

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 March 31, 2013

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE 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 April 30, 2013, the Company had 41,583,097 shares of common stock, \$0.0001 par value, issued and outstanding.

Documents incorporated by reference: None

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**LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
AND SUBSIDIARY  
(a development stage company)**

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## Forward-Looking Statements

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

**PART I - FINANCIAL INFORMATION**

**ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
AND SUBSIDIARY  
(a development stage company)**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

	<u>March 31,</u> <u>2013</u>	<u>December 31,</u> <u>2012</u>
	(Unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash	\$ 1,374,581	\$ 1,655,122
Money market funds	6,135	6,134
Advances on research and development contract services	66,085	51,575
Prepaid expenses and other current assets	34,286	40,179
<b>Total current assets</b>	<u>1,481,087</u>	<u>1,753,010</u>
<b>Total assets</b>	<u>\$ 1,481,087</u>	<u>\$ 1,753,010</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 72,885	\$ 80,416
Research and development contract liabilities	30,536	14,019
Liquidated damages payable under registration rights agreement	74,000	74,000
Due to stockholder	92,717	92,717
<b>Total current liabilities</b>	<u>270,138</u>	<u>261,152</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; authorized – 10,000,000 shares; issued – none	—	—
Common stock, \$0.0001 par value; authorized - 100,000,000 shares; issued and outstanding – 41,583,097 shares at March 31, 2013 and December 31, 2012	4,158	4,158
Additional paid-in capital	13,117,868	13,064,831
Deficit accumulated during the development stage	(11,911,077)	(11,577,131)
<b>Total stockholders' equity</b>	<u>1,210,949</u>	<u>1,491,858</u>
<b>Total liabilities and stockholders' equity</b>	<u>\$ 1,481,087</u>	<u>\$ 1,753,010</u>

See accompanying notes to condensed consolidated financial statements.

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.**  
**AND SUBSIDIARY**  
(a development stage company)

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

	Three Months Ended March 31,		Period from August 9, 2005 (Inception) to March 31, 2013 (Cumulative)
	2013	2012	
Revenues	\$ —	\$ —	\$ —
Costs and expenses:			
General and administrative costs	167,642	318,311	5,400,582
Depreciation	—	—	1,909
Research and development costs	166,305	273,552	4,736,097
Reverse merger costs	—	—	50,000
Total costs and expenses	<u>333,947</u>	<u>591,863</u>	<u>10,188,588</u>
Loss from operations	(333,947)	(591,863)	(10,188,588)
Interest income	1	5	27,435
Interest expense	—	—	(2,469)
Fair value of warrant extensions	—	—	(1,339,431)
Fair value of warrant discount	—	—	(334,024)
Liquidated damages under registration rights agreement	—	—	(74,000)
Net loss	<u>\$ (333,946)</u>	<u>\$ (591,858)</u>	<u>\$ (11,911,077)</u>
Net loss per common share – basic and diluted	<u>\$ (0.01)</u>	<u>\$ (0.02)</u>	
Weighted average common shares outstanding – basic and diluted	<u>41,583,097</u>	<u>35,320,680</u>	

See accompanying notes to condensed consolidated financial statements.

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
AND SUBSIDIARY**  
(a development stage company)

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

Period from August 9, 2005 (Inception) to March 31, 2013

	Common Stock		Advances Under Equity Financing	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total Stockholders ' Equity (Deficiency)
	Shares	Amount				
Balance, August 9, 2005 (inception)	—	\$ —	\$ —	\$ —	\$ —	\$ —
Shares issued to founding stockholder	19,021,786	1,902	—	(402)	—	1,500
Net loss	—	—	—	—	(16,124)	(16,124)
Balance, December 31, 2005	19,021,786	1,902	—	(402)	(16,124)	(14,624)
Shares issued in connection with reverse merger transaction	4,005,177	401	—	62,099	—	62,500
Shares issued in private placement, net of offering costs	3,555,220	355	—	969,017	—	969,372
Stock-based compensation expense	—	—	—	97,400	—	97,400
Net loss	—	—	—	—	(562,084)	(562,084)
Balance, December 31, 2006	26,582,183	2,658	—	1,128,114	(578,208)	552,564
Shares issued in private placement, net of offering costs	999,995	100	—	531,220	—	531,320
Stock-based compensation expense	250,000	25	—	890,669	—	890,694
Stock-based research and development expense	—	—	—	50,836	—	50,836
Net loss	—	—	—	—	(1,648,488)	(1,648,488)
Balance, December 31, 2007	27,832,178	2,783	—	2,600,839	(2,226,696)	376,926
Stock-based compensation expense	—	—	—	357,987	—	357,987
Stock-based research and development expense	100,000	10	—	213,051	—	213,061
Net loss	—	—	—	—	(1,271,522)	(1,271,522)
Balance, December 31, 2008	27,932,178	2,793	—	3,171,877	(3,498,218)	(323,548)
Shares issued in private placements, net of offering costs	2,420,000	242	—	1,096,808	—	1,097,050
Advances under equity financing	—	—	1,200,000	—	—	1,200,000
Stock-based compensation expense	150,000	15	—	745,965	—	745,980
Stock-based research and development expense	—	—	—	132,933	—	132,933
Net loss	—	—	—	—	(1,551,333)	(1,551,333)
Balance, December 31, 2009	30,502,178	\$ 3,050	\$ 1,200,000	\$ 5,147,583	\$ (5,049,551)	\$ 1,301,082

(Continued)

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
AND SUBSIDIARY**  
(a development stage company)

**CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIENCY) (Continued)**

Period from August 9, 2005 (Inception) to March 31, 2013

	Common Stock		Advances Under Equity Financing	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total Stockholders ' Equity (Deficiency)
	Shares	Amount				
Shares issued in private placements, net of offering costs	4,575,000	\$ 458	\$ (1,200,000)	\$ 2,287,042	\$ —	\$ 1,087,500
Stock-based compensation expense	—	—	—	160,712	—	160,712
Stock-based research and development expense	—	—	—	67,222	—	67,222
Net loss	—	—	—	—	(880,250)	(880,250)
Balance, December 31, 2010	35,077,178	3,508	—	7,662,559	(5,929,801)	1,736,266
Exercise of stock options	181,964	18	—	4,982	—	5,000
Stock-based compensation expense	—	—	—	204,898	—	204,898
Stock-based research and development expense	—	—	—	982	—	982
Fair value of warrant extension	—	—	—	199,839	—	199,839
Net loss	—	—	—	—	(2,067,964)	(2,067,964)
Balance, December 31, 2011	35,259,142	3,526	—	8,073,260	(7,997,765)	79,021
Exercise of stock options	241,955	24	—	33,309	—	33,333
Exercise of stock warrants	6,082,000	608	—	2,467,642	—	2,468,250
Stock-based compensation expense	—	—	—	723,554	—	723,554
Stock-based research and development expense	—	—	—	293,450	—	293,450
Fair value of warrant discount	—	—	—	334,024	—	334,024
Fair value of warrant extensions	—	—	—	1,139,592	—	1,139,592
Net loss	—	—	—	—	(3,579,366)	(3,579,366)
Balance, December 31, 2012	41,583,097	4,158	—	13,064,831	(11,577,131)	1,491,858
Stock-based compensation expense	—	—	—	53,037	—	53,037
Net loss	—	—	—	—	(333,946)	(333,946)
Balance, March 31, 2013 (Unaudited)	41,583,097	\$ 4,158	\$ —	\$ 13,117,868	\$ (11,911,077)	\$ 1,210,949

See accompanying notes to condensed consolidated financial statements.

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
AND SUBSIDIARY**  
(a development stage company)

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

	<b>Three Months Ended March 31,</b>		<b>Period from August 9, 2005 (Inception) to March 31, 2013 (Cumulative)</b>
	<b>2013</b>	<b>2012</b>	
<b>Cash flows from operating activities:</b>			
Net loss	\$ (333,946)	\$ (591,858)	\$ (11,911,077)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>			
Depreciation	—	—	1,909
Stock-based expenses included in general and administrative	53,037	213,954	3,234,012
Stock-based expenses included in research and development	—	—	758,484
Fair value of warrant extensions	—	—	1,339,431
Fair value of warrant discount	—	—	334,024
<b>Changes in operating assets and liabilities:</b>			
<b>(Increase) decrease in -</b>			
Advances on research and development contract services	(14,510)	(62)	(66,085)
Prepaid expenses and other current assets	5,893	12,625	(34,286)
<b>Increase (decrease) in -</b>			
Accounts payable and accrued expenses	(7,531)	(22,126)	72,885
Liquidated damages payable under registration rights agreement	—	—	74,000
Research and development contract liabilities	16,517	138,504	30,536
<b>Net cash used in operating activities</b>	<b>(280,540)</b>	<b>(248,963)</b>	<b>(6,166,167)</b>
<b>Cash flows from investing activities:</b>			
(Increase) decrease in money market funds	(1)	269,995	(6,135)
Purchase of office equipment	—	—	(1,909)
<b>Net cash provided by (used in) investing activities</b>	<b>(1)</b>	<b>269,995</b>	<b>(8,044)</b>
<b>Cash flows from financing activities:</b>			
Proceeds from exercise of stock options	—	33,333	38,333
Proceeds from exercise of warrants	—	—	2,468,250
Proceeds from sale of common stock to consulting firm	—	—	250
Proceeds from sale of common stock to founder	—	—	1,500
Proceeds from issuance of notes payable to consultant	—	—	200,000
Repayment of notes payable to consultant	—	—	(200,000)
Cash acquired in reverse merger transaction	—	—	62,500
Gross proceeds from sale of securities	—	—	5,331,389
Payment of private placement offering costs	—	—	(446,147)
Advances received from stockholder	—	—	92,717
<b>Net cash provided by financing activities</b>	<b>—</b>	<b>33,333</b>	<b>7,548,792</b>

(Continued)

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
AND SUBSIDIARY**  
(a development stage company)

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

	Three Months Ended March 31,		Period from August 9, 2005 (Inception) to March 31, 2013 (Cumulative)
	2013	2012	
<b>Cash:</b>			
Net increase (decrease)	(280,541)	54,365	1,374,581
Balance at beginning of period	<u>1,655,122</u>	<u>14,301</u>	<u>—</u>
Balance at end of period	<u>\$ 1,374,581</u>	<u>\$ 68,666</u>	<u>\$ 1,374,581</u>
<b>Supplemental disclosures of cash flow information:</b>			
<b>Cash paid for -</b>			
Interest	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2,469</u>
Income taxes	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>
<b>Non-cash financing activities:</b>			
Decrease in advances under equity financing	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,200,000</u>
Aggregate exercise price of warrants and options exercised on a cashless basis	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 193,598</u>

See accompanying notes to condensed consolidated financial statements.

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.**  
**AND SUBSIDIARY**  
(a development stage company)

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

**Three Months Ended March 31, 2013 and 2012, and  
Period from August 9, 2005 (Inception) to March 31, 2013 (Cumulative)**

**1. Basis of Presentation**

The condensed consolidated financial statements of Lixte Biotechnology Holdings, Inc. (“Holdings”) and its wholly-owned subsidiary, Lixte Biotechnology, Inc. (hereinafter referred to collectively as the “Company”, unless the context indicates otherwise) at March 31, 2013, for the three months ended March 31, 2013 and 2012, and for the period from August 9, 2005 (inception) to March 31, 2013 (cumulative), are unaudited. In the opinion of management, all adjustments (including normal recurring adjustments) have been made that are necessary to present fairly the financial position of the Company as of March 31, 2013, the results of its operations for the three months ended March 31, 2013 and 2012, and for the period from August 9, 2005 (inception) to March 31, 2013 (cumulative), and its cash flows for the three months ended March 31, 2013 and 2012, and for the period from August 9, 2005 (inception) to March 31, 2013 (cumulative). 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, 2012 has been derived from the Company’s audited financial statements.

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, 2012, as filed with the SEC.

**2. Organization and Business Operations**

***Organization***

On June 30, 2006, Lixte Biotechnology, Inc., a privately-held Delaware corporation (“Lixte”) incorporated on August 9, 2005, completed a reverse merger transaction with SRKP 7, Inc. (“SRKP”), a non-trading public shell company, whereby Lixte became a wholly-owned subsidiary of SRKP. On December 7, 2006, SRKP amended its Certificate of Incorporation to change its name to Lixte Biotechnology Holdings, Inc.

For financial reporting purposes, Lixte was considered the accounting acquirer in the merger and the merger was accounted for as a reverse merger. Accordingly, the historical financial statements presented herein are those of Lixte. The stockholders’ equity section of SRKP was retroactively restated for all periods presented to reflect the accounting effect of the reverse merger transaction. All costs associated with the reverse merger transaction were expensed as incurred.

The Company is considered a “development stage company” under current accounting standards, as it 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 presently 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. However, 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 in which errors in normal cellular processing lead to loss of functions important to normal cell function, such as Gaucher’s disease). 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 from treatment with 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. In the past decade, there has been an unprecedented expansion in knowledge of biochemical defects in the cancer cell. 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, 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, for the treatment of cancer. 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.

On December 19, 2011, an article in the December 12, 2011 edition of the Proceedings of the National Academy of Sciences in the United States reported that the Company’s investigational drug LB-205 was shown to have therapeutic potential in a laboratory model of the genetic illness Gaucher’s disease. Patent applications are pending on the use of LB-205 for this purpose.

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 Neurologic Disorders and Stroke (“NINDS”), National Institutes of Health (“NIH”) under a continuing 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, glioblastoma multiforme (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 treatment of brain tumors depends upon the ability of compounds to penetrate a physiological barrier (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 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 IND application to the FDA to conduct a Phase 1 clinical trial of LB-100, and engaged the contract research organization ("CRO") responsible for the clinical development of the Company's lead compound, LB-100, to prepare an IND application for filing with the FDA. This task included preparing the detailed clinical protocol known as the "Investigator's Brochure", a document containing a detailed summary of all that is known about LB-100, and development of the formal IND application for submission to the FDA. The CRO also established the procedures for assuring appropriate collection and reporting of data generated during the clinical trial of LB-100 to the FDA.

The Company filed an IND application with the FDA on April 30, 2012, and on July 24, 2012, the FDA notified the Company that it would allow initiation of a Phase 1 clinical trial of LB-100. The purpose of the clinical trial is to demonstrate that LB-100 can be administered safely to human beings at a dose and at a frequency that achieves the desired pharmacologic effect; in this case, inhibition of a specific enzyme, without being associated with toxicities considered unacceptable. The Phase 1 clinical trial of LB-100 is designed to determine the maximum tolerable dose of LB-100 given alone and then in combination with a standard widely use anti-cancer drug. As a prelude to determining the therapeutic effectiveness of LB-100 in a subsequent Phase 2 clinical trial of common cancers, a key goal of the initial portion of the Phase 1 clinical trial will be to demonstrate that the target enzyme of LB-100, protein phosphatase 2A (PP2A), can be inhibited in humans with readily tolerable toxicity. As an anti-cancer drug, LB-100 is likely to be used at maximum tolerable doses, but for the potential treatment of non-malignant diseases, such as acute vascular diseases and metabolic diseases, lower doses may achieve therapeutic benefit by inhibition of the target enzyme, PP2A, thus opening up the possibility of a host of therapeutic applications for LB-100 and related proprietary compounds. The Phase 1 clinical trial of LB-100 began in April 2013 with the entry of patients into the clinical trial, and is being carried out by a nationally recognized comprehensive cancer center. The clinical trial is estimated to take from 18 to 30 months and cost approximately \$2,000,000.

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. The Company's approach has been to operate with a minimum of overhead, moving compounds forward as efficiently and inexpensively as possible, and to raise funds to support each of these stages as certain milestones are reached. The commencement of a Phase 1 clinical trial is a milestone in the Company's goal of developing a successful product platform.

### ***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 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 during this period primarily through the recurring sale of its equity securities and the exercise of outstanding warrants. As a result, the Company's independent registered public accounting firm, in its report on the Company's 2012 consolidated financial statements, has raised 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 March 31, 2013, the Company had not yet commenced any revenue-generating operations. All activity through March 31, 2013 has been related to the Company's formation, 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. Prior to June 30, 2006, the Company's cash requirements were funded by advances from the Company's founder aggregating \$92,717.

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 generate a profit.

The Company's major focus in 2013 has been to initiate and proceed with a Phase 1 clinical trial of its lead phosphatase inhibitor, LB-100. The Phase 1 clinical trial of LB-100 began in April 2013 with the entry of patients into the clinical trial, and is being carried out by a nationally recognized comprehensive cancer center. The clinical trial is estimated to take from 18 to 30 months and cost approximately \$2,000,000.

In May and June 2012, the Company raised \$2,468,250 by offering a 25% discount to warrant holders as an inducement to exercise their warrants for cash through June 15, 2012. The Company believes that this amount will be sufficient to meet its operating needs through at least December 31, 2013, and that during this period the Company will initiate and proceed with its Phase 1 clinical trial of LB-100, continue the two drug development programs currently in process, and expand its patent portfolio, including the maintenance of its applications for international protection of lead compounds of both the LB-100 and LB-200 series.

The amount and timing of future cash requirements will depend on the pace of these programs, particularly the completion of the Phase 1 clinical trial of LB-100. After completion of the Phase 1 clinical trial, the next step will be to determine the anti-cancer activity of LB-100, in combination with a widely used anti-cancer drug, against a specific type of human cancer in Phase 2 clinical trials. Market conditions present uncertainty as to the Company's ability to secure additional funds, as well as its ability to reach profitability. There can be no assurances that the Company will be able to secure additional financing, or obtain favorable terms on such financing if it is available, or as to the Company's ability to achieve positive earnings and cash flows from operations.

The Company believes that it currently has sufficient funds to initiate and proceed with the Phase 1 clinical trial of LB-100 and to continue to fund its operating plans through at least December 31, 2013. Accordingly, in late 2013 or early 2014, in order to continue to fund the Company's operations in 2014 and thereafter, it is likely that the Company will be required to raise additional capital. If cash resources are insufficient to satisfy the Company's cash requirements at that time, 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, through strategic alliances that may require the Company to relinquish rights to certain of its products, or to discontinue its operations entirely.

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

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

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

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

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

## ***Research and Development***

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

Research and development costs are expensed as incurred over the life of the underlying contracts on the straight-line basis, unless the achievement of milestones, the completion of contracted work, or other information indicates that a different expensing schedule is more appropriate. Payments made pursuant to research and development contracts are initially recorded as advances on research and development contract services in the Company's balance sheet and then charged to research and development costs in the Company's statement of operations as those contract services are performed. Expenses incurred under research and development contracts in excess of amounts advanced are recorded as research and development contract liabilities in the Company's balance sheet, with a corresponding charge to research and development costs in the Company's statement of operations. The Company reviews the status of its research and development contracts on a quarterly basis.

The funds paid to NINDS of the NIH pursuant to the CRADA represented an advance on research and development costs and therefore had future economic benefit. Accordingly, such costs have been charged to expense when they are actually expended by the provider, which is, effectively, as they performed the research activities that they were contractually committed to provide. Absent information that would indicate that a different expensing schedule was more appropriate (such as, for example, from the achievement of performance milestones or the completion of contract work), such advances have been expensed over the contractual service term on a straight-line basis, which, in management's opinion, reflects a reasonable estimate of when the underlying research and development costs were being incurred. The CRADA terminated as scheduled on April 1, 2013.

## ***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 \$96,679 and \$38,162 for the three months ended March 31, 2013 and 2012, respectively, and \$1,506,076 for the period from August 9, 2005 (inception) to March 31, 2013 (cumulative). Patent costs are included in research and development costs in the Company's condensed consolidated statements of operations.

## ***Royalties***

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

## ***Income Taxes***

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

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

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

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

On January 1, 2007, the Company adopted accounting rules which address the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under these rules, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate settlement. These accounting rules also provide guidance on de-recognition, classification, interest and penalties on income taxes, accounting in interim periods and requires increased disclosures. As of March 31, 2013, no liability for unrecognized tax benefits was required to be recorded.

The Company files income tax returns in the U.S. federal jurisdiction and is subject to income tax examinations by federal tax authorities for the year 2009 and thereafter. The Company's policy is to record interest and penalties on uncertain tax provisions as income tax expense. As of March 31, 2013, the Company has no accrued interest or penalties related to uncertain tax positions.

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

The Company periodically issues stock options and warrants 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 in the Company's financial statements on a straight-line basis 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 Scientific Advisory Board committee members and 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.

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

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

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

At March 31, 2013 and 2012, the Company excluded the outstanding securities summarized below, which entitle the holders thereof to acquire shares of common stock, from its calculation of earnings per share, as their effect would have been anti-dilutive.

	<u>2013</u>	<u>2012</u>
Warrants	6,828,800	13,454,552
Stock options	3,650,000	3,150,000
Total	<u>10,478,800</u>	<u>16,604,552</u>

### *Fair Value of Financial Instruments*

The carrying amounts of cash, money market funds, advances on research and development contract services, prepaid expenses and other current assets, accounts payable and accrued expenses, research and development contract liabilities, liquidated damages payable under registration rights agreement and due to stockholder approximate their respective fair values due to the short-term nature of these items.

### *Use of Estimates*

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

### *Recent Accounting Pronouncements*

In December 2011, the Financial Accounting Standards Board (the “FASB”) issued ASU No. 2011-11, Balance Sheet (Topic 210): Disclosures about Offsetting Assets and Liabilities. This guidance requires an entity to disclose information about offsetting and related arrangements to enable users of its financial statements to understand the effect of those arrangements on its financial position. The guidance will be applied retrospectively and is effective for annual and interim reporting periods beginning on or after January 1, 2013. The adoption of this guidance did not have any impact on the Company’s consolidated financial statement disclosures.

In July 2012, the FASB issued ASU No. 2012-02, Intangibles - Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment. This guidance allows entities the option to first assess qualitative factors to determine whether it is necessary to perform the quantitative impairment test. If the qualitative assessment indicates that it is more-likely-than-not that the fair value of an indefinite-lived intangible asset is less than its carrying amount, the quantitative impairment test is required. Otherwise, no testing is required. The guidance is effective for the Company in the period beginning January 1, 2013. The adoption of this guidance did not have any impact on the Company’s consolidated financial statements.

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. Share Exchange Agreement, Private Placements and Common Stock Warrants**

### *Share Exchange Agreement*

On June 30, 2006, pursuant to a Share Exchange Agreement dated as of June 8, 2006 (the “Share Exchange Agreement”) by and among the Company, Dr. John S. Kovach (“Seller”) and Lixte, the Company issued 19,021,786 shares of its common stock in exchange for all of the issued and outstanding shares of Lixte (the “Exchange”). Previously, on October 3, 2005, Lixte had issued 1,500 shares of its no par value common stock to its founder for \$1,500, which constituted all of the issued and outstanding shares of Lixte prior to the Exchange. As a result of the Exchange, Lixte became a wholly-owned subsidiary of the Company.

Pursuant to the Exchange, the Company issued to the Seller 19,021,786 shares of its common stock. The Company had a total of 25,000,832 shares of common stock issued and outstanding after giving effect to the Exchange and the 1,973,869 shares of common stock issued in the initial closing of the private placement.

As a result of the Exchange and the shares of common stock issued in the initial closing of the private placement, on June 30, 2006, the stockholders of the Company immediately prior to the Exchange owned 4,005,177 shares of common stock, equivalent to approximately 16% of the issued and outstanding shares of the Company's common stock, and the former stockholder of Lixte acquired control of the Company.

In connection with the Exchange, the Company paid WestPark Capital, Inc. a cash fee of \$50,000.

### ***Private Placements***

On June 30, 2006, concurrently with the closing of the Exchange, the Company sold an aggregate of 1,973,869 shares of its common stock to accredited investors in an initial closing of a private placement at a per share price of \$0.333, resulting in aggregate gross proceeds to the Company of \$657,299. The Company paid to WestPark Capital, Inc., as placement agent, a commission of 10% and a non-accountable fee of 4% of the gross proceeds of the private placement and issued five-year warrants to purchase common stock equal to (a) 10% of the number of shares sold in the private placement exercisable at \$0.333 per share and (b) an additional 2% of the number of shares sold in the private placement also exercisable at \$0.333 per share. A total of 236,864 warrants were issued. Net cash proceeds to the Company, after the deduction of all private placement offering costs and expenses, were \$522,939.

On July 27, 2006, the Company sold an aggregate of 1,581,351 shares of its common stock to accredited investors in a second closing of the private placement at a per share price of \$0.333 resulting in aggregate gross proceeds to the Company of \$526,590. The Company paid to WestPark Capital, Inc., as placement agent, a commission of 10% and a non-accountable fee of 4% of the gross proceeds of the private placement and issued five-year warrants to purchase common stock equal to (a) 10% of the number of shares sold in the private placement exercisable at \$0.333 per share and (b) an additional 2% of the number of shares sold in the private placement also exercisable at \$0.333 per share. A total of 189,762 warrants were issued. Net cash proceeds to the Company were \$446,433.

In conjunction with the private placement of common stock, the Company issued a total of 426,626 five-year warrants to WestPark Capital, Inc. exercisable at the per share price of the common stock sold in the private placement (\$0.333 per share). The warrants issued to WestPark Capital, Inc. do not contain any price anti-dilution provisions. However, such warrants contained cashless exercise provisions and demand registration rights, but the warrant holder has agreed to waive any claims to monetary damages or financial penalties for any failure by the Company to comply with such registration requirements. Based on the foregoing, the warrants were accounted for as equity and were not accounted for separately from the common stock and additional paid-in capital accounts. The warrants had no accounting impact on the Company's consolidated financial statements.

As part of the Company's private placement of its securities completed on July 27, 2006, the Company entered into a registration rights agreement with the purchasers, whereby the Company agreed to register the shares of common stock sold in the private placement, and to maintain the effectiveness of such registration statement, subject to certain conditions. The agreement required the Company to file a registration statement within 45 days of the closing of the private placement and to have the registration statement declared effective within 120 days of the closing of the private placement. On September 8, 2006, the Company filed a registration statement on Form SB-2 to register 3,555,220 shares of the common stock sold in the private placement. Since the registration statement was not declared effective by the Securities and Exchange Commission within 120 days of the closing of the private placement, the Company was required to pay each investor prorated liquidated damages equal to 1.0% of the amount raised per month, payable monthly in cash.

On the date of the closing of the private placement, the Company believed it would meet the deadlines under the registration rights agreement with respect to filing a registration statement and having it declared effective by the Securities and Exchange Commission. As a result, the Company did not record any liabilities associated with the registration rights agreement at June 30, 2006. At December 31, 2006, the Company determined that the registration statement covering the shares sold in the private placement would not be declared effective within the requisite time frame and therefore recorded a current liability representing six months liquidated damages under the registration rights agreement aggregating approximately \$74,000. The Company's registration statement on Form SB-2 was declared effective by the Securities and Exchange Commission on May 14, 2007. At March 31, 2013, the registration penalty payable to the investors had not been paid, and has been included in the Company's balance sheet as a current liability for all periods presented.

On December 12, 2007, the Company sold an aggregate of 999,995 shares of its common stock to accredited investors in a second private placement at a per share price of \$0.65, resulting in aggregate gross proceeds to the Company of \$650,000. The Company paid to WestPark Capital, Inc., as placement agent, a commission of 10% and a non-accountable fee of 4% of the gross proceeds of the private placement and issued five-year warrants to purchase common stock equal to (a) 10% of the number of shares sold in the private placement exercisable at \$0.65 per share and (b) an additional 2% of the number of shares sold in the private placement also exercisable at \$0.65 per share. Net cash proceeds to the Company were \$531,320.

In conjunction with the second private placement of common stock, the Company issued a total of 120,000 five-year warrants to WestPark Capital, Inc. exercisable at the per share price of the common stock sold in the private placement (\$0.65 per share). The warrants issued to WestPark Capital, Inc. did not contain any price anti-dilution provisions. However, such warrants contain cashless exercise provisions and demand registration rights, but the warrant holder has agreed to waive any claims to monetary damages or financial penalties for any failure by the Company to comply with such registration requirements. Based on the foregoing, the warrants were accounted for as equity and were not accounted for separately from the common stock and additional paid-in capital accounts. The warrants had no accounting impact on the Company's consolidated financial statements. On December 12, 2012, the above described warrants expired unexercised.

As part of the Company's second private placement of its securities completed on December 12, 2007, the Company entered into a registration rights agreement with the purchasers, whereby the Company agreed to register the shares of common stock sold in the second private placement at its sole cost and expense. The registration rights agreement terminates at such time as the common shares may be sold in market transactions without regard to any volume limitations. The registration rights agreement requires the Company to file a registration statement within 75 days of receipt of written demand from holders who represent at least 50% of the common shares issued pursuant to the second private placement, provided that no demand shall be made for less than 500,000 shares, and to use its best efforts to cause such registration statement to become and remain effective for the requisite period. The registration rights agreement also provides for unlimited piggyback registration rights. The registration rights agreement does not provide for any penalties in the event that the Company is unable to comply with its terms.

During the year ended December 31, 2009, the Company completed three closings of the third private placement of common stock units, consisting of a total of 1,420,000 shares of common stock and 1,420,000 warrants to acquire common stock, as follows:

On February 10, 2009, the Company sold an aggregate of 658,000 common stock units to accredited investors in a first closing of a third private placement at a per unit price of \$0.50, resulting in aggregate gross proceeds to the Company of \$329,000. Net cash proceeds to the Company were \$269,790.

On March 2, 2009, the Company sold an aggregate of 262,000 common stock units to accredited investors in a second closing of the third private placement at a per unit price of \$0.50, resulting in aggregate gross proceeds to the Company of \$131,000. Net cash proceeds to the Company were \$112,460.

On April 6, 2009, the Company sold an aggregate of 500,000 common stock units to accredited investors in a third closing of the third private placement at a per unit price of \$0.50, resulting in aggregate gross proceeds to the Company of \$250,000. Net cash proceeds to the Company were \$214,800.

Each unit sold in the third private placement consisted of one share of the Company's common stock and a five-year warrant to purchase an additional share of the Company's common stock on a cashless exercise basis at an exercise price of \$0.50 per common share. The Company paid to WestPark Capital, Inc., as placement agent, a commission of 10% and a non-accountable fee of 4% of the gross proceeds of the third private placement and issued five-year warrants to purchase common stock equal to (a) 10% of the number of shares sold in the third private placement exercisable at \$0.50 per share and 10% of the number of shares issuable upon exercise of warrants issued in the third private placement exercisable at \$0.50 per share; and (b) an additional 2% of the number of shares sold in the third private placement also exercisable at \$0.50 per share and 2% of the number of shares issuable upon exercise of the warrants issued in the third private placement exercisable at \$0.50 per share.

In conjunction with the closings of the third private placement of common stock units during the year ended December 31, 2009, the Company issued a total of 340,800 five-year warrants to WestPark Capital, Inc., which are exercisable at the per unit price of the common stock units sold in the third private placement (\$0.50 per unit). Included in the 340,800 warrants issued to WestPark Capital, Inc. are 170,400 warrants which are only exercisable with respect to common shares that are acquired by investors upon their exercise of the warrants acquired as part of the units sold in the third private placement. The warrants issued to WestPark Capital, Inc. do not contain any price anti-dilution provisions. However, such warrants contain cashless exercise provisions and demand registration rights, but the warrant holder has agreed to waive any claims to monetary damages or financial penalties for any failure by the Company to comply with such registration requirements. Based on the foregoing, the warrants were accounted for as equity and were not accounted for separately from the common stock and additional paid-in capital accounts. The warrants had no accounting impact on the Company's consolidated financial statements. On May 10, 2012, warrants to purchase 1,440 shares of common stock were exercised.

At the request of the holders, the Company has agreed to include any shares sold in the third private placement and any shares issuable upon exercise of the related warrants to be included in any registration statement filed with the Securities and Exchange Commission permitting the resale of such shares, subject to customary cutbacks, at the Company's sole cost and expense.

Effective November 6, 2009, the Company sold 1,000,000 common stock units to an accredited investor in a fourth private placement at a per unit price of \$0.50, resulting in proceeds to the Company of \$500,000. There were no commissions paid with respect to the fourth private placement. The closing price of the Company's common stock on November 6, 2009 was \$0.50 per share.

Each unit sold in the fourth private placement consisted of one share of the Company's common stock, one three-year warrant to purchase an additional share of the Company's common stock at an exercise price of \$0.50 per share, and one three-year warrant to purchase an additional share of the Company's common stock at an exercise price of \$0.75 per share. The warrants do not have any reset provisions.

At the request of the holder, the Company has agreed to include the shares sold in the fourth private placement and any shares issuable upon exercise of the related warrants in any registration statement filed by the Company with the Securities and Exchange Commission permitting the resale of such securities, subject to customary cutbacks. The units sold were not registered under the Securities Act of 1933, as amended (the "Act"), in reliance upon the exemption from registration contained in Section 4(2) of the Act and Regulation D promulgated thereunder. Based on the foregoing, the warrants were accounted for as equity and were not accounted for separately from the common stock and additional paid-in capital accounts. The warrants had no accounting impact on the Company's consolidated financial statements.

Effective January 20, 2010, the Company raised \$1,787,500 in a fifth private placement of units sold to certain of its existing stockholders or their designees, all of whom were accredited investors, consisting of an aggregate of 3,575,000 units at a purchase price of \$0.50 per unit. Each unit consisted of one share of common stock, one three-year warrant to purchase a share of common stock at an exercise price of \$0.50 per share, and one three-year warrant to purchase a share of common stock at an exercise price of \$0.75 per share. The warrants do not have any reset provisions. The closing price of the Company's common stock on January 20, 2010 was \$0.49 per share. There were no commissions paid with respect to the private placement. Upon request by the holder, the Company has agreed to include the shares issued and those shares issuable upon exercise of the warrants in any registration statement filed by the Company with the Securities and Exchange Commission permitting the resale of such securities, subject to customary cutbacks. The units sold were not registered under the Act, in reliance upon the exemption from registration contained in Section 4(2) of the Act and Regulation D promulgated thereunder. The Company accounted for the issuance of the units as a capital transaction. As of December 31, 2009, \$1,200,000 had been advanced to the Company under this private placement, with the balance of \$587,500 being received by the Company in January 2010.

Effective February 22, 2010, the Company raised \$500,000 through the sale to an accredited investor of 1,000,000 units at a purchase price of \$0.50 per unit. Each unit consisted of one share of common stock, one three-year warrant to purchase a share of common stock at an exercise price of \$0.50 per share, and one three year-year warrant to purchase a share of common stock at an exercise price of \$0.75 per share. The warrants do not have any reset provisions. The closing price of the Company's common stock on February 22, 2010 was \$0.50 per share. There were no commissions paid with respect to the private placement. Upon request by the holder, the Company has agreed to include the shares issued and those shares issuable upon exercise of the warrants in any registration statement filed by the Company with the Securities and Exchange Commission permitting the resale of such securities, subject to customary cutbacks. The units sold were not registered under the Act, in reliance upon the exemption from registration contained in Section 4(2) of the Act and Regulation D promulgated thereunder. The Company accounted for the issuance of the units as a capital transaction.

If and when the aforementioned stock warrants are exercised, the Company expects to satisfy such stock obligations through the issuance of authorized but unissued shares of common stock.

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

On July 27, 2009, the Company entered into an agreement with Pro-Active Capital Group, LLC (“Pro-Active”) to retain Pro-Active on a non-exclusive basis for a period of twelve months to provide consulting advice to assist the Company in obtaining research coverage, gaining web-site exposure and coverage on financial blogs and web-sites, enhancing the Company’s visibility to the institutional, retail brokerage and on-line trading communities, and organizing, or assisting in organizing, investor road-shows and presentations. In exchange for such consulting advice, at the initiation of the agreement, the Company agreed to issue to Pro-Active 150,000 shares of restricted common stock and three-year warrants to purchase an aggregate of 150,000 shares of common stock, exercisable 50,000 at \$0.75 per share, 50,000 at \$1.00 per share, and 50,000 at \$1.25 per share. The fair value of the 150,000 shares issued was determined to be \$100,500 (\$0.67 per share), reflecting the price per share of the Company’s common stock, as quoted on the OTC Bulletin Board, on the transaction date. The fair value of the three-year warrants, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$97,500 (\$0.65 per share). The \$198,000 aggregate fair value of the shares and warrants issued was charged to operations as stock-based compensation on July 27, 2009, since the shares and warrants were fully vested and non-forfeitable on the date of issuance. On July 27, 2012, the above described warrants expired unexercised.

On June 30, 2011, WestPark Capital, Inc. exercised warrants to acquire 152,874 shares of common stock, obtained in connection with its role as placement agent for the June 30, 2006 private placement, on a cashless basis. Such cashless exercise resulted in WestPark Capital, Inc. receiving a net of 100,929 shares of common stock.

On July 27, 2011, the Company agreed to extend the remaining portion of the warrants obtained by WestPark Capital, Inc. in connection with its role as placement agent for the June 30, 2006 private placement, consisting of warrants to acquire 273,752 shares of common stock, from July 27, 2011 to July 27, 2012. In conjunction with the extension of these warrants, the cashless exercise feature was deleted. The fair value of the warrant extension, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$199,839 (\$0.73 per share), and was charged to operations on July 27, 2011. The fair value of the warrant extension was calculated using the following input variables: stock price - \$0.79 per share; exercise price - \$0.333 per share; expected life - 1 year; expected volatility – 308.8%; expected dividend yield - 0%; risk-free interest rate – 0.14%.

On July 16, 2012, the Company’s Board of Directors agreed to permit the exercise of the above described warrants to acquire 273,752 shares of common stock of the Company on a cashless basis, provided that the cashless exercise price was increased by 20%, from \$0.333 to \$0.3996 per share. Accordingly, on July 16, 2012, warrants to acquire 273,752 shares of common stock, issued in connection with WestPark Capital, Inc.’s role as placement agent for the June 30, 2006 private placement, were exercised on a cashless basis. Such cashless exercise resulted in the net issuance of 141,955 shares of common stock. The Company’s closing stock price on July 16, 2012 was \$0.83 per share. As the fair value of the warrants immediately after the modification was less than the fair value of the warrants immediately prior to the modification (both amounts being calculated pursuant to the Black-Scholes option-pricing model), the Company did not record any accounting adjustment with respect to the warrant modification.

On May 3, 2012, the Company offered to all of its warrant holders an inducement to exercise early, by reducing the exercise price of currently outstanding warrants by 25%, if exercised on a cash basis by June 15, 2012. The exercise prices of the warrants before reduction ranged from \$0.333 to \$1.25 per share, and the offer was open until the sooner of receiving \$3,000,000 in net proceeds, or June 15, 2012, subject to the Company's right to extend the offer to June 30, 2012. The offer was subject to certain conditions. As a result of the discount warrant offer, warrants to acquire 6,082,000 shares of the Company's common stock were exercised at discounts ranging from \$0.125 to \$0.188 per share. The exercise of the warrants generated aggregate net proceeds to the Company of \$2,468,250. The aggregate fair value of the warrant discounts, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$334,024 (an average of \$0.05 per share issued), and such amount was charged to operations during the months of May and June of 2012. The fair value of the warrant discounts attributed to the exercise of 5,082,000 warrants was calculated using the following input variables: stock price on date of exercise - \$0.69 to \$0.84 per share; stated exercise price - \$0.50; discounted exercise price - \$0.375 per share; expected life - 157 days to 661 days; expected volatility - 150.1%; expected dividend yield - 0%; risk-free interest rate - 0.24%. The fair value of the warrant discounts attributed to the exercise of 1,000,000 warrants was calculated using the following input variables: stock price on date of exercise - \$0.69 per share; stated exercise price - \$0.75; discounted exercise price - \$0.563 per share; expected life - 157 days; expected volatility - 150.1%; expected dividend yield - 0%; risk-free interest rate - 0.24%.

On September 11, 2012, the Company's Board of Directors extended outstanding warrants to acquire 5,080,000 shares of the Company's common stock that were purchased by investors as part of the offerings that closed on January 20, 2010 and February 22, 2010, to June 30, 2014. Included in such extension were warrants to acquire 505,000 shares of common stock at \$0.50 per share scheduled to expire on January 20, 2013, warrants to acquire 3,575,000 shares of common stock at \$0.75 per share scheduled to expire on January 20, 2013, and warrants to acquire 1,000,000 shares at \$0.75 per share scheduled to expire on February 22, 2013. The fair value of the warrant extensions, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$1,139,592 (average of \$0.22 per share), and such amount was charged to operations on September 11, 2012. The fair value of the warrant extensions were calculated using the following input variables: stock price - \$0.65 per share; exercise price - \$0.50 and \$0.75 per share; expected life - 526 days and 493 days; expected volatility - 148.4%; expected dividend yield - 0%; risk-free interest rate - 0.29%.

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

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Warrants outstanding at December 31, 2011	13,454,552	\$ 0.607	
Issued	—	—	
Exercised	(6,355,752)	0.535	
Expired	(270,000)	0.844	
Warrants outstanding at December 31, 2012	6,828,800	0.667	
Issued	—	—	
Exercised	—	—	
Expired	—	—	
Warrants outstanding at March 31, 2013	<u>6,828,800</u>	<u>\$ 0.667</u>	<u>1.17</u>
Warrants exercisable at December 31, 2012	<u>6,659,840</u>	<u>\$ 0.672</u>	
Warrants exercisable at March 31, 2013	<u>6,659,840</u>	<u>\$ 0.672</u>	<u>1.17</u>

The exercise prices of common stock warrants outstanding and exercisable are as follows at March 31, 2013:

Exercise Prices	Warrants Outstanding (Shares)	Warrants Exercisable (Shares)
\$ 0.500	2,253,800	2,084,840
\$ 0.750	4,575,000	4,575,000
	<u>6,828,800</u>	<u>6,659,840</u>

Based on a fair market value of \$0.35 per share on March 31, 2013, there were no exercisable but unexercised in-the-money common stock warrants on that date. Accordingly, there was no intrinsic value attributed to exercisable but unexercised common stock warrants at March 31, 2013.

Based on a fair market value of \$0.25 per share on December 31, 2012, 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, 2012.

At March 31, 2013, warrants exercisable do not include warrants to acquire 168,960 shares of common stock that are contingent upon the exercise of warrants contained in units sold as part of the third private placement, as described above.

#### 5. Money Market Funds — Fair Value

Money market funds at March 31, 2013 and December 31, 2012 consisted of investments in shares of Morgan Stanley New York Municipal Money Market Trust with market values of \$6,135 and \$6,134, 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 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: quoted prices (unadjusted) 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 that 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 for the asset or liability are only used when there is little, if any, market activity for the asset or liability at the measurement date. 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 balance sheet on a recurring basis. The following table presents money market funds at their level within the fair value hierarchy at March 31, 2013 and December 31, 2012.

	<u>Total</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
<b>March 31, 2013:</b>				
Money market funds	\$ 6,135	\$ 6,135	\$ —	\$ —
<b>December 31, 2012:</b>				
Money market funds	\$ 6,134	\$ 6,134	\$ —	\$ —

## 6. Related Party Transactions

Prior to June 30, 2006, the Company's founding stockholder and Chief Executive Officer, Dr. John Kovach, had periodically made advances to the Company to meet operating expenses. Such advances are non-interest-bearing and are due on demand. At March 31, 2013 and December 31, 2012, stockholder advances outstanding and due to Dr. Kovach totaled \$92,717.

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

In view of the Company's development stage status and limited resources, Dr. Kovach did not receive any compensation from the Company prior to 2011. However, on February 18, 2011, the Company's Board of Directors approved a salary for Dr. Kovach of \$5,000 per month beginning March 15, 2011. Dr. Kovach was paid a salary of \$15,000 during the three months ended March 31, 2013 and 2012, and \$122,500 for the period from August 9, 2005 (inception) to March 31, 2013 (cumulative).

Dr. Kovach is not involved in other business activities but could, in the future, become involved in other business opportunities that become available. Accordingly, he 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.

On April 7, 2010, the Company entered into an agreement with Dr. Mel Sorensen, a member of the Company's Board of Directors, for consultation and advice regarding the preparation and strategy for obtaining FDA allowance of a clinical trial of the lead compound of the LB-100 series. The initial term of the agreement was for one year and provided for an annual fee of \$25,000, payable in two installments of \$12,500 on April 15, 2010 and October 15, 2010. On February 18, 2011, the Company's Board of Directors approved a one-year extension of the agreement for an additional annual fee of \$25,000, payable in two installments of \$12,500 on April 15, 2011 and October 15, 2011. On May 21, 2012, the Company entered into a new agreement with Dr. Mel Sorensen for continuing consultation and advice. The term of the new agreement is for the period from May 21, 2012 to May 31, 2013 and provides for a fee of \$25,000, payable in two installments of \$12,500 on May 21, 2012 and December 1, 2012. All installments have been paid as due. Consulting and advisory fees charged to operations pursuant to these agreements were \$6,250 and \$6,250 for the three months ended March 31, 2013 and 2012, respectively, and \$70,833 for the period from August 9, 2005 (inception) to March 31, 2013 (cumulative), and are included in research and development costs in the Company's condensed consolidated statements of operations.

On March 17, 2010, the Company engaged Theradex Systems, Inc. ("Theradex") to assist the Company in bringing LB-100 through the FDA approval process and to provide other services. Theradex is an international CRO that provides professional services for the clinical research and development of pharmaceutical compounds. Total fees charged to operations for services paid to Theradex pursuant to this arrangement were \$7,393 and \$54,187 for the three months ended March 31, 2013 and 2012, respectively, and \$186,980 for the period from August 9, 2005 (inception) to March 31, 2013 (cumulative), and are included in research and development costs in the Company's condensed consolidated statements of operations. Dr. Robert B. Royds, the founder, Chairman of the Board and Medical Director of Theradex, was appointed to the Company's Board of Directors on May 2, 2011. Dr. Royds died on March 23, 2013.

On September 21, 2012, the Company entered into a work order agreement with Theradex 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 a nationally recognized comprehensive cancer and is estimated to take from 18 to 30 months and cost approximately \$2,000,000, with such payments expected to be divided approximately evenly between payments to Theradex for services rendered and payments for pass-through costs for the clinical center, laboratory costs and investigator costs. Total costs charged to operations for services paid to Theradex pursuant to this arrangement were \$48,783 for the three months ended March 31, 2013, the first period for which costs were incurred under this agreement, and are included in research and development costs in the Company's condensed consolidated statements of operations.

Stock-based compensation arrangements involving members of the Company's Board of Directors are described at Note 7. Total stock-based compensation expense relating to directors, officers and other related parties was \$53,037 and \$213,954 for the three months ended March 31, 2013 and 2012, respectively, and \$3,532,248 for the period from August 9, 2005 (inception) to March 31, 2013 (cumulative).

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

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

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

There were no new transactions during the three months ended March 31, 2013 that required an assessment of value pursuant to the Black-Scholes option-pricing model. For the purpose of assessing value for transactions requiring re-evaluation at March 31, 2013 that were entered into in prior periods, the Black-Scholes option-pricing model utilized the following inputs for the three months ended March 31, 2013: exercise price per share - \$0.98; stock price per share - \$0.35; expected dividend yield - 0.00%; expected volatility - 155.1%; average risk-free interest rate - 0.23%; expected life - 3.25 years.

There were no new transactions during the three months ended March 31, 2012 that required an assessment of value pursuant to the Black-Scholes option-pricing model. For the purpose of assessing value for transactions requiring re-evaluation at March 31, 2012 that were entered into in prior periods, the Black-Scholes option-pricing model utilized the following inputs for the three months ended March 31, 2012: exercise price per share - \$0.98 to \$1.00; stock price per share - \$0.88; expected dividend yield - 0.00%; expected volatility - 287.6%; average risk-free interest rate - 0.84%; expected life - 4.25 to 4.51 years.

As the Company's common stock commenced trading on September 24, 2007, the Company was able to utilize such trading data to generate revised volatility factors as of the various subsequent measurement dates.

On June 30, 2006, effective with the closing of the Exchange, the Company granted to Dr. Philip Palmedo, an outside director of the Company, stock options to purchase an aggregate of 200,000 shares of common stock, exercisable for a period of five years at \$0.333 per share, with one-third of the options (66,666 shares) vesting immediately upon joining the Board and one-third vesting annually on each of June 30, 2007 and 2008. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$62,000 (\$0.31 per share), of which \$20,666 was charged to operations on June 30, 2006, and the remaining \$41,334 was charged to operations ratably from July 1, 2006 through June 30, 2008. On June 30, 2011, these options to acquire 200,000 shares of common stock expired unexercised.

On June 30, 2006, effective with the closing of the Exchange, the Company also granted to Dr. Palmedo additional stock options to purchase 190,000 shares of common stock exercisable for a period of five years at \$0.333 per share for services rendered in developing the business plan for Lixte, all of which were fully vested upon issuance. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$58,900 (\$0.31 per share), and was charged to operations at June 30, 2006. On June 30, 2011, Dr. Palmedo exercised options to acquire 100,000 shares of common stock, which were part of this grant, on a cashless basis. Such cashless exercise resulted in Dr. Palmedo receiving a net of 66,020 shares of common stock. The remaining options to acquire 290,000 shares of common stock, which were also a part of this grant, expired unexercised on June 30, 2011.

On June 30, 2011, the Company granted to Dr. Palmedo stock options to purchase 200,000 shares of common stock, exercisable for a period of five years from the date of grant at \$0.98 per share, which was the fair market value of the Company's common stock on such date. The options vest ratably in equal quarterly installments of 25,000 shares beginning July 1, 2011. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be \$196,000 (\$0.98 per share). During the three months ended March 31, 2013 and 2012, the Company recorded charges to operations of \$24,131 and \$24,399, respectively, with respect to these options.

On June 30, 2006, effective with the closing of the Exchange, the Company granted to Dr. Stefan Madajewicz and Dr. Iwao Ojima, two members of its Scientific Advisory Committee, stock options to purchase an aggregate of 100,000 shares of common stock (50,000 each) exercisable for a period of five years at \$0.333 per share, with one-half of the options vesting annually on each of June 30, 2007 and June 30, 2008. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was charged to operations ratably from July 1, 2006 through June 30, 2008.

In August 2008, Dr. Madajewicz resigned from his position and waived his right to his vested stock option to purchase 50,000 shares of common stock.

On June 30, 2011, Dr. Ojima exercised options to acquire 15,015 shares of common stock for a cash payment of \$5,000. Dr. Ojima's remaining options to acquire 34,985 shares of common stock expired unexercised.

On June 30, 2011, the Company granted to Dr. Ojima stock options to purchase 50,000 shares of common stock, exercisable for a period of five years from the date of grant at \$0.98 per share, which was the fair market value of the Company's common stock on such date. The options vest ratably in equal quarterly installments of 6,250 shares beginning July 1, 2011. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be \$49,000 (\$0.98 per share). During the three months ended March 31, 2013 and 2012, the Company recorded charges to operations of \$5,739 and \$10,260, respectively, with respect to these options.

On February 5, 2007, the Company entered into an agreement (the "Chem-Master Agreement") with Chem-Master International, Inc. ("Chem-Master"), a company co-owned by Francis Johnson, a consultant to the Company, pursuant to which the Company granted a five-year option to purchase 100,000 shares of the Company's common stock at an exercise price of \$0.333 per share. The fair value of this option, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$31,000 (\$0.31 per share) which was charged to operations as research and development costs on February 5, 2007 as the option was fully vested and non-forfeitable on the date of issuance. The Company has the right to terminate the Chem-Master Agreement at any time during its term upon sixty days prior written notice. On February 5, 2009, provided that the Chem-Master Agreement had not been terminated prior to such date, the Company agreed to grant Chem-Master a second five-year option to purchase an additional 100,000 shares of the Company's common stock at an exercise price of \$0.333 per share. As of September 30, 2008, the Company determined that it was likely that this option would be issued. Accordingly, the fair value of the option was reflected as a charge to operations for the period from October 1, 2008 through February 5, 2009. The Company granted the second five-year option on February 5, 2009. On February 4, 2012, Chem-Master exercised the option to acquire 100,000 shares of common stock previously granted on February 5, 2007 for a cash payment of \$33,333.

On January 29, 2008, the Chem-Master Agreement was amended to extend its term to February 15, 2014. Pursuant to the amendment, the Company issued 100,000 shares of its restricted common stock and granted an option to purchase 200,000 shares of common stock. The option was exercisable for a period of two years from the vesting date at \$1.65 per share, with one-half (100,000 shares) vesting on August 1, 2009, and one-half (100,000 shares) vesting on February 1, 2011. The restricted common stock issued, which was valued at \$75,000, was charged to operations as research and development costs on January 29, 2008. The initial fair value of the option, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$96,000 (\$0.48 per share) and was charged to operations ratably during the period from February 1, 2008 through February 1, 2011. On August 1, 2011, the option to acquire 100,000 shares of common stock that vested on August 1, 2009 expired unexercised. On February 1, 2013, the option to acquire the remaining 100,000 shares of common stock that vested on February 1, 2011 also expired unexercised.

On September 11, 2012, the Company granted to Chem-Master a stock option to purchase 500,000 shares of common stock, 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 this option, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$293,450 (\$0.59 per share), which was charged to operations as research and development costs on September 11, 2012, as the option was fully vested and non-forfeitable on the date of issuance. The option includes cashless exercise provisions.

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.

On September 12, 2007, in conjunction with his appointment as a director of the Company, the Company granted to Dr. Stephen Carter stock options to purchase an aggregate of 200,000 shares of common stock under the 2007 Plan, exercisable for a period of five years from vesting date at \$0.333 per share, with one-half (100,000 shares) vesting annually on each of September 12, 2008 and 2009. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$204,000 (\$1.02 per share), and was charged to operations ratably from September 12, 2007 through September 12, 2009. Effective April 20, 2010, Dr. Carter resigned as a director for personal reasons. Consequently, pursuant to the stock option agreement, Dr. Carter had twelve months from April 20, 2010 to exercise his stock options to acquire 200,000 shares of the Company's common stock. On April 20, 2011, Dr. Carter's stock options expired unexercised.

On September 12, 2007, the Company entered into a consulting agreement with Gil Schwartzberg, pursuant to which the Company granted to Mr. Schwartzberg stock options to purchase an aggregate of 1,000,000 shares of common stock, exercisable for a period of the earlier of four years from the vesting date or the termination of the consulting agreement at \$1.00 per share, with one-half of the options (500,000 shares) vesting immediately and one-half of the options (500,000 shares) vesting on September 12, 2008. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be \$945,000 (\$0.945 per share), of which \$465,000 was attributed to the fully-vested options and was thus charged to operations on September 12, 2007. The remaining unvested portion of the fair value of the options was charged to operations ratably from September 12, 2007 through September 12, 2008. On September 12, 2011, options to acquire 500,000 shares of common stock expired unexercised. On September 12, 2012, options to acquire the remaining 500,000 shares of common stock expired unexercised.

On October 15, 2009, the Company amended the above described consulting agreement with Gil Schwartzberg to extend it for an additional four years and granted to Mr. Schwartzberg stock options to purchase an additional aggregate of 1,000,000 shares of common stock, exercisable for a period of the earlier of four years from the vesting date or the termination of the consulting agreement at \$1.00 per share, with one-half of the options (500,000 shares) vesting immediately and one-half (500,000 shares) vesting on October 15, 2010. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$750,000 (\$0.75 per share) on October 15, 2009, of which \$375,000 was attributed to the fully-vested options and was thus charged to operations on October 15, 2009. The remaining unvested portion of the fair value of the options was charged to operations ratably from October 15, 2009 through October 15, 2010.

On October 5, 2011, the Company granted to Mr. Schwartzberg stock options to purchase an aggregate of 500,000 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 \$1.00 per share. One-quarter of the options vested immediately, with the balance vesting in three equal quarterly installments beginning on January 5, 2012. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be \$325,000 (\$0.65 per share) and was charged to operations ratably from October 5, 2011 through October 4, 2012. During the three months ended March 31, 2012, the Company recorded a charge to operations of \$154,986, with respect to these options.

On September 11, 2012, the Company granted to Mr. Schwartzberg stock options to purchase 500,000 shares of common stock, exercisable for a period of the earlier of five years from the date of grant or the termination of the consulting agreement at \$1.00 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 \$286,100 (\$0.57 per share), which was charged to operations on September 11, 2012, as the options were fully vested and non-forfeitable on the date of issuance.

On September 12, 2007, the Company entered into a consulting agreement with Francis Johnson, a co-owner of Chem-Master International, Inc., and granted to Professor Johnson stock options to purchase an aggregate of 300,000 shares of common stock, exercisable for a period of four years from the vesting date at \$0.333 per share, with one-third (100,000 shares) vesting annually on each of September 12, 2008, 2009 and 2010. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be \$300,000 (\$1.00 per share). The unvested portion of the fair value of the options was charged to operations from September 12, 2007 through September 12, 2010. On September 12, 2012, options to acquire 100,000 shares expired unexercised.

On September 20, 2007, the Company entered into a one-year consulting agreement (the "Mirador Agreement") with Mirador Consulting, Inc. ("Mirador"), pursuant to which Mirador was to provide the Company with various financial services. Pursuant to the Mirador Agreement, the Company agreed to pay Mirador \$5,000 per month and also agreed to sell Mirador 250,000 shares of the Company's restricted common stock for \$250 (\$0.001 per share). The fair value of this transaction was determined to be in excess of the purchase price by \$262,250 (\$1.049 per share), reflecting the difference between the \$0.001 purchase price and the \$1.05 price per share as quoted on the OTC Bulletin Board on the transaction date, and was charged to operations as stock-based compensation on September 20, 2007, since the shares were fully vested and non-forfeitable on the date of issuance.

On October 7, 2008, the Company appointed Dr. Mel Sorensen to its Board of Directors. Dr. Sorensen was paid an annual consulting fee of \$40,000, payable in quarterly installments over a one year period commencing October 7, 2008, to assist the Company in identifying a strategic partner. Dr. Sorensen was also granted a stock option to purchase 200,000 shares of the Company's common stock, exercisable at \$0.50 per share for a period of five years from each tranche's vesting date. The option vested as to 25,000 shares on January 1, 2009, and a further 25,000 shares vested on the first day of each subsequent calendar quarter until all of the shares were vested. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$100,000 (\$0.50 per share), and was charged to operations ratably from October 7, 2008 through October 7, 2010.

Effective May 1, 2011, in connection with his election to the Company's Board of Directors, Dr. Robert B. Royds was granted stock options to purchase 200,000 shares of the Company's common stock, vesting 25,000 shares on May 1, 2011, and 25,000 shares quarterly thereafter until all of the shares are vested, exercisable for a period of five years from each tranche's vesting date, at \$0.98 per share, which was the fair market value of the Company's common stock on such date. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$196,000 (\$0.98 per share), and was charged to operations ratably from May 2, 2011 through February 1, 2013. During the three months ended March 31, 2013 and 2012, the Company recorded charges to operations of \$8,548 and \$24,309, respectively, with respect to these options. Dr. Royds died on March 23, 2013. As a result of the death of Dr. Royds, pursuant to the stock option agreement, Dr. Royds' executor has twelve months from March 23, 2013 to exercise his stock options to acquire 200,000 shares of the Company's common stock.

Effective September 16, 2012, in connection with her election to the Company's Board of Directors, Dr. Kathleen P. Mullinix was granted stock options to purchase 200,000 shares of the Company's common stock, vesting 25,000 shares on September 16, 2012, and 25,000 shares quarterly thereafter until all of the shares are vested, exercisable for a period of five years from the date of grant at \$0.65 per share, which was the fair market value of the Company's common stock on such date. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$118,000 (\$0.59 per share), and is being charged to operations from September 16, 2012 through June 16, 2014. During the three months ended March 31, 2013, the Company recorded a charge to operations of \$14,619 with respect to these options.

If and when the aforementioned stock options are exercised, the Company expects to satisfy such stock obligations through the issuance of authorized but unissued shares of common stock.

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

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Options outstanding at December 31, 2011	3,250,000	\$ 0.884	
Granted	1,200,000	0.796	
Exercised	(100,000)	0.333	
Expired	(600,000)	0.889	
Options outstanding at December 31, 2012	3,750,000	0.870	
Granted	—	—	
Exercised	—	—	
Expired	(100,000)	1.650	
Options outstanding at March 31, 2013	<u>3,650,000</u>	<u>\$ 0.848</u>	<u>2.84</u>
Options exercisable at December 31, 2012	<u>3,512,500</u>	<u>\$ 0.876</u>	
Options exercisable at March 31, 2013	<u>3,493,750</u>	<u>\$ 0.854</u>	<u>2.78</u>

Total deferred compensation expense for the outstanding value of unvested stock options was approximately \$97,400 at March 31, 2013, which is being recognized subsequent to March 31, 2013 over a weighted-average period of approximately eleven months.

The exercise prices of common stock options outstanding and exercisable are as follows at March 31, 2013:

Exercise Prices	Options Outstanding (Shares)	Options Exercisable (Shares)
\$ 0.333	300,000	300,000
\$ 0.500	200,000	200,000
\$ 0.650	700,000	575,000
\$ 0.980	450,000	418,750
\$ 1.000	2,000,000	2,000,000
	<u>3,650,000</u>	<u>3,493,750</u>

The intrinsic value of exercisable but unexercised in-the-money stock options at March 31, 2013 was approximately \$5,100, based on a fair market value of \$0.35 per share on March 31, 2013. Based on a fair market value of \$0.25 per share on December 31, 2012, there were no exercisable but unexercised in-the-money stock options on that date. Accordingly, there was no intrinsic value attributed to exercisable but unexercised stock options at December 31, 2012.

Outstanding options to acquire 156,250 shares of the Company's common stock had not vested at March 31, 2013.

## **8. Commitments and Contingencies**

### ***Cooperative Research and Development Agreement (CRADA)***

Effective March 22, 2006, the Company entered into a CRADA with the NINDS of the NIH. The CRADA was extended through a series of amendments and remained in effect until April 1, 2013. The CRADA provided for the collaboration between the parties in the identification and evaluation of agents that target the Nuclear Receptor CoRepressor (N-CoR) pathway for glioma cell differentiation. The CRADA also provided that NINDS and the Company would conduct research to determine if expression of N-CoR correlates with prognosis in glioma patients. Pursuant to the CRADA, the Company initially agreed to provide funds under the CRADA in the amount of \$200,000 per year to fund two technical assistants for the technical, statistical and administrative support for the research activities, as well as to pay for supplies and travel expenses. The first \$200,000 was due within 180 days of the effective date and was paid in full on July 6, 2006. The second \$200,000 was paid in full on June 29, 2007. In June 2008, the CRADA was extended to September 30, 2009, with no additional funding required for the period between July 1, 2008 and September 30, 2008. For the period from October 1, 2008 through September 30, 2009, the Company agreed to provide additional funding under the CRADA of \$200,000, to be paid in four quarterly installments of \$50,000, each commencing on October 1, 2008. The first and second quarterly installments of \$50,000 were paid on September 29, 2008 and March 5, 2009, respectively. During August 2009, the Company entered into an amendment to the CRADA to extend its term from September 30, 2009 through September 30, 2011. Pursuant to such amendment, the Company agreed to aggregate payments of \$100,000 in two installments of \$50,000, payable on October 1, 2010 and January 5, 2011, inclusive of any prior unpaid commitments. The October 1, 2010 installment was paid on September 29, 2010 and the January 5, 2011 installment was paid on December 27, 2010. In September 2011, the CRADA was amended to extend its term to June 1, 2012 and to provide additional funding of \$50,000, payable in two installments of \$25,000 each on October 1, 2011 and February 5, 2012. The October 1, 2011 installment was paid on October 12, 2011, and by mutual agreement, the February 5, 2012 installment was paid on May 1, 2012. In August 2012, the CRADA was extended to April 1, 2013, with no additional funding requirement. The CRADA terminated as scheduled on April 1, 2013.

### ***Patent License Agreement***

Effective September 19, 2008, the Company entered into a Patent License Agreement (the "PLA") with the NIH providing the Company with an exclusive license for all patents submitted jointly with the NIH under the CRADA. The PLA provided for an initial payment of \$25,000 to the NIH within 60 days of September 19, 2008, and for a minimum annual royalty of \$30,000 on January 1 of each calendar year following the year in which the CRADA is terminated. The PLA also provided for the Company to pay (i) specified royalties based on net sales by the Company and its sub-licensees, reduced by the amount of the minimum annual royalty for that year, (ii) certain benchmark royalties upon the achievement of certain clinical benchmarks, and (iii) sublicensing royalties for the granting of sublicenses, with respect to joint patents. The Company paid the initial \$25,000 obligation on November 10, 2008, which was charged to general and administrative costs. As of December 31, 2012, no amounts were due pursuant to the PLA. Due to the termination of the CRADA on April 1, 2013, the Company expects to pay a minimum annual royalty of \$30,000 to the NIH beginning on January 1, 2014 and each year thereafter.

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

On February 5, 2007, the Company entered into a two-year agreement pursuant to which the Company engaged Chem-Master to synthesize a compound designated as LB-100, and any other compound synthesized by Chem-Master pursuant to the Company's request, which have potential use in treating a disease, including, without limitation, cancers such as glioblastomas. Pursuant to the Chem-Master Agreement, the Company agreed to reimburse Chem-Master for the cost of materials, labor, and expenses for other items used in the synthesis process, and also agreed to grant Chem-Master a five-year option to purchase shares of the Company's common stock. The Company has the right to terminate the Chem-Master Agreement at any time during its term upon sixty days prior written notice. On January 29, 2008, the Chem-Master Agreement was amended to extend its term to February 15, 2014, and to expressly provide for the design and synthesis of a new series of compounds designated as LB-300. The Company also periodically enters into other agreements with Chem-Master for other services. The Company did not incur any expense for the costs of materials, labor and expenses related to its agreements with Chem-Master during the three months ended March 31, 2013 and 2012.

On February 2, 2012, the Company entered into an agreement with MRI Global for a series of studies. As of March 31, 2013, work orders for studies having a total estimated cost of \$99,000 were in process under this agreement. As of March 31, 2013, the Company had paid \$58,500 towards these work orders.

At various times, the Company has entered into agreements with Ash Stevens to conduct various studies. As of March 31, 2013, contracts with a total estimated cost of \$62,000 were in process, of which \$58,935 had been paid.

On March 17, 2010, the Company engaged Theradex to assist the Company in bringing LB-100 through the FDA approval process and to provide other services. Theradex is an international CRO that provides professional services for the clinical research and development of pharmaceutical compounds. Total fees charged to operations for services paid to Theradex pursuant to this arrangement were \$7,393 and \$54,187 for the three months ended March 31, 2013 and 2012, respectively, and \$186,980 for the period from August 9, 2005 (inception) to March 31, 2013 (cumulative), and are included in research and development costs in the Company's condensed consolidated statements of operations. Dr. Robert B. Royds, the founder, Chairman of the Board and Medical Director of Theradex, was appointed to the Company's Board of Directors on May 2, 2011. Dr. Royds died on March 23, 2013.

On September 21, 2012, the Company entered into a work order agreement with Theradex 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 a nationally recognized comprehensive cancer center and is estimated to take from 18 to 30 months and cost approximately \$2,000,000, with such payments expected to be divided approximately evenly between payments to Theradex for services rendered and payments for pass-through costs for the clinical center, laboratory costs and investigator costs. Total costs charged to operations for services paid to Theradex pursuant to this arrangement were \$48,783 for the three months ended March 31, 2013, the first period for which costs were incurred under this agreement, and are included in research and development costs in the Company's condensed consolidated statements of operations.

The following table sets forth the Company's principal cash obligations and commitments for the next five fiscal years as of March 31, 2013 aggregating \$2,316,461, of which \$195,253 is included in current liabilities in the condensed consolidated balance sheet at March 31, 2013. Amounts included in the 2013 column represent amounts due at March 31, 2013 for the remainder of the 2013 fiscal year ending December 31, 2013.

	<b>Total</b>	<b>Payments Due By Year</b>				
		<b>2013</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>
Research and development contracts	\$ 58,205	\$ 58,205	\$ —	\$ —	\$ —	\$ —
Theradex work order agreement	1,971,539	571,539	1,000,000	400,000	—	—
Patent license agreement	120,000	—	30,000	30,000	30,000	30,000
Liquidated damages payable under registration rights agreement	74,000	74,000	—	—	—	—
Due to stockholder	92,717	92,717	—	—	—	—
<b>Total</b>	<b>\$ 2,316,461</b>	<b>\$ 796,461</b>	<b>\$ 1,030,000</b>	<b>\$ 430,000</b>	<b>\$ 30,000</b>	<b>\$ 30,000</b>

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

### **Overview**

On June 30, 2006, Lixte Biotechnology, Inc., a privately-held Delaware corporation ("Lixte") incorporated on August 9, 2005, completed a reverse merger transaction with SRKP 7, Inc. ("SRKP"), a non-trading public shell company, whereby Lixte became a wholly-owned subsidiary of SRKP. On December 7, 2006, SRKP amended its Certificate of Incorporation to change its name to Lixte Biotechnology Holdings, Inc. ("Holdings"). Unless the context indicates otherwise, Lixte and Holdings are hereinafter collectively referred to as the "Company".

For financial reporting purposes, Lixte was considered the accounting acquirer in the merger and the merger was accounted for as a reverse merger. Accordingly, the historical financial statements presented herein are those of Lixte. The stockholders' equity section of SRKP was retroactively restated for all periods presented to reflect the accounting effect of the reverse merger transaction. All costs associated with the reverse merger transaction were expensed as incurred.

The Company is considered a "development stage company" under current accounting standards, as it 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 presently traded on the OTCQB operated by the OTC Markets under the symbol "LIXT".

### **Recent Developments**

On March 23, 2013, Dr. Robert B. Royds, a member of the Company's Board of Directors, died. Dr. Royds was the founder, Chairman of the Board, and Medical Director of Theradex Systems, Inc. ("Theradex"), the organization which the Company has contracted with to manage and administer the Phase 1 clinical trial of the Company's LB-100 compound. Theradex is an international contract research organization ("CRO") that provides professional services for the clinical research and development of pharmaceutical compounds. The death of Dr. Royds is not expected to have any impact on the management and administration of the Phase 1 clinical trial.

### **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 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 during this period primarily through the recurring sale of its equity securities and the exercise of outstanding warrants. As a result, the Company's independent registered public accounting firm, in its report on the Company's 2012 consolidated financial statements, has raised 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 consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties.

At March 31, 2013, the Company had not yet commenced any revenue-generating operations. All activity through March 31, 2013 has been related to the Company's formation, 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. Prior to June 30, 2006, the Company's cash requirements were funded by advances from the Company's founder aggregating \$92,717.

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 generate a profit.

The Company's major focus in 2013 is to initiate a Phase 1 clinical trial of its lead phosphatase inhibitor, LB-100. The Phase 1 clinical trial of LB-100 began in April 2013 with the entry of patients into the clinical trial, and is being carried out by a nationally recognized comprehensive cancer center. The clinical trial is estimated to take from 18 to 30 months and cost approximately \$2,000,000.

In May and June 2012, the Company raised \$2,468,250 by offering a 25% discount to warrant holders as an inducement to exercise their warrants for cash through June 15, 2012. The Company believes that this amount will be sufficient to meet its operating needs through at least December 31, 2013, and that during this period the Company will be able to continue its Phase 1 clinical trial of LB-100, continue the two drug development programs currently in process, and expand its patent portfolio, including the maintenance of its applications for international protection of lead compounds of both the LB-100 and LB-200 series.

The amount and timing of future cash requirements will depend on the pace of these programs, particularly the completion of the Phase 1 clinical trial of LB-100. After completion of the Phase 1 clinical trial, the next step will be to determine the anti-cancer activity of LB-100, in combination with a widely used anti-cancer drug, against a particular type of human cancer in Phase 2 clinical trials. Market conditions present uncertainty as to the Company's ability to secure additional funds, as well as its ability to reach profitability. There can be no assurances that the Company will be able to secure additional financing, or obtain favorable terms on such financing if it is available, or as to the Company's ability to achieve positive earnings and cash flows from operations.

The Company believes it currently has sufficient funds to continue the Phase 1 clinical trial of LB-100 and to fund its operating plans through at least December 31, 2013. Accordingly, in late 2013 or early 2014, in order to continue to fund the Company's operations in 2014 and thereafter, it is likely that the Company will be required to raise additional capital. If cash resources are insufficient to satisfy the Company's cash requirements at that time, 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, 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 December 2011, the Financial Accounting Standards Board (the "FASB") issued ASU No. 2011-11, Balance Sheet (Topic 210): Disclosures about Offsetting Assets and Liabilities. This guidance requires an entity to disclose information about offsetting and related arrangements to enable users of its financial statements to understand the effect of those arrangements on its financial position. The guidance will be applied retrospectively and is effective for annual and interim reporting periods beginning on or after January 1, 2013. The adoption of this guidance did not have any impact on the Company's consolidated financial statement disclosures.

In July 2012, the FASB issued ASU No. 2012-02, Intangibles - Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment. This guidance allows entities the option to first assess qualitative factors to determine whether it is necessary to perform the quantitative impairment test. If the qualitative assessment indicates that it is more-likely-than-not that the fair value of an indefinite-lived intangible asset is less than its carrying amount, the quantitative impairment test is required. Otherwise, no testing is required. The guidance is effective for the Company in the period beginning January 1, 2013. The adoption of this guidance did not have any impact on the Company's consolidated financial statements.

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.

#### **Critical Accounting Policies and Estimates**

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

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

### **Research and Development**

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

Research and development costs are expensed as incurred over the life of the underlying contracts on the straight-line basis, unless the achievement of milestones, the completion of contracted work, or other information indicates that a different expensing schedule is more appropriate. Payments made pursuant to research and development contracts are initially recorded as advances on research and development contract services in the Company's balance sheet and then charged to research and development costs in the Company's statement of operations as those contract services are performed. Expenses incurred under research and development contracts in excess of amounts advanced are recorded as research and development contract liabilities in the Company's balance sheet, with a corresponding charge to research and development costs in the Company's statement of operations. The Company reviews the status of its research and development contracts on a quarterly basis.

The funds paid to NINDS of the NIH pursuant to the CRADA represented an advance on research and development costs and therefore had future economic benefit. Accordingly, such costs have been charged to expense when they are actually expended by the provider, which is, effectively, as they performed the research activities that they were contractually committed to provide. Absent information that would indicate that a different expensing schedule was more appropriate (such as, for example, from the achievement of performance milestones or the completion of contract work), such advances have been expensed over the contractual service term on a straight-line basis, which, in management's opinion, reflects a reasonable estimate of when the underlying research and development costs were being incurred. The CRADA terminated as scheduled on April 1, 2013.

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

## **Plan of Operation**

### *General Overview of Plans*

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

The research on brain tumors was conducted in collaboration with the National Institute of Neurological Disorders and Stroke ("NINDS") of the National Institutes of Health ("NIH") under a Cooperative Research and Development Agreement ("CRADA") entered into on March 22, 2006. The CRADA was extended through a series of amendments and remained in effect until April 1, 2013. The research at NINDS was led by Dr. Zhengping Zhuang, an internationally recognized investigator in the molecular pathology of cancer. Dr. Zhuang 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 Food and Drug Administration ("FDA") for clinical trials. The CRADA terminated as scheduled on April 1, 2013.

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

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

The Company's longer-term objective is to secure one or more strategic partnerships with pharmaceutical companies with major programs in cancer, anti-fungal treatments, and/or neuroprotective measures.

The significant diversity of the potential therapeutic value of the Company's compounds 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. However, 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 in which errors in normal cellular processing lead to loss of functions important to normal cell function, such as Gaucher's disease). 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 from treatment with 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. In the past decade, there has been an unprecedented expansion in knowledge of biochemical defects in the cancer cell. 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, 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, for the treatment of cancer. 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.

On December 19, 2011, an article in the December 12, 2011 edition of the Proceedings of the National Academy of Sciences in the United States reported that the Company's investigational drug, LB-205, was shown to have therapeutic potential in a laboratory model of the genetic illness Gaucher's disease. Patent applications are pending on the use of LB-205 for this purpose.

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 Neurologic Disorders and Stroke (“NINDS”), National Institutes of Health (“NIH”) under a continuing 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, glioblastoma multiforme (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 treatment of brain tumors depends upon the ability of compounds to penetrate a physiological barrier (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 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 IND application to the FDA to conduct a Phase 1 clinical trial of LB-100, and engaged the CRO responsible for the clinical development of the Company’s lead compound, LB-100, to prepare an IND application for filing with the FDA. This task included preparing the detailed clinical protocol known as the "Investigator's Brochure", a document containing a detailed summary of all that is known about LB-100, and development of the formal IND application for submission to the FDA. The CRO also established the procedures for assuring appropriate collection and reporting of data generated during the clinical trial of LB-100 to the FDA.

The Company filed an IND application with the FDA on April 30, 2012, and on July 24, 2012, the FDA notified the Company that it would allow initiation of a Phase 1 clinical trial of LB-100. The purpose of the clinical trial is to demonstrate that LB-100 can be administered safely to human beings at a dose and at a frequency that achieves the desired pharmacologic effect; in this case, inhibition of a specific enzyme, without being associated with toxicities considered unacceptable. The Phase 1 clinical trial of LB-100 is designed to determine the maximum tolerable dose of LB-100 given alone and then in combination with a standard widely use anti-cancer drug. As a prelude to determining the therapeutic effectiveness of LB-100 in a subsequent Phase 2 clinical trial of common cancers, a key goal of the initial portion of the Phase 1 clinical trial will be to demonstrate that the target enzyme of LB-100, protein phosphatase 2A (PP2A), can be inhibited in humans with readily tolerable toxicity. As an anti-cancer drug, LB-100 is likely to be used at maximum tolerable doses, but for the potential treatment of non-malignant diseases, such as acute vascular diseases and metabolic diseases, lower doses may achieve therapeutic benefit by inhibition of the target enzyme, PP2A, thus opening up the possibility of a host of therapeutic applications for LB-100 and related proprietary compounds. The Phase 1 clinical trial of LB-100 began in April 2013 with the entry of patients into the clinical trial, and is being carried out by a nationally recognized comprehensive cancer center. The clinical trial is estimated to take from 18 to 30 months and cost approximately \$2,000,000.

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. The Company's approach has been to operate with a minimum of overhead, moving compounds forward as efficiently and inexpensively as possible, and to raise funds to support each of these stages as certain milestones are reached. The commencement of a Phase 1 clinical trial is a milestone in the Company's goal of developing a successful product platform.

## **Results of Operations**

The Company is a development stage company and had not commenced revenue-generating operations at March 31, 2013.

### **Three Months Ended March 31, 2013 and 2012**

General and Administrative. For the three months ended March 31, 2013, general and administrative costs were \$167,642, which consisted of the fair value of stock options issued to directors and consultants of \$53,037, consulting and professional fees of \$80,369, insurance expense of \$8,904, officer's salary and related costs of \$16,823, stock transfer fees of \$1,995, travel and entertainment costs of \$1,514, and other operating costs of \$5,000.

For the three months ended March 31, 2012, general and administrative costs were \$318,311, which consisted of the fair value of stock options issued to directors and consultants of \$213,954, consulting and professional fees of \$71,644, insurance expense of \$6,375, officer's salary and related costs of \$16,977, stock transfer fees of \$3,106, travel and entertainment costs of \$2,587, and other operating costs of \$3,668.

A significant component of the fair value of stock options issued to directors and consultants of \$213,954 for the three months ended March 31, 2012 was a \$154,986 amortization expense for the fair value of stock options to acquire 500,000 shares of the Company's common stock that were issued to Gil Schwartzberg on October 5, 2011 that were totally amortized prior to the three months ended March 31, 2013.

Research and Development. For the three months ended March 31, 2013, research and development costs were \$166,305, which consisted of patent costs of \$96,679, third-party contractor costs of \$63,376, and consulting fees to a related party of \$6,250.

Third-party contractor costs of \$63,376 for the three months ended March 31, 2013 includes \$48,783 related to the Phase 1 clinical trial of LB-100.

For the three months ended March 31, 2012, research and development costs were \$273,552, which consisted of patent costs of \$38,162, third-party contractor costs of \$229,140, and consulting fees to a related party of \$6,250.

Net Loss. For the three months ended March 31, 2013, the Company incurred a net loss of \$333,946, as compared to a net loss of \$591,858 for the three months ended March 31, 2012.

### **Liquidity and Capital Resources – March 31, 2013**

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, the Company's independent registered public accounting firm, in its report on the Company's 2012 consolidated financial statements, has raised substantial doubt about the Company's ability to continue as a going concern (see "Going Concern" above).

In May and June 2012, the Company raised \$2,468,250 by offering a 25% discount to warrant holders as an inducement to exercise their warrants for cash through June 15, 2012. The Company believes that this amount will be sufficient to meet its operating needs through at least December 31, 2013, and that during this period it will initiate its Phase 1 clinical trial of LB-100, continue the two drug development programs currently in process, and expand its patent portfolio, including the maintenance of its applications for international protection of lead compounds of both the LB-100 and LB-200 series.

At March 31, 2013, the Company had a working capital surplus of \$1,210,949, as compared to working capital surplus of \$1,491,858 at December 31, 2012, a decrease in working capital of \$280,909 for the three months ended March 31, 2013. At March 31, 2013, the Company had cash and money market funds aggregating \$1,380,716, as compared to \$1,661,256 at December 31, 2012, a decrease of \$280,540 for the three months ended March 31, 2013. The decrease in working capital and cash during the three months ended March 31, 2013 was the result of cash utilized by the Company in its operating activities.

The Company filed an IND application with the FDA on April 30, 2012, and on July 24, 2012, the FDA notified the Company that it would allow initiation of a Phase 1 clinical trial of LB-100. The purpose of the clinical trial is to demonstrate that LB-100 can be administered safely to human beings at a dose and at a frequency that achieves the desired pharmacologic effect; in this case, inhibition of a specific enzyme, without being associated with toxicities considered unacceptable. The Phase 1 clinical trial of LB-100 began in April 2013 with the entry of patients into the clinical trial, and is being carried out by a nationally recognized comprehensive cancer center. The clinical trial is estimated to take from 18 to 30 months and cost approximately \$2,000,000.

The Company believes that it currently has sufficient funds to continue the Phase 1 clinical trial of LB-100 and fund its operating plans through at least December 31, 2013. Accordingly, in late 2013 or early 2014, in order to continue to fund the Company's operations in 2014 and thereafter, it is likely that the Company will be required to raise additional capital. If cash resources are insufficient to satisfy the Company's cash requirements at that time, 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, 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 three months ended March 31, 2013, operating activities utilized cash of \$280,540, as compared to utilizing cash of \$248,963 for the three months ended March 31, 2012, to support the Company's ongoing research and development activities.

Investing Activities. For the three months ended March 31, 2013, investing activities consisted of a \$1 increase in money market funds from interest earned during the period. For the three months ended March 31, 2012, investing activities consisted of \$269,995 being withdrawn from a money market fund.

Financing Activities. There were no financing activities during the three months ended March 31, 2013. For the three months ended March 31, 2012, financing activities consisted of \$33,333 of proceeds from the exercise of stock options

## **Principal Commitments**

Effective March 22, 2006, the Company entered into a CRADA with the NINDS of the NIH. The CRADA was extended through a series of amendments and remained in effect until April 1, 2013. The CRADA provided for the collaboration between the parties in the identification and evaluation of agents that target the Nuclear Receptor CoRepressor (N-CoR) pathway for glioma cell differentiation. The CRADA also provided that NINDS and the Company would conduct research to determine if expression of N-CoR correlates with prognosis in glioma patients. Pursuant to the CRADA, the Company initially agreed to provide funds under the CRADA in the amount of \$200,000 per year to fund two technical assistants for the technical, statistical and administrative support for the research activities, as well as to pay for supplies and travel expenses. The first \$200,000 was due within 180 days of the effective date and was paid in full on July 6, 2006. The second \$200,000 was paid in full on June 29, 2007. In June 2008, the CRADA was extended to September 30, 2009, with no additional funding required for the period between July 1, 2008 and September 30, 2008. For the period from October 1, 2008 through September 30, 2009, the Company agreed to provide additional funding under the CRADA of \$200,000, to be paid in four quarterly installments of \$50,000, each commencing on October 1, 2008. The first and second quarterly installments of \$50,000 were paid on September 29, 2008 and March 5, 2009, respectively. During August 2009, the Company entered into an amendment to the CRADA to extend its term from September 30, 2009 through September 30, 2011. Pursuant to such amendment, the Company agreed to aggregate payments of \$100,000 in two installments of \$50,000, payable on October 1, 2010 and January 5, 2011, inclusive of any prior unpaid commitments. The October 1, 2010 installment was paid on September 29, 2010 and the January 5, 2011 installment was paid on December 27, 2010. In September 2011, the CRADA was amended to extend its term to June 1, 2012 and to provide additional funding of \$50,000, payable in two installments of \$25,000 each on October 1, 2011 and February 5, 2012. The October 1, 2011 installment was paid on October 12, 2011, and by mutual agreement, the February 5, 2012 installment was paid on May 1, 2012. In August 2012, the CRADA was extended to April 1, 2013, with no additional funding requirement. The CRADA terminated as scheduled on April 1, 2013.

Effective September 19, 2008, the Company entered into a Patent License Agreement (the "PLA") with the NIH providing the Company with an exclusive license for all patents submitted jointly with the NIH under the CRADA. The PLA provided for an initial payment of \$25,000 to the NIH within 60 days of September 19, 2008, and for a minimum annual royalty of \$30,000 on January 1 of each calendar year following the year in which the CRADA is terminated. The PLA also provided for the Company to pay (i) specified royalties based on net sales by the Company and its sub-licensees, reduced by the amount of the minimum annual royalty for that year, (ii) certain benchmark royalties upon the achievement of certain clinical benchmarks, and (iii) sublicensing royalties for the granting of sublicenses, with respect to joint patents. The Company paid the initial \$25,000 obligation on November 10, 2008, which was charged to general and administrative costs. As of December 31, 2012, no amounts were due pursuant to the PLA. Due to the termination of the CRADA on April 1, 2013, the Company expects to pay a minimum annual royalty of \$30,000 to the NIH beginning on January 1, 2014 and each year thereafter.

On February 5, 2007, the Company entered into a two-year agreement pursuant to which the Company engaged Chem-Master to synthesize a compound designated as LB-100, and any other compound synthesized by Chem-Master pursuant to the Company's request, which have potential use in treating a disease, including, without limitation, cancers such as glioblastomas. Pursuant to the Chem-Master Agreement, the Company agreed to reimburse Chem-Master for the cost of materials, labor, and expenses for other items used in the synthesis process, and also agreed to grant Chem-Master a five-year option to purchase shares of the Company's common stock. The Company has the right to terminate the Chem-Master Agreement at any time during its term upon sixty days prior written notice. On January 29, 2008, the Chem-Master Agreement was amended to extend its term to February 15, 2014, and to expressly provide for the design and synthesis of a new series of compounds designated as LB-300. The Company also periodically enters into other agreements with Chem-Master for other services. The Company did not incur any expense for the costs of materials, labor and expenses related to its agreements with Chem-Master during the three months ended March 31, 2013 and 2012,

On February 2, 2012, the Company entered into an agreement with MRI Global for a series of studies. As of March 31, 2013, work orders for studies having a total estimated cost of \$99,000 were in process under this agreement. As of March 31, 2013, the Company had paid \$58,500 towards these work orders.

At various times, the Company has entered into agreements with Ash Stevens to conduct various studies. As of March 31, 2013, contracts with a total estimated cost of \$62,000 were in process, of which \$58,935 had been paid.

On March 17, 2010, the Company engaged Theradex to assist the Company in bringing LB-100 through the FDA approval process and to provide other services. Theradex is an international CRO that provides professional services for the clinical research and development of pharmaceutical compounds. Total fees charged to operations for services paid to Theradex pursuant to this arrangement were \$7,393 and \$54,187 for the three months ended March 31, 2013 and 2012, respectively, and \$186,980 for the period from August 9, 2005 (inception) to March 31, 2013 (cumulative), and are included in research and development costs in the Company's condensed consolidated statements of operations. Dr. Robert B. Royds, the founder, Chairman of the Board and Medical Director of Theradex, was appointed to the Company's Board of Directors on May 2, 2011. Dr. Royds died on March 23, 2013.

On September 21, 2012, the Company entered into a work order agreement with Theradex 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 a nationally recognized comprehensive cancer and is estimated to take from 18 to 30 months and cost approximately \$2,000,000, with such payments expected to be divided approximately evenly between payments to Theradex for services rendered and payments for pass-through costs for the clinical center, laboratory costs and investigator costs. Total costs charged to operations for services paid to Theradex pursuant to this arrangement were \$48,783 for the three months ended March 31, 2013, the first period for which costs were incurred under this agreement, and are included in research and development costs in the Company's condensed consolidated statements of operations.

The following table sets forth the Company's principal cash obligations and commitments for the next five fiscal years as of March 31, 2013 aggregating \$2,316,461, of which \$195,253 is included in current liabilities in the condensed consolidated balance sheet at March 31, 2013. Amounts included in the 2013 column represent amounts due at March 31, 2013 for the remainder of the 2013 fiscal year ending December 31, 2013.

	Total	Payments Due By Year				
		2013	2014	2015	2016	2017
Research and development contracts	\$ 58,205	\$ 58,205	\$ —	\$ —	\$ —	\$ —
Theradex work order agreement	1,971,539	571,539	1,000,000	400,000	—	—
Patent license agreement	120,000	—	30,000	30,000	30,000	30,000
Liquidated damages payable under registration rights agreement	74,000	74,000	—	—	—	—
Due to stockholder	92,717	92,717	—	—	—	—
Total	<u>\$ 2,316,461</u>	<u>\$ 796,461</u>	<u>\$ 1,030,000</u>	<u>\$ 430,000</u>	<u>\$ 30,000</u>	<u>\$ 30,000</u>

#### Off-Balance Sheet Arrangements

At March 31, 2013, the Company did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

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

Not applicable.

### **ITEM 4. CONTROLS AND PROCEDURES**

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

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

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

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

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

## **PART II - OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

The Company is currently not a party to any pending or threatened legal proceedings.

### **ITEM 1A. RISK FACTORS**

Not applicable.

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

Not applicable.

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

### **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

### **ITEM 5. OTHER INFORMATION**

On March 23, 2013, Dr. Robert B. Royds, a member of the Company's Board of Directors, died. Dr. Royds was the founder, Chairman of the Board, and Medical Director of Theradex Systems, Inc. ("Theradex"), the organization which the Company has contracted with to manage and administer the Phase 1 clinical trial of the Company's LB-100 compound. Theradex is an international contract research organization that provides professional services for the clinical research and development of pharmaceutical compounds. The death of Dr. Royds is not expected to have any impact on the management and administration of the Phase 1 clinical trial.

### **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.

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(Registrant)

Date: May 9, 2013

By: /s/ JOHN S. KOVACH

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

INDEX TO EXHIBITS

Exhibit Number	Description of Document
31.1	Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. (1)
32.1	Officer's Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. (1)
(1)	Filed herewith.

**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: May 9, 2013

By: /s/ JOHN S. KOVACH

John S. Kovach  
Chief Executive Officer and  
Chief Financial Officer

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

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

(i) The Quarterly Report on Form 10-Q of the Company for the quarterly period ended March 31, 2013 (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: May 9, 2013

By: /s/ JOHN S. KOVACH

John S. Kovach  
Chief Executive Officer and  
Chief Financial Officer

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