

---

**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, 2015**

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

**Commission file number: 000-51476**

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.**

(Exact name of registrant as specified in its charter)

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

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

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Large accelerated filer   
Non-accelerated filer

Accelerated filer   
Smaller reporting company

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

Yes  No

As of October 31, 2015, the Company had 47,875,814 shares of common stock, \$0.0001 par value, issued and outstanding.

Documents incorporated by reference: None

---

---

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

**TABLE OF CONTENTS**

	<b><u>Page Number</u></b>
<b><u>PART I - FINANCIAL INFORMATION</u></b>	
<u>Item 1. Condensed Consolidated Financial Statements</u>	F-1
<u>Condensed Consolidated Balance Sheets - September 30, 2015 (Unaudited) and December 31, 2014</u>	F-1
<u>Condensed Consolidated Statements of Operations (Unaudited) - Three Months and Nine Months Ended September 30, 2015 and 2014</u>	F-2
<u>Condensed Consolidated Statement of Stockholders' Equity (Unaudited) - Nine Months Ended September 30, 2015</u>	F-3
<u>Condensed Consolidated Statements of Cash Flows (Unaudited) - Nine Months Ended September 30, 2015 and 2014</u>	F-4
<u>Notes to Condensed Consolidated Financial Statements (Unaudited) - Three Months and Nine Months Ended September 30, 2015 and 2014</u>	F-5
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	4
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	17
<u>Item 4. Controls and Procedures</u>	17
<b><u>PART II - OTHER INFORMATION</u></b>	
<u>Item 1. Legal Proceedings</u>	18
<u>Item 1A. Risk Factors</u>	18
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	18
<u>Item 3. Defaults Upon Senior Securities</u>	18
<u>Item 4. Mine Safety Disclosures</u>	18
<u>Item 5. Other Information</u>	18
<u>Item 6. Exhibits</u>	18
<u>SIGNATURES</u>	19

## Forward-Looking Statements

This Quarterly Report on Form 10-Q of Lixte Biotechnology Holdings, Inc. (the “Company”) contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, and Section 21E of the Securities Exchange Act of 1934. These might include statements regarding the Company’s financial position, business strategy and other plans and objectives for future operations, and assumptions and predictions about future product demand, supply, manufacturing, costs, marketing and pricing factors are all forward-looking statements. These statements are generally accompanied by words such as “intend,” “anticipate,” “believe,” “estimate,” “potential(ly),” “continue,” “forecast,” “predict,” “plan,” “may,” “will,” “could,” “would,” “should,” “expect” or the negative of such terms or other comparable terminology. The Company believes that the assumptions and expectations reflected in such forward-looking statements are reasonable, based on information available to it on the date hereof, but the Company cannot provide assurances that these assumptions and expectations will prove to have been correct or that the Company will take any action that the Company may presently be planning. These forward-looking statements are inherently subject to known and unknown risks and uncertainties. Actual results or experience may differ materially from those expected, anticipated or implied in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, regulatory policies or changes thereto, available cash, research and development results, competition from other similar businesses, and market and general economic factors. This discussion should be read in conjunction with the condensed consolidated financial statements and notes thereto included in Item 1 of this Quarterly Report on Form 10-Q and the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2014, including the section entitled “Item 1A. Risk Factors”. The Company does not intend to update or revise any forward-looking statements to reflect new information, future events or otherwise.

PART I - FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

	<u>September 30, 2015</u> (Unaudited)	<u>December 31, 2014</u>
<b>ASSETS</b>		
Current assets:		
Cash	\$ 217,557	\$ 44,411
Money market funds	524,087	213,699
Advances on research and development contract services	217,284	231,177
Prepaid expenses and other current assets	68,138	50,012
Total current assets	<u>1,027,066</u>	<u>539,299</u>
Total assets	<u>\$ 1,027,066</u>	<u>\$ 539,299</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 121,184	\$ 122,534
Research and development contract liabilities, including \$46,697 and \$18,436 to Theradex at September 30, 2015 and December 31, 2014, respectively	100,998	58,186
Due to Chairman and major stockholder	—	92,717
Total current liabilities	<u>222,182</u>	<u>273,437</u>
Commitments and contingencies		
Stockholders' equity:		
Series A convertible preferred stock, \$0.0001 par value, \$10.00 per share stated value, \$50.00 per share redemption value; 175,000 shares authorized, issued and outstanding at September 30, 2015; aggregate redemption value of \$8,750,000; liquidation preference based on assumed conversion into common shares; 2,187,500 shares of common stock issuable upon conversion	1,750,000	—
Common stock, \$0.0001 par value; authorized – 100,000,000 shares; issued and outstanding – 47,875,814 shares and 45,483,097 shares at September 30, 2015 and December 31, 2014, respectively	4,787	4,548
Additional paid-in capital	17,006,515	15,979,475
Accumulated deficit	(17,956,418)	(15,718,161)
Total stockholders' equity	<u>804,884</u>	<u>265,862</u>
Total liabilities and stockholders' equity	<u>\$ 1,027,066</u>	<u>\$ 539,299</u>

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

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

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Revenues	\$ —	\$ —	\$ —	\$ —
<b>Costs and expenses:</b>				
General and administrative costs, including \$6,250 and \$82,107 to related parties for the three months ended September 30, 2015 and 2014, respectively, and \$93,651 and \$531,794 for the nine months ended September 30, 2015 and 2014, respectively	155,307	192,317	615,615	926,882
Research and development costs, including \$162,425 and \$85,440 to Theradex for the three months ended September 30, 2015 and 2014, respectively, and \$670,540 and \$265,918 for the nine months ended September 30, 2015 and 2014, respectively	624,405	309,103	1,416,940	807,597
Total costs and expenses	<u>779,712</u>	<u>501,420</u>	<u>2,032,555</u>	<u>1,734,479</u>
Loss from operations	(779,712)	(501,420)	(2,032,555)	(1,734,479)
Interest income	25	27	71	56
Fair value of warrant extensions	—	—	(34,016)	(302,691)
Fair value of warrant discount	—	—	(171,757)	(134,420)
Net loss	<u>\$ (779,687)</u>	<u>\$ (501,393)</u>	<u>\$ (2,238,257)</u>	<u>\$ (2,171,534)</u>
Net loss per common share – basic and diluted	<u>\$ (0.02)</u>	<u>\$ (0.01)</u>	<u>\$ (0.05)</u>	<u>\$ (0.05)</u>
Weighted average common shares outstanding – basic and diluted	<u>47,060,597</u>	<u>45,483,097</u>	<u>46,428,767</u>	<u>44,042,438</u>

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

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

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

**Nine Months Ended September 30, 2015**

	<b>Series A Convertible Preferred Stock</b>		<b>Common Stock</b>		<b>Additional Paid-in Capital</b>	<b>Accumulated Deficit</b>	<b>Total Stockholders' Equity</b>
	<b>Shares</b>	<b>Amount</b>	<b>Shares</b>	<b>Par Value</b>			
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Par Value</u>			
Balance, December 31, 2014	—	\$ —	45,483,097	\$ 4,548	\$ 15,979,475	\$ (15,718,161)	\$ 265,862
Fair value of warrant extensions	—	—	—	—	34,016	—	34,016
Fair value of warrant discounts	—	—	—	—	171,757	—	171,757
Sales of Series A Convertible Preferred Stock	175,000	1,750,000	—	—	—	—	1,750,000
Costs incurred in connection with sale of Series A convertible preferred stock	—	—	—	—	(12,608)	—	(12,608)
Exercise of warrants	—	—	1,050,000	105	314,895	—	315,000
Conversion of advances due to Chairman and major stockholder	—	—	92,717	9	92,708	—	92,717
Stock-based compensation expense	—	—	1,250,000	125	426,272	—	426,397
Net loss	—	—	—	—	—	(2,238,257)	(2,238,257)
Balance, September 30, 2015	<u>175,000</u>	<u>\$ 1,750,000</u>	<u>47,875,814</u>	<u>\$ 4,787</u>	<u>\$ 17,006,515</u>	<u>\$ (17,956,418)</u>	<u>\$ 804,884</u>

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

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

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

	<b>Nine Months Ended September 30,</b>	
	<b>2015</b>	<b>2014</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (2,238,257)	\$ (2,171,534)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
<b>Stock-based compensation expense included in -</b>		
General and administrative costs	157,370	513,042
Research and development costs	269,027	166,466
<b>Fair value of warrant -</b>		
Extensions	34,016	302,691
Discounts	171,757	134,420
<b>Changes in operating assets and liabilities:</b>		
<b>(Increase) decrease in -</b>		
Advances on research and development contract services	13,893	4,350
Prepaid expenses and other current assets	(18,126)	(21,081)
<b>Increase (decrease) in -</b>		
Accounts payable and accrued expenses	(1,350)	22,716
Research and development contract liabilities	42,812	57,829
<b>Net cash used in operating activities</b>	<b>(1,568,858)</b>	<b>(991,101)</b>
<b>Cash flows from investing activities:</b>		
Increase in money market funds	(310,388)	(887,554)
<b>Net cash used in investing activities</b>	<b>(310,388)</b>	<b>(887,554)</b>
<b>Cash flows from financing activities:</b>		
Proceeds from sale of Series A Convertible Preferred Stock	1,750,000	—
Cash payments made for costs incurred in connection with sale of Series A Convertible Preferred Stock	(12,608)	—
Proceeds from exercise of warrants	315,000	1,412,500
<b>Net cash provided by financing activities</b>	<b>2,052,392</b>	<b>1,412,500</b>
<b>Cash:</b>		
Net increase (decrease)	173,146	(466,155)
Balance at beginning of period	44,411	475,019
<b>Balance at end of period</b>	<b>\$ 217,557</b>	<b>\$ 8,864</b>
<b>Supplemental disclosures of cash flow information:</b>		
<b>Cash paid for -</b>		
Interest	\$ —	\$ —
Income taxes	\$ —	\$ —
<b>Non-cash financing activities:</b>		
Conversion of advances due to Chairman and major stockholder to common stock	<b>\$ 92,717</b>	<b>\$ —</b>

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

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

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

**Three Months and Nine Months Ended September 30, 2015 and 2014**

**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, 2015, and for the three months and nine months ended September 30, 2015 and 2014, 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, 2015, and the results of its operations for the three months and nine months ended September 30, 2015 and 2014, and its cash flows for the nine months ended September 30, 2015 and 2014. 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, 2014 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, 2014, as filed with the SEC.

**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. The Company’s activities are subject to significant risks and uncertainties, including the need for additional capital, as described below. The Company has not yet commenced any 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”.

***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, consisting of protein phosphatase inhibitors (PTase-i), designated by the Company as the LB-100 series of compounds, and histone deacetylase inhibitors (HDACi), designated by the Company as the LB-200 series of compounds. Compounds of both types also have potential use in the prevention and treatment of neurodegenerative diseases. The LB-100 series consists of novel structures, which have the potential to be first in their class, and may be useful in the treatment of not only several types of cancer but also vascular and metabolic diseases. The LB-200 series contains compounds which have the potential to be the most effective in its class and may be useful for the treatment of chronic hereditary diseases, such as Gaucher's disease, in addition to cancer and neurodegenerative diseases.

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 United States Food and Drug Administration ("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 was designed to be conducted in two parts. In Part 1, the maximum tolerable dose ("MTD") of LB-100 is determined. In Part 2, the MTD of LB-100, in combination with the standard cytotoxic drug docetaxel (which is a well-established anti-mitotic chemotherapy medication approved by the FDA for the treatment of various cancers), is determined.

The Phase 1 clinical trial of LB-100 began in April 2013 with the entry of patients into the clinical trial 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. As the accrual of patients was slower than anticipated, in October 2014 the Company entered into a Clinical Research Agreement ("CRA") with US Oncology Research, LLC, a large community-based research network based in Texas, to increase the rate of entry of patients into the clinical trial by adding four more active clinical oncologic research sites.

The costs of Part 1 of the Phase 1 clinical trial have exceeded the Company's estimates in part because patients were able to tolerate higher doses of LB-100 than originally expected, thus requiring more dose escalation steps to determine the MTD of LB-100 given alone. In addition, patients have been achieving stabilization without any dose-limiting toxicity ("DLT"), remaining on treatment with LB-100 for longer periods of time than is usual in a Phase 1 clinical trial of a new drug in patients failing all previous treatments. The Company's interpretation of the clinical trial results to date is that LB-100 as a single agent has activity against several types of cancer, as evidenced by stabilization of progressive disease in the absence of DLT. The Company is continuing to administer LB-100 to patients if there is no cancer progression and the patient feels well and has no significant toxicity.

The Company had planned to proceed with Part 2 of the Phase 1 clinical trial to determine the toxicity of LB-100 in combination with docetaxel against a specific solid tumor for which single agent docetaxel is indicated. However, two developments have altered this plan. First, LB-100 appears to have anticancer activity in its own right, and second, preclinical studies indicate that LB-100 in combination with cisplatin (a widely used cytotoxic drug) is more active than LB-100 in combination with docetaxel. LB-100 significantly potentiates the standard anti-cancer drug cisplatin against several tumor types, including hepatocellular cancer and ovarian cancer. In addition, it has been reported that inhibition of the enzyme-target of LB-100, PP2A, inhibits certain variants of the hematologic disorder known as myelodysplastic syndrome ("MDS"). Accordingly, the Company has decided not to proceed with Part 2 of the Phase 1 clinical trial, and has initiated planning for Phase 2 clinical trials in 2016 to evaluate the effectiveness of LB-100 alone for the treatment of MDS and in combination with a platinum compound for the treatment of ovarian and/or hepatocellular cancer.

The Company had previously estimated that Part 1 and Part 2 of the Phase 1 clinical trial would be completed by September 30, 2015 and September 30, 2016, respectively, at a total cost of approximately \$2,615,000. As the Company has decided not to proceed with Part 2 of the Phase 1 clinical trial, the Company estimates that this clinical trial will be completed by December 31, 2015 at a total cost of approximately \$1,800,000.

### ***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 has concluded that there is substantial doubt about the Company's ability to continue as a going concern, and the Company's independent registered public accounting firm, in their report on the Company's consolidated financial statements for the year ended December 31, 2014, has expressed substantial doubt about the Company's ability to continue as a going concern.

The Company's ability to continue as a going concern is dependent upon its ability to raise additional 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, 2015, the Company had not yet commenced any revenue-generating operations. All activity through September 30, 2015 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, 2015, the Company had cash and money market funds aggregating \$741,644. The sale of preferred shares in March 2015 (see Note 4), which generated proceeds of \$1,750,000, and the exercise of warrants in April 2015 (see Note 4), which generated proceeds of \$315,000, provided the Company with sufficient funds to complete Part 1 of its Phase 1 clinical trial of its lead anti-cancer compound LB-100 and to fund its ongoing operating expenses through approximately January 31, 2016.

The amount and timing of future cash requirements depend on the pace and design of the Company's clinical trial program. The Company expects that it will need to raise approximately \$2,000,000 of additional capital in the first quarter of 2016, likely in the form of equity, to fund operations, including the continuing costs of its clinical trial program and the support of its patent portfolio. The availability of such capital would allow the Company to conduct a Phase 2 clinical trial of LB-100 as a single agent in 2016.

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

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

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

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

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

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

#### ***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 ratably over the life of the underlying contracts, unless the achievement of milestones, the completion of contracted work, or other information indicates that a different expensing schedule is more appropriate. The costs of the Phase 1 clinical trial of LB-100 that are being paid through Theradex, the CRO, are recorded and expensed based upon the documentation provided by the CRO when it becomes available. 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 \$139,485 and \$83,869 for the three months ended September 30, 2015 and 2014, respectively, and \$351,711 and \$239,668 for the nine months ended September 30, 2015 and 2014, respectively. Patent costs are included in research and development costs in the Company’s condensed consolidated statements of operations.

#### ***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 by December 31, 2015.

The Phase 1 clinical trial is currently estimated to cost approximately \$1,800,000, with such payments expected to be allocated approximately 60% for services provided by Theradex and approximately 40% for pass-through costs for clinical center laboratory costs and investigator costs over the life of the clinical trial. Total costs charged to operations through September 30, 2015 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, total \$1,361,578, of which \$159,042 and \$83,483 were incurred during the three months ended September 30, 2015 and 2014, respectively, or approximately 25% and 27% of research and development costs for the three months ended September 30, 2015 and 2014, respectively. During the nine months ended September 30, 2015 and 2014, the Company incurred \$659,750 and \$256,716, respectively, or approximately 47% and 32% of research and development costs for the nine months ended September 30, 2015 and 2014, respectively. Costs pursuant to this agreement are included in research and development costs in the Company's condensed consolidated statements of operations.

### ***Income Taxes***

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

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

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

The Company is subject to U.S. federal income taxes and income taxes of various state tax jurisdictions. As the Company's net operating losses have yet to be utilized, all previous tax years remain open to examination by Federal authorities and other jurisdictions in which the Company currently operates or has operated in the past. The Company had no unrecognized tax benefits as of September 30, 2015 and December 31, 2014 and does not anticipate any material amount of unrecognized tax benefits within the next 12 months.

The Company accounts for uncertainties in income tax law under a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns as prescribed by GAAP. The tax effects of a position are recognized only if it is "more-likely-than-not" to be sustained by the taxing authority as of the reporting date. If the tax position is not considered "more-likely-than-not" to be sustained, then no benefits of the position are recognized. As of September 30, 2015, the Company had not recorded any liability for uncertain tax positions. In subsequent periods, any interest and penalties related to uncertain tax positions will be recognized as a component of income tax expense.

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

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

The Company accounts for stock-based payments to officers and directors by measuring the cost of services received in exchange for equity awards based on the grant date fair value of the awards, with the cost recognized as compensation expense on the straight-line basis in the Company's financial statements over the vesting period of the awards. The Company accounts for stock-based payments to 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 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, 2015 and 2014.

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

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

At September 30, 2015 and 2014, the Company excluded the outstanding securities summarized below, which entitle the holders thereof to acquire shares of common stock, from its calculation of earnings per share, as their effect would have been anti-dilutive.

	<b>September 30,</b>	
	<b>2015</b>	<b>2014</b>
Series A Convertible Preferred Stock	2,187,500	—
Common stock warrants	—	2,928,800
Common stock options	8,250,000	7,375,000
Total	<u>10,437,500</u>	<u>10,303,800</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.

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

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2014-09 (ASU 2014-09), *Revenue from Contracts with Customers*. ASU 2014-09 will eliminate transaction- and industry-specific revenue recognition guidance under current GAAP and replace it with a principle based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. Based on the FASB's Exposure Draft Update issued on April 29, 2015, *Revenue from Contracts With Customers (Topic 606): Deferral of the Effective Date*, it is expected that ASU 2014-09 will now be effective for reporting periods beginning after December 15, 2017, with early adoption permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. Entities will be able to transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. The adoption of ASU 2014-09 is not expected to have any impact on the Company's financial statement presentation or disclosures.

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

In January 2015, the FASB issued Accounting Standards Update No. 2015-01 (ASU 2015-01), *Income Statement – Extraordinary and Unusual Items (Subtopic 225-20)*. ASU 2015-01 eliminates from GAAP the concept of extraordinary items. Subtopic 225-20, *Income Statement – Extraordinary and Unusual Items*, required that an entity separately classify, present, and disclose extraordinary events and transactions. Presently, an event or transaction is presumed to be an ordinary and usual activity of the reporting entity unless evidence clearly supports its classification as an extraordinary item. Paragraph 225-20-45-2 contains the following criteria that must both be met for extraordinary classification: (1) Unusual nature. The underlying event or transaction should possess a high degree of abnormality and be of a type clearly unrelated to, or only incidentally related to, the ordinary and typical activities of the entity, taking into account the environment in which the entity operates. (2) Infrequency of occurrence. The underlying event or transaction should be of a type that would not reasonably be expected to recur in the foreseeable future, taking into account the environment in which the entity operates. If an event or transaction meets the criteria for extraordinary classification, an entity is required to segregate the extraordinary item from the results of ordinary operations and show the item separately in the income statement, net of tax, after income from continuing operations. The entity also is required to disclose applicable income taxes and either present or disclose earnings-per-share data applicable to the extraordinary item. ASU 2015-01 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. A reporting entity may apply the guidance prospectively. A reporting entity also may apply the guidance retrospectively to all prior periods presented in the financial statements. Early adoption is permitted provided that the guidance is applied from the beginning of the fiscal year of adoption. The adoption of ASU 2015-01 is not expected to have any impact on the Company's financial statement presentation or disclosures.

In February 2015, the FASB issued Accounting Standards Update No. 2015-02 (ASU 2015-02), *Consolidation (Topic 810)*. ASU 2015-02 changes the guidance with respect to the analysis that a reporting entity must perform to determine whether it should consolidate certain types of legal entities. All legal entities are subject to reevaluation under the revised consolidation mode. ASU 2015-02 affects the following areas: (1) limited partnerships and similar legal entities; (2) evaluating fees paid to a decision maker or a service provider as a variable interest; (3) the effect of fee arrangements on the primary beneficiary determination; (4) the effect of related parties on the primary beneficiary determination; and (5) certain investment funds. ASU 2015-02 is effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted, including adoption in an interim period. If an entity early adopts the guidance in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. A reporting entity may apply the amendments in this guidance using a modified retrospective approach by recording a cumulative-effect adjustment to equity as of the beginning of the fiscal year of adoption. A reporting entity also may apply the amendments retrospectively. The adoption of ASU 2015-02 is not expected to have any impact on the Company's financial statement presentation or disclosures.

In April 2015, the FASB issued Accounting Standards Update No. 2015-03 (ASU 2015-03), *Interest – Imputation of Interest (Subtopic 835-30)*. ASU 2015-03 simplifies the presentation of debt issuance costs and requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the new guidance. ASU 2015-3 is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within that fiscal year. Early adoption is permitted for financial statements that have not been previously issued. An entity is required to apply the new guidance on a retrospective basis, wherein the balance sheet of each individual period presented is adjusted to reflect the period-specific effects of applying the new guidance. Upon transition, an entity is required to comply with the applicable disclosures for a change in an accounting principle. These disclosures include the nature of and reason for the change in accounting principle, the transition method, a description of the prior-period information that has been retrospectively adjusted, and the effect of the change on the financial statement line items (i.e., debt issuance cost asset and the debt liability). The adoption of ASU 2015-03 is not expected to have any impact on the Company's financial statement presentation or disclosures.

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

#### **4. Stockholders' Equity**

##### ***Preferred Stock***

The Company has authorized a total of 10,000,000 shares of preferred stock, par value \$0.001 per share. On March 17, 2015, the Company filed a Certificate of Designation, Preferences, Rights and Limitations, (the "Certificate of Designation") of its Series A Convertible Preferred Stock with the Delaware Secretary of State to amend the Company's certificate of incorporation. The number of shares designated as Series A Convertible Preferred Stock is 175,000 (which shall not be subject to increase without the written consent of a majority of the holders of the Series A Convertible Preferred Stock or as otherwise set forth in the Certificate of Designation). Accordingly, as of September 30, 2015, 9,825,000 shares of preferred stock were undesignated and may be issued with such rights and powers as the Board of Directors may designate.

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

The Preferred Shares have a dividend equal to 1% of the annual net revenue of the Company until converted or redeemed. Each of the Preferred Shares may be converted, at the option of the holder, into 12.5 shares of common stock (subject to customary anti-dilution provisions) and the Preferred Shares are subject to mandatory conversion at the conversion rate in the event of a merger or sale transaction resulting in gross proceeds to the Company of at least \$21,875,000. The Preferred Shares have a liquidation preference based on their assumed conversion to common shares.

If fully converted, the Preferred Shares would convert into 2,187,500 shares of common stock, representing an effective price per share of common stock of \$0.80. On the effective date of the transaction, the closing price of the Company's common stock was \$0.25 per share. The Company has the right to redeem the Preferred Shares up to the fifth anniversary of the closing date at a price per share equal to \$50.00. The Preferred Shares have no right to cash, except for the payment of the aforementioned dividend if and when the Company is able to generate revenues, and do not have any registration rights.

Based on the attributes of the Preferred Shares described above, the Company has determined to account for the Preferred Shares as a permanent component of stockholders' equity. Legal costs of \$12,608 incurred with respect to the issuance of the Preferred Shares were charged directly to additional paid-in capital.

### ***Common Stock***

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

See Note 7 for information with respect to the issuance of common stock in connection with various stock-based compensation arrangements.

### ***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 discount 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 January 28, 2014 warrant extension and discount offers, warrants to acquire 3,900,000 shares of the Company's common stock were exercised in April 2014 at exercise prices ranging from \$0.25 to \$0.375 per share. The exercise of the warrants generated aggregate net proceeds to the Company of \$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%.

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

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

A summary of common stock warrant activity during the nine months ended September 30, 2015, including warrants to purchase common stock that were issued in conjunction with the Company's private placements, is presented below. For presentation purposes, warrants that were extended are considered as outstanding for the entire period in which such extension occurs.

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Life (in Years)</u>
Warrants outstanding at December 31, 2014	2,928,800	\$ 0.592	
Issued	—	—	
Exercised	(1,050,000)	0.300	
Expired	(1,878,800)	0.294	
Warrants outstanding at September 30, 2015	<u>—</u>	<u>\$ —</u>	<u>—</u>
Warrants exercisable at December 31, 2014	2,807,840	\$ 0.596	
Warrants exercisable at September 30, 2015	<u>—</u>	<u>\$ —</u>	<u>—</u>

Based on a fair market value of \$0.24 per share on December 31, 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 December 31, 2014.

## 5. Money Market Funds

Money market funds at September 30, 2015 and December 31, 2014 consisted of investments in shares of Morgan Stanley New York Municipal Money Market Trust with a market value of \$524,087 and \$213,699, 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, 2015 and December 31, 2014.

	<u>Total</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
<b>September 30, 2015:</b>				
Money market funds	\$ 524,087	\$ 524,087	\$ —	\$ —
<b>December 31, 2014:</b>				
Money market funds	\$ 213,699	\$ 213,699	\$ —	\$ —

## 6. Related Party Transactions

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

Dr. Kovach was paid a salary of \$15,000 for the three months ended September 30, 2015 and 2014 and \$45,000 for the nine months ended September 30, 2015 and 2014, 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 condensed consolidated 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 was for a term of six months at a base rate of \$875 per month and was not renewed upon its expiration in December 2014. 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 were \$12,000 and \$12,000 for the three months ended September 30, 2015 and 2014, respectively, and \$36,000 and \$38,000 for the nine months ended September 30, 2015 and 2014, respectively.

Effective January 1, 2014, the Company entered into an Advisory Agreement with Dr. Kathleen P. Mullinix, a member of the Board of Directors of the Company, effective for an initial term of one year through December 31, 2014 to advise on business development matters. The Advisory Agreement provides for annual cash compensation of \$25,000. The term of the Advisory Agreement is automatically extended for a term of one year annually unless a notice of intent to terminate is given by either party at least 90 days before the end of the applicable term. Accordingly, the Advisory Agreement was extended for an additional term of one year effective January 1, 2015. Consulting and advisory fees charged to operations pursuant to this agreement were \$6,250 during the three months ended September 30, 2015 and 2014, and \$18,750 during the nine months ended September 30, 2015 and 2014. All such amounts 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, affiliates and related parties was \$0 and \$75,857 for the three months ended September 30, 2015 and 2014, respectively, and \$74,901 and \$513,044 for the nine months ended September 30, 2015 and 2014, 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.

On June 20, 2007, the Board of Directors of the Company approved the 2007 Stock Compensation Plan (the "2007 Plan"), which provides for the granting of awards, consisting of common stock options, stock appreciation rights, performance shares, or restricted shares of common stock, to employees and independent contractors, for up to 2,500,000 shares of the Company's common stock, under terms and condition, as determined by the Company's Board of Directors. As of September 30, 2015, stock options for 650,000 shares had been issued under the 2007 Plan, and stock options for 1,850,000 were available for issuance under the 2007 Plan.

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.

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

Risk-free interest rate	0.68% to 1.66%
Expected dividend yield	0%
Expected volatility	243%
Expected life	3.5 to 5.0 years

For options requiring an assessment of value during the nine months ended September 30, 2014, the fair value of each option award was estimated using the Black-Scholes option-pricing model with the following assumptions:

Risk-free interest rate	0.30% to 1.67%
Expected dividend yield	0%
Expected volatility	173%
Expected life	3.0 to 4.5 years

On January 28, 2014, the Company approved a second amendment to the Company's consulting agreement with Gil Schwartzberg, a significant stockholder of and consultant to the Company, dated September 12, 2007 to extend it for an additional four years to January 28, 2019 and granted to Mr. Schwartzberg stock options to purchase an additional aggregate of 4,000,000 shares of common stock, exercisable for a period of the earlier of five years from the grant date or the termination of the consulting agreement at \$0.50 per share, with one-half of the 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 was 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 was charged to operations ratably from January 28, 2014 through January 28, 2015. During the three months ended September 30, 2015 and 2014, the Company recorded charges to operations of \$0 and \$75,857, respectively, with respect to these options. During the nine months ended September 30, 2015 and 2014, the Company recorded charges to operations of \$74,901 and \$486,145, respectively, with respect to these options.

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 was being charged to operations from September 16, 2012 through June 16, 2014. During the three months ended September 30, 2014 and the nine months ended September 30, 2014, the Company recorded charges to operations of \$0 and \$26,899, 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 ended September 30, 2015 and 2014, the Company recorded a (credit)/charge to operations of (\$4,056) and \$857 with respect to these options. During the nine months ended September 30, 2015 and 2014, the Company recorded a (credit)/charge to operations of (\$183) and \$4,316 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 October 7, 2014, the Company entered into an Advisory Agreement with Andrew Robell for consultation and advice with respect to identifying and assessing potential licensing and strategic opportunities through September 30, 2016. In connection with the agreement, the Company granted stock options to Mr. Robell to purchase 200,000 shares of the Company's common stock, vesting 100,000 shares on October 7, 2014 and 100,000 shares on October 7, 2015, exercisable for a period of five years from the date of grant at \$0.50 per share. The fair value of these 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 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 October 7, 2014 through October 7, 2015. During the three months and nine months ended September 30, 2015, the Company recorded a (credit)/charge to operations of (\$3,341) and \$9,775, respectively, with respect to these options.

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

Effective September 14, 2015, the Company entered into a Collaboration Agreement with BioPharmaWorks LLC (“BioPharmaWorks”), pursuant to which the Company engaged BioPharmaWorks to perform certain services for the Company as described at Note 8. In connection with the Collaboration Agreement, the Company agreed to issue to BioPharmaWorks 1,000,000 fully-vested shares of the Company’s common stock, valued at \$260,000, based upon the closing price of the Company’s common stock of \$0.26 per share, on September 14, 2015. Additionally, the Company issued to BioPharmaWorks two options in the form of warrants, to purchase 1,000,000 shares (500,000 shares per warrant) of the Company’s common stock. The first warrant vests on September 14, 2016, and is exercisable for a period of five years from the date of grant at \$1.00 per share. The second warrant vests on September 14, 2017, and is exercisable for a period of five years from the date of grant at \$2.00 per share. The fair value of the first and second warrants, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$128,400 (\$0.2568 per share) and \$127,850 (\$0.2557 per share), respectively. During the three months and nine months ended September 30, 2015, the Company recorded a charge to operations of \$265,157 with respect to these common shares and warrants.

Total stock-based compensation expense was \$257,760 and \$120,214 for the three months ended September 30, 2015 and 2014, respectively, and \$426,397 and \$679,510 for the nine months ended September 30, 2015 and 2014, respectively.

A summary of stock option activity during the nine months ended September 30, 2015 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, 2014	6,850,000	\$ 0.582	
Granted	1,500,000	1.083	
Exercised	—	—	
Expired	(100,000)	0.500	
Options outstanding at September 30, 2015	<u>8,250,000</u>	<u>\$ 0.674</u>	<u>2.95</u>
Options exercisable at December 31, 2014	<u>4,675,000</u>	<u>\$ 0.626</u>	
Options exercisable at September 30, 2015	<u>7,100,000</u>	<u>\$ 0.564</u>	<u>2.39</u>

Total deferred compensation expense for the outstanding value of unvested stock options was approximately \$159,000 at September 30, 2015, which is being recognized subsequent to September 30, 2015 over a weighted-average period of approximately eighteen months.

The exercise prices of common stock options outstanding and exercisable are as follows at September 30, 2015:

Exercise Prices	Options Outstanding (Shares)	Options Exercisable (Shares)
\$ 0.130	100,000	50,000
\$ 0.250	1,000,000	1,000,000
\$ 0.500	4,200,000	4,100,000
\$ 0.650	700,000	700,000
\$ 0.980	250,000	250,000
\$ 1.000	1,500,000	1,000,000
\$ 2.000	500,000	—
	<u>8,250,000</u>	<u>7,100,000</u>

The intrinsic value of exercisable but unexercised in-the-money stock options at September 30, 2015 was approximately \$1,500, based on a fair market value of \$0.16 per share on September 30, 2015.

The intrinsic value of exercisable but unexercised in-the-money stock options at December 31, 2014 was approximately \$2,750, based on a fair market value of \$0.24 per share on December 31, 2014.

Outstanding options to acquire 1,150,000 shares of the Company's common stock had not vested at September 30, 2015.

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

## **8. Commitments and Contingencies**

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 by December 31, 2015. The Phase 1 clinical trial is currently estimated to cost approximately \$1,800,000, with such payments expected to be allocated approximately 60% for services provided by Theradex and approximately 40% for pass-through costs for clinical center laboratory costs and investigator costs over the life of the clinical trial. Total costs charged to operations through September 30, 2015 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, totaled \$1,361,578, of which \$159,042 and \$83,483 were incurred during the three months ended September 30, 2015 and 2014, respectively, and \$659,750 and \$256,716 were incurred during the nine months ended September 30, 2015 and 2014, 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. The agreement was automatically renewed on its anniversary date for an additional one-year term. Consulting and advisory fees charged to operations pursuant to this agreement were \$4,000 during the three months ended September 30, 2015 and 2014, and \$12,000 during the nine months ended September 30, 2015 and 2014.

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

On October 7, 2014, the Company entered into an agreement with ProActive Capital Resources Group LLC for strategic advisory, investor relations and public relations services through October 6, 2015. Among other things, the agreement provides for compensation in the form of a monthly fee of \$1,500 in cash. Fees charged to operations pursuant to this agreement were \$4,500 and \$3,000 during the three months ended September 30, 2015 and 2014, respectively, and \$13,500 and \$9,000 during the nine months ended September 30, 2015 and 2014, respectively.

Effective September 14, 2015, the Company entered into a Collaboration Agreement with BioPharmaWorks, pursuant to which the Company engaged BioPharmaWorks to perform certain services for the Company. Those services include, among other things: (a) assisting the Company to (i) commercialize its products and strengthen its patent portfolio, (ii) identify large pharmaceutical companies with potential interest in the Company's product pipeline, and (iii) prepare and deliver presentations concerning the Company's products; (b) at the request of the Board of Directors, serving as backup management for up to three months should the Company's chief executive officer and scientific leader be temporarily unable to carry out his duties; (c) being available for consultation in drug discovery and development; and (d) identifying providers and overseeing tasks relating to clinical use and commercialization of new compounds. The Collaboration Agreement is for an initial term of two years and automatically renews for subsequent annual periods unless terminated by a party not less than 60 days prior to the expiration of the applicable period. In connection with the Collaboration Agreement, the Company agreed to pay BioPharmaWorks a monthly fee of \$10,000, subject to the right of the Company to pay a negotiated hourly rate in lieu of the monthly payment, and agreed to issue to BioPharmaWorks certain equity-based compensation are described at Note 7. Fees charged to operations pursuant to this agreement were \$5,000 during the three months and nine months ended September 30, 2015.

The following table sets forth the Company's principal cash obligations and commitments for the next five fiscal years as of September 30, 2015 aggregating \$575,223, of which \$96,657 is included in current liabilities in the Company's condensed consolidated balance sheet at September 30, 2015. Amounts included in the 2015 column represent amounts due at September 30, 2015 for the remainder of the 2015 fiscal year ending December 31, 2015.

	<u>Total</u>	<u>Payments Due By Year</u>				
		<u>2015</u>	<u>2016</u>	<u>2017</u>	<u>2018</u>	<u>2019</u>
Research and development contracts	\$ 71,121	\$ 71,121	\$ —	\$ —	\$ —	\$ —
Clinical trial agreements	258,602	258,602	—	—	—	—
Consulting agreements	245,500	35,500	120,000	90,000	—	—
Total	<u>\$ 575,223</u>	<u>\$ 365,223</u>	<u>\$ 120,000</u>	<u>\$ 90,000</u>	<u>\$ —</u>	<u>\$ —</u>

### 9. Subsequent Events

Effective as of October 28, 2015, the Company entered into a two-year advisory agreement with Dr. Fritz Henn, M.D., Ph.D., for consultation and advice on the development of certain of the Company's products for clinical neurological and neuropsychiatric applications. The advisory agreement is automatically extendable on an annual basis subsequent to October 28, 2017 unless a notice of intent to terminate is given by either party at least 90 days before the end of the applicable term. In connection with the advisory agreement, Dr. Henn was granted stock options to purchase 200,000 shares of the Company's common stock, with 100,000 shares vesting on October 28, 2015, and 100,000 shares vesting on October 28, 2016. The options are exercisable for a period of five years from the grant date at \$0.50 per share. Dr. Henn is an internationally recognized investigative neuroscientist and psychiatrist.

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

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

### Overview

Lixte Biotechnology Holdings, Inc., a Delaware corporation, including its wholly-owned Delaware subsidiary, Lixte Biotechnology, Inc. (collectively, the "Company") is engaged in research and development activities with respect to anti-cancer treatments and other common non-malignant diseases. The Company's activities are subject to significant risks and uncertainties, including the need for additional capital, as described below. The Company has not yet commenced any 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 has concluded that there is substantial doubt about the Company's ability to continue as a going concern, and the Company's independent registered public accounting firm, in their report on the Company's consolidated financial statements for the year ended December 31, 2014, has expressed substantial doubt about the Company's ability to continue as a going concern.

The Company's ability to continue as a going concern is dependent upon its ability to raise additional 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, 2015, the Company had not yet commenced any revenue-generating operations. All activity through September 30, 2015 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, 2015, the Company had cash and money market funds aggregating \$741,644. The sale of preferred shares in March 2015, which generated proceeds of \$1,750,000, and the exercise of warrants in April 2015, which generated proceeds of \$315,000, provided the Company with sufficient funds to complete Part 1 of its Phase 1 clinical trial of its lead anti-cancer compound LB-100 and to fund its ongoing operating expenses through approximately January 31, 2016.

The amount and timing of future cash requirements depend on the pace and design of the Company's clinical trial program. The Company expects that it will need to raise approximately \$2,000,000 of additional capital in the first quarter of 2016, likely in the form of equity, to fund operations, including the continuing costs of its clinical trial program and the support of its patent portfolio. The availability of such capital would allow the Company to conduct a Phase 2 clinical trial of LB-100 as a single agent in 2016.

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

## Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update No. 2014-09 (ASU 2014-09), *Revenue from Contracts with Customers*. ASU 2014-09 will eliminate transaction- and industry-specific revenue recognition guidance under current GAAP and replace it with a principle based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. Based on the FASB’s Exposure Draft Update issued on April 29, 2015, *Revenue from Contracts With Customers (Topic 606): Deferral of the Effective Date*, it is expected that ASU 2014-09 will now be effective for reporting periods beginning after December 15, 2017, with early adoption permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. Entities will be able to transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. The adoption of ASU 2014-09 is not expected to have any impact on the Company’s financial statement presentation or disclosures.

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

In January 2015, the FASB issued Accounting Standards Update No. 2015-01 (ASU 2015-01), *Income Statement – Extraordinary and Unusual Items (Subtopic 225-20)*. ASU 2015-01 eliminates from GAAP the concept of extraordinary items. Subtopic 225-20, *Income Statement – Extraordinary and Unusual Items*, required that an entity separately classify, present, and disclose extraordinary events and transactions. Presently, an event or transaction is presumed to be an ordinary and usual activity of the reporting entity unless evidence clearly supports its classification as an extraordinary item. Paragraph 225-20-45-2 contains the following criteria that must both be met for extraordinary classification: (1) Unusual nature. The underlying event or transaction should possess a high degree of abnormality and be of a type clearly unrelated to, or only incidentally related to, the ordinary and typical activities of the entity, taking into account the environment in which the entity operates. (2) Infrequency of occurrence. The underlying event or transaction should be of a type that would not reasonably be expected to recur in the foreseeable future, taking into account the environment in which the entity operates. If an event or transaction meets the criteria for extraordinary classification, an entity is required to segregate the extraordinary item from the results of ordinary operations and show the item separately in the income statement, net of tax, after income from continuing operations. The entity also is required to disclose applicable income taxes and either present or disclose earnings-per-share data applicable to the extraordinary item. ASU 2015-01 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. A reporting entity may apply the guidance prospectively. A reporting entity also may apply the guidance retrospectively to all prior periods presented in the financial statements. Early adoption is permitted provided that the guidance is applied from the beginning of the fiscal year of adoption. The adoption of ASU 2015-01 is not expected to have any impact on the Company’s financial statement presentation or disclosures.

In February 2015, the FASB issued Accounting Standards Update No. 2015-02 (ASU 2015-02), *Consolidation (Topic 810)*. ASU 2015-02 changes the guidance with respect to the analysis that a reporting entity must perform to determine whether it should consolidate certain types of legal entities. All legal entities are subject to reevaluation under the revised consolidation mode. ASU 2015-02 affects the following areas: (1) limited partnerships and similar legal entities; (2) evaluating fees paid to a decision maker or a service provider as a variable interest; (3) the effect of fee arrangements on the primary beneficiary determination; (4) the effect of related parties on the primary beneficiary determination; and (5) certain investment funds. ASU 2015-02 is effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted, including adoption in an interim period. If an entity early adopts the guidance in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. A reporting entity may apply the amendments in this guidance using a modified retrospective approach by recording a cumulative-effect adjustment to equity as of the beginning of the fiscal year of adoption. A reporting entity also may apply the amendments retrospectively. The adoption of ASU 2015-02 is not expected to have any impact on the Company's financial statement presentation or disclosures.

In April 2015, the FASB issued Accounting Standards Update No. 2015-03 (ASU 2015-03), *Interest – Imputation of Interest (Subtopic 835-30)*. ASU 2015-03 simplifies the presentation of debt issuance costs and requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the new guidance. ASU 2015-3 is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within that fiscal year. Early adoption is permitted for financial statements that have not been previously issued. An entity is required to apply the new guidance on a retrospective basis, wherein the balance sheet of each individual period presented is adjusted to reflect the period-specific effects of applying the new guidance. Upon transition, an entity is required to comply with the applicable disclosures for a change in an accounting principle. These disclosures include the nature of and reason for the change in accounting principle, the transition method, a description of the prior-period information that has been retrospectively adjusted, and the effect of the change on the financial statement line items (i.e., debt issuance cost asset and the debt liability). The adoption of ASU 2015-03 is not expected to have any impact on the Company's financial statement presentation or disclosures.

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

### **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 by December 31, 2015. The Phase 1 clinical trial is currently estimated to cost approximately \$1,800,000, with such payments expected to be allocated approximately 60% for services provided by Theradex and approximately 40% for pass-through costs for clinical center laboratory costs and investigator costs over the life of the clinical trial. Total costs charged to operations through September 30, 2015 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, were \$1,361,578, of which \$159,042 and \$83,483 were incurred during the three months ended September 30, 2015 and 2014, respectively, or approximately 25% and 27% of research and development costs for the three months ended September 30, 2015 and 2014, respectively. During the nine months ended September 30, 2015 and 2014, the Company incurred \$659,750 and \$256,716, respectively, or approximately 47% and 32% of research and development costs for the nine months ended September 30, 2015 and 2014, respectively. 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 ratably over the life of the underlying contracts, unless the achievement of milestones, the completion of contracted work, or other information indicates that a different expensing schedule is more appropriate. The costs of the Phase 1 clinical trial of LB-100 that are being paid through Theradex, the CRO, are recorded and expensed based upon the documentation provided by the CRO when it becomes available. 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, in combination 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 has been to determine the safety and appropriate dose of LB-100 when used alone and in combination with widely used anti-cancer drugs in its Phase 1 clinical trial. The Company's longer-term objective is to secure one or more strategic partnerships with pharmaceutical companies with major programs in cancer, vascular disease and/or neurologic disease.

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

## **Operating Plans**

The Company's primary focus is developing new treatments for human cancers for which better therapies are urgently needed. The scope of potential applications of the Company's products has expanded to other common non-malignant diseases, including vascular diseases (heart attacks and stroke, diabetes, 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, consisting of protein phosphatase inhibitors (PTase-i), designated by the Company as the LB-100 series of compounds, and histone deacetylase inhibitors (HDACi), designated by the Company as the LB-200 series of compounds. Compounds of both types also have potential use in the prevention and treatment of neurodegenerative diseases. The LB-100 series consists of novel structures, which have the potential to be first in their class, and may be useful in the treatment of not only several types of cancer but also vascular and metabolic diseases. The LB-200 series contains compounds which have the potential to be the most effective in its class and may be useful for the treatment of chronic hereditary diseases, such as Gaucher's disease, in addition to cancer and neurodegenerative diseases.

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

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

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

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

The Company's primary objective has been to bring one lead compound of the LB-100 series to clinical trial. In 2012, the Company completed the pre-clinical studies needed to prepare an Investigational New Drug ("IND") application to the United States Food and Drug Administration ("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 was designed to be conducted in two parts. In Part 1, the maximum tolerable dose ("MTD") of LB-100 is determined. In Part 2, the MTD of LB-100, in combination with the standard cytotoxic drug docetaxel (which is a well-established anti-mitotic chemotherapy medication approved by the FDA for the treatment of various cancers), is determined.

The Phase 1 clinical trial of LB-100 began in April 2013 with the entry of patients into the clinical trial 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. As the accrual of patients was slower than anticipated, in October 2014 the Company entered into a Clinical Research Agreement ("CRA") with US Oncology Research, LLC, a large community-based research network based in Texas, to increase the rate of entry of patients into the clinical trial by adding four more active clinical oncologic research sites.

The costs of Part 1 of the Phase 1 clinical trial have exceeded the Company's estimates in part because patients were able to tolerate higher doses of LB-100 than originally expected, thus requiring more dose escalation steps to determine the MTD of LB-100 given alone. In addition, patients have been achieving stabilization without any dose-limiting toxicity ("DLT"), remaining on treatment with LB-100 for longer periods of time than is usual in a Phase 1 clinical trial of a new drug in patients failing all previous treatments. The Company's interpretation of the clinical trial results to date is that LB-100 as a single agent has activity against several types of cancer, as evidenced by stabilization of progressive disease in the absence of DLT. The Company is continuing to administer LB-100 to patients if there is no cancer progression and the patient feels well and has no significant toxicity.

As a prelude to determining the therapeutic effectiveness of LB-100 in a subsequent Phase 2 clinical trial of common cancers, a key goal of Part 1 of the Phase 1 clinical trial was to demonstrate that the target enzyme of LB-100, protein phosphatase 2A ("PP2A"), can be inhibited in humans with readily tolerable toxicity. Part 1 of the current clinical trial of LB-100 is continuing with escalating doses in groups of three patients to determine the MTD. As an anti-cancer drug, LB-100 is likely to be used at maximum tolerable doses. However, 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.

As this is an experimental treatment not reimbursable by medical insurance, the cost of continuing treatment beyond the standard two cycles (one cycle is defined as the administration of the drug daily for three days every three weeks) that are required for the assessment of toxicity at a given dose level has been more than double the expected cost.

The costs of the Phase 1 clinical trial of LB-100 are being paid to or through Theradex, the CRO responsible for the clinical development of LB-100. Total costs charged to operations through September 30, 2015 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, totaled \$1,361,578, of which \$159,042 and \$83,483 were incurred during the three months ended September 30, 2015 and 2014, respectively, and \$659,750 and \$256,716 were incurred during the nine months ended September 30, 2015 and 2014, respectively.

The Company had planned to proceed with Part 2 of the Phase 1 clinical trial to determine the toxicity of LB-100 in combination with docetaxel against a specific solid tumor for which single agent docetaxel is indicated. However, two developments have altered this plan. First, LB-100 appears to have anticancer activity in its own right, and second, preclinical studies indicate that LB-100 in combination with cisplatin (a widely used cytotoxic drug) is more active than LB-100 in combination with docetaxel. LB-100 significantly potentiates the standard anti-cancer drug cisplatin against several tumor types, including hepatocellular cancer and ovarian cancer. In addition, it has been reported that inhibition of the enzyme-target of LB-100, PP2A, inhibits certain variants of the hematologic disorder known as myelodysplastic syndrome ("MDS"). Accordingly, the Company has decided not to proceed with Part 2 of the Phase 1 clinical trial, and has initiated planning for Phase 2 clinical trials in 2016 to evaluate the effectiveness of LB-100 alone for the treatment of MDS and in combination with a platinum compound for the treatment of ovarian and/or hepatocellular cancer.

The Company had previously estimated that Part 1 and Part 2 of the Phase 1 clinical trial would be completed by September 30, 2015 and September 30, 2016, respectively, at a total cost of approximately \$2,615,000. As the Company has decided not to proceed with Part 2 of the Phase 1 clinical trial, the Company estimates that this clinical trial will be completed by December 31, 2015 at a total cost of approximately \$1,800,000.

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

## Results of Operations

The Company is considered a development stage company at September 30, 2015, as 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.

### Three Months Ended September 30, 2015 and 2014

General and Administrative. For the three months ended September 30, 2015, general and administrative costs were \$155,307, which consisted of a credit for the vested portion of the fair value of stock options and warrants issued to directors and consultants of \$3,341, consulting and professional fees of \$117,421, insurance expense of \$15,646, officer's salary and related costs of \$16,864, stock transfer fees of \$2,537, travel and entertainment costs of \$2,300, filing fees of \$1,389, and other operating costs of \$2,491.

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, stock transfer fees of \$2,918, travel and entertainment costs of \$6,402, investor relations of \$8,085 and other operating costs of \$6,790.

General and administrative costs decreased by \$37,010 or 19.2% in 2015 as compared to 2014, primarily as a result of a decrease of \$79,198 in stock-based compensation and a decrease in investor relations of \$8,085, offset by an increase in professional fees of \$52,039.

The charge to operations for the fair value of stock options issued to directors and consultants of \$75,857 during the three months ended September 30, 2014 consisted of 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 three months ended September 30, 2015, research and development costs were \$624,405, which consisted of the vested portion of the fair value of common stock and stock options and warrants of \$261,101, patent costs of \$139,485, and contractor costs of \$223,819, including \$159,042 to Theradex in connection with the Phase 1 clinical trial of LB-100.

The charge to operations for the fair value of common stock and stock options and warrants of \$261,101 for the three months ended September 30, 2015 consisted primarily of the fair value of (i) 1,000,000 shares of fully-vested common stock and (ii) stock options and warrants to acquire 1,000,000 shares of the Company's common stock, vesting over the next two years, which were issued to BioPharmaWorks on September 14, 2015.

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 of \$44,357, patent costs of \$83,869, and contractor costs of \$180,877, including \$83,483 to Theradex in connection with the Phase 1 clinical trial of LB-100.

A significant component of the fair value of stock options issued to consultants of \$44,357 for the three months ended September 30, 2014 was \$43,500 charged to operations for the fair value of stock options to acquire 1,000,000 shares of the Company's common stock that were assigned to Daniel Von Hoff, a member of the Company's Scientific Advisory Board, by Gil Schwartzberg, a significant stockholder of and consultant to the Company. 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.

Research and development costs increased by \$315,302 or 102.0% in 2015 as compared to 2014, which consisted of an increase in the vested portion of the fair value of common stock and stock options of \$216,744, an increase in patent costs of \$55,616, and an increase in contractor costs of \$42,942, including an increase of \$75,559 to Theradex in connection with the Phase 1 clinical trial of LB-100, offset by a decrease of \$32,617 in other contract costs.

Net Loss. For the three months ended September 30, 2015, the Company incurred a net loss of \$779,687, as compared to a net loss of \$501,393 for the three months ended September 30, 2014.

## Nine Months Ended September 30, 2015 and 2014

General and Administrative. For the nine months ended September 30, 2015, general and administrative costs were \$615,615, which consisted of the vested portion of the fair value of stock options issued to directors and consultants of \$161,426 (including \$76,750 of such costs as described at Note 7), consulting and professional fees of \$320,642, insurance expense of \$43,295, officer's salary and related costs of \$50,613, stock transfer fees of \$8,153, travel and entertainment costs of \$9,800, and other operating costs of \$21,686.

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, 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, licensing fees of \$30,000, and other operating costs of \$30,350.

General and administrative costs decreased by \$311,267 or 33.6% in 2015 as compared to 2014, primarily as a result of a decrease of \$351,618 in stock-based compensation.

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 \$486,145 charged to operations for the fair value of stock options to acquire 4,000,000 shares of the Company's common stock that were issued to Gil Schwartzberg on January 28, 2014 for his continuing contributions to the Company's financial strategy.

Research and Development. For the nine months ended September 30, 2015, research and development costs were \$1,416,940, which consisted of the vested portion of the fair value of common stock, and stock options and warrants, of \$264,971, patent costs of \$351,711, and contractor costs of \$800,258, including \$659,750 to Theradex in connection with the Phase 1 clinical trial of LB-100.

A significant component of the fair value of common stock, and stock options and warrants, of \$264,971 for the nine months ended September 30, 2015 consisted primarily of the fair value of (i) 1,000,000 shares of fully-vested common stock and (ii) stock options and warrants to acquire 1,000,000 shares of the Company's common stock, vesting over the next two years, which were issued to BioPharmaWorks on September 14, 2015.

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 of \$166,464, patent costs of \$239,668, and contractor costs of \$401,465, including \$256,716 to Theradex in connection with the Phase 1 clinical trial of LB-100.

A significant component of the fair value of stock options issued to consultants of \$166,464 for the nine months ended September 30, 2014 was \$118,650 charged to operations for the fair value of stock options to acquire 500,000 shares of the Company's common stock that were issued to Francis Johnson on June 26, 2014 for his contributions to the Company's compound development activities and \$43,500 charged to operations for the fair value of stock options to acquire 1,000,000 shares of the Company's common stock that were assigned to Daniel Von Hoff, a member of the Company's Scientific Advisory Board, by Gil Schwartzberg, a significant stockholder of and consultant to the Company. 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.

Research and development costs increased by \$609,343 or 75.5% in 2015 as compared to 2014, as a result of an increase of \$98,507 in costs relating to the vested portion of the fair value of stock options, \$112,043 in patent costs, and \$398,793 in contractor costs, including an increase of \$403,034 to Theradex in connection with the Phase 1 clinical trial of LB-100, offset by a decrease of \$4,241 in other contract costs.

Fair Value of Warrant Extensions. During the nine months ended September 30, 2015, the Company incurred an expense of \$34,016 for the fair value of extending the expiration dates of warrants to acquire 2,928,800 shares of common stock from March 31, 2015 to April 15, 2015.

During the nine months ended September 30, 2014, the Company incurred an expense of \$302,691 for the fair value of extending the expiration dates of warrants, including \$224,074 for the extension of warrants to acquire 2,928,800 shares of common stock that were purchased by investors as part of private placements that closed in 2009 and 2010 to March 31, 2014, and \$78,617 for the extension of warrants to acquire 1,748,800 shares of common stock scheduled to expire between February and April 2014 to June 30, 2014.

Fair Value of Warrant Discount. During the nine months ended September 30, 2015, the Company incurred an expense of \$171,757 for the fair value of discounts offered to warrant holders as an inducement for the early exercise of warrants to acquire 2,928,800 shares of common stock. The discounts ranged from \$0.25 to \$0.375 per share. The subsequent exercise of warrants resulted in the issuance of 1,050,000 shares of common stock and generated net proceeds to the Company of \$315,000 in April 2015.

During the nine months ended September 30, 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 6,828,800 shares of common stock. The discounts ranged from \$0.25 to \$0.375 per share. The subsequent exercise of warrants resulted in the issuance of 3,900,000 shares of common stock and generated net proceeds to the Company of \$1,412,500 in April 2014.

Net Loss. For the nine months ended September 30, 2015, the Company incurred a net loss of \$2,238,257, as compared to a net loss of \$2,171,534 for the nine months ended September 30, 2014.

### **Liquidity and Capital Resources – September 30, 2015**

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, 2015, the Company had working capital of \$804,884 (including advances on research and development contract services of \$217,284), as compared to working capital of \$265,862 at December 31, 2014, an increase in working capital of \$539,022 for the nine months ended September 30, 2015, primarily as a result of the sale on March 17, 2015 of 175,000 shares of the Company's non-voting Series A Convertible Preferred Stock at a price per share of \$10.00, for an aggregate purchase price of \$1,750,000, and \$315,000 from the exercise of warrants in April 2015, which resulted in the issuance of 1,050,000 shares of the Company's common stock. At September 30, 2015, the Company had cash and money market funds aggregating \$741,644, as compared to \$258,110 at December 31, 2014, an increase of \$483,534 for the nine months ended September 30, 2015. The Company expects to receive a refund of approximately \$182,000 with respect to advances on research and development contract services subsequent to the completion of Part 1 of its Phase 1 clinical trial of LB-100 (which is expected to be completed by December 31, 2015).

At September 30, 2015, the Company estimates that it has sufficient funds to complete Part 1 of its Phase 1 clinical trial of its lead anti-cancer compound LB-100 and to fund its ongoing operating expenses through approximately January 31, 2016. Accordingly, based on the Company's current clinical trial plans, the Company expects that it will need to raise approximately \$2,000,000 of additional capital in the first quarter of 2016, likely in the form of equity, to fund operations, including the continuing costs of its clinical trial program and the support of its patent portfolio. The availability of such capital would allow the Company to conduct a Phase 2 clinical trial of LB-100 as a single agent in 2016.

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

Operating Activities. For the nine months ended September 30, 2015, operating activities utilized cash of \$1,568,858, as compared to utilizing cash of \$991,101 for the nine months ended September 30, 2014, to support the Company's ongoing research and development activities.

**Investing Activities.** For the nine months ended September 30, 2015, investing activities consisted of an increase in money market funds of \$310,388, primarily as a result of proceeds from the sale of 175,000 shares of the Company's non-voting Series A Convertible Preferred Stock on March 17, 2015, and proceeds received from the exercise of warrants in April 2015, which resulted in the issuance of 1,050,000 shares of the Company's common stock. 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.

**Financing Activities.** For the nine months ended September 30, 2015, financing activities consisted of \$1,750,000 in proceeds received from the sale of 175,000 shares of the Company's non-voting Series A Convertible Preferred Stock at an aggregate purchase price of \$1,750,000 on March 17, 2015, less costs of \$12,608 associated with the sale, and \$315,000 in proceeds received from the exercise of warrants, which resulted in the issuance of 1,050,000 shares of the Company's common stock in April 2015. 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.

### **Principal Commitments**

On September 21, 2012, the Company entered into a work order agreement with Theradex, the CRO responsible for the clinical development of the Company's lead 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 by September 30, 2015. The Phase 1 clinical trial is currently estimated to cost approximately \$1,800,000, with such payments expected to be allocated approximately 60% for services provided by Theradex and approximately 40% for pass-through costs for clinical center laboratory costs and investigator costs over the life of the clinical trial. Total costs charged to operations through September 30, 2015 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, totaled \$1,361,578, of which \$159,042 and \$83,483 were incurred during the three months ended September 30 and 2014, respectively, and \$659,750 and \$256,716 were incurred during the nine months ended September 30, 2015 and 2014, 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. The agreement was automatically renewed on its anniversary date for an additional one-year term. Consulting and advisory fees charged to operations pursuant to this agreement were \$4,000 during the three months ended September 30, 2015 and 2014, and \$12,000 during the nine months ended September 30, 2015 and 2014.

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

On October 7, 2014, the Company entered into an agreement with ProActive Capital Resources Group LLC for strategic advisory, investor relations and public relations services through October 6, 2015. Among other things, the agreement provides for compensation in the form of a monthly fee of \$1,500 in cash. Fees charged to operations pursuant to this agreement were \$4,500 and \$3,000 during the three months ended September 30, 2015 and 2014, respectively, and \$13,500 and \$9,000 during the nine months ended September 30, 2015 and 2014, respectively.

Effective September 14, 2015, the Company entered into a Collaboration Agreement with BioPharmaWorks LLC (“BioPharmaWorks”), pursuant to which the Company engaged BioPharmaWorks to perform certain services for the Company. Those services include, among other things: (a) assisting the Company to (i) commercialize its products and strengthen its patent portfolio, (ii) identify large pharmaceutical companies with potential interest in the Company’s product pipeline, and (iii) prepare and deliver presentations concerning the Company’s products; (b) at the request of the Board of Directors, serving as backup management for up to three months should the Company’s chief executive officer and scientific leader be temporarily unable to carry out his duties; (c) being available for consultation in drug discovery and development; and (d) identifying providers and overseeing tasks relating to clinical use and commercialization of new compounds. The Collaboration Agreement is for an initial term of two years and automatically renews for subsequent annual periods unless terminated by a party not less than 60 days prior to the expiration of the applicable period. In connection with the Collaboration Agreement, the Company agreed to pay BioPharmaWorks a monthly fee of \$10,000, subject to the right of the Company to pay a negotiated hourly rate in lieu of the monthly payment, and agreed to issue to BioPharmaWorks certain equity-based compensation. Fees charged to operations pursuant to this agreement were \$5,000 during the three months and nine months ended September 30, 2015.

The following table sets forth the Company’s principal cash obligations and commitments for the next five fiscal years as of September 30, 2015 aggregating \$575,223, of which \$96,657 is included in current liabilities in the Company’s condensed consolidated balance sheet at September 30, 2015. Amounts included in the 2015 column represent amounts due at September 30, 2015 for the remainder of the 2015 fiscal year ending December 31, 2015.

	<b>Total</b>	<b>Payments Due By Year</b>				
		<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
Research and development contracts	\$ 71,121	\$ 71,121	\$ —	\$ —	\$ —	\$ —
Clinical trial agreements	258,602	258,602	—	—	—	—
Consulting agreements	245,500	35,500	120,000	90,000	—	—
<b>Total</b>	<b>\$ 575,223</b>	<b>\$ 365,223</b>	<b>\$ 120,000</b>	<b>\$ 90,000</b>	<b>\$ —</b>	<b>\$ —</b>

#### **Off-Balance Sheet Arrangements**

At September 30, 2015, 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 inadvertently neglected to timely account for securities authorized to be issued effective October 7, 2014, as described at Note 7 to the condensed consolidated financial statements included elsewhere in this document. The securities were issued on or about July 31, 2015. The Company believes that such a failure of internal controls was an anomalous one-time event, as the Company has not had any internal control failures of a similar nature since becoming a public company under its current management in June 2006. The Company has instituted additional internal control procedures to prevent a recurrence of such an event.

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

As of the date of this filing, there have been no material changes to the Risk Factors included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2014, as filed with the SEC on March 27, 2015 (the "2014 Form 10-K"). The Risk Factors set forth in the 2014 Form 10-K should be read carefully in connection with evaluating the Company's business and in connection with the forward-looking statements contained in this Quarterly Report on Form 10-Q. Any of the risks described in the 2014 Form 10-K could materially adversely affect the Company's business, financial condition or future results and the actual outcome of matters as to which forward-looking statements are made. These are not the only risks that the Company faces. Additional risks and uncertainties not currently known to the Company or that the Company currently deems to be immaterial also may materially adversely affect the Company's business, financial condition and/or operating results.

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

Effective September 14, 2015, the Company entered into a Collaboration Agreement with BioPharmaWorks LLC ("BioPharmaWorks"), pursuant to which the Company engaged BioPharmaWorks to perform certain services for the Company. Those services include, among other things: (a) assisting the Company to (i) commercialize its products and strengthen its patent portfolio, (ii) identify large pharmaceutical companies with potential interest in the Company's product pipeline, and (iii) prepare and deliver presentations concerning the Company's products; (b) at the request of the Board of Directors, serving as backup management for up to three months should the Company's chief executive officer and scientific leader be temporarily unable to carry out his duties; (c) being available for consultation in drug discovery and development; and (d) identifying providers and overseeing tasks relating to clinical use and commercialization of new compounds. In connection with the Collaboration Agreement, the Company agreed to issue to BioPharmaWorks 1,000,000 fully-vested shares of the Company's common stock, valued at \$260,000, based upon the closing price of the Company's common stock of \$0.26 per share, on September 14, 2015. Additionally, the Company issued to BioPharmaWorks two options in the form of warrants, to purchase 1,000,000 shares (500,000 shares per warrant) of the Company's common stock. The first warrant vests on September 14, 2016, and is exercisable for a period of five years from the date of grant at \$1.00 per share. The second warrant vests on September 14, 2017, and is exercisable for a period of five years from the date of grant at \$2.00 per share. The fair value of the first and second warrants, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$128,400 (\$0.2568 per share) and \$127,850 (\$0.2557 per share), respectively.

### 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 10, 2015

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
4.1	Form of First Warrant to purchase common stock issued to BioPharmaWorks dated September 14, 2015, incorporated by reference to Exhibit 4.01 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on September 18, 2015.
4.2	Form of Second Warrant to purchase common stock issued to BioPharmaWorks dated September 14, 2015, incorporated by reference to Exhibit 4.02 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on September 18, 2015.
4.3*	Stock Option Agreement to purchase common stock issued to Dr. Fritz Henn dated October 28, 2015.
10.1	Collaboration Agreement between Lixte Biotechnology Holdings, Inc. and BioPharmaWorks LLC effective September 14, 2015, incorporated by reference to Exhibit 10.01 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on September 18, 2015.
10.2*	Advisory Agreement between Lixte Biotechnology Holdings, Inc. and Dr. Fritz Henn effective as of October 28, 2015.
31.1*	Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Officer's Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document

\* Filed herewith.

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

## STOCK OPTION AGREEMENT

THIS STOCK OPTION AGREEMENT (“Agreement”) is made as of October 28, 2015 (the “Grant Date”) by and between LIXTE BIOTECHNOLOGY HOLDINGS, INC., a Delaware corporation (the “Company”), and FRITZ HENN, M.D., Ph.D. (the “Optionee”).

WHEREAS, Optionee has entered into an Advisory Agreement with the Company (the “Advisory Agreement”) which provides, inter alia, that the Company will grant Optionee stock options.

NOW, THEREFORE, in consideration of the mutual benefit to be derived herefrom and pursuant to the Consulting Agreement, the Company and Optionee agree as follows:

1. Grant of Option. The Company hereby grants to Optionee the right, privilege and option (the “Option”) to purchase 200,000 shares of its common stock (“Option Shares”) at an exercise price of \$0.50 per share (the “Exercise Price”), in the manner and subject to the conditions provided hereinafter.

2. Vesting and Exercise of Option. The Option shall vest as follows: options to purchase 100,000 Option Shares vesting as of the Grant Date with the remainder vesting on the first anniversary of the Grant Date. Any exercise may be with respect to any part or all of the Option Shares then vested and exercisable pursuant to the Option.

3. Termination of Option. Except as otherwise provided in this Agreement, to the extent not previously exercised, the Option shall terminate upon the first to occur of any of the following events:

(a) Five years from the date hereof;

(b) the date that Optionee is no longer acting under the Advisory Agreement because (i) a Notice of Intent to Terminate is issued by Optionee; or (ii) the Company terminates the Advisory Agreement “for cause”; or

(c) the breach by Optionee of any provision of this Agreement.

4. Method of Exercise. The Option shall be exercised by written notice to the Company by the Optionee (or assignee). Such written notice shall state the number of shares with respect to which the Option is being exercised and designate a time, during normal business hours of the Company, for the delivery thereof (“Exercise Date”), which time shall be at least ten days after the giving of such notice unless an earlier date shall have been mutually agreed upon. At the time specified in the written notice, the Company shall deliver to the Optionee a certificate or certificates for such shares. Notwithstanding the foregoing, the Company may postpone delivery of any certificate or certificates after notice of exercise for such reasonable period as may be required to comply with any applicable listing requirements of any securities exchange. In the event an Option shall be exercisable by any person other than the Optionee, the required notice under this Section shall be accompanied by appropriate proof of the right of such person to exercise the option. The Exercise Price shall be payable in full on or before the option Exercise Date by full payment in cash or certified bank or cashier’s check or pursuant to a net share exercise wherein Optionee shall receive Option Shares as follows:

---

$$X = \frac{Y(A-B)}{A}$$

where X = the number of Option Shares

Y = the number of Option Shares with respect to which this Option is being exercised

A = Fair Market Value of one share of the Company's Common Stock (at the date of calculation)

B = the Exercise Price.

As used herein, Fair Market Value means the last sales price reported by Bloomberg Financial Markets for the trading day immediately preceding the Exercise Date.

5. Restrictions on Exercise and Delivery. The exercise of the Option shall be subject to the condition that, if at any time the Company shall determine, in its sole and absolute discretion,

(a) the satisfaction of any withholding tax or other withholding liabilities, is necessary or desirable as a condition of, or in connection with, such exercise or the delivery or purchase of Stock pursuant thereto,

(b) the listing, registration, or qualification of any shares deliverable upon such exercise is desirable or necessary, under any state or federal law, as a condition of, or in connection with, such exercise or the delivery or purchase of shares pursuant thereto,

(c) the consent or approval of any regulatory body is necessary or desirable as a condition of, or in connection with, such exercise or the delivery or purchase of shares pursuant thereto, or

(d) in the case of any assignee, appropriate investment representations.

then in any such event, such exercise shall not be effective unless such withholding, listing, registration, qualification, consent or approval shall have been effected or obtained free of any conditions not acceptable to the Company. Optionee shall execute such documents and take such other actions as are required by the Company to enable him to effect or obtain such withholding, listing, registration, qualification, consent or approval. Neither the Company nor any officer or member of the Company's Board of Directors, shall have any liability with respect to the non-issuance or failure to sell shares as the result of any suspensions of exercisability imposed pursuant to this Section.

6. Assignability. This Option may not be sold, pledged, assigned or transferred in any manner other than by will or by the laws of intestate succession, and may be exercised during the lifetime of Optionee only by Optionee. Any transfer by Optionee of any Option granted under this Agreement shall void such Option and the Company shall have no further obligation with respect to such Option. No Option shall be pledged or hypothecated in any way, nor shall any Option be subject to execution, attachment or similar process.

7. Restrictive Legends. To the extent required under the securities laws, each certificate evidencing the Option Shares acquired upon exercise of the Option hereunder, including any certificate issued to any transferee thereof, shall be imprinted with appropriate legends.

8. Rights as Stockholder. Neither Optionee nor any assignee, executor, administrator, heirs or legatees, shall be, or have any rights or privileges of a stockholder of the Company in respect of the Option Shares unless and until certificates representing such Stock shall have been issued in Optionee's name.

9. Adjustments. In the event of any stock dividend or split, or recapitalization, combination, exchange or similar change affecting the Stock, there shall be an appropriate adjustment of the number of Option Shares and the Exercise Price. In the event that the Company is sold, merged, consolidated, reorganized or liquidated, the Board of Directors may take any one or more of the following actions as to outstanding Options (i) provide that the Options shall be assumed, or substantially equivalent Options shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof) on such terms as the Board of Directors determines to be appropriate, (ii) in the event of a sale or similar transaction under the terms of which holders of the Common Stock of the Company receive a payment for each share surrendered in the transaction (the "Sales Price"), make or provide for a payment to each Option equal to the amount by which (A) the Sales Price times the number of shares of Common Stock subject to outstanding Options exceeds (B) the aggregate exercise price of all such outstanding Options, in exchange for the termination of such Options, or (iii) make such other adjustments, if any, as the Board of Directors determines to be necessary or advisable to provide Optionee with a benefit substantially similar to that to which the Optionee would have been entitled had such event not occurred.

10. Notices. Any notice to be given under the terms of this Agreement shall be addressed to the Company at its principal office, and any notice to be given to Optionee shall be addressed to such Optionee at the address maintained by the Company for such person or at such other address as the Optionee may specify in writing to the Company.

11. Binding Effect. This Agreement shall be binding upon and inure to the benefit of Optionee, his heirs and successors, and of the Company, its successors and assigns.

12. Governing Law. This Agreement shall be governed by the laws of the State of Delaware.

[Signature Page Follows]

IN WITNESS WHEREOF, this Agreement is effective as of, and the date of grant shall be October 28, 2015.

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.**

By: /s/ John S. Kovach

Name: John S. Kovach

Title: President

**OPTIONEE:**

/s/ Fritz Henn, M.D., Ph.D.

Fritz Henn, M.D., Ph.D.

ADVISORY AGREEMENT

This ADVISORY AGREEMENT (this “Agreement”), is entered into effective as of October 28, 2015, by and between Lixte Biotechnology Holdings, Inc., a Delaware corporation (the “Company”), and Fritz Henn, M.D., Ph.D. (“Advisor”).

RECITALS

WHEREAS, Advisor has certain knowledge, expertise, experience and reputation with respect to which the Company desires to avail itself; and

WHEREAS, upon the terms and subject to the conditions of this Agreement, the Company desires to retain Advisor to provide certain advisory services to the Company, and Advisor wishes to render such services.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual promises and agreements herein contained, Advisor and the Company by this Agreement agree as follows:

1. Engagement. The Company hereby agrees that, commencing on October 28, 2015 (the “Effective Date”), the Company shall engage Advisor and Advisor hereby accepts such engagement with the Company, upon the terms and subject to the conditions hereinafter set forth.

2. Term. The initial term of Advisor’s engagement under this Agreement (the “Initial Term”) shall commence on the Effective Date and, subject to the provisions of Section 6, shall continue until October 28, 2017. The Initial Term and any subsequent one year term (each a “Term”) shall automatically be 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.

3. Services. Advisor shall advise on the development of certain of the Company’s products for clinical neurological and neuropsychiatric applications. Advisor shall not be required to devote any specific amount of time hereunder but will be generally available as and when reasonably needed.

4. No Authority to Bind. Except as directed and authorized by the Chief Executive Officer of the Company in writing, Advisor shall not execute or agree to any contract, agreement or instrument on behalf of the Company.

5. Compensation. As sole compensation for the services to be rendered hereunder, the Company shall grant to Advisor five-year options (the “Options”) to purchase 200,000 shares of the Company’s common stock with an exercise price of \$0.50 per share vesting one-half upon the Effective Date and the remainder on the first anniversary of the Effective Date.

6. Termination. The Company may terminate this Agreement at any time “for cause” upon delivery of written notice to Advisor, in which case such termination shall be effective immediately upon Advisor’s receipt of the written notice.

“Cause” shall mean:

(a) Advisor is convicted of, or pleads *nolo contendere* (no contest) to, any crime (whether or not involving the Company) constituting a felony in the jurisdiction involved; or

(b) Advisor is in material breach of any provision of this Agreement or any other agreement with the Company, or willfully fails to or refuses to comply with the lawful directives of the Chief Executive Officer or the Board of Directors of the Company in the performance of his duties under this Agreement (other than a failure caused by temporary disability).

7. Proprietary Rights and Nondisclosure and Nonuse of Confidential Information.

7.1 It is understood that during the term of this Agreement, Advisor may be exposed to information that is confidential and proprietary to the Company. All such information (hereinafter “Lixte Confidential Information”), whether written or oral, tangible or intangible, that is made available, disclosed, or otherwise made known to Advisor by the Company or its employees under this Agreement shall be considered confidential and shall be considered the sole property of the Company. Lixte Confidential Information shall be (a) marked as confidential, or (b) otherwise represented by the disclosing party as confidential either before or within a reasonable time after its disclosure to the receiving party. This obligation of confidentiality shall remain in effect for a period of five (5) years after the expiration or termination of this Agreement.

7.2 The obligations of confidentiality set forth in Paragraph 7.1 shall not apply to any information that:

(a) is or hereafter becomes generally available to the public other than by reason of any default with respect to a confidentiality obligation under this Agreement; or

(b) was already known to the recipient as evidenced by prior written documents in its possession; or

(c) is disclosed to the recipient by a third party who is not in default of any confidentiality obligation to the disclosing party hereunder;  
or

(d) is developed by or on behalf of the receiving party, without reliance on confidential information received hereunder as evidenced by written documents in his possession; or

(e) has been approved in writing by one party for publication by the other party; or

(f) is required to be disclosed in compliance with applicable laws or regulations.

8. Nonsolicitation; Nondisparagement. Advisor acknowledges that during the course of Advisor's engagement by the Company, Advisor has and will continue to have the opportunity to develop relationships with existing employees, consultants, and other business associates of the Company, which relationships constitute goodwill of the Company and that the Company would be irreparably damaged if Advisor were to take actions that would damage or misappropriate such goodwill. Advisor accordingly agrees that during the period commencing on the Effective Date and ending on the first anniversary of the conclusion of the Term, Advisor shall not, directly or indirectly, either for the benefit of Advisor or any other person, do any of the following:

(a) Solicit any employee of the Company to terminate such employee's employment with the Company, or employ any such individual during such employee's employment with the Company and for a period of six months after such individual terminates employment with the Company;

(b) Solicit any advisor or consultant of the Company to terminate such person's relationship with the Company; or

(c) Make any public statement, comment or remark that disparages the integrity or competence of a Company officer, director, employee, or shareholder, that disparages any product or service of the Company, or that is reasonably likely to cause injury to the relationships between the Company and any existing or prospective contractual counterparty, supplier, customer, employee, consultant or other business associate of the Company. Likewise, the Company agrees that it shall not make any public statement, comment or remark that disparages the integrity or competence of Advisor.

9. Status as Advisor.

9.1 Intention of the Parties. It is mutually understood and agreed that Advisor, while performing all responsibilities under this Agreement, is and shall at all times be, act, function, and perform all services and responsibilities in the legal capacity of an independent contractor. It is mutually understood and agreed that no work, act, commission or omission of any act by Advisor or the Company pursuant to the terms and conditions of this Agreement shall be construed to make or render Advisor an employee of the Company. Furthermore, Advisor shall not, under any circumstances, hold himself out to be an employee of the Company.

9.2 Independent Advisor to Control Performance. The Company shall have no right or authority to direct or control Advisor with respect to the performance of Advisor's duties under this Agreement, or with respect to any other matter, except as otherwise provided by this Agreement. It is further understood that Advisor is free to contract with other companies to provide professional services, as long as that service does not violate the provisions of Sections 7 or 8.

9.3 Expenses. Except as provided in this Section 9.3, Advisor shall be fully responsible to pay any and all expenses and disbursements that he incurs in the performance of any services or obligations covered by this Agreement. The Company shall, however, reimburse Advisor for all actual and reasonable travel expenses incurred by Advisor when Advisor is traveling at the request of the Company in connection with his duties; provided, that (i) Advisor shall not be entitled to reimbursement for any individual expenditure in excess of \$1,000, unless such expenditure shall have been pre-approved in writing by the Company's Chief Executive Officer, and (ii) Advisor shall not be entitled to reimbursement for a particular expenditure if Advisor does not submit to the Company sufficient documentation evidencing such expenditure.

9.4 Taxes and Benefit Programs. Advisor shall be liable and responsible to pay any and all taxes relating to all amounts paid to Advisor hereunder. It is understood and agreed that because Advisor is not an employee of the Company, the Company shall not withhold any taxes from amounts paid to Advisor. Advisor shall be fully and solely responsible to report income and expenses. Advisor acknowledges that he is solely responsible for his own tax planning and that the Company has not provided Advisor with any tax advice regarding the tax implications of this Agreement. It is also understood and agreed that Advisor shall not be eligible to participate in any benefits or programs sponsored or financed by the Company for its employees.

#### 10. Miscellaneous.

10.1 Notices. All notices, requests, demands and other communications required or permitted to be given hereunder shall be in writing and shall be deemed to have been duly given upon receipt, if delivered personally, upon confirmation of receipt, if given by electronic facsimile and on the third business day following mailing, if mailed first-class, postage prepaid, registered or certified mail addressed as follows:

If to the Company to:

Lixte Biotechnology Holdings, Inc.  
248 Route 25A, No. 2  
East Setauket, New York 11733  
Attention: John Kovach, M.D.  
Phone: (631) 751-2882  
Fax: (631) 982-5050  
Email: jkovach@lixte.com

If to Advisor:

Fritz Henn MD, PhD

Phone: 516-320-0898  
e-mail: fiitz.henn@mssm.edu

Any party may by notice given in accordance with this Section 11.1 to the other parties designate another address or person for receipt of notices hereunder.

10.2 Entire Agreement. This Agreement contains the entire agreement of the parties with respect to the subject matter hereof. This Agreement may be amended, superceded, canceled, renewed or extended, and the terms hereof or thereof may be waived, only by a written instrument signed by each of the parties hereto or thereto or, in the case of a waiver, by the party waiving compliance.

10.3 Attorneys' Fees. If any legal action or arbitration arises under this Agreement, arises by reason of any asserted breach of it, or arises between the parties and is related in any way to the subject matter of the Agreement, the prevailing party shall be entitled to recover all costs and expenses, including reasonable attorneys' fees, arbitration costs, investigative costs, reasonable accounting fees and charges for experts.

10.4 Binding Effect; Assignment. This Agreement shall be binding upon and inure to the benefit of the parties and their respective permitted successors and permitted assigns. Neither this Agreement nor any of the rights hereunder may be assigned by any party, nor may any party delegate any obligations hereunder or thereunder, without the written consent of the other party hereto or thereto; provided, however, that the Company may assign its rights hereunder to any subsidiary or to any person or entity that acquires, directly or indirectly, all or substantially all of the Company's business (whether through acquisition of assets, stock or any other means). Any non-permitted assignment or attempted assignment shall be void, *ab initio*. Nothing herein is intended or shall be construed to give any person any legal or equitable right, remedy or claim under or in respect of this Agreement or any provision contained herein, except as otherwise provided herein.

10.5 Counterparts. This Agreement may be executed by the parties in separate counterparts, each of which when so executed and delivered shall be an original, but all such counterparts shall together constitute one and the same instrument. Delivery of any counterpart signature page of this Agreement, written communication or notice hereunder by facsimile shall be equally as effective as delivery of a manually executed original of such counterpart signature page, communication or notice.

10.6 Further Assurances. Each party hereto shall execute such documents and other papers and take such further actions as may be reasonably required or desirable to carry out the provisions of this Agreement and the transactions contemplated hereby.

10.7 Agreement Authorized. Advisor hereby represents and warrants that he is free to enter into this Agreement and that he is free to render its services pursuant to this Agreement, and that Advisor is not subject to any obligation or restriction that would prevent him from discharging his duties under this Agreement, and agrees to indemnify and hold harmless the Company from and with respect to any liability, damages or costs, including attorneys' fees, arising out of any breach by Advisor of this representation and warranty.

10.8 Governing Law. The validity, interpretation and construction of this Agreement and each part thereof will be governed by the laws of the State of New York.

10.9 Entire Agreement. This Agreement, and any other agreement explicitly mentioned herein, by and between the Company and Advisor, set forth the entire agreement between the Company and Advisor with respect to the subject matter hereof, and supersedes any and all prior agreements between the Company and Advisor, whether written or oral, relating to any or all matters covered by and contained or otherwise dealt with in this Agreement. This Agreement does not constitute a commitment of the Company with regard to Advisor's engagement, express or implied, other than to the extent expressly provided for herein.

10.10 Survival at Termination. The termination of this Agreement shall not affect the obligations to the parties hereunder which by the nature thereof are intended to survive any such termination including, without limitation, the obligations of Advisor under Sections 7 and 8.

IN WITNESS WHEREOF, the parties hereto have duly executed this Advisory Agreement as of the day and year first above written.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

By: /s/ John Kovach

Name: John Kovach

Its: President

/s/ Fritz Henn, M.D., Ph.D.

Fritz Henn, M.D., Ph.D.

**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 10, 2015

By: /s/ JOHN S. KOVACH

John S. Kovach

Chief Executive Officer and Chief Financial Officer

---

**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, 2015 (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 10, 2015

By: /s/ JOHN S. KOVACH

John S. Kovach

Chief Executive Officer and Chief Financial Officer

---