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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, 2014**

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  Accelerated filer   
Non-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 October 31, 2014, the Company had 45,483,097 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 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. For example, 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. However, 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, 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, 2013, 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**

	<b>September 30, 2014</b>	<b>December 31, 2013</b>
	(Unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash	\$ 8,864	\$ 475,019
Money market funds	893,689	6,135
Advances on research and development contract services	29,530	33,880
Prepaid expenses and other current assets	64,087	43,006
Total current assets	996,170	558,040
Total assets	\$ 996,170	\$ 558,040
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 130,490	\$ 107,774
Research and development contract liabilities, including \$52,836 and \$34,398 to a related party at September 30, 2014 and December 31, 2013, respectively	105,112	47,283
Liquidated damages payable under registration rights agreement	74,000	74,000
Due to stockholder	92,717	92,717
Total current liabilities	402,319	321,774
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; authorized – 10,000,000 shares; issued – none	—	—
Common stock, \$0.0001 par value; authorized – 100,000,000 shares; issued and outstanding – 45,483,097 shares and 41,583,097 shares at September 30, 2014 and December 31, 2013, respectively	4,548	4,158
Additional paid-in capital	15,712,810	13,184,081
Accumulated deficit	(15,123,507)	(12,951,973)
Total stockholders' equity	593,851	236,266
Total liabilities and stockholders' equity	\$ 996,170	\$ 558,040

See accompanying notes to condensed consolidated financial statements.

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenues	\$ —	\$ —	\$ —	\$ —
Costs and expenses:				
General and administrative costs, including \$82,107 and \$14,697 to related parties for the three months ended September 30, 2014 and 2013, respectively, and \$531,794 and \$100,907 for the nine months ended September 30, 2014 and 2013, respectively	192,317	93,154	926,882	380,808
Research and development costs, including \$85,440 and \$91,950 to related parties for the three months ended September 30, 2014 and 2013, respectively, and \$265,918 and \$233,355 for the nine months ended September 30, 2014 and 2013, respectively	309,103	219,898	807,597	634,998
Total costs and expenses	<u>501,420</u>	<u>313,052</u>	<u>1,734,479</u>	<u>1,015,806</u>
Loss from operations	(501,420)	(313,052)	(1,734,479)	(1,015,806)
Interest income	27	1	56	2
Fair value of warrant extensions	—	—	(302,691)	—
Fair value of warrant discount	—	—	(134,420)	—
Net loss	<u>\$ (501,393)</u>	<u>\$ (313,051)</u>	<u>\$ (2,171,534)</u>	<u>\$ (1,015,804)</u>
Net loss per common share – Basic and diluted	<u>\$ (0.01)</u>	<u>\$ (0.01)</u>	<u>\$ (0.05)</u>	<u>\$ (0.02)</u>
Weighted average common shares outstanding – Basic and diluted	<u>45,483,097</u>	<u>41,583,097</u>	<u>44,042,438</u>	<u>41,583,097</u>

See accompanying notes to condensed consolidated financial statements.

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

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

**Nine Months Ended September 30, 2014**

	<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>			
Balance, December 31, 2013	41,583,097	\$ 4,158	\$ 13,184,081	\$ (12,951,973)	\$ 236,266
Exercise of stock warrants	3,900,000	390	1,412,110	—	1,412,500
Fair value of warrant extensions	—	—	302,691	—	302,691
Fair value of warrant discount	—	—	134,420	—	134,420
Stock-based compensation expense	—	—	679,508	—	679,508
Net loss	—	—	—	(2,171,534)	(2,171,534)
Balance, September 30, 2014	<u>45,483,097</u>	<u>\$ 4,548</u>	<u>\$ 15,712,810</u>	<u>\$ (15,123,507)</u>	<u>\$ 593,851</u>

See accompanying notes to condensed consolidated financial statements.

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

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

	Nine Months Ended September 30,	
	2014	2013
Cash flows from operating activities:		
Net loss	\$ (2,171,534)	\$ (1,015,804)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense included in -		
General and administrative costs	513,042	104,264
Research and development costs	166,466	—
Fair value of warrant -		
Extensions	302,691	—
Discount	134,420	—
Changes in operating assets and liabilities:		
(Increase) decrease in -		
Advances on research and development contract services	4,350	15,420
Prepaid expenses and other current assets	(21,081)	(381)
Increase (decrease) in -		
Accounts payable and accrued expenses	22,716	(15,799)
Research and development contract liabilities	57,829	48,150
Net cash used in operating activities	(991,101)	(864,150)
Cash flows from investing activities:		
Increase in money market funds	(887,554)	(1)
Net cash used in investing activities	(887,554)	(1)
Cash flows from financing activities:		
Proceeds from exercise of warrants	1,412,500	—
Net cash provided by financing activities	1,412,500	—
Cash:		
Net decrease	(466,155)	(864,151)
Balance at beginning of period	475,019	1,655,122
Balance at end of period	\$ 8,864	\$ 790,971
Supplemental disclosures of cash flow information:		
Cash paid for -		
Interest	\$ —	\$ —
Income taxes	\$ —	\$ —

See accompanying notes to condensed consolidated financial statements.

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

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

**Three Months and Nine Months Ended September 30, 2014 and 2013**

**1. Basis of Presentation**

The condensed consolidated financial statements of Lixte Biotechnology Holdings, Inc., a Delaware corporation, and its wholly-owned Delaware subsidiary, Lixte Biotechnology, Inc. (collectively, the “Company”), at September 30, 2014, and for the three months and nine months ended September 30, 2014 and 2013, 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, 2014, and the results of its operations for the three months and nine months ended September 30, 2014 and 2013, and its cash flows for the nine months ended September 30, 2014 and 2013. Operating results for the interim periods presented are not necessarily indicative of the results to be expected for a full fiscal year. The condensed balance sheet at December 31, 2013 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, 2013, as filed with the SEC.

The Company is considered a development stage company, as the Company’s has not yet commenced any revenue-generating operations, does not have any cash flows from operations, and is dependent on debt and equity funding to finance its operations.

In June 2014, as discussed in Note 3, the Financial Accounting Standards Board issued new guidance that removed all incremental financial reporting requirements from generally accepted accounting principles in the United States for development stage entities. The Company early adopted this new guidance effective June 30, 2014, as a result of which all inception-to-date financial information and disclosures have been omitted from this report.

**2. Business Operations**

*Business*

The Company is engaged in research and development activities with respect to anti-cancer treatments and other common non-malignant diseases. As the Company’s planned principal operations have not yet commenced, the Company activities are subject to significant risks and uncertainties, including the need to obtain additional financing, as described below.

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

*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, and genetic diseases, such as Gaucher’s disease) in which errors in normal cellular processing lead to loss of functions important to normal cell function. 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: 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.

On August 16, 2011, the United States Patent and Trademark Office (the "PTO") awarded a patent to the Company for its lead compound, LB-100, as well as for a number of structurally related compounds. On November 15, 2011, the PTO awarded a patent to the Company for a lead compound in the LB-200 series and a compound in the LB-100 series as neuroprotective agents for the prevention and treatment of neurodegenerative diseases. On March 27, 2012, the PTO awarded a patent to the Company for its lead compound LB-201, as well as for a number of structurally related compounds. Patent applications on these compounds and their use are pending world-wide.

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 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 the clinical trial is 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 began in April 2013 with the entry of patients into the clinical trial (NCT01837667 at [www.clinicaltrials.gov](http://www.clinicaltrials.gov)) and was 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. 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 ongoing Phase 1 clinical trial of LB-100. The Company estimates that the Phase 1 clinical trial will be completed between March and June 2015 at a total cost of approximately \$2,000,000, which will be paid to or through Theradex, the CRO responsible for the clinical development of LB-100. Total costs charged to operations through September 30, 2014 for services paid to or through Theradex pursuant to this arrangement were \$538,820, of which \$86,440 and \$87,088 were incurred during the three months ended September 30, 2014 and 2013, respectively, and \$260,100 and \$210,950 were incurred during the nine months ended September 30, 2014 and 2013, respectively. The final cost of the clinical trial is variable, depending upon the number of patients needed to be medically screened to determine if they meet the criteria for entry into the study and ultimately upon the total number of patients entered into the study to establish the proper doses of the drug for Phase 2 clinical trials.

After completion of the Phase 1 clinical trial of LB-100, subject to the availability of funds, the Company anticipates that the next steps in its clinical development will be to determine the anti-cancer activity of LB-100 as a single agent against a specific hematological cancer in a Phase 1/2 clinical trial, and in combination with docetaxel against a specific solid tumor in a Phase 2 clinical trial for which single agent docetaxel is indicated.

### ***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 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 believes that there is 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 capital and to ultimately achieve sustainable revenues and profitable operations. The Company's condensed consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties.

At September 30, 2014, the Company had not yet commenced any revenue-generating operations. All activity through September 30, 2014 has been related to the Company's capital raising efforts and research and development activities. As such, the Company has yet to generate any cash flows from operations, and is dependent on debt and equity funding from both related and unrelated parties to finance its operations.

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

At September 30, 2014, the Company had cash and money market funds aggregating \$902,553, the result primarily of \$1,412,500 raised by the Company in April 2014 by offering a 50% discount to warrant holders as an inducement to exercise their warrants for cash. The amount and timing of future cash requirements will depend on the pace of the Company's programs, in particular the completion of the Phase 1 clinical trial of LB-100. The Company believes that it has sufficient funds to continue with the Phase 1 clinical trial of LB-100 and to fund its operating plans through approximately June 30, 2015. Accordingly, the Company will need to raise additional capital in 2015, likely in the form of equity. 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. 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 products, or to discontinue its operations entirely.

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

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

The accompanying condensed consolidated financial statements include the financial statements of Holdings and its wholly-owned subsidiary, Lixte. Intercompany balances and transactions have been eliminated in consolidation.

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

The Company's cash balances may periodically exceed federally insured limits. The Company has not experienced a loss in such accounts to date. The Company maintains its accounts with financial institutions with high credit ratings.

#### ***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 as incurred over the life of the underlying contracts on the straight-line basis, unless the achievement of milestones, the completion of contracted work, or other information indicates that a different expensing schedule is more appropriate. 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. Patent costs were \$83,869 and \$86,424 for the three months ended September 30, 2014 and 2013, respectively, and \$239,667 and \$286,019 for the nine months ended September 30, 2014 and 2013, respectively. Patent costs are included in research and development costs in the Company's condensed consolidated statements of operations.

#### ***Royalties***

Pursuant to a Patent License Agreement with the NIH that provides the Company with an exclusive license for all patents submitted jointly with the NIH under the CRADA, various categories of royalties at various rates and amounts are payable, including minimum annual royalties (subject to an offset for royalties from net sales), royalties on net sales, royalties based on the achievement of certain benchmarks, and royalties based on granting sublicense agreements, with respect to joint patents. Such royalties are accrued and paid when they become legal obligations, and are charged to general and administrative costs.

#### ***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 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, is being carried out by nationally recognized comprehensive cancer centers, and is estimated to be completed between March and June 2015. The Phase 1 clinical trial is estimated to cost approximately \$2,000,000, with such payments expected to be divided approximately evenly between payments to Theradex for services rendered and payments for pass-through costs for the clinical center's laboratory costs and investigator costs. Total costs charged to operations through September 30, 2014 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, were \$538,820, of which \$86,440 and \$87,088 were incurred during the three months ended September 30, 2014 and 2013, respectively, or approximately 33% and 40% of research and development costs for the three months ended September 30, 2014 and 2013, respectively. During the nine months ended September 30, 2014 and 2013, the Company incurred \$260,100 and \$210,950, respectively, or approximately 34% and 33% of research and development costs for the nine months ended September 30, 2014 and 2013, respectively. The costs charged to operations for amounts paid to or through Theradex for services relating to the Phase 1 clinical trial of LB-100 are expected to represent a larger percentage of total research and development costs during the fiscal years ending December 31, 2014 and 2015 as compared to prior fiscal years. Costs pursuant to this agreement are included in research and development costs in the Company's condensed consolidated statements of operations (see Note 6).

### ***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.

For federal income tax purposes, net operating losses can be carried forward for a period of 20 years until they are either utilized or until they expire.

On January 1, 2007, the Company adopted accounting rules which address the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under these rules, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate settlement. These accounting rules also provide guidance on de-recognition, classification, interest and penalties on income taxes, accounting in interim periods and requires increased disclosures. As of September 30, 2014, no liability for unrecognized tax benefits was required to be recorded.

The Company files income tax returns in the U.S. federal jurisdiction and is subject to income tax examinations by federal tax authorities for the year 2009 and thereafter. The Company's policy is to record interest and penalties on uncertain tax provisions as income tax expense. As of September 30, 2014, the Company has no accrued interest or penalties related to uncertain tax positions.

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

The Company periodically issues stock options to officers, directors and consultants for services rendered. Options vest and expire according to terms established at the grant date.

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 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.

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 options vest, they are valued on each vesting date and an adjustment is recorded for the difference between the value already recorded and the then current value on the date of vesting.

The fair value of 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 security 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.

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 to satisfy stock option exercises.

### ***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, 2014 and 2013.

### ***Earnings Per Share***

The Company's computation of earnings per share ("EPS") includes basic and diluted EPS. Basic EPS is measured as the income (loss) available to common shareholders 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., warrants and 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.

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 warrants and stock options outstanding are anti-dilutive.

At September 30, 2014 and 2013, 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.

	<u>2014</u>	<u>2013</u>
Warrants	2,928,800	6,828,800
Stock options	7,375,000	3,550,000
Total	<u>10,303,800</u>	<u>10,378,800</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.

### *Use of Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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. Actual results could differ from those estimates.

### *Recent Accounting Pronouncements*

In April 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2014-08 (ASU 2014-08), *Presentation of Financial Statements (Topic 205) and Property, Plant and Equipment (Topic 360)*. ASU 2014-08 amends the requirements for reporting discontinued operations and requires additional disclosures about discontinued operations. Under ASU 2014-08, only disposals representing a strategic shift in operations or that have a major effect on the Company's operations and financial results should be presented as discontinued operations. ASU 2014-08 is effective for annual periods beginning after December 15, 2014. As the Company is engaged in research and development activities and the Company's planned principal operations have not yet commenced, the Company does not expect the adoption of this guidance to have any impact on the Company's financial statement presentation or disclosures.

In May 2014, the 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 U.S. 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, 2016, and early adoption is not permitted. Entities can transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. As the Company does not expect to have any operating revenues for the foreseeable future, the Company does not expect the adoption of this guidance to have any impact on the Company's financial statement presentation or disclosures.

In June 2014, the FASB issued Accounting Standards Update No. 2014-10 (ASU 2014-10) *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*. ASU 2014-10 eliminated the requirement to present inception-to-date information about income statement line items, cash flows, and equity transactions, and clarifies how entities should disclose the risks and uncertainties related to their activities. ASU 2014-10 also eliminated an exception provided to development stage entities in Consolidations (ASC Topic 810) for determining whether an entity is a variable interest entity on the basis of the amount of investment equity that is at risk. The presentation and disclosure requirements in Topic 915 will no longer be required for interim and annual reporting periods beginning after December 15, 2014, and the revised consolidation standards will take effect in annual periods beginning after December 15, 2015. Early adoption was permitted. The Company adopted the provisions of ASU 2014-10 effective June 30, 2014, and accordingly, is no longer presenting the inception-to-date financial information and disclosures formerly required in its financial statements.

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 Company is currently evaluating the impact the adoption of ASU 2014-15 on the Company's financial statement presentation and 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. Common Stock and Common Stock Warrants

On January 28, 2014, the Company's Board of Directors extended to June 30, 2014 outstanding warrants to acquire 1,748,800 shares of the Company's common stock exercisable at \$0.50 per share that were issued to investors and the placement agent in connection with private placements that closed on February 10, 2009, March 2, 2009 and April 6, 2009. On September 30, 2012, the Company had previously extended all other outstanding warrants to June 30, 2014. Included in the January 2014 extension were warrants to acquire 815,920 shares of common stock scheduled to expire on February 10, 2014, warrants to acquire 312,880 shares of common stock scheduled to expire on March 2, 2014, and warrants to acquire 620,000 shares of common stock scheduled to expire on April 6, 2014. 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 \$78,617 (average of \$0.04 per share), and such amount was charged to operations on January 28, 2014. The fair value of the warrant extensions was calculated using the following input variables: stock price - \$0.15 per share; exercise price - \$0.50 per share; expected life - 13 to 153 days; expected volatility - 262%; expected dividend yield - 0%; risk-free interest rate - 1.51%.

On January 28, 2014, the Company offered to all of its warrant holders an inducement to exercise early by reducing the exercise price of currently outstanding warrants by 50%, if exercised on a cash basis by April 15, 2014. The exercise prices of the warrants before reduction were \$0.50 per share (2,253,800 warrants) and \$0.75 per share (4,575,000 warrants). 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 \$134,420 (an average of \$0.02 per share), and such amount was charged to operations on January 28, 2014. The fair value of the warrant extensions was calculated using the following input variables: stock price - \$0.15 per share; exercise price - \$0.50 and \$0.75 per share; expected life - 77 days (the period during which the discount was available); expected volatility - 262%; expected dividend yield - 0%; risk-free interest rate - 1.51%.

As a result of the discount warrant offer, warrants to acquire 3,900,000 shares of the Company's common stock were exercised in April 2014 at discounts ranging from \$0.25 to \$0.375 per share. The exercise of the warrants generated aggregate net proceeds to the Company of \$1,412,500.

On June 4, 2014, the Company's Board of Directors extended to March 31, 2015 outstanding warrants to acquire 2,928,800 shares of the Company's common stock that were issued to investors and the placement agent in connection with private placements that closed on February 10, 2009, March 2, 2009, April 6, 2009 and January 20, 2010, provided that the warrants were exercised in cash. Warrants to acquire 1,853,800 shares of the Company's common stock were exercisable at \$0.50 per share and 1,075,000 were exercisable at \$0.75 per share. All warrants extended were scheduled to expire on June 30, 2014. 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 \$224,074 (average of \$0.08 per share), and such amount was charged to operations on June 4, 2014. The fair value of the warrant extensions was calculated using the following input variables: stock price - \$0.22 per share; exercise price - \$0.50 and \$0.75 per share; expected life - 26 to 300 days; expected volatility - 173%; expected dividend yield - 0%; risk-free interest rate - 0.10%.

A summary of common stock warrant activity, including warrants to purchase common stock that were issued in conjunction with the Company's private placements, is presented in the tables below. For presentation purposes, warrants that were extended are considered as outstanding for the entire period in which such extension occurs.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Warrants outstanding at December 31, 2013	6,828,800	0.667	
Issued	—	—	
Exercised	(3,900,000)	0.263	
Expired	—	—	
Warrants outstanding at September 30, 2014	<u>2,928,800</u>	<u>\$ 0.592</u>	<u>0.50</u>
Warrants exercisable at December 31, 2013	6,659,840	\$ 0.672	
Warrants exercisable at September 30, 2014	<u>2,807,840</u>	<u>\$ 0.596</u>	<u>0.50</u>

The exercise prices of common stock warrants outstanding and exercisable are as follows at September 30, 2014:

Exercise Prices	Warrants Outstanding (Shares)	Warrants Exercisable (Shares)
\$ 0.500	1,853,800	1,732,840
\$ 0.750	1,075,000	1,075,000
	<u>2,928,800</u>	<u>2,807,840</u>

Based on a fair market value of \$0.14 per share on September 30, 2014, there were no exercisable but unexercised in-the-money common stock warrants on that date. Accordingly, there was no intrinsic value attributed to exercisable but unexercised common stock warrants at September 30, 2014.

Based on a fair market value of \$0.13 per share on December 31, 2013, there were no exercisable but unexercised in-the-money common stock warrants on that date. Accordingly, there was no intrinsic value attributed to exercisable but unexercised common stock warrants at December 31, 2013.

At September 30, 2014, warrants exercisable do not include warrants to acquire 120,960 shares of common stock that are contingent upon the exercise of warrants contained in units sold as part of the third private placement, as described above.

## 5. Money Market Funds

Money market funds at September 30, 2014 and December 31, 2013 consisted of investments in shares of Morgan Stanley New York Municipal Money Market Trust with a market value of \$893,689 and \$6,135, respectively.

The Morgan Stanley New York Municipal Money Market Trust is an open-end fund incorporated in the USA. The Fund's objective is as high level of daily income exempt from federal and New York income tax as is consistent with stability of principal and liquidity. The Fund invests in high quality, short-term municipal obligations that pay interest exempt from federal and NY taxes.



The following table presents money market funds at their level within the fair value hierarchy at September 30, 2014 and December 31, 2013.

	<u>Total</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
<b>September 30, 2014:</b>				
Money market funds	\$ 893,689	\$ 893,689	\$ —	\$ —
<b>December 31, 2013:</b>				
Money market funds	\$ 6,135	\$ 6,135	\$ —	\$ —

## 6. Related Party Transactions

Advances from the Company's founding stockholder and Chief Executive Officer, Dr. John Kovach, are non-interest bearing and are due on demand. At September 30, 2014 and December 31, 2013, such stockholder advances outstanding and due to Dr. Kovach totaled \$92,717.

Dr. Kovach was paid a salary of \$15,000 for the three months ended September 30, 2014 and 2013, and \$45,000 for the nine months ended September 30, 2014 and 2013, 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 financial statements and, accordingly, have not been reflected therein.

On June 18, 2014, the Company entered into a sub-lease agreement for shared office space in New York City with the Eric Forman Law Office, a party providing legal and consulting services to the Company. The sub-lease is for a term of six months at a base rate of \$875 per month. Eric Forman is the son-in-law of Gil Schwartzberg, a significant stockholder of and consultant to the Company. Legal and consulting fees charged to operations for services rendered by Eric Forman for the three months and nine months ended September 30, 2014 were \$12,000 and \$34,000, respectively. The Company recognized similar charges aggregating \$12,000 for the year ended December 31, 2013, all of which were recorded in the quarter ended December 31, 2013.

On May 21, 2012, the Company entered into an agreement with Dr. Mel Sorensen, a former member of the Company's Board of Directors, for consultation and advice regarding the preparation and strategy for obtaining FDA allowance of a clinical trial of the lead compound of the LB-100 series. The term of the agreement was for the period from May 21, 2012 to May 31, 2013 and provided for a fee of \$25,000, payable in two installments of \$12,500 on May 21, 2012 and December 1, 2012. Consulting and advisory fees charged to operations pursuant to this agreement was \$-0- and \$10,417 for the three months and nine months ended September 30, 2013, respectively, and are included in research and development costs in the Company's condensed consolidated statements of operations. Effective April 16, 2014, Dr. Sorensen resigned from the Company's Board of Directors for personal reasons.

Periodically, the Company has entered into agreements with Ascentage Pharma Group to conduct various studies. As of September 30, 2014, contracts with a total estimated cost of \$93,830, of which \$56,176 had been paid, were in process. Ascentage Pharma Group is a spin-off of Ascenta Therapeutics, of which Dr. Sorensen is the President and Chief Executive Officer and a director. Ascentage Pharma Group and Ascenta Therapeutics have a continuing business relationship and certain common shareholders. However, Dr. Sorensen does not have any direct business relationship with or ownership in Ascentage Pharma Group.

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 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, is being carried out by nationally recognized comprehensive cancer centers, and is estimated to be completed between March and June 2015. The Phase 1 clinical trial is estimated to cost approximately \$2,000,000, with such payments expected to be divided approximately evenly between payments to Theradex for services rendered and payments for pass-through costs for the clinical center's laboratory costs and investigator costs. Total costs charged to operations through September 30, 2014 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, totaled \$538,820, of which \$86,440 and \$87,088 were incurred during the three months ended September 30, 2014 and 2013, respectively, and \$260,100 and \$210,950 were incurred during the nine months ended September 30, 2014 and 2013, respectively. Costs pursuant to this agreement are included in research and development costs in the Company's condensed consolidated statements of operations. On May 2, 2011, Dr. Robert B. Royds, the founder, Chairman of the Board and Medical Director of Theradex, was appointed to the Company's Board of Directors. Dr. Royds died on March 23, 2013. The death of Dr. Royds is not expected to have any impact on the management and administration of the Phase 1 clinical trial of LB-100.

In addition to the above described agreement with Theradex, the Company has also from time to time engaged Theradex to assist the Company in bringing LB-100 through the FDA approval process and to provide other regulatory services. These costs were not material for all periods presented.

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 initial term and any subsequent one year term shall be automatically extended on an annual basis unless a notice of intent to terminate is given by either party at least 90 days before the end of the applicable term. The Advisory Agreements provides for compensation of \$25,000 annually, payable in two installments of \$12,500, with the first payment due on January 31, 2014 and the second payment due on July 1, 2014. Total fees charged to operations for services paid to pursuant to this agreement were \$6,250 and \$18,750 for the three months and nine months ended September 30, 2014, respectively, and are 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 are described at Note 7. Total stock-based compensation expense relating to directors, officers and other related parties was \$75,857 and \$14,697 for the three months ended September 30, 2014 and 2013, respectively, and \$513,044 and \$100,907 for the nine months ended September 30, 2014 and 2013, respectively.

## **7. Stock-Based Compensation**

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

The fair value of each option awarded is estimated on the date of grant and subsequent measurement dates using the Black-Scholes option-pricing model. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because the Company's stock options have characteristics significantly different from those of traded options, and because changes in the subjective assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its stock options. The expected dividend yield assumption is based on the Company's expectation of dividend payouts. 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. Expected life of the options is the average of the vesting term and the full contractual term of the options.

New transactions during the nine months ended September 30, 2014 that required an assessment of value pursuant to the Black-Scholes option-pricing model utilized the following inputs: exercise price per share - \$0.25; stock price per share - \$0.25; expected dividend yield - 0.00%; expected volatility - 173%; average risk-free interest rate - 1.67%; expected life - 5 years. For the purpose of assessing value for transactions requiring re-evaluation at September 30, 2014, the Black-Scholes option-pricing model utilized the following inputs: exercise price per share - \$0.13 to \$0.50; stock price per share - \$0.14; expected dividend yield - 0.00%; expected volatility - 380%; average risk-free interest rate - 1.75%; expected life - 4.25 years.

There were no new transactions during the nine months ended September 30, 2013 that required an assessment of value pursuant to the Black-Scholes option-pricing model. Additionally, there were no transactions entered into in prior periods that required re-evaluation of assessed value at September 30, 2013.

On June 30, 2011, the Company granted to Dr. Philip F. Palmedo, a director of the Company, stock options to purchase 200,000 shares of common stock, exercisable for a period of five years from the date of grant at \$0.98 per share, which was the fair market value of the Company's common stock on such date. The options vest ratably in equal quarterly installments of 25,000 shares beginning July 1, 2011. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be \$196,000 (\$0.98 per share). During the three months ended September 30, 2014 and 2013, the Company recorded charges to operations of \$-0- and \$-0-, respectively, with respect to these options. During the nine months ended September 30, 2014 and 2013, the Company recorded charges to operations of \$-0- and \$48,530, respectively, with respect to these options.

On June 30, 2011, the Company granted to Dr. Iwao Ojima stock options to purchase 50,000 shares of common stock, exercisable for a period of five years from the date of grant at \$0.98 per share, which was the fair market value of the Company's common stock on such date. The options vest ratably in equal quarterly installments of 6,250 shares beginning July 1, 2011. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be \$49,000 (\$0.98 per share). During the three months ended September 30, 2014 and 2013, the Company charged operations of \$-0- and \$-0-, respectively, with respect to these options. During the nine months ended September 30, 2014 and 2013, the Company recorded charges to operations of \$-0- and \$3,357, respectively, with respect to these options.

On January 28, 2014, the Company approved a second amendment to the Company's consulting agreement with Gil Schwartzberg dated September 12, 2007 to extend it 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 options (2,000,000 shares) vesting immediately and one-half of the options (2,000,000 shares) vesting on January 28, 2015. The fair value of these 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 is attributed to the options fully-vested on January 28, 2014 and as such was charged to operations on that date. The remaining unvested portion of the fair value of the options will be charged to operations ratably from January 28, 2014 through January 28, 2015. During the three months and nine months ended September 30, 2014, the Company recorded charges to operations of \$75,857 and \$187,945 with respect to the remaining unvested portion of the options.

Effective May 1, 2011, in connection with his election to the Company's Board of Directors, Dr. Robert B. Royds was granted stock options to purchase 200,000 shares of the Company's common stock, vesting 25,000 shares on May 1, 2011, and 25,000 shares quarterly thereafter until all of the shares are vested, exercisable for a period of five years from each tranche's vesting date, at \$0.98 per share, which was the fair market value of the Company's common stock on such date. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$196,000 (\$0.98 per share), and was charged to operations ratably from May 2, 2011 through February 1, 2013. During the three months and nine months ended September 30, 2013, the Company recorded charges to operations of \$0 and \$8,548, respectively, with respect to these options. Dr. Royds died on March 23, 2013. The stock options expired unexercised.

Effective September 16, 2012, in connection with her election to the Company's Board of Directors, Dr. Kathleen P. Mullinix was granted stock options to purchase 200,000 shares of the Company's common stock, vesting 25,000 shares on September 16, 2012, and 25,000 shares quarterly thereafter until all of the shares are vested, exercisable for a period of five years from the date of grant at \$0.65 per share, which was the fair market value of the Company's common stock on such date. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$118,000 (\$0.59 per share), and is being charged to operations from September 16, 2012 through June 16, 2014. During the three months ended September 30, 2014 and 2013, the Company recorded charges to operations of \$-0- and \$14,697, respectively, with respect to these options. During the nine months ended September 30, 2014 and 2013, the Company recorded charges to operations of \$26,899 and \$43,829, respectively, with respect to these 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 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 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 from December 24, 2013 through June 24, 2017. During the three months and nine months ended September 30, 2014, the Company recorded charges to operations of \$857 and \$4,316, respectively, with respect to these options.

On June 26, 2014, the Company granted to Francis Johnson, a consultant to the Company and a co-owner of Chem-Master International, Inc., a vendor of the Company, immediately vesting stock options to purchase 500,000 shares of common stock, exercisable for a period of five years from the grant date at \$0.25 per share. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$118,650 (\$0.24 per share), which was charged to operations on that date. The options were granted to Mr. Johnson as compensation for his contributions to the Company's compound development activities.

On July 15, 2014, Gil Schwartzberg, a significant stockholder of and consultant to the Company, assigned fully-vested stock options to acquire 1,000,000 shares of the Company's common stock to Daniel Von Hoff, a member of the Company's Scientific Advisory Committee. The options assigned included options to acquire 500,000 shares that had been previously granted to Mr. Schwartzberg on October 15, 2009, are exercisable at \$1.00 per share, and expire on October 15, 2014, and options for 500,000 shares that had been previously granted to Mr. Schwartzberg on October 5, 2011, are exercisable at \$1.00 per share, and expire on October 5, 2016. As Mr. Schwartzberg is considered an affiliate of the Company for accounting and securities purposes, the fair value of the stock options assigned by Mr. Schwartzberg to Mr. Von Hoff for the benefit of the Company were recorded as a contribution to capital and a charge to operations. The fair value of the options assigned, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$43,500 (average of \$0.04 per share), and such amount was charged to operations on July 15, 2014. The fair value of the options assigned was calculated using the following input variables: stock price - \$0.15 per share; exercise price - \$1.00 per share; expected life - 92 and 812 days; expected volatility - 173%; expected dividend yield - 0%; risk-free interest rate - 0.03% and 0.49%.

A summary of stock option activity is presented in the tables below.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Options outstanding at December 31, 2013	3,150,000	0.818	
Granted	4,500,000	0.472	
Exercised	—	—	
Expired	(275,000)	0.345	
Options outstanding at September 30, 2014	<u>7,375,000</u>	<u>\$ 0.623</u>	<u>3.48</u>
Options exercisable at December 31, 2013	3,000,000	\$ 0.843	
Options exercisable at September 30, 2014	<u>5,300,000</u>	<u>\$ 0.677</u>	<u>2.69</u>

Total deferred compensation expense for the outstanding value of unvested stock options was approximately \$102,000 at September 30, 2014, which is being recognized subsequent to September 30, 2014 over a weighted-average period of approximately seven months.

The exercise prices of common stock options outstanding and exercisable are as follows at September 30, 2014:

Exercise Prices	Options Outstanding (Shares)	Options Exercisable (Shares)
\$ 0.130	100,000	25,000
\$ 0.250	500,000	500,000
\$ 0.500	4,125,000	2,125,000
\$ 0.650	700,000	700,000
\$ 0.980	450,000	450,000
\$ 1.000	1,500,000	1,500,000
	<u>7,375,000</u>	<u>5,300,000</u>

The intrinsic value of exercisable but unexercised in-the-money stock options at September 30, 2014 was approximately \$250, based on a fair market value of \$0.14 per share on September 30, 2014.

Based on a fair market value of \$0.13 per share on December 31, 2013, there were no exercisable but unexercised in-the-money stock options on that date. Accordingly, there was no intrinsic value attributed to exercisable but unexercised stock options at December 31, 2013.

Outstanding options to acquire 2,075,000 shares of the Company's common stock had not vested at September 30, 2014.

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

## 8. Commitments and Contingencies

Effective September 19, 2008, the Company entered into a Patent License Agreement (the "PLA") with the NIH providing the Company with an exclusive license for all patents submitted jointly with the NIH under the CRADA. The PLA provided for an initial payment of \$25,000 to the NIH within 60 days of September 19, 2008, and for a minimum annual royalty of \$30,000 on January 1 of each calendar year following the year in which the CRADA is terminated. The PLA also provided for the Company to pay (i) specified royalties based on net sales by the Company and its sub-licensees, reduced by the amount of the minimum annual royalty for that year, (ii) certain benchmark royalties upon the achievement of certain clinical benchmarks, and (iii) sublicensing royalties for the granting of sublicenses, with respect to joint patents. The Company paid the initial \$25,000 obligation on November 10, 2008, which was charged to general and administrative costs. Due to the termination of the CRADA on April 1, 2013, the Company became obligated for a minimum annual royalty of \$30,000 to the NIH beginning in 2014 and each year thereafter. As of January 31, 2014, a minimum royalty of \$30,000 was due pursuant to the PLA, which was charged to general and administrative costs on that date and is included in accounts payable and accrued expenses in the accompanying condensed consolidated balance sheet at September 30, 2014. During April 2014, the Company advised the NIH of its intent to terminate this license.

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 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, is being carried out by nationally recognized comprehensive cancer centers, and is estimated to be completed between March and June 2015. The Phase 1 clinical trial is estimated to cost approximately \$2,000,000, with such payments expected to be divided approximately evenly between payments to Theradex for services rendered and payments for pass-through costs for the clinical center's laboratory costs and investigator costs. Total costs charged to operations through September 30, 2014 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, were \$538,820, of which \$86,440 and \$87,088 were incurred during the three months ended September 30, 2014 and 2013, respectively, and \$260,100 and \$210,950 were incurred during the nine months ended September 30, 2014 and 2013, respectively. Costs pursuant to this agreement are included in research and development costs in the Company's condensed consolidated statements of operations.

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 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 is for one year and provides for a quarterly cash fee of \$4,000. Consulting and advisory fees charged to operations pursuant to this agreement were \$4,000 and \$12,000 during the three months and nine months ended September 30, 2014.

The following table sets forth the Company's principal cash obligations and commitments for the next five fiscal years as of September 30, 2014 aggregating \$1,936,138, of which \$301,829 is included in current liabilities in the condensed consolidated balance sheet at September 30, 2014. Amounts included in the 2014 column represent amounts due at September 30, 2014 for the remainder of the 2014 fiscal year ending December 31, 2014.

	Total	Payments Due By Year				
		2014	2015	2016	2017	2018
Research and development contracts	\$ 106,994	\$ 106,994	\$ —	\$ —	\$ —	\$ —
Clinical trial agreements	1,505,802	255,802	1,250,000	—	—	—
Patent license agreement	150,000	30,000	30,000	30,000	30,000	30,000
Operating leases	2,625	2,625	—	—	—	—
Consulting agreements	4,000	4,000	—	—	—	—
Liquidated damages payable under registration rights agreement	74,000	74,000	—	—	—	—
Due to stockholder	92,717	92,717	—	—	—	—
Total	<u>\$ 1,936,138</u>	<u>\$ 566,138</u>	<u>\$ 1,280,000</u>	<u>\$ 30,000</u>	<u>\$ 30,000</u>	<u>\$ 30,000</u>

## 9. Subsequent Events

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's Board of Directors 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 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 is attributed to the options fully-vested on October 7, 2014 and as such will be charged to operations on that date. The remaining unvested portion of the fair value of the options will be charged to operations ratably from October 7, 2014 through October 7, 2015.

## 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 engaged in research and development activities with respect to anti-cancer treatments and other common non-malignant diseases. The Company has not yet commenced any revenue-generating operations, does not have any cash flows from operations, and is dependent on debt and equity funding to finance its operations.

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 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 believes that there is 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 capital and to ultimately achieve sustainable revenues and profitable operations. The Company's condensed consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties.

At September 30, 2014, the Company had not yet commenced any revenue-generating operations. All activity through September 30, 2014 has been related to the Company's capital raising efforts and research and development activities. As such, the Company has yet to generate any cash flows from operations, and is dependent on debt and equity funding from both related and unrelated parties to finance its operations.

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

At September 30, 2014, the Company had cash and money market funds aggregating \$902,553, the result primarily of \$1,412,500 raised by the Company in April 2014 by offering a 50% discount to warrant holders as an inducement to exercise their warrants for cash. The amount and timing of future cash requirements will depend on the pace of the Company's programs, in particular the completion of the Phase 1 clinical trial of LB-100. The Company believes that it has sufficient funds to continue with the Phase 1 clinical trial of LB-100 and to fund its operating plans through approximately June 30, 2015. Accordingly, the Company will need to raise additional capital in 2015, likely in the form of equity. 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. 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 products, or to discontinue its operations entirely.

## Recent Accounting Pronouncements

In April 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update No. 2014-08 (ASU 2014-08), *Presentation of Financial Statements (Topic 205) and Property, Plant and Equipment (Topic 360)*. ASU 2014-08 amends the requirements for reporting discontinued operations and requires additional disclosures about discontinued operations. Under ASU 2014-08, only disposals representing a strategic shift in operations or that have a major effect on the Company’s operations and financial results should be presented as discontinued operations. ASU 2014-08 is effective for annual periods beginning after December 15, 2014. As the Company is engaged in research and development activities and the Company’s planned principal operations have not yet commenced, the Company does not expect the adoption of this guidance to have any impact on the Company’s consolidated financial statement presentation or disclosures.

In May 2014, the 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 U.S. 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, 2016, and early adoption is not permitted. Entities can transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. As the Company does not expect to have any operating revenues for the foreseeable future, the Company does not expect the adoption of this guidance to have any impact on the Company’s consolidated financial statement presentation or disclosures.

In June 2014, the FASB issued Accounting Standards Update No. 2014-10 (ASU 2014-10) *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*. ASU 2014-10 eliminated the requirement to present inception-to-date information about income statement line items, cash flows, and equity transactions, and clarifies how entities should disclose the risks and uncertainties related to their activities. ASU 2014-10 also eliminated an exception provided to development stage entities in Consolidations (ASC Topic 810) for determining whether an entity is a variable interest entity on the basis of the amount of investment equity that is at risk. The presentation and disclosure requirements in Topic 915 will no longer be required for interim and annual reporting periods beginning after December 15, 2014, and the revised consolidation standards will take effect in annual periods beginning after December 15, 2015. Early adoption was permitted. The Company adopted the provisions of ASU 2014-10 effective June 30, 2014, and accordingly, is no longer presenting the inception-to-date financial information and disclosures formerly required.

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 Company is currently evaluating the impact the adoption of ASU 2014-15 on the Company’s financial statement presentation and 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.

## 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 Systems, Inc. ("Theradex"), the CRO responsible for the clinical development of the Company's lead 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, is being carried out by nationally recognized comprehensive cancer centers, and is estimated to be completed between March and June 2015. The Phase 1 clinical trial is estimated to cost approximately \$2,000,000, with such payments expected to be divided approximately evenly between payments to Theradex for services rendered and payments for pass-through costs for the clinical center's laboratory costs and investigator costs. Total costs charged to operations through September 30, 2014 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, were \$538,820, of which \$86,440 and \$87,088 were incurred during the three months ended September 30, 2014 and 2013, respectively, or approximately 33% and 40% of research and development costs for the three months ended September 30, 2014 and 2013, respectively. During the nine months ended September 30, 2014 and 2013, the Company incurred \$260,100 and \$210,950, respectively, or approximately 34% and 33% of research and development costs for the nine months ended September 30, 2014 and 2013, respectively. The costs charged to operations for amounts paid to or through Theradex for services relating to the Phase 1 clinical trial of LB-100 are expected to represent a larger percentage of total research and development costs during the fiscal years ending December 31, 2014 and 2015 as compared to prior fiscal years. 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 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 as incurred over the life of the underlying contracts on the straight-line basis, unless the achievement of milestones, the completion of contracted work, or other information indicates that a different expensing schedule is more appropriate. 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 stock options to officers, directors and consultants for services rendered. Options vest and expire according to terms established at the grant date.

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 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.

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 options vest, they are valued on each vesting date and an adjustment is recorded for the difference between the value already recorded and the then current value on the date of vesting.

The fair value of 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 security 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.

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 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. 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, combined with any of several standard anti-cancer drugs, have broad activity affecting many different cell types of cancer. This is unusual and important because these compounds may be useful for treatment of cancer in general.

The research on brain tumors was conducted in collaboration 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”) entered into on March 22, 2006. The CRADA was extended through a series of amendments and remained in effect until April 1, 2013. The research at NINDS was led by Dr. Zhengping Zhuang, an internationally recognized investigator in the molecular pathology of cancer who was aided by two senior research technicians supported by the Company as part of the CRADA. The goal of the CRADA was to develop more effective drugs for the treatment of GBM through the processes required to gain allowance from the FDA for clinical trials. The CRADA terminated as scheduled on April 1, 2013.

During 2009, the Company signed material transfer agreements with academic investigators at major cancer centers in the United States, as well as with one investigator in China with a unique animal model of a sarcoma, to expand molecular and applied studies of the anti-cancer activity of the Company’s compounds. The Company retained the right to all discoveries made in these studies.

The Company’s immediate focus is to determine the safety and appropriate dose of LB-100 when used alone and when used in combination with a widely used anti-cancer drug in its Phase 1 clinical trial. The Company believes the potent activity of these drugs, in combination with standard non-specific chemotherapeutic drugs against a diverse array of common and uncommon cancers of adults and children, merits bringing this treatment to patients as rapidly as possible. If favorable treatment responses are also noted in the Phase 1 clinical trial, the Company would expect there to be increased interest by potential investors and by large pharmaceutical companies looking to add an entirely new approach to their anti-cancer drug portfolios. However, clinical benefit often is not apparent until a new compound advances to a Phase 2 clinical trial, which, if warranted, would be anticipated to follow the 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, anti-fungal treatments, and/or neuroprotective measures.

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, and genetic diseases, such as Gaucher’s disease) in which errors in normal cellular processing lead to loss of functions important to normal cell function. 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: 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.

On August 16, 2011, the United States Patent and Trademark Office (the “PTO”) awarded a patent to the Company for its lead compound, LB-100, as well as for a number of structurally related compounds. On November 15, 2011, the PTO awarded a patent to the Company for a lead compound in the LB-200 series and a compound in the LB-100 series as neuroprotective agents for the prevention and treatment of neurodegenerative diseases. On March 27, 2012, the PTO awarded a patent to the Company for its lead compound, LB-201, as well as for a number of structurally related compounds. Patent applications on these compounds and their use are pending world-wide

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 needed to prepare an Investigational New Drug (“IND”) application to the FDA to conduct a Phase 1 clinical trial of LB-100, and engaged the CRO responsible for the clinical development of the Company’s lead compound, LB-100, to prepare an IND application for filing with the FDA. This task included preparing the detailed clinical protocol known as the “Investigator’s Brochure”, a document containing a detailed summary of all that is known about LB-100, and development of the formal IND application for submission to the FDA. The CRO also established the procedures for assuring appropriate collection and reporting of data generated during the clinical trial of LB-100 to 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 the clinical trial is 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 is designed to determine the maximum tolerable dose of LB-100 given alone and then in combination with a standard widely use anti-cancer drug. 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 the initial portion of the Phase 1 clinical trial will be to demonstrate that the target enzyme of LB-100, protein phosphatase 2A (PP2A), can be inhibited in humans with readily tolerable toxicity. As an anti-cancer drug, LB-100 is likely to be used at maximum tolerable doses, but for the potential treatment of non-malignant diseases, such as acute vascular diseases and metabolic diseases, 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 Phase 1 clinical trial of LB-100 began in April 2013 with the entry of patients into the clinical trial (NCT01837667 at [www.clinicaltrials.gov](http://www.clinicaltrials.gov)) and was 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. 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 ongoing Phase 1 clinical trial of LB-100. The Company estimates that the Phase 1 clinical trial will be completed between March and June 2015 at a total cost of approximately \$2,000,000, which will be paid to or through Theradex, the CRO responsible for the clinical development of LB-100. Total costs charged to operations through September 30, 2014 for services paid to Theradex pursuant to this arrangement were \$538,820, of which \$86,440 and \$87,088 were incurred during the three months ended September 30, 2014 and 2013, respectively, and \$260,100 and \$210,950 were incurred during the nine months ended September 30, 2014 and 2013, respectively. The final cost of the clinical trial is variable, depending upon the number of patients needed to be medically screened to determine if they meet the criteria for entry into the study and ultimately upon the total number of patients entered into the study to establish the proper doses of the drug for Phase 2 clinical trials.

After completion of the Phase 1 clinical trial of LB-100, subject to the availability of funds, the Company anticipates that the next steps in its clinical development will be to determine the anti-cancer activity of LB-100 as a single agent against a specific hematological cancer in a Phase 1/2 clinical trial, and in combination with docetaxel against a specific solid tumor in a Phase 2 clinical trial for which single agent docetaxel is indicated.

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. 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. The commencement of a Phase 1 clinical trial is a milestone in the Company's goal of developing a successful product platform.

## **Results of Operations**

The Company had not commenced revenue-generating operations at September 30, 2014.

### **Three Months Ended September 30, 2014 and 2013**

General and Administrative. For the three months ended September 30, 2014, general and administrative costs were \$192,317, which consisted of the fair value of stock options issued to directors and consultants of \$75,857, consulting and professional fees of \$65,382, insurance expense of \$10,245, officer's salary and related costs of \$16,638, investor relations of \$8,085, stock transfer fees of \$2,918, travel and entertainment costs of \$6,402, and other operating costs of \$6,790.

For the three months ended September 30, 2013, general and administrative costs were \$93,154, which consisted of the fair value of stock options issued to directors and consultants of \$14,697, consulting and professional fees of \$34,378, insurance expense of \$9,339, officer's salary and related costs of \$16,703, filing fees of \$8,167, stock transfer fees of \$2,510, travel and entertainment costs of \$2,841, and other operating costs of \$4,519.

General and administrative costs increased by \$99,163 or 106.5% in 2014 as compared to 2013, primarily as a result of an increase of \$61,160 in stock-based compensation and an increase of \$31,004 in legal and other consulting fees.

**Research and Development.** For the three months ended September 30, 2014, research and development costs were \$309,103, which consisted of the vested portion of the fair value of stock options issued to a member of the Company's Scientific Advisory Committee of \$44,357, patent costs of \$83,869, and contractor costs of \$180,877, including \$86,440 to a related party in connection with the Phase 1 clinical trial of LB-100.

For the three months ended September 30, 2013, research and development costs were \$219,898, which consisted of patent costs of \$86,424, and contractor costs of \$133,474, including \$87,088 to a related party in connection with the Phase 1 clinical trial of LB-100.

Research and development costs increased by \$89,205 or 40.6% in 2014 as compared to 2013, primarily as a result of an increase of \$44,357 in stock-based compensation and an increase of \$47,403 in contractor costs.

**Net Loss.** For the three months ended September 30, 2014, the Company incurred a net loss of \$501,393, as compared to a net loss of \$313,051 for the three months ended September 30, 2013.

#### **Nine Months Ended September 30, 2014 and 2013**

**General and Administrative.** For the nine months ended September 30, 2014, general and administrative costs were \$926,882, which consisted of the fair value of stock options issued to directors and consultants of \$513,044, consulting and professional fees of \$249,309, royalties of \$30,000, insurance expense of \$29,313, officer's salary and related costs of \$50,409, stock transfer fees of \$10,465, travel and entertainment costs of \$13,992, filing fees of \$9,173, investor relations of 8,085 and other operating costs of \$13,092.

For the nine months ended September 30, 2013, general and administrative costs were \$380,808, which consisted of the fair value of stock options issued to directors and consultants of \$104,264, consulting and professional fees of \$160,194, insurance expense of \$27,534, officer's salary and related costs of \$50,198, stock transfer fees of \$7,031, travel and entertainment costs of \$10,072, filing fees of \$10,167, and other operating costs of \$11,348.

General and administrative costs increased by \$546,074 or 143.4% in 2014 as compared to 2013, primarily as a result of a increase of \$408,780 in stock-based compensation, an increase of \$30,000 in royalties, and an increase of \$89,115 in legal and other consulting fees.

A significant component of the fair value of stock options issued to directors and consultants of \$513,044 for the nine months ended September 30, 2014 was the \$486,145 expense 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.

**Research and Development.** For the nine months ended September 30, 2014, research and development costs were \$807,597, which consisted of the vested portion of the fair value of stock options issued to a member of the Company's Scientific Advisory Committee of \$166,464, patent costs of \$239,667, and contractor costs of \$401,466, including \$260,100 to a related party in connection with the Phase 1 clinical trial of LB-100.

For the nine months ended September 30, 2013, research and development costs were \$634,998, which consisted of patent costs of \$286,019, contractor costs of \$338,562, including \$210,950 to a related party in connection with the Phase 1 clinical trial of LB-100, and consulting fees to a related party of \$10,417.

Research and development costs increased by \$172,599 or 27.2% in 2014 as compared to 2013, primarily as a result of an increase of \$166,464 in stock-based compensation.

**Fair Value of Warrant Extensions.** During the nine months ended September 30, 2014, the Company incurred an expense of \$302,691 for the fair value of extending the expiration dates of various warrants, including \$78,617 for the extension of expiration dates of warrants to acquire 1,748,800 shares of the Company's common stock to June 30, 2014, and \$224,074 for the further extension of those expiration dates to March 31, 2015 for warrants to acquire 2,928,800 shares of the Company's common stock that were purchased by investors as part of private placements that closed in 2009 and 2010, and were to have expired unexercised on June 30, 2014.

Fair Value of Warrant Discount. During the nine months ended September 30, 2014, the Company incurred an expense of \$134,420 for the fair value of discounts offered to warrant holders as an inducement for the early exercise of warrants to acquire 3,900,000 shares of the Company's common stock. The discounts ranged from \$0.25 to \$0.375 per share. The exercise of the warrants generated net proceeds to the Company of \$1,412,500 in April 2014.

Net Loss. For the nine months ended September 30, 2014, the Company incurred a net loss of \$2,171,534, as compared to a net loss of \$1,015,804 for the nine months ended September 30, 2013.

#### **Liquidity and Capital Resources – September 30, 2014**

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 is in the development stage and has not generated any 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 through the recurring sale of its equity securities. As a result, management believes that there is substantial doubt about the Company's ability to continue as a going concern (see "Going Concern" above").

At September 30, 2014, the Company had working capital of \$593,851, as compared to working capital of \$236,266 at December 31, 2013, an increase in working capital of \$357,585 for the nine months ended September 30, 2014. At September 30, 2014, the Company had cash and money market funds aggregating \$902,553, as compared to \$481,154 at December 31, 2013, an increase of \$421,399 for the nine months ended September 30, 2014. The increase in working capital, cash and money market funds during the nine months ended September 30, 2014 was the result of \$1,412,500 raised by the Company in April 2014 by offering a 50% discount to warrant holders as an inducement to exercise their warrants for cash.

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 the clinical trial is 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 began in April 2013 with the entry of patients into the clinical trial, and is being carried out by a nationally recognized comprehensive cancer center. The Company estimates that the Phase 1 clinical trial will be completed between March and June 2015 at a total cost of approximately \$2,000,000, which will be paid to or through Theradex, the CRO responsible for the clinical development of LB-100. Total costs charged to operations through September 30, 2014 for services paid to or through Theradex pursuant to this arrangement were \$538,820, of which \$86,440 and \$87,088 were incurred during the three months ended September 30, 2014 and 2013, respectively, and \$260,100 and \$210,950 were incurred during the nine months ended September 30, 2014 and 2013, respectively, which have been included in research and development expenses in the condensed consolidated statement of operations.

The Company believes that it has sufficient funds to continue with the Phase 1 clinical trial of LB-100 and to fund its operating plans through approximately June 30, 2015. The amount and timing of future cash requirements will depend on the pace of the Company's programs, in particular the completion of the Phase 1 clinical trial of LB-100. Accordingly, the Company will need to raise additional capital in 2015, likely in the form of equity. 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. 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 products, or to discontinue its operations entirely.

Operating Activities. For the nine months ended September 30, 2014, operating activities utilized cash of \$991,101, as compared to utilizing cash of \$864,150 for the nine months ended September 30, 2013, to support the Company's ongoing research and development activities.

**Investing Activities.** For the nine months ended September 30, 2014, investing activities consisted of an increase in money market funds of \$887,554 due primarily as a result of proceeds received from the exercise of warrants in April 2014. For the nine months ended September 30, 2013, investing activities consisted of a \$1 increase in money market funds from interest earned during the period.

**Financing Activities.** For the nine months ended September 30, 2014, financing activities consisted of \$1,412,500 in proceeds received from the exercise of warrants for the purchase of 3,900,000 shares of the Company's common stock in April 2014. There were no financing activities during the nine months ended September 30, 2013.

### Principal Commitments

Effective September 19, 2008, the Company entered into a Patent License Agreement (the "PLA") with the NIH providing the Company with an exclusive license for all patents submitted jointly with the NIH under the CRADA. The PLA provided for an initial payment of \$25,000 to the NIH within 60 days of September 19, 2008, and for a minimum annual royalty of \$30,000 on January 1 of each calendar year following the year in which the CRADA is terminated. The PLA also provided for the Company to pay (i) specified royalties based on net sales by the Company and its sub-licensees, reduced by the amount of the minimum annual royalty for that year, (ii) certain benchmark royalties upon the achievement of certain clinical benchmarks, and (iii) sublicensing royalties for the granting of sublicenses, with respect to joint patents. The Company paid the initial \$25,000 obligation on November 10, 2008, which was charged to general and administrative costs. Due to the termination of the CRADA on April 1, 2013, the Company became obligated for a minimum annual royalty of \$30,000 to the NIH beginning in 2014 and each year thereafter. As of January 31, 2014, a minimum royalty of \$30,000 was due pursuant to the PLA, which was charged to general and administrative costs on that date and is included in accounts payable and accrued expenses in the accompanying condensed consolidated balance sheet at September 30, 2014. During April 2014, the Company advised the NIH of its intent to terminate this license.

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 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, is being carried out by nationally recognized comprehensive cancer centers, and is estimated to be completed between March and June 2015. The Phase 1 clinical trial is estimated to cost approximately \$2,000,000, with such payments expected to be divided approximately evenly between payments to Theradex for services rendered and payments for pass-through costs for the clinical center's laboratory costs and investigator costs. Total costs charged to operations through September 30, 2014 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, were \$538,820, of which \$86,440 and \$87,088 were incurred during the three months ended September 30, 2014 and 2013, respectively, and \$260,100 and \$210,950 were incurred during the nine months ended September 30, 2014 and 2013, respectively. Costs pursuant to this agreement are included in research and development costs in the Company's condensed consolidated statements of operations. The final cost of the clinical trial is variable, depending upon the number of patients needed to be medically screened to determine if they meet the criteria for entry into the study and ultimately upon the total number of patients entered into the study to establish the proper doses of the drug for Phase 2 clinical trials.

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 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 is for one year and provides for a quarterly cash fee of \$4,000. Consulting and advisory fees charged to operations pursuant to this agreement were \$4,000 and \$12,000 during the three months and nine months ended September 30, 2014.

The following table sets forth the Company's principal cash obligations and commitments for the next five fiscal years as of September 30, 2014 aggregating \$1,936,138, of which \$301,829 is included in current liabilities in the condensed consolidated balance sheet at September 30, 2014. Amounts included in the 2014 column represent amounts due at September 30, 2014 for the remainder of the 2014 fiscal year ending December 31, 2014.

	Total	Payments Due By Year				
		2014	2015	2016	2017	2018
Research and development contracts	\$ 106,994	\$ 106,994	\$ —	\$ —	\$ —	\$ —
Clinical trial agreements	1,505,802	255,802	1,250,000	—	—	—
Patent license agreement	150,000	30,000	30,000	30,000	30,000	30,000
Operating leases	2,625	2,625	—	—	—	—
Consulting agreements	4,000	4,000	—	—	—	—
Liquidated damages payable under registration rights agreement	74,000	74,000	—	—	—	—
Due to stockholder	92,717	92,717	—	—	—	—
Total	<u>\$ 1,936,138</u>	<u>\$ 566,138</u>	<u>\$ 1,280,000</u>	<u>\$ 30,000</u>	<u>\$ 30,000</u>	<u>\$ 30,000</u>

### Off-Balance Sheet Arrangements

At September 30, 2014, 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 currently not a party to any pending or threatened legal proceedings.

**ITEM 1A RISK FACTORS**

Not applicable.

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

Not applicable.

**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 12, 2014

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:

Exhibit Number	Description of Document
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 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 12, 2014

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, 2014 (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 12, 2014

By: /s/ JOHN S. KOVACH

John S. Kovach  
Chief Executive Officer and  
Chief Financial Officer

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