resources Group LLC for strategic advisory, investor relations and public relations services through October 6, 2015. Among other things, the agreement provided for compensation in the form of a monthly cash fee of \$1,500. The Company recorded a charge to operations pursuant to this agreement of \$4,500 and \$13,500 for the three months and nine months ended September 30, 2015, respectively.

Effective September 14, 2015, the Company entered into a Collaboration Agreement with BioPharmaWorks, pursuant to which the Company engaged BioPharmaWorks to perform certain services for the Company. Those services include, among other things: (a) assisting the Company to (i) commercialize its products and strengthen its patent portfolio, (ii) identify large pharmaceutical companies with potential interest in the Company’s product pipeline, and (iii) prepare and deliver presentations concerning the Company’s products; (b) at the request of the Board of Directors, serving as backup management for up to three months should the Company’s Chief Executive Officer and scientific leader be temporarily unable to carry out his duties; (c) being available for consultation in drug discovery and development; and (d) identifying providers and overseeing tasks relating to clinical use and commercialization of new compounds. BioPharmaWorks was founded in 2015 by former Pfizer scientists with extensive multi-disciplinary research and development and drug development experience. The Collaboration Agreement is for an initial term of two years and automatically renews for subsequent annual periods unless terminated by a party not less than 60 days prior to the expiration of the applicable period. In connection with the Collaboration Agreement, the Company agreed to pay BioPharmaWorks a monthly fee of \$10,000, subject to the right of the Company to pay a negotiated hourly rate in lieu of the monthly payment, and agreed to issue to BioPharmaWorks certain equity-based compensation as described at Note 8. The Company recorded a charge to operations pursuant to this Collaboration Agreement of \$30,000 and \$90,000 during the three months and nine months ended September 30, 2016, respectively.

#### Summary of Principal Cash Obligations and Commitments

The following table sets forth the Company’s principal cash obligations and commitments for the next five fiscal years as of September 30, 2016 aggregating \$357,899, of which \$82,532 is included in current liabilities in the Company’s condensed consolidated balance sheet at September 30, 2016. Amounts included in the 2016 column represent amounts due at September 30, 2016 for the remainder of the 2016 fiscal year ending December 31, 2016.

	Total	Payments Due By Year				
		2016	2017	2018	2019	2020
Research and development contracts	\$ 38,870	\$ 38,870	\$ —	\$ —	\$ —	\$ —
Clinical trial agreements	190,029	190,029	—	—	—	—
Consulting agreements	129,000	39,000	90,000	—	—	—
Total	<u>\$ 357,899</u>	<u>\$ 267,899</u>	<u>\$ 90,000</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

#### Off-Balance Sheet Arrangements

At September 30, 2016, the Company did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.



### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Not applicable.

### ITEM 4. CONTROLS AND PROCEDURES

#### (a) Evaluation of Disclosure Controls and Procedures

The Company carried out an evaluation, under the supervision and with the participation of its management, consisting of its principal executive officer and principal financial officer (who is the same person), of the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act (defined below)). Based upon that evaluation, the Company's principal executive officer and principal financial officer concluded that, as of the end of the period covered in this report, the Company's disclosure controls and procedures were effective to ensure that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the required time periods and is accumulated and communicated to the Company's management, consisting of the Company's principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

The Company's management, consisting of its principal executive officer and principal financial officer, does not expect that its disclosure controls and procedures or its internal controls will prevent all error or fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Furthermore, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Due to the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. In addition, as conditions change over time, so too may the effectiveness of internal controls. However, management believes that the financial statements included in this report fairly present, in all material respects, the Company's financial condition, results of operations and cash flows for the periods presented.

#### (b) Changes in Internal Controls Over Financial Reporting

The Company's management, consisting of its principal executive officer and principal financial officer, has determined that no change in the Company's internal control over financial reporting (as that term is defined in Rules 13(a)-15(f) and 15(d)-15(f) of the Securities Exchange Act of 1934) occurred during or subsequent to the end of the period covered in this report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

## PART II - OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

The Company is not currently subject to any pending or threatened legal actions or claims.

### ITEM 1A. RISK FACTORS

As of the date of this filing, there have been no material changes to the Risk Factors included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2015, as filed with the SEC on March 28, 2016 (the "2015 Form 10-K"). The Risk Factors set forth in the 2015 Form 10-K should be read carefully in connection with evaluating the Company's business and in connection with the forward-looking statements contained in this Quarterly Report on Form 10-Q. Any of the risks described in the 2015 Form 10-K could materially adversely affect the Company's business, financial condition or future results and the actual outcome of matters as to which forward-looking statements are made. These are not the only risks that the Company faces. Additional risks and uncertainties not currently known to the Company or that the Company currently deems to be immaterial also may materially adversely affect the Company's business, financial condition and/or operating results.

### ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Effective September 12, 2016, in connection with his continuing role as a consultant to the Company, Francis Johnson was granted fully-vested stock options under the 2007 Plan to purchase 500,000 shares of the Company's common stock. The stock options are exercisable for a period of five years from the date of grant at \$0.20 per share. The fair market value of the Company's common stock on the date of grant was \$0.20 per share. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$98,901 (\$0.1978 per share).

### ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

### ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

### ITEM 5. OTHER INFORMATION

Not applicable.

### ITEM 6. EXHIBITS

A list of exhibits required to be filed as part of this report is set forth in the Index to Exhibits, which is presented elsewhere in this document, and is incorporated herein by reference.

**SIGNATURES**

In accordance with the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

(Registrant)

Date: November 4, 2016

By: /s/ JOHN S. KOVACH

John S. Kovach  
Chief Executive Officer and Chief Financial Officer  
(Principal financial and accounting officer)

## INDEX TO EXHIBITS

The following documents are filed as part of this report:

<u>Exhibit Number</u>	<u>Description of Document</u>
31.1*	Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Officer's Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document

\* Filed herewith.

\*\* In accordance with Regulation S-T, the XBRL related information on Exhibit No. 101 to this Quarterly Report on Form 10-Q shall be deemed "furnished" herewith but not "filed".



**CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER  
UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, John S. Kovach, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Lixte Biotechnology Holdings, 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. I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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 my 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. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's Board of Directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2016

By: /s/ JOHN S. KOVACH

John S. Kovach  
Chief Executive Officer and Chief Financial Officer

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**CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER  
UNDER SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, John S. Kovach, the Chief Executive Officer and Chief Financial Officer of Lixte Biotechnology Holdings, Inc. (the "Company"), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that:

(i) The Quarterly Report on Form 10-Q of the Company for the quarterly period ended September 30, 2016 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

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

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Date: November 4, 2016

By: /s/ JOHN S. KOVACH

John S. Kovach  
Chief Executive Officer and Chief Financial Officer

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