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

FORM 10-K

[X] **ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2014

[ ] **TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number: 000-51476

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**20-2903526**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
248 Route 25A, No. 2 East Setauket, New York	**11733**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number: **(631) 942-7959**

Securities registered under Section 12(b) of the Act: None.

Securities registered under Section 12(g) of the Act: Common Stock.

Indicate by check mark whether the registrant is a well-known seasoned issuer as defined in Rule 405 of the Securities Act. Yes [ ] No [X]

Indicate by check mark whether the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. [ ]

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the issuer was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [X] No [ ]

Indicate by check mark if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-K contained in this form, and no disclosure will be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

Indicate by check mark whether registrant is a "large accelerated filer, "accelerated filer," non-accelerated filer" or "smaller reporting company reporting company" as such terms are defined in Rule 12b-2 of the Exchange Act (check one):

Large Accelerated Filer [ ] Accelerated Filer [ ] Non-Accelerated Filer [ ] Smaller Reporting Company [X]

Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes [ ] No [X]

Issuer's revenues for its fiscal year ended December 31, 2014: $0

The aggregate market value of the common stock held by non-affiliates of the registrant as of June 30, 2014 was approximately $1,898,350.

There were 45,575,814 shares of the Company's common stock outstanding on March 20, 2015.

Documents incorporated by reference: None.

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Introductory Comment

Throughout this Annual Report on Form 10-K, the terms "we," "us," "our," "our company," "Lixte," the "Company" and the "Registrant" refer to Lixte Biotechnology Holdings, Inc.., a Delaware corporation, and Lixte Biotechnology, Inc., our wholly-owned subsidiary.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (the "Report") contains certain forward-looking statements. For example, statements regarding our 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. We believe that the assumptions and expectations reflected in such forward-looking statements are reasonable, based on information available to us on the date hereof, but we cannot assure you that these assumptions and expectations will prove to have been correct or that we will take any action that we 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, competition from other similar businesses, and market and general policies, competition from other similar businesses, and market and general economic factors. This discussion should be read in conjunction with the consolidated financial statements and notes thereto included in this Report.

If one or more of these or other risks or uncertainties materialize, or if our underlying assumptions prove to be incorrect, actual results may vary materially from what we project. Any forward-looking statement you read in this Report reflects our current views with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our operations, results of operations, growth strategy, and liquidity. All subsequent forward-looking statements attributable to us or individuals acting on our behalf are expressly qualified in their entirety by this paragraph. You should specifically consider the factors identified in this Report, which would cause actual results to differ before making an investment decision. We are under no duty to update any of these forward-looking statements after the date of this Report or to conform these statements to actual results.

PART I

ITEM 1. BUSINESS

Company Overview

Lixte Biotechnology Holdings, Inc., a Delaware corporation, including its wholly-owned Delaware subsidiary, Lixte Biotechnology, Inc. (collectively, the "Company"), was created to capitalize on opportunities for the Company to develop low cost, specific and sensitive tests for the early detection of cancers to better estimate prognosis, to monitor treatment response, and to reveal targets for development of more effective treatments. However, over the past several years, the Company has evolved into what is now primarily a cancer drug discovery company, using biomarker technology to develop new and potentially more effective anti-cancer drugs for life-threatening diseases and other common non-malignant diseases.

The Company's activities are subject to significant risks and uncertainties, including the need to obtain additional financing, as described below.

Description of Business

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, such as Gaucher's disease) in which errors in normal cellular processing lead to loss of functions important to normal cell function. This has occurred because the targets selected by the Company have multiple functions in the cell, which, when altered, result in different disorders that may benefit by treatment from the Company's products.

The Company's drug discovery process is based on discerning clues to potential new targets for disease treatments reported in the increasingly large body of literature identifying the molecular variants which characterize human cancers and other non-cancer disorders. 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 for the treatment of cancer, protein phosphatase inhibitors (PTase-i), designated by the Company as the LB-100 series of compounds, and histone deacetylase inhibitors (HDACi), designated by the Company as the LB-200 series of compounds. Compounds of both types also have potential use in the prevention and treatment of neurodegenerative diseases.

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

On August 16, 2011, the United States Patent and Trademark Office (the "PTO") awarded a patent to the Company for its lead compound, LB-100, as well as for a number of structurally related compounds. On November 10, 2011, the PTO issued an Official Notice of Allowance in conjunction with the Company's patent application for the structure and synthesis of its compounds of the LB-200 series. On November 15, 2011, the PTO awarded a patent to the Company for its 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. Patent applications on these compounds are pending worldwide. The Company's issued patents are summarized below at "Intellectual Property."

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

The second class of drugs under development by the Company, the LB-200 series, 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 have broad activity against many cancer types, have neuroprotective activity, and have 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. Potentially, this type of protective activity may have application to a broad spectrum of other chronic neurodegenerative diseases, including Parkinson's Disease and Amytrophic 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 Investigation New Drug ("IND") application to the United States Food and Drug Administration ("FDA") to conduct a Phase 1 clinical trial of LB-100, and engaged the 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, 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 began in April 2013 with the entry of patients into the clinical trial (NCTO 1837667 at www.clinicaltrials.gov) and was initiated at the City of Hope National Medical Center in Duarte, California, and was extended in December 2013 to include the Mayo Clinic in Rochester, Minnesota, both of which are Comprehensive Cancer Centers designated by the National Cancer Institute. As the accrual of patients was slower than anticipated, in October 2014 the Company entered into a Clinical Research Agreement ("CRA") with US Oncology Research, LLC, a large community-based research network based in Texas, to increase the rate of entry of patients into the ongoing clinical trial by adding four more active clinical oncologic research sites.

The Company originally estimated that the Phase 1 clinical trial of LB-100 would be completed during the quarter ending June 30, 2015 at a total cost of approximately $2,038,000. The Company currently estimates that the first part of the clinical trial will be completed by June 30, 2015, and the second part of the clinical trial will be completed by June 30, 2016, at a total cost of approximately $2,615,000.

The costs of the Phase 1 clinical trial of LB-100 are being paid to or through Theradex Systems, Inc. ("Theradex"), the CRO responsible for the clinical development of LB-100. Total costs charged to operations through December 31, 2014 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, totaled $702,255, of which $423,534 and $278,721 were incurred during the years ended December 31, 2014 and 2013, respectively. The final cost of the clinical trial is variable, depending upon the number of patients needed to be medically screened to determine if they meet the criteria for entry into the clinical trial and ultimately upon the total number of patients entered into the clinical trial to establish the proper doses of the drug for a Phase 2 clinical trial.

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 is 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 next step in the clinical development of LB-100 after the completion of a Phase 1 clinical trial is to test LB-100 in combination with docetaxel in a Phase 2 trial. In order to do this, the Company must demonstrate in its ongoing Phase 1 trial 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, and then demonstrate that it can be combined with the standard cytotoxic drug docetaxel with acceptable toxicity. Given the recent reports that LB-100 may be active in certain hemotologic cancers, once the acceptable dose of LB-100 alone is determined in the Phase 1 clinical trial, resources permitting, the Company may explore the activity of LB-100 alone and/or in combination with drugs used for the treatment of del5qMDS and/or CML.

As a result of the Company receiving $1,750,000 from the sale of shares of preferred stock effective March 17, 2015, the Company believes that it has sufficient funds to complete the ongoing Phase 1 clinical trial of its lead anti-cancer compound LB-100 and to fund its ongoing operating expenses, including maintaining its patent portfolio, through June 30, 2016.

The amount and timing of future cash requirements will depend on the pace of the Company's clinical programs, in particular the completion of the Phase 1 clinical trial of LB-100. The Company expects that it will need to raise additional capital no later than mid-2016, likely in the form of equity, to fund operations, including the continuing costs of its clinical trial program and to maintain its patent portfolio. However, academic investigators have recently published pre-clinical data suggesting that LB-100 alone and/or in combination with standard treatments may be useful in the treatment of two different hematologic cancers. As the single agent dose of LB-100 is expected to be determined by June 30, 2015, the Company may consider raising additional funds during 2015 for the conduct of a Phase 1b/II clinical trial of LB-100 in a hematologic malignancy before the Company completes Part 2 of the current Phase 1 clinical trial.

National Cancer Institute Experimental Therapeutics Program

On September 17, 2010, the National Cancer Institute (NCI) Experimental Therapeutics (NExT) Program Senior Advisory Committee (SAC) approved a collaboration by the NCI with the Company for clinical evaluation of LB-100. This collaboration is a milestone-based approach in which NCI will first confirm studies of the LB-100 compound in an animal model of glioblastoma multiforme, the most common form of brain tumor of adults, and conduct an initial exploratory toxicology study in an animal model. At milestone intervals, the SAC will re-evaluate project progress before considering assignment of additional support and resources to this project. As noted below, the NExT group advised the Company on several aspects of the process of pre-clinical characterization of LB-100 needed for submission of an IND and carried out an initial toxicological study of LB-100 in rats. This study was used to guide the subsequent formal toxicology studies based on good laboratory practice (GLP) completed in rats and dogs by the Company with a contract research organization. The Company subsequently conducted its own GLP toxicity studies and submitted an IND for a clinical trial of LB-100, which acknowledged the early assistance of the NExT program in planning the design of animal studies.

The NExT program of the NCI is a unique partnership with the NCI to facilitate oncology drug discovery and development. The program is not a grant or a contract, but provides access to the NCI's drug discovery and preclinical development resources, including expert advice concerning the various requirements for bringing a new compound to initial clinical trial. Participation in the NExT program is via a competitive application. The Company was admitted to the program in September 2010. The Company received advice as to how to proceed with pre-clinical development of its lead compound LB-100 and the NCI performed one rodent toxicology study with LB-100. The Company was not responsible for any costs or payments, and neither party obtained or incurred any material rights or obligations. As is standard for the NExT program, there was no specific agreement, other than to limit support to pre-clinical development pending validation of anti-tumor activity in a specific tumor model. Activity deemed less than sufficient to warrant extension of NExT support toward clinical development led to termination of the Company's participation in the program on July 21, 2011. As noted above, the Company subsequently carried out the pre-clinical studies for and obtained an IND from the FDA to study LB-100 in a Phase 1 clinical trial.

Publications; Presentations

The following publications have included articles discussing the Company's compounds:

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. The Company has patent applications pending on the use of LB-205 for this purpose.

On June 18, 2013, an article was published in Clinical Cancer Research showing that LB-100 is a radiotherapy sensitizing agent that increases the effectiveness of x-ray treatment against human pancreatic cancer cells in an animal model, as the Company has shown for two other types of human cancers. These results are in keeping with the ability of LB-100 to enhance the effectiveness of existing cytotoxic treatments, both chemotherapy and radiotherapy, against different types of cancers. Because LB-100 itself does not readily enter the brain in animal models, the Company has developed new related compounds which have been shown to penetrate the blood brain barrier (entering the brain after systemic injection) in mice, and is evaluating the effectiveness of these compounds in the treatment of brain tumors in animal models.

The June 25, 2013 issue of the Proceedings of the National Academy of Sciences reported that scientists at the National Institutes of Health had determined that one of the Company's 200 series compounds significantly reduced the extent of structural damage in the brain and lessened neurological functional impairment in a rat model of traumatic brain injury (TBI). Given the need for methods to reduce injury to the brain after acute injuries caused by explosive devices, sports injuries and accidental falls, the Company is seeking partners in the private and governmental sectors to assist in developing these compounds for clinical evaluation.

In May 2014 an article was published in Molecular Cancer Therapeutics reporting that LB-100 enhanced the therapeutic effectiveness of chemotherapeutic drugs (doxorubicin and cisplatin) without significantly enhancing toxicity against hepatocellular cancer (HCC) in animal models. HCC is the most common cancer in Asia and one of the leading causes of death from cancer worldwide.

In October 2014, investigators reported in Cancer Letters that LB-100 enhanced the therapeutic effectiveness of chemotherapy in animal models of pancreatic cancer can without significantly enhancing toxicity.

In November 2014, investigators from the National Institutes of Health reported in Molecular Cancer Therapeutics that LB-100 overcomes the resistance of cisplatin-resistant human ovarian cancer cells in the peritoneal cavity of animals. This finding is of particular interest as platinum-based chemotherapy drugs are the first-line treatment for women with unresectable ovarian cancer and patients so treated eventually relapse because of development of platinum-resistant disease.

In November 2014, Dr. Kovach, in an invited talk, presented a summary of the anti-cancer activity of LB-100 at the annual Therapeutics Area Partnership Meeting in Boston, Massachusetts. This meeting was sponsored by Kantar Health, which selected LB-100 as one of the top 10 oncology projects to watch in 2015 (see press release from Kantar Health at www.lixte.com).

In December 2014, scientists from the Terry Fox Cancer Center, Vancouver, British Columbia, reported at the Annual Society of Hematology Meeting that LB-100 is active alone and potentiates the activity of Imatinib (Gleevec) against human cell lines of chronic myelogenous leukemia (CML), both imatinib-naïve CML cells and Imatinib-resistant CML cells. Although virtually all patients with CML worldwide receive Imatinib as initial therapy and most patients have an excellent response, almost every patient relapses because of development of Imatinib–resistance.

Intellectual Property

The Company's products will derive directly from its intellectual property, including the property covered by its patents. These patents now cover sole rights to the composition and synthesis of the LB-100 and LB-200 series of drugs. Joint patent applications with the NIH have been filed for the treatment of glioblastoma multiforme, medulloblastoma, and neuroblastoma. The Company has also filed claims for the use of certain homologs of both series of drugs for the potential treatment of neurodegenerative diseases such as Alzheimer's Disease and Parkinson's Disease, Amyotrophic Lateral Sclerosis (ALS, or Lou Gehrig's Disease), stroke, and traumatic brain injury and of homologs of the LB-200 series for treatment of serious systemic fungal infections and for the treatment of common fungal infections of the skin and nails. Other claims cover biomarkers uniquely associated with specific types of cancer that may provide the bases for assays suitable for cancer detection and patents for development of a tool for screening new compounds for anti-cancer activity.

Patents for composition of matter and for several uses of both the LB-100 series (oxabicycloheptanes and –heptenes) and the LB-200 series (histone deacetylase inhibitors; HDACi) have been issued in the US, Mexico, and Australia with notice of intent to patent from the Japanese patent office. Patents for the LB-100 series and the LB-200 series have been filed in the U.S. and widely internationally (PCT).

Issued patents include:

LB-100 Series Compounds
Oxabicycloheptanes and Oxabicycloheptenes, Their Preparation and Use

Patent	Priority Date	Type	Expiration Date
US 7,998,957	Feb 6, 2008	Composition and Use in Cancer Treatment	2/20/2030
US 8,227,473	Aug 1, 2009	Composition and Use in Cancer Treatment	2/20/2030
US 8,426,444 Divisional	Feb 6, 2008	Composition and Use in Cancer Treatment	2/6/2028
LB-200 Series Compounds HDAC Inhibitors			
US 8,143,445	Oct 1, 2008	Composition and Use in Cancer Treatment	8/23/2029
US 8,455,688 Divisional	Oct 1, 2008	Composition and Use in Cancer Treatment	10/1/2028
LB-100 and LB-200 Series Compounds Neuroprotective Agents for the Prevention and Treatment of Neurodegenerative Diseases			
US 8,058,268	Aug 1, 2009	Use in Treatment of Multiple CNS Diseases	12/31/2029
US 8,329,719 Divisional	Aug 1, 2009	Use in Treatment of Multiple CNS Diseases	7/29/2029

The Market

Anti-Cancer Drugs

The Company has developed two series of pharmacologically active drugs, the LB-100 series and the LB-200 series. The Company believes that the mechanism by which compounds of the LB-100 series affect cancer cell growth is different from all cancer agents currently approved for clinical use. Lead compounds from each series have activity against a broad spectrum of common and rarer human cancers in cell culture systems. In addition, compounds from both series have anti-cancer activity in animal models of glioblastoma multiforme, neuroblastoma, and medulloblastoma, all cancers of neural tissue. Lead compounds of the LB-100 series also have activity against melanoma, breast cancer and sarcoma in animal models and enhance the effectiveness of commonly used anti-cancer drugs in these model systems. The enhancement of anti-cancer activity of these anti-cancer drugs occurs at doses of LB-100 that do not significantly increase toxicity in animals. It is therefore hoped that when combined with standard anti-cancer regimens against many tumor types, the Company's compounds will improve therapeutic benefit without enhancing toxicity in humans.

Diagnostic Biomarkers

The Company has filed patents on two biomarkers, one associated primarily with cancers of neural tissue such as glioblastoma multiforme, and a second biomarker that is present not only in brain cancers but also in the more common human cancers.

Discovery of the biomarker associated with GBMs provided the insight to the Company's team that led to the synthesis and development of the LB-100 and LB-200 series. Apart from therapeutic considerations, a biomarker for GBMs reflecting the presence of the disease in biopsies and in cerebrospinal fluid may be valuable for confirming diagnosis and/or documenting effectiveness of treatment and recurrence of disease. The second biomarker may be useful as a tool for screening new compounds for anti-cancer activity in general because it appears to be present in many human cancers. The Company is not presently pursuing development of use of these biomarkers, but is open to partnering with a diagnostic company to validate the usefulness of one or both markers.

Marketing Plan

The primary goal of the Company is to take LB-100 through Phase 1 clinical trials. Because of the novelty and spectrum of activity of LB-100, the Company believes it is reasonably likely it will find a partner in the pharmaceutical industry with interest in this compound. The Company, however, would prefer to delay partnering/licensing until the potential value of its products is augmented by demonstrating there is no impediment to clinical evaluation and a therapeutic dose level is determined in clinical trials. Demonstration of clinical usefulness would be expected to substantially increase the value of the Company's product.

Research and Development

Further development of lead compounds from each of the LB-100 and LB-200 series requires pharmacokinetic/pharmacodynamic characterization (how long a drug persists in the blood and how long the drug is active at the intended target) and large animal toxicologic evaluation under conditions meeting FDA requirements. Most anti-cancer drugs fail in development because of unacceptable toxicity. By analogy with mechanistically related compounds, there is good reason to believe, however, that lead compounds of both series of drugs will be able to be given to humans safely by routes and at doses resulting in concentration of drug producing anti-cancer activity in animal model systems. The Company has demonstrated that lead compounds of both types affect their intended targets at doses that produce anti-cancer activity without discernable toxicity in animal models and has completed the large animal toxicity studies that were required for the submission of the IND for the Phase 1 clinical trial of LB-100.

One of the Company's most valuable resources is its scientific team, a coalition of various experts brought together through contracts and other collaborative arrangements. The team has expertise in cancer biology, proteomics (cancer biomarkers), medicinal and synthetic chemistry, pharmacology, clinical oncology, and drug evaluation. In a short period of time and at very low cost, this group has developed lead compounds of two different classes of drugs that are poised for development as new treatments for several types of cancer. The initial cancer targets are expected to be melanoma or glioblastoma multiforme.

Product Overview

The Company's products will derive directly from its intellectual property, consisting of patents and applications for patents. The Company's patents now cover sole rights to the composition and synthesis of the LB-100 and LB-200 series of drugs. Joint patent applications with NIH have been filed for the treatment of glioblastoma multiforme, medulloblastoma, and neuroblastoma. The Company has also filed claims for the use of certain homologs of both series of drugs for the potential treatment of neurodegenerative diseases such as Alzheimer's Disease and Parkinson's Disease, Amyotrophic Lateral Sclerosis (ALS, or Lou Gehrig's Disease), stroke, and traumatic brain injury and of homologs of the LB-200 series for treatment of serious systemic fungal infections and for the treatment of common fungal infections of the skin and nails. Other claims cover biomarkers uniquely associated with specific types of cancer that may provide the bases for assays suitable for cancer detection and patents for development of a tool for screening new compounds for anti-cancer activity.

The Company believes that there are four main markets for potential products that it may develop.

1. Improved Anti-Cancer Treatments . The primary focus of the Company is improved chemotherapy regimens for cancers not curable by surgery or radiation.

2. Treatments for Neurodegenerative Diseases . Most experts believe that at present there are no significantly effective drugs available for the delay of progression, as well as prevention, of the common neurodegenerative diseases, including Alzheimer's Disease, Parkinson's Disease, and Amyotrophic Lateral Sclerosis Disease (ALS, or Lou Gehrig's Disease), among a host of rarer chronic diseases of the brain. The Company is exploring mechanisms to evaluate its compounds for these activities with experts in the field, in academic or other not-for–profit settings.

3. Treatments for Vascular Diseases . Non-patentable compounds which reduce the extent of tissue damage after experimental induction of myocardial ischemia in animal models affect the same enzyme targeted by the Company's LB-100 compound, raising the possibility that these agents may have therapeutic benefit in heart attacks and potentially strokes due to acute blood vessel blockage.

4. Treatments for Fungal Infections of the Skin . LB-200 compounds have activity against the most common fungal infections of humans and animals in cell culture and animal models.

Product Development

The Company is subject to FDA regulations as it conducts clinical trials. Additionally, any product for which the Company obtains marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continual review and periodic inspections by the FDA and other regulatory bodies. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with the Company's products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturer or manufacturing processes, or failure to comply with regulatory requirements, may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recall, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

Competition

The life sciences industry is highly competitive and subject to rapid and profound technological change. The Company believes that several companies are investigating biomarkers for every human cancer. These companies include firms seeking a better understanding of molecular variability in human brain tumors with the objective to be able to use such information to design better treatments. The Company's present and potential competitors include major pharmaceutical companies, as well as specialized biotechnology and life sciences firms in the United States and in other countries. Most of these companies have considerably greater financial, technical and marketing resources than the Company does. Additional mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated in the Company's competitors. The Company's existing or prospective competitors may develop processes or products that are more effective than the Company's or be more effective at implementing their technologies to develop commercial products faster. The Company's competitors may succeed in obtaining patent protection and/or receiving regulatory approval for commercializing products before the Company does. Developments by the Company's competitors may render the Company's product candidates obsolete or non-competitive.

The Company also experiences competition from universities and other research institutions, and the Company is likely to compete with others in acquiring technology from those sources. There can be no assurance that others will not develop technologies with significant advantages over those that the Company is seeking to develop. Any such development could harm the Company's business.

The Company faces competition from other companies seeking to identify and commercialize cancer biomarkers. The Company also competes with universities and other research institutions engaged in research in these areas. Many of the Company's competitors have greater technical and financial resources than the Company does.

The Company's ability to compete successfully is based on numerous factors, including:

- the cost-effectiveness of any product that the Company ultimately commercializes relative to competing products;
- the ease of use and ready availability of any product that the Company brings to market;
- the accuracy of a diagnostic test designed by the Company in detecting cancers, including overcoming the propensity for "false positive" results; and
- the relative speed with which the Company is able to bring any product resulting from its research to market in its target markets.

If the Company is unable to distinguish its products from competing products, or if competing products reach the market first, the Company may be unable to compete successfully with current or future competitors.

Employees

As of December 31, 2014, the Company had no full-time employees. Dr. Kovach is a Professor (part-time) in the Department of Preventive Medicine at the State University of New York (SUNY) in Stony Brook, New York. He received approvals from the School of Medicine of SUNY-Stony Brook and from the New York State Ethics Commission to operate the Company and to hold greater than 5% of the Company's outstanding shares.

Dr. Kovach devotes approximately 50% of his efforts per year to research planning and management. Dr. Kovach's contributions are made outside of his academic responsibilities. He directs, coordinates and manages the scientific and business development of the Company with the advice of the Company's Board of Directors, the advisory committee, and, from time to time, various consultants with specific expertise.

Government Regulation

Studies done under the CRADA were carried out in compliance with applicable Statutes, Executive Capital Orders, HHS regulations and all FDA, CDC, and NIH policies as specified in Article 13, 13.1 and 13.2, of the PHS CRADA agreement.

The Company's business is subject to the regulations of the FDA as it conducts clinical trials. Clinical trials are research studies to answer specific questions about new therapies or new ways of using known treatments. Clinical trials determine whether new drugs or treatments are both safe and effective and the FDA has determined that carefully conducted clinical trials are the fastest and safest way to find treatments that work in people.

The first phase of clinical trials, Phase 1 trials, are the initial studies to determine the metabolism and pharmacologic action of drugs in humans and side effects associated with increasing doses, and to gain early evidence of effectiveness. Patients entering such trials are those for whom no means of therapy is known to be associated with benefit. Such studies, including a proposal for the conduct of the clinical trial, require approval by the FDA.

The FDA also requires that an independent review body consider the benefits and risks of a clinical trial and grant approval for the proposed study including selecting of initial doses, plans for escalation of dose, plans for modification of dose if toxicity is encountered, plans for monitoring the wellbeing of individuals participating in the study, and for defining and measuring, to the extent possible, any untoward effects related to drug administration. Serious adverse effects, such as life-threatening toxicities and death, are immediately reportable to the review body and to the FDA. To minimize risk when studying a new drug, the initial dose is well below that expected to cause any toxicity. No more than three patients are entered at a given dose. In general, dose is not escalated within patients. Once safety is established by the absence of toxicity or low toxicity in a group of three patients, a planned higher dose is then evaluated in a subsequent group of three individuals and so on until dose-limiting toxicity is encountered. The dose level producing definite but acceptable toxicity is then selected as the dose level to be evaluated in Phase 2 trials. Thus, the goal of Phase 1 studies is to determine the appropriate dose level for evaluation of drug efficacy in patients with the same type of tumor at comparable stages of progression for whom no beneficial treatment is established.

In addition to regulations imposed by the FDA, depending on the Company's future activities, the Company may become subject to regulation under various federal and state statutes and regulations, such as the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Research Conservation and Recovery Act, national restrictions on technology transfer, and import, export and customs regulations. From time to time, other federal agencies and congressional committees have indicated an interest in implementing further regulation of biotechnology applications. The Company is not able to predict whether any such regulations will be adopted or whether, if adopted, such regulations will apply to the Company's business, or whether the Company or its collaborators would be able to comply with any applicable regulations.

In addition, as the Company intends to market its products in international markets, the Company may be required to obtain separate regulatory approvals from the European Union and many other foreign jurisdictions. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. The Company may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize its products in any market. As the Company is currently in the development stage, the Company cannot predict the impact on it from any such regulations.

ITEM 1A. RISK FACTORS

The following risk factors, together with the other information presented in this Report, including the financial statements and the notes thereto, should be considered by investors.

Risks Related to Business

We are engaged in early stage research and as such may not be successful in our efforts to develop a portfolio of commercially viable products.

A key element of our strategy is to discover, develop and commercialize a portfolio of new drugs and diagnostic tests. We are seeking to do so through our internal research programs. A significant portion of the research that we are conducting involves new and unproven technologies. Research programs to identify new disease targets and product candidates require substantial technical, financial and human resources whether or not any candidates or technologies are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for any of the following reasons:

- the research methodology used may not be successful in identifying potential product candidates. However, the Company has identified two promising lead candidate compounds which have activity in animal models, one of which, LB-100, is currently in a Phase 1 clinical trial;
- product candidates for diagnostic tests may on further study be shown to not obtain an acceptable level of accuracy; or
- product candidates for drugs may on further study be shown to have harmful side effects or other characteristics that indicate they are unlikely to be effective drugs.

If we are unable to discover suitable potential product candidates, develop additional delivery technologies through internal research programs or in-license suitable products or delivery technologies on acceptable business terms, our business prospects will suffer.

Our auditors have included a going concern modification in their opinion; we do not expect to obtain any revenues for several years and there is no assurance that we will ever generate revenue or be profitable .

The Company's 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. Furthermore, the Company has experienced recurring 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 their report on the Company's 2014 consolidated financial statements, have raised substantial doubt about the Company's ability to continue as a going concern.

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, and 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 does not have sufficient resources to fully develop and commercialize any products that may arise from its research. Accordingly, the Company will need to raise additional funds to do so.

As a result of the Company receiving $1,750,000 from the sale of shares of preferred stock effective March 17, 2015, the Company believes that it has sufficient funds to complete the ongoing Phase 1 clinical trial of its lead anti-cancer compound LB-100 and to fund its ongoing operating expenses, including maintaining its patent portfolio, through June 30, 2016.

The amount and timing of future cash requirements will depend on the pace of the Company's clinical programs, in particular the completion of the Phase 1 clinical trial of LB-100. The Company expects that it will need to raise additional capital no later than mid-2016, likely in the form of equity, to fund operations, including the continuing costs of its clinical trial program and to maintain its patent portfolio. However, academic investigators have recently published pre-clinical data suggesting that LB-100 alone and/or in combination with standard treatments may be useful in the treatment of two different hematologic cancers. As the single agent dose of LB-100 is expected to be determined by June 30, 2015, the Company may consider raising additional funds during 2015 for the conduct of a Phase 1b/II clinical trial of LB-100 in a hematologic malignancy before the Company completes Part 2 of the current Phase 1 clinical trial.

After completion of the Phase 1 clinical trial, the next step will be to determine the anti-cancer activity of LB-100 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. If cash resources are insufficient to satisfy the Company's liquidity requirements, the Company would be required to scale back or discontinue its technology and product development programs, or obtain funds, if available, through strategic alliances that may require the Company to relinquish rights to certain of its technologies products, or to discontinue its operations entirely.

If we were to materially breach any existing or future license or collaboration agreements, we could lose our ability to commercialize the related technologies, and our business could be materially and adversely affected.

We intend to enter into intellectual property licenses and agreements, all of which will be integral to our business. These licenses and agreements impose various research, development, commercialization, sublicensing, royalty, indemnification, insurance and other obligations on us. If we or our collaborators fail to perform under these agreements or otherwise breach obligations imposed by them, we could lose intellectual property rights that are important to our business.

We may not be successful in establishing additional strategic collaborations, which could adversely affect our ability to develop and commercialize products.

In the future, we may seek opportunities to establish new collaborations, joint ventures and strategic collaborations for the development and commercialization of products we discover. We face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. We may not be successful in our efforts to establish additional strategic collaborations or other alternative arrangements. Even if we are successful in our efforts to establish a collaboration or agreement, the terms that we establish may not be favorable to us. Finally, such strategic alliances or other arrangements may not result in successful products and associated revenue.

The life sciences industry is highly competitive and subject to rapid technological change.

The life sciences industry is highly competitive and subject to rapid and profound technological change. Our present and potential competitors include major pharmaceutical companies, as well as specialized biotechnology and life sciences firms in the United States and in other countries. Most of these companies have considerably greater financial, technical and marketing resources than we do. Additional mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated in our competitors. Our existing or prospective competitors may develop processes or products that are more effective than ours or be more effective at implementing their technologies to develop commercial products faster. Our competitors may succeed in obtaining patent protection and/or receiving regulatory approval for commercializing products before us. Developments by our competitors may render our product candidates obsolete or non-competitive.

We also experience competition from universities and other research institutions, and we are likely to compete with others in acquiring technology from those sources. There can be no assurance that others will not develop technologies with significant advantages over those that we are seeking to develop. Any such development could harm our business.

We may be unable to compete successfully with our competitors.

We face competition from other companies seeking to identify and commercialize cancer biomarkers. We also compete with universities and other research institutions engaged in research in these areas. Many of our competitors have greater technical and financial resources than we do.

Our ability to compete successfully is based on numerous factors, including:

- the cost-effectiveness of any product we ultimately commercialize relative to competing products;
- the ease of use and ready availability of any product we bring to market;
- the accuracy of a diagnostic test designed by us in detecting cancers, including overcoming the propensity for "false positive" results; and
- the relative speed with which we are able to bring any product resulting from our research to market in our target markets.

If we are unable to distinguish our products from competing products, or if competing products reach the market first, we may be unable to compete successfully with current or future competitors. This would cause our revenues to decline and affect our ability to achieve profitability.

We depend on certain key scientific personnel for our success who do not work full time for us. The loss of any such personnel could adversely affect our business, financial condition and results of operations.

Our success depends on the continued availability and contributions of our Chief Executive Officer and founder, Dr. John S. Kovach. In particular, Dr. Kovach is 77 years old, and, because of his arrangement with the State University of New York, does not devote his full time to us, although Dr. Kovach generally devotes a minimum of twenty hours a week to our business. The loss of services of Dr. Kovach could delay or reduce our product development and commercialization efforts. Furthermore, recruiting and retaining qualified scientific personnel to perform future research and development work will be critical to our success. The loss of members of our scientific personnel, or our inability to attract or retain other qualified personnel or advisors, could significantly weaken our management, harm our ability to compete effectively and harm our business.

Dr. Kovach is involved in other business activities and may face a conflict in selecting between their other business interests and our business.

Dr. John Kovach, our Chief Executive Officer, is also a Professor (part-time) in the Department of Preventive Medicine at SUNY-Stony Brook. He may also become involved in the future with other business opportunities which may become available. Accordingly, Dr. Kovach may face a conflict in selecting between us and their other business interests. We have not formulated a policy for the resolution of such conflicts.

We expect to rely heavily on third parties for the conduct of clinical trials of our product candidates. If these clinical trials are not successful, or if we or our collaborators are not able to obtain the necessary regulatory approvals, we will not be able to commercialize our product candidates.

In order to obtain regulatory approval for the commercial sale of our product candidates, we and our collaborators will be required to complete extensive preclinical studies as well as clinical trials in humans to demonstrate to the FDA and foreign regulatory authorities that our product candidates are safe and effective.

Dr. Kovach is experienced in the design and conduct of early clinical cancer trials, having been the lead investigator for a National Cancer Institute Phase 1 contract for ten years at the Mayo Clinic, Rochester, Minnesota. The Company, however, has no experience in conducting clinical trials and expects to rely heavily on collaborative partners and contract research organizations for their performance and management of clinical trials of our product candidates.

Our products under development may not be effective in treating any of our targeted disorders or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may prevent or limit their commercial use. Institutional review boards or regulators, including the FDA, may hold, suspend or terminate our clinical research or the clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements or if, in their opinion, the participating subjects are being exposed to unacceptable health risks. Additionally, the failure of third parties conducting or overseeing the operation of the clinical trials to perform their contractual or regulatory obligations in a timely fashion could delay the clinical trials. Failure of clinical trials can occur at any stage of testing. Any of these events would adversely affect our ability to market a product candidate.

The development process necessary to obtain regulatory approval is lengthy, complex and expensive. If we and our collaborative partners do not obtain necessary regulatory approvals, then our business would not be successful and the market price of our common stock could decline substantially.

To the extent that we, or our collaborative partners, are able to successfully advance a product candidate through the clinic, we, or such partner, will be required to obtain regulatory approval prior to marketing and selling such product. The process of obtaining FDA and other required regulatory approvals is expensive. The time required for FDA and other approvals is uncertain and typically takes a number of years, depending on the complexity and novelty of the product.

Any regulatory approval to market a product may be subject to limitations on the indicated uses for which we, or our collaborative partners, may market the product. These limitations may restrict the size of the market for the product and affect reimbursement by third-party payors. In addition, regulatory agencies may not grant approvals on a timely basis or may revoke or significantly modify previously granted approvals.

We, or our collaborative partners, also are subject to numerous foreign regulatory requirements governing the manufacturing and marketing of our potential future products outside of the United States. The approval procedure varies among countries, additional testing may be required in some jurisdictions, and the time required to obtain foreign approvals often differs from that required to obtain FDA approvals. Moreover, approval by the FDA does not ensure approval by regulatory authorities in other countries, and vice versa.

As a result of these factors, we, or our collaborative partners, may not successfully begin or complete clinical trials in the time periods estimated, if at all. Moreover, if we, or our collaborative partners, incur costs and delays in development programs or fail to successfully develop and commercialize products based upon our technologies, we may not become profitable and our stock price could decline substantially.

Even if our products are approved by regulatory authorities, if we fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continual review and periodic inspections by the FDA and other regulatory bodies. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturer or manufacturing processes, or failure to comply with regulatory requirements, may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recall, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products abroad.

We intend to market our products in international markets. In order to market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

We are subject to uncertainty relating to health care reform measures and reimbursement policies which, if not favorable to our product candidates, could hinder or prevent our product candidates' commercial success.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care may adversely affect:

- our ability to generate revenues and achieve profitability;
- the future revenues and profitability of our potential customers, suppliers and collaborators; and
- the availability of capital.

In certain foreign markets, the pricing of prescription pharmaceuticals is subject to government control. In the United States, given recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict the effects of the implementation of any new legislation or whether any current legislative or regulatory proposals affecting our business will be adopted, the implementation of new legislation or the announcement or adoption of current proposals could have a material and adverse effect on our business, financial condition and results of operations.

Our ability to commercialize our product candidates successfully will depend in part on the extent to which governmental authorities, private health insurers and other organizations establish appropriate reimbursement levels for the cost of our products and related treatments. Third-party payors are increasingly challenging the prices charged for medical products and services. Also, the trend toward managed health care in the United States, which could significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care or reduce government insurance programs, may result in lower prices for our product candidates or exclusion of our product candidates from reimbursement programs. The cost containment measures that health care payors and providers are instituting and the effect of any health care reform could materially and adversely affect our results of operations.

If physicians and patients do not accept the products that we may develop, our ability to generate product revenue in the future will be adversely affected.

The product candidates that we may develop may not gain market acceptance among physicians, healthcare payors, patients and the medical community. This will adversely affect our ability to generate revenue. Market acceptance of and demand for any product that we may develop will depend on many factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- convenience and ease of administration;
- prevalence and severity of adverse side effects;
- availability of alternative treatments or diagnostic tests;
- cost effectiveness;
- effectiveness of our marketing strategy and the pricing of any product that we may develop;
- publicity concerning our products or competitive products; and
- our ability to obtain third-party coverage or reimbursement.

We face the risk of product liability claims and may not be able to obtain insurance.

Our business exposes us to the risk of product liability claims that is inherent in the testing, manufacturing, and marketing of drugs and related devices. Although we will obtain product liability and clinical trial liability insurance when appropriate, this insurance is subject to deductibles and coverage limitations. We may not be able to obtain or maintain adequate protection against potential liabilities. In addition, if any of our product candidates are approved for marketing, we may seek additional insurance coverage. If we are unable to obtain insurance at acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may harm our business. These liabilities could prevent or interfere with our product commercialization efforts. Defending a suit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity or reduced acceptance of our products in the market.

We cannot be certain we will be able to obtain patent protection to protect our product candidates and technology.

We cannot be certain that all patents applied for will be issued. In 2011, the Company received US patents for its lead compound, LB-100, as an anti-cancer agent and for the use of compounds of both the LB-100 and the LB-200 series for the prevention and treatment of neurodegenerative diseases. If a third party has also filed a patent application relating to an invention claimed by us or our licensors, we may be required to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention, which could result in substantial uncertainties and cost for us, even if the eventual outcome is favorable to us. The degree of future protection for our proprietary rights is uncertain. For example:

- we or our licensors might not have been the first to make the inventions covered by our pending or future patent applications;
- we or our licensors might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our patent applications will not result in an issued patent or patents, or that the scope of protection granted by any patents arising from our patent applications will be significantly narrower than expected;
- any patents under which we hold ultimate rights may not provide us with a basis for commercially-viable products, may not provide us with any competitive advantages or may be challenged by third parties as not infringed, invalid, or unenforceable under United States or foreign laws;
- any patent issued to us in the future or under which we hold rights may not be valid or enforceable; or
- we may develop additional proprietary technologies that are not patentable and which may not be adequately protected through trade secrets; for example if a competitor independently develops duplicative, similar, or alternative technologies.

If we are not able to protect and control our unpatented trade secrets, know-how and other technological innovation, we may suffer competitive harm.

We also rely on proprietary trade secrets and unpatented know-how to protect our research and development activities, particularly when we do not believe that patent protection is appropriate or available. However, trade secrets are difficult to protect. We will attempt to protect our trade secrets and unpatented know-how by requiring our employees, consultants and advisors to execute a confidentiality and non-use agreement. We cannot guarantee that these agreements will provide meaningful protection, that these agreements will not be breached, that we will have an adequate remedy for any such breach, or that our trade secrets will not otherwise become known or independently developed by a third party. Our trade secrets, and those of our present or future collaborators that we utilize by agreement, may become known or may be independently discovered by others, which could adversely affect the competitive position of our product candidates.

We may incur substantial costs enforcing our patents, defending against third-party patents, invalidating third-party patents or licensing third-party intellectual property, as a result of litigation or other proceedings relating to patent and other intellectual property rights.

We may not have rights under some patents or patent applications that may cover technologies that we use in our research, drug targets that we select, or product candidates that we seek to develop and commercialize. Third parties may own or control these patents and patent applications in the United States and abroad. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. We or our collaborators therefore may choose to seek, or be required to seek, a license from the third-party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or forced to cease some aspect of our business operations, as a result of patent infringement claims, which could harm our business.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. Although we are not currently a party to any patent litigation or any other adversarial proceeding, including any interference proceeding declared before the United States Patent and Trademark Office, regarding intellectual property rights with respect to our products and technology, we may become so in the future. We are not currently aware of any actual or potential third party infringement claim involving our products. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. The outcome of patent litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of the adverse party, especially in biotechnology related patent cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. If a patent or other proceeding is resolved against us, we may be enjoined from researching, developing, manufacturing or commercializing our products without a license from the other party and we may be held liable for significant damages. We may not be able to obtain any required license on commercially acceptable terms or at all.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could harm our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

If we are unable to protect our intellectual property rights, our competitors may develop and market products with similar features that may reduce demand for our potential products.

The following factors are important to our success:

- receiving patent protection for our product candidates;
- preventing others from infringing our intellectual property rights; and
- maintaining our patent rights and trade secrets.

We will be able to protect our intellectual property rights in patents and trade secrets from unauthorized use by third parties only to the extent that such intellectual property rights are covered by valid and enforceable patents or are effectively maintained as trade secrets.

Because issues of patentability involve complex legal and factual questions, the issuance, scope and enforceability of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. U.S. patents and patent applications may also be subject to interference proceedings, and U.S. patents may be subject to reexamination proceedings in the U.S. Patent and Trademark Office and foreign patents may be subject to opposition or comparable proceedings in corresponding foreign patent offices, which proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, reexamination and opposition proceedings may be costly. Thus, any patents that we own or license from others may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third-party receiving the patent rights sought by us, which in turn could affect our ability to market a potential product to which that patent filing was directed. Our pending patent applications, those that we may file in the future, or those that we may license from third parties may not result in patents being issued. If issued, they may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, others may independently develop similar technologies or duplicate any technology that we have developed. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. For example, compulsory licenses may be required in cases where the patent owner has failed to "work" the invention in that country, or the third-party has patented improvements. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patent and other intellectual property protection, which makes it difficult to stop infringement.

In addition, our ability to enforce our patent rights depends on our ability to detect infringement. It is difficult to detect infringers who do not advertise the compounds that are used in their products. Any litigation to enforce or defend our patent rights, even if we prevail, could be costly and time-consuming and would divert the attention of management and key personnel from business operations.

We will also rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. We will seek to protect this information by entering into confidentiality agreements with parties that have access to it, such as strategic partners, collaborators, employees and consultants. Any of these parties may breach these agreements and disclose our confidential information or our competitors might learn of the information in some other way. If any trade secret, know-how or other technology not protected by a patent were disclosed to, or independently developed by, a competitor, our business, financial condition and results of operations could be materially adversely affected.

If our third-party manufacturers' facilities do not follow current good manufacturing practices, our product development and commercialization efforts may be harmed.

There are a limited number of manufacturers that operate under the FDA's and European Union's good manufacturing practices regulations and are capable of manufacturing products. Third-party manufacturers may encounter difficulties in achieving quality control and quality assurance and may experience shortages of qualified personnel. A failure of third-party manufacturers to follow current good manufacturing practices or other regulatory requirements and to document their adherence to such practices may lead to significant delays in the availability of products for commercial use or clinical study, the termination of, or hold on, a clinical study, or may delay or prevent filing or approval of marketing applications for our products. In addition, we could be subject to sanctions being imposed on us, including fines, injunctions and civil penalties. Changing manufacturers may require additional clinical trials and the revalidation of the manufacturing process and procedures in accordance with FDA mandated current good manufacturing practices and will require FDA approval. This revalidation may be costly and time consuming. If we are unable to arrange for third-party manufacturing of our products, or to do so on commercially reasonable terms, we may not be able to complete development or marketing of our products.

If we fail to obtain an adequate level of reimbursement for our products by third-party payors, there may be no commercially viable markets for our products or the markets may be much smaller than expected.

The availability and levels of reimbursement by governmental and other third-party payors affect the market for our products. The efficacy, safety and cost-effectiveness of our products as well as the efficacy, safety and cost-effectiveness of any competing products will determine the availability and level of reimbursement. These third-party payors continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services. In certain countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to twelve months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct clinical trials that compare the cost-effectiveness of our products to other available therapies. If reimbursement for our products is unavailable, limited in scope or amount or if pricing is set at unsatisfactory levels, our revenues would be reduced and our results of operations would be negatively impacted.

Another development that may affect the pricing of drugs is regulatory action regarding drug reimportation into the United States. The Medicare Prescription Drug, Improvement and Modernization Act of 2003, which became law in December 2003, requires the Secretary of the U.S. Department of Health and Human Services to promulgate regulations allowing drug reimportation from Canada into the United States under certain circumstances. These provisions will become effective only if the Secretary certifies that such imports will pose no additional risk to the public's health and safety and result in significant cost savings to consumers. To date, the Secretary has made no such finding, but he could do so in the future. Proponents of drug reimportation may also attempt to pass legislation that would remove the requirement for the Secretary's certification or allow reimportation under circumstances beyond those anticipated under current law. If legislation is enacted, or regulations issued, allowing the reimportation of drugs, it could decrease the reimbursement we would receive for any products that we may commercialize, negatively affecting our anticipated revenues and prospects for profitability.

Risks Related to Capital Structure

There is no assurance of an established public trading market, which would adversely affect the ability of our investors to sell their securities in the public market.

Although our common stock is registered under the Exchange Act and our stock is traded on the OTCQB operated by the OTC Markets, an active trading market for the securities does not yet exist and may not exist or be sustained in the future. The OTCQB is an over-the-counter market that provides significantly less liquidity than the NASDAQ Stock Market. Quotes for stocks included on the OTCQB are not listed in the financial sections of newspapers as are those for the NASDAQ Stock Market. Therefore, prices for securities traded solely on the OTCQB may be difficult to obtain and holders of common stock may be unable to resell their securities at or near their original offering price or at any price. Market prices for our common stock will be influenced by a number of factors, including:

- the issuance of new equity securities pursuant to a future offering or acquisition;
- changes in interest rates;
- competitive developments, including announcements by competitors of new products or services or significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;
- variations in quarterly operating results;
- changes in financial estimates by securities analysts;
- the depth and liquidity of the market for our common stock;
- investor perceptions of our company and the medical device industry generally; and
- general economic and other national conditions.

Shares eligible for future sale may adversely affect the market price of our common stock, as the future sale of a substantial amount of outstanding stock in the public marketplace could reduce the price of our common stock.

Dr. John Kovach, our current Chief Executive Officer, received shares of our stock in a reverse merger effective June 30, 2006. He is currently eligible to sell some of his shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144 promulgated under the Securities Act ("Rule 144"), subject to certain limitations. Rule 144 also permits the sale of securities, without any limitations, by a non-affiliate that has satisfied a six-month holding period. Any substantial sale of common stock pursuant to Rule 144 may have an adverse effect on the market price of our common stock by creating an excessive supply. In this connection, from June 30, 2006 through December 31, 2014, we have sold an aggregate of 11,550,215 shares of common stock in private placements, 600,000 shares were issued for services, 81,036 shares were issued as a result of the exercise of stock options, and 10,224,884 shares were issued as a result of the exercise of stock warrants. All of these shares are currently eligible to be sold under Rule 144.

Our common stock is considered a "penny stock" and may be difficult to sell.

Our common stock is considered to be a "penny stock" since it meets one or more of the definitions in Rules 15g-2 through 15g-6 promulgated under Section 15(g) of the Exchange Act. These include but are not limited to the following: (i) the stock trades at a price less than $5.00 per share; (ii) it is NOT traded on a "recognized" national exchange; (iii) it is NOT quoted on the NASDAQ Stock Market, or even if so, has a price less than $5.00 per share; or (iv) it is issued by a company with net tangible assets less than $2.0 million, if in business more than a continuous three years, or with average revenues of less than $6.0 million for the past three years. The principal result or effect of being designated a "penny stock" is that securities broker-dealers cannot recommend the stock but must trade in it on an unsolicited basis.

Additionally, Section 15(g) of the Exchange Act and Rule 15g-2 promulgated thereunder by the SEC require broker-dealers dealing in penny stocks to provide potential investors with a document disclosing the risks of penny stocks and to obtain a manually signed and dated written receipt of the document before effecting any transaction in a penny stock for the investor's account.

Potential investors in our common stock are urged to obtain and read such disclosure carefully before purchasing any shares that are deemed to be "penny stock." Moreover, Rule 15g-9 requires broker-dealers in penny stocks to approve the account of any investor for transactions in such stocks before selling any penny stock to that investor. This procedure requires the broker-dealer to: (i) obtain from the investor information concerning his or her financial situation, investment experience and investment objectives; (ii) reasonably determine, based on that information, that transactions in penny stocks are suitable for the investor and that the investor has sufficient knowledge and experience as to be reasonably capable of evaluating the risks of penny stock transactions; (iii) provide the investor with a written statement setting forth the basis on which the broker-dealer made the determination in (ii) above; and (iv) receive a signed and dated copy of such statement from the investor, confirming that it accurately reflects the investor's financial situation, investment experience and investment objectives. Compliance with these requirements may make it more difficult for holders of our common stock to resell their shares to third parties or to otherwise dispose of them in the market or otherwise.

Our principal stockholder has significant influence over our company.

Dr. John Kovach, our principal stockholder and our Chief Executive Officer, beneficially owns approximately 37.6% of our outstanding common stock (the Company's only voting security currently issued and outstanding). As a result, Dr. Kovach possesses significant influence, giving him the practical ability, among other things, to elect all of the members of the Board of Directors and to approve significant corporate transactions. Such stock ownership and control may also have the effect of delaying or preventing a future change in control, impeding a merger, consolidation, takeover or other business combination or discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

The Company conducts the preclinical research required for bringing a compound to clinical trial at contract research organizations. The Company maintains a single office in a designated area of Dr. Kovach's residence and receives mail at the post office depot, 248 Route 25A, No. 2, East Setauket, New York 11733. Management does not believe that any additional facilities are needed at this time.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock trades on the OTCQB under the symbol "LIXT". There is very limited trading of our stock on the OTCQB. The stock market in general has experienced extreme stock price fluctuations in the past few years. In some cases, these fluctuations have been unrelated to the operating performance of the affected companies. Many companies have experienced dramatic volatility in the market prices of their common stock. We believe that a number of factors, both within and outside our control, could cause the price of our common stock to fluctuate, perhaps substantially. Factors such as the following could have a significant adverse impact on the market price of our common stock:

- Our ability to obtain additional financing and, if available, the terms and conditions of the financing;
- Our financial position and results of operations;
- Concern as to, or other evidence of, the safety or efficacy of any future proposed products and services or our competitors' products and services;
- Announcements of technological innovations or new products or services by us or our competitors;
- U.S. and foreign governmental regulatory actions;
- The development of litigation against us;
- Period-to-period fluctuations in our operating results;
- Changes in estimates of our performance by any securities analysts;
- Possible regulatory requirements on our business;
- The issuance of new equity securities pursuant to a future offering;
- Changes in interest rates;
- Competitive developments, including announcements by competitors of new products or services or significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;
- Variations in quarterly operating results;
- Change in financial estimates by securities analysts;
- The depth and liquidity of the market for our common stock;
- Investor perceptions of us; and
- General economic and other national conditions.

The following table sets forth the range of reported closing prices of the Company's common stock during the periods presented. Such quotations reflect prices between dealers in securities and do not include any retail mark-up, markdown or commissions, and may not necessarily represent actual transactions.

	High	Low
Year Ended December 31, 2013		
First Quarter	$ 0.74	$ 0.25
Second Quarter	$ 0.35	$ 0.20
Third Quarter	$ 0.83	$ 0.50
Fourth Quarter	$ 0.71	$ 0.20

	High	Low
Year Ended December 31, 2014		
First Quarter	$ 0.21	$ 0.07
Second Quarter	$ 0.55	$ 0.15
Third Quarter	$ 0.49	$ 0.11
Fourth Quarter	$ 0.49	$ 0.10

Holders

As of March 20, 2015, there were 45,575,814 shares of our common stock outstanding, held by approximately 84 stockholders of record. This does not include an indeterminate number of beneficial owners of securities whose shares are held in the names of various brokerage firms and clearing agencies.

Dividends

Our dividend policy will be determined by our Board of Directors and will depend upon a number of factors, including our financial condition and performance, our cash needs and expansion plans, income tax consequences, and the restrictions that applicable laws and any credit or other contractual arrangements may then impose. We have not paid any cash dividends on our common stock and at the current time we do not anticipate paying a cash dividend on our common stock in the foreseeable future.

Securities Authorized For Issuance Under Equity Incentive Plans

Set forth in the table below is information regarding awards made through compensation plans or arrangements through December 31, 2014, the most recently completed fiscal year.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column 2)
	(1)	(2)	(3)
Equity Compensation Plans Approved by Security Holders	N/A	$ N/A	N/A
Equity Compensation Plans Not Approved by Security Holders	6,850,000	$ 0.52	1,850,000(1)

(1) Represents shares available under the Company's 2007 Stock Option Plan.

ITEM 6. SELECTED FINANCIAL DATA

Not Applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

Lixte Biotechnology Holdings, Inc., a Delaware corporation, including its wholly-owned Delaware subsidiary, Lixte Biotechnology, Inc. (collectively, the "Company") is engaged in research and development activities with respect to anti-cancer treatments and other common non-malignant diseases. The Company has not yet commenced any revenue-generating operations, does not have any cash flows from operations, and is dependent on debt and equity funding to finance its operations.

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

Recent Developments

On March 6, 2015, the Company advised holders of its outstanding common stock purchase warrants that it would extend the expiration date of the warrants, all of which are currently scheduled to expire on March 31, 2015, to April 15, 2015, and that it would reduce the cash exercise prices of the warrants by 50%. Warrants are currently outstanding to acquire a total of 2,928,800 shares of common stock, of which 1,075,000 warrants are exercisable at $0.75 per share and 1,853,800 warrants are exercisable at $0.50 per share. If all of the outstanding warrants are exercised, the Company would receive cash proceeds of $866,575 and the Company would issue 2,928,800 shares of common stock, reflecting an average exercise price of approximately $0.30 per share. The Company expects to record a charge to operations of approximately $200,000 during the three months ending March 31, 2015 with respect to the extension of the warrants and the reduction in the warrant exercise price.

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

Effective March 17, 2015, the Company entered into a Securities Purchase Agreement with a current stockholder of the Company who owned 10.6% of the Company's issued and outstanding shares of common stock immediately prior to the financing transaction, pursuant to which such stockholder purchased 175,000 shares of the Company's non-voting Series A Convertible Preferred Stock (the "Preferred Shares") at a price per share of $10.00, representing an aggregate purchase price of $1,750,000. The Preferred Shares have a dividend of 1% of the annual net revenue of the Company until converted or redeemed. Each of the Preferred Shares may be converted, at the option of the holder, into 12.5 shares of common stock (subject to customary anti-dilution provisions) and the Preferred Shares are subject to mandatory conversion at the conversion rate in the event of a merger or sale transaction resulting in gross proceeds to the Company of at least $21,875,000. If fully converted, the Preferred Shares would convert into 2,187,500 shares of common stock, representing an effective price per share of common stock of $0.80. On the effective date of the transaction, the closing price of the Company's common stock was $0.25 per share. The Company has the right to redeem the Preferred Shares up to the fifth anniversary of the closing date at a price per share equal to $50.00. The Company will account for the Preferred Shares as a component of shareholders' equity.

The following table sets forth the condensed consolidated balance sheet of the Company as of December 31, 2014 on an as reported basis and on an unaudited pro forma basis, giving effect to the sale on March 17, 2015, of 175,000 shares of the Company's Series A Convertible Preferred Stock at a price of $10.00 per share, representing an aggregate purchase price of $1,750,000, and the conversion of $92,717 of advances to the Company by Dr. John Kovach, the Company's Chief Executive Officer, into 92,717 shares of the Company's common stock, also on March 17, 2015.

	Actual - As Reported	Pro Forma - As Adjusted (Unaudited)
ASSETS		
Total current assets	$ 539,299	$ 2,289,299
Total assets	$ 539,299	$ 2,289,299
LIABILITIES AND STOCKHOLDERS' EQUITY		
Total current liabilities	$ 273,437	$ 180,720
Total liabilities	273,437	180,720
STOCKHOLDERS' EQUITY		
Series A convertible preferred stock, $0.0001 par value, $10.00 per share stated value, $50.00 per share redemption value; aggregate dividend equal to 1% of annual net revenue; aggregate redemption value of $8,750,000; liquidation preference based on conversion to common shares; preferred shares authorized: 175,000; preferred shares issued and outstanding: 175,000; common shares issuable upon conversion at 12.5 common shares per share of preferred stock: 2,187,500 shares, as adjusted	—	1,750,000
Common stock, $0.0001 par value, authorized – 100,000,000 shares; issued and outstanding – 45,483,097 shares, as reported, and 45,575,814 shares, as adjusted	4,548	4,557
Additional paid-in capital	15,979,475	16,072,183
Accumulated deficit	(15,718,161)	(15,718,161)
Total stockholders' equity	265,862	2,108,579
Total liabilities and stockholders' equity	$ 539,299	$ 2,289,299

Going Concern

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

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

At December 31, 2014, the Company had not yet commenced any revenue-generating operations. All activity through December 31, 2014 has been related to the Company's capital raising efforts and research and development activities. As such, the Company has yet to generate any cash flows from operations, and is dependent on debt and equity funding from both related and unrelated parties to finance its operations.

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

At December 31, 2014, the Company had cash and money market funds aggregating $258,110. As a result of the Company receiving $1,750,000 from the sale of shares of preferred stock effective March 17, 2015, the Company believes that it has sufficient funds to complete the ongoing Phase 1 clinical trial of its lead anti-cancer compound LB-100 and to fund its ongoing operating expenses, including maintaining its patent portfolio, through June 30, 2016.

The amount and timing of future cash requirements will depend on the pace of the Company's clinical programs, in particular the completion of the Phase 1 clinical trial of LB-100. The Company expects that it will need to raise additional capital no later than mid-2016, likely in the form of equity, to fund operations, including the continuing costs of its clinical trial program and to maintain its patent portfolio. However, academic investigators have recently published pre-clinical data suggesting that LB-100 alone and/or in combination with standard treatments may be useful in the treatment of two different hematologic cancers. As the single agent dose of LB-100 is expected to be determined by June 30, 2015, the Company may consider raising additional funds during 2015 for the conduct of a Phase 1b/II clinical trial of LB-100 in a hematologic malignancy before the Company completes Part 2 of the current Phase 1 clinical trial.

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

Recent Accounting Pronouncements

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

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

In August 2014, the FASB issued Accounting Standards Update No. 2014-15 (ASU 2014-15), *Presentation of Financial Statements – Going Concern (Subtopic 205-10)* . ASU 2014-15 provides guidance as to management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. In connection with preparing financial statements for each annual and interim reporting period, an entity's management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). Management's evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued (or at the date that the financial statements are available to be issued when applicable). Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or available to be issued). ASU 2014-15 is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The Company is currently evaluating the impact the adoption of ASU 2014-15 on the Company's financial statement presentation and disclosures.

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

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

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

Concentration of Risk

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

On September 21, 2012, the Company entered into a work order agreement with Theradex Systems, Inc. ("Theradex"), the CRO responsible for the clinical development of the Company's lead compound, LB-100, to manage and administer the Phase 1 clinical trial of LB-100. Dr. Robert B. Royds, the founder, Chairman of the Board of Directors and Medical Director of Theradex, had been previously appointed to the Company's Board of Directors on May 2, 2011 and died on March 23, 2013. The Phase 1 clinical trial of LB-100, which began during April 2013 with the entry of patients into the clinical trial, is being carried out by nationally recognized comprehensive cancer centers, and is estimated to be completed by June 30, 2016. The Phase 1 clinical trial is estimated to cost approximately $2,615,000, with such payments expected to be allocated approximately 60% for services provided by Theradex and approximately 40% for pass-through costs for clinical center laboratory costs and investigator costs. Total costs charged to operations through December 31, 2014 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, totaled $702,255, of which $423,534 and $278,721 were incurred during the years ended December 31, 2014 and 2017, respectively, or approximately 38% and 32% of research and development costs for the years ended December 31, 2014 and 2013, respectively. The costs charged to operations for amounts paid to or through Theradex for services relating to the Phase 1 clinical trial of LB-100 are expected to represent a larger percentage of total research and development costs during the fiscal years ending December 31, 2015 and 2016 as compared to prior fiscal years. Costs pursuant to this agreement are included in research and development costs in the Company's consolidated statements of operations.

Critical Accounting Policies and Estimates

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

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

Research and Development

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

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

Patent Costs

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

Stock-Based Compensation

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

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

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

The fair value of stock-based compensation is determined utilizing the Black-Scholes option-pricing model, and is affected by several variables, the most significant of which are the life of the equity award, the exercise price of the security as compared to the fair market value of the common stock on the grant date, and the estimated volatility of the common stock over the term of the equity award.

The Company recognizes the fair value of stock-based compensation awards in general and administrative costs and in research and development costs, as appropriate, in the Company's statement of operations.

Income Taxes

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

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

Plan of Operation

General Overview of Plans

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

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

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

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

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

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

Operating Plans

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

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

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

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

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

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

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

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

The Company's primary objective has been to bring one lead compound of the LB-100 series to clinical trial. In 2012, the Company completed the pre-clinical studies needed to prepare an Investigational New Drug ("IND") application to the United States Food and Drug Administration ("FDA") to conduct a Phase 1 clinical trial of LB-100, and engaged the CRO responsible for the clinical development of the Company's lead compound, LB-100, to prepare an IND application for filing with the FDA. This task included preparing the detailed clinical protocol known as the "Investigator's Brochure", a document containing a detailed summary of all that is known about LB-100, and development of the formal IND application for submission to the FDA. The CRO also established the procedures for assuring appropriate collection and reporting of data generated during the clinical trial of LB-100 to the FDA.

The Company filed an IND application with the FDA on April 30, 2012, and on July 24, 2012, the FDA notified the Company that it would allow initiation of a Phase 1 clinical trial of LB-100. The purpose of the clinical trial is to demonstrate that LB-100 can be administered safely to human beings at a dose and at a frequency that achieves the desired pharmacologic effect; in this case, inhibition of a specific enzyme, without being associated with toxicities considered unacceptable. The Phase 1 clinical trial of LB-100 is divided into two parts: the first part is designed to determine the maximum tolerable dose of LB-100 given alone, and the second part is designed to determine the maximum tolerable dose of LB-100 in combination with a standard widely used anti-cancer drug, docetaxel, a well-established anti-mitotic chemotherapy medication approved by the FDA for the treatment of various cancers. 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 first part of the Phase 1 clinical trial is 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 (NCTO 1837667 at www.clinicaltrials.gov) and was initiated at the City of Hope National Medical Center in Duarte, California, and was extended in December 2013 to include the Mayo Clinic in Rochester, Minnesota, both of which are Comprehensive Cancer Centers designated by the National Cancer Institute. As the accrual of patients was slower than anticipated, in October 2014 the Company entered into a Clinical Research Agreement ("CRA") with US Oncology Research, LLC, a large community-based research network based in Texas, to increase the rate of entry of patients into the ongoing clinical trial by adding four more active clinical oncologic research sites.

The Company originally estimated that the Phase 1 clinical trial of LB-100 would be completed during the quarter ending June 30, 2015 at a total cost of approximately $2,038,000. The Company currently estimates that the first part of the clinical trial will be completed by June 30, 2015 and the second part of the clinical trial will be completed by June 30, 2016, at a total cost of approximately $2,615,000.

The costs of the Phase 1 clinical trial of LB-100 are being paid to or through Theradex, the CRO responsible for the clinical development of LB-100. Total costs charged to operations through December 31, 2014 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, totaled $702,255, of which $423,534 and $278,721 were incurred during the years ended December 31, 2014 and 2013, respectively. The final cost of the clinical trial is variable, depending upon the number of patients needed to be medically screened to determine if they meet the criteria for entry into the clinical trial and ultimately upon the total number of patients entered into the clinical trial to establish the proper doses of the drug for Phase 2 clinical trials.

The Phase 1 clinical trial of LB-100 is being conducted in two parts. In Part 1, the dose of LB-100 to be administered alone in a subsequent Phase 2 clinical trial is being determined, and in Part 2, the dose of LB-100, in combination with the standard cytotoxic drug docetaxel is being determined. Part 1 of the current clinical trial is anticipated to be concluded in the second quarter of 2015 and Part 2 of the current clinical trial is anticipated to be concluded in the second quarter of 2016.

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

As a compound moves through the FDA approval process, it becomes an increasingly valuable property, but at a cost of additional investment at each stage. The Company's approach has been to operate with a minimum of overhead, moving compounds forward as efficiently and inexpensively as possible, and to raise funds to support each of these stages as certain milestones are reached. The commencement of a Phase 1 clinical trial is a milestone in the Company's goal of developing a successful product platform.

Results of Operations

The Company is considered a development stage company at December 31, 2014, as the Company has not yet commenced any revenue-generating operations, does not have any cash flows from operations, and is dependent on debt and equity funding to finance its operations.

Years Ended December 31, 2014 and 2013

General and Administrative . For the year ended December 31, 2014, general and administrative costs were $1,285,173, which consisted of the vested portion of the fair value of stock options issued to directors and consultants of $775,124, consulting and professional fees of $323,544, insurance expense of $43,138, officer's salary and related costs of $67,219, stock transfer fees of $12,888, travel and entertainment costs of $19,235, filing fees of $9,173, investor relations of $8,085 and other operating costs of $26,767.

For the year ended December 31, 2013, general and administrative costs were $494,959, which consisted of the fair value of stock options issued to directors and consultants of $119,125, consulting and professional fees of $211,170, insurance expense of $37,116, officer's salary and related costs of $66,952, stock transfer fees of $9,358, travel and entertainment costs of $11,574, filing fees of $11,225, and other operating costs of $28,439.

General and administrative costs increased by $790,214 or 159.7% in 2014 as compared to 2013, primarily as a result of an increase of $655,999 in stock-based compensation and an increase of $112,374 in legal and other consulting fees.

A significant component of the fair value of stock options issued to directors and consultants of $775,124 for the year ended December 31, 2014 was the $732,699 expense for the fair value of stock options to acquire 4,000,000 shares of the Company's common stock that were issued to Gil Schwartzberg on January 28, 2014 for his continuing contributions to the Company's financial strategy.

Research and Development . For the year ended December 31, 2014, research and development costs were $1,117,970, which consisted of the vested portion of the fair value of stock options of $171,049 comprised of $52,399 for a member of the Company's Scientific Advisory Committee and $118,650 to a consultant as compensation for his contributions to the Company's compound development activities, patent costs of $342,625, and contractor costs of $604,296, including $423,534 to a related party in connection with the Phase 1 clinical trial of LB-100.

For the year ended December 31, 2013, research and development costs were $879,886, which consisted of patent costs of $405,285, contractor costs of $464,184, including $278,721 to a related party in connection with the Phase 1 clinical trial of LB-100, and consulting fees to a related party of $10,417.

Research and development costs increased by $238,084 or 27.1% in 2014 as compared to 2013, primarily as a result of an increase of $170,924 in stock-based compensation and an increase of $140,112 in contractor costs.

Fair Value of Warrant Extensions . During the year ended December 31, 2014, the Company incurred an expense of $302,691 for the fair value of extending the expiration dates of various warrants, including $78,617 for the extension of the expiration dates to June 30, 2014 for warrants to acquire 1,748,800 shares of the Company's common stock, and $224,074 for the extension of the expiration dates to March 31, 2015 for warrants to acquire 2,928,800 shares of the Company's common stock. All of the warrants that were extended were issued in conjunction with the private placement that closed in 2009 and were scheduled to expire at various times in 2014.

Fair Value of Warrant Discount . During the year ended December 31, 2014, the Company incurred an expense of $134,420 for the fair value of discounts offered to warrant holders as an inducement for the early exercise of warrants to acquire 3,900,000 shares of the Company's common stock. The discounts ranged from $0.25 to $0.375 per share. The exercise of the warrants generated net proceeds to the Company of $1,412,500 in April 2014.

Gain from Reversal of Registration Rights Penalty Obligation . At December 31, 2014, the Company recorded a gain of $74,000 from the reversal of a registration rights penalty obligation that it had previously recorded on December 31, 2006, and for which no payments had been made through December 31, 2014.

Net Loss . For the year ended December 31, 2014, the Company incurred a net loss of $2,766,188, as compared to a net loss of $1,374,842 for the year ended December 31, 2013.

Liquidity and Capital Resources – December 31, 2014

The Company's consolidated financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company is in the development stage and has not generated any revenues from operations to date, and does not expect to do so in the foreseeable future. The Company has experienced recurring operating losses and negative operating cash flows since inception, and has financed its working capital requirements through the recurring sale of its equity securities. As a result, management believes that there is substantial doubt about the Company's ability to continue as a going concern (see "Going Concern" above").

At December 31, 2014, the Company had working capital of $265,862, as compared to working capital of $236,266 at December 31, 2013, an increase in working capital of $29,596 for the year ended December 31, 2014, primarily as a result of the elimination of the $74,000 registration rights penalty obligation from the Company's balance sheet at December 31, 2014. At December 31, 2014, the Company had cash and money market funds aggregating $258,110, as compared to $481,154 at December 31, 2013, a decrease of $223,048 for the year ended December 31, 2014.

Subsequent to December 31, 2014, non-interest bearing advances of $92,717 due to the Company's Chairman and major stockholder, which were included in current liabilities in the Company's consolidated balance sheets, were converted into 92,717 shares of the Company's common stock. The Company also received $1,750,000 from the sale of shares of preferred stock effective March 17, 2015, as a result of which the Company believes that it has sufficient funds to complete the ongoing Phase 1 clinical trial of its lead anti-cancer compound LB-100 and to fund its ongoing operating expenses, including maintaining its patent portfolio, through June 30, 2016.

The Company will need to raise additional capital by mid-2016, likely in the form of equity, to fund operations, including the continuing costs of its clinical trial program and to maintain its patent portfolio. Market conditions present uncertainty as to the Company's ability to secure additional funds. There can be no assurances that the Company will be able to secure additional financing on acceptable terms, or at all, as and when necessary to continue to conduct operations. If cash resources are insufficient to satisfy the Company's ongoing cash requirements, the Company would be required to scale back or discontinue its technology and product development programs and/or clinical trials, or obtain funds, if available (although there can be no certainty), through strategic alliances that may require the Company to relinquish rights to certain of its products, or to discontinue its operations entirely.

Operating Activities . For the year ended December 31, 2014, operating activities utilized cash of $1,635,544, as compared to utilizing cash of $1,180,102 for the year ended December 31, 2013, to support the Company's ongoing research and development activities.

Investing Activities . For the year ended December 31, 2014, investing activities consisted of an increase in money market funds of $207,564 due primarily as a result of proceeds received from the exercise of warrants in April 2014. For the year ended December 31, 2013, investing activities consisted of a $1 increase in money market funds from interest earned during the period.

Financing Activities . For the year ended December 31, 2014, financing activities consisted of $1,412,500 in proceeds received from the exercise of warrants to purchase of 3,900,000 shares of the Company's common stock in April 2014. There were no financing activities during the year ended December 31, 2013.

Principal Commitments

On September 21, 2012, the Company entered into a work order agreement with Theradex, the CRO responsible for the clinical development of the Company's lead compound, LB-100, to manage and administer the Phase 1 clinical trial of LB-100. The Phase 1 clinical trial of LB-100, which began during April 2013 with the entry of patients into the clinical trial, is being carried out by nationally recognized comprehensive cancer centers, and is estimated to be completed by June 30, 2016. The Phase 1 clinical trial is currently estimated to cost approximately $2,615,000, with such payments expected to be allocated approximately 60% for services provided by Theradex and approximately 40% for pass-through costs for clinical center laboratory costs and investigator costs. Total costs charged to operations through December 31, 2014 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, totaled $702,255, of which $423,534 and $278,721 were incurred during the years ended December 31, 2014 and 2013, respectively. Costs pursuant to this agreement are included in research and development costs in the Company's consolidated statements of operations. The final cost of the clinical trial is variable, depending upon the number of patients needed to be medically screened to determine if they meet the criteria for entry into the study and ultimately upon the total number of patients entered into the study to establish the proper doses of the drug for Phase 2 clinical trials.

On December 24, 2013, the Company entered into an agreement with NDA Consulting Corp. ("NDA") for consultation and advice in the field of oncology research and drug development. As part of the agreement, NDA agreed to cause its president, Dr. Daniel D. Von Hoff, M.D., to become a member of the Company's Scientific Advisory Committee. The term of the agreement is for one year and provides for a quarterly cash fee of $4,000. The agreement was automatically renewed on its anniversary date for an additional one year term. Consulting and advisory fees charged to operations pursuant to this agreement were $16,000 during the year ended December 31, 2014.

Effective January 1, 2014, the Company entered into an Advisory Agreement with Dr. Kathleen P. Mullinix, a member of the Board of Directors of the Company, effective for an initial term of one year through December 31, 2014 to advise on business development matters. The Advisory Agreement provides for annual cash compensation of $25,000. The term of the Advisory Agreement is automatically extended for a term of one year annually unless a notice of intent to terminate is given by either party at least 90 days before the end of the applicable term. Accordingly, the Advisory Agreement was extended for an additional term of one year effective January 1, 2015. The Company charged $25,000 to operations for services provided under this agreement during the year ended December 31, 2014, which amount was included in general and administrative costs in the Company's 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 December 31, 2014 aggregating $1,839,548, of which $150,903 is included in current liabilities in the Company's consolidated balance sheet at December 31, 2014.

		Payments Due By Year				
	Total	**2015**	**2016**	**2017**	**2018**	**2019**
Research and development contracts	$ 60,530	$ 60,530	$ —	$ —	$ —	$ —
Clinical trial agreements	1,670,301	1,020,301	650,000	—	—	—
Consulting agreements	16,000	16,000	—	—	—	—
Due to Chairman and major stockholder	92,717	92,717	—	—	—	—
Total	$ 1,839,548	$ 1,189,548	$ 650,000	$ —	$ —	$ —

Off-Balance Sheet Arrangements

At December 31, 2014, the Company did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Not Applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements and notes thereto and the related report of our independent registered public accounting firm are attached to this Annual Report beginning on page F-1.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not Applicable.

ITEM 9A(T). CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file with the SEC under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, consisting of our principal executive and financial officer (who is the same person), to allow for timely decisions regarding required disclosure. As required by SEC Rule 15d-15(b), we carried out an evaluation, under the supervision and with the participation of the our management, consisting of our principal executive and financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the most recent fiscal year covered by this report. Based on the foregoing, our principal executive and financial officer concluded that our disclosure controls and procedures are effective to ensure the information required to be disclosed in our reports filed or submitted under the Exchange Act is timely recorded, processed and reported within the time periods specified in the SEC's rules and forms.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) under the Exchange Act. Our internal control over financial reporting is designed to ensure that material information regarding our operations is made available to management and the board of directors to provide them reasonable assurance that the published financial statements are fairly presented. There are limitations inherent in any internal control, such as the possibility of human error and the circumvention or overriding of controls. As a result, even effective internal controls can provide only reasonable assurance with respect to financial statement preparation. As conditions change over time so too may the effectiveness of internal controls.

Our management, consisting of our chief executive officer and chief financial officer, has evaluated our internal control over financial reporting as of December 31, 2014 based on the framework in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations (COSO) of the Treadway Commission, as subsequently updated on May 14, 2013 and which became effective after December 15, 2014. Based on this assessment, our management has concluded that our internal control over financial reporting was effective as of December 31, 2014.

This annual report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this annual report.

Changes In Internal Control Over Financial Reporting

There were no changes in our internal controls over financial reporting during or subsequent to the fourth quarter of the year ended December 31, 2014 that materially affected or are reasonably likely to affect our internal controls over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table and text set forth the names of all directors and executive officer of our Company as of December 31, 2014. The Board of Directors is comprised of only one class. All of the directors will serve until the next annual meeting of stockholders and until their successors are elected and qualified, or until their earlier death, retirement, resignation or removal. There are no family relationships between or among the directors, executive officers or persons nominated or charged by our Company to become directors or executive officers. The executive officer serves at the discretion of the Board of Directors, and is appointed to serve until the first Board of Directors meeting following the annual meeting of stockholders. The brief descriptions of the business experience of each director and executive officer and an indication of directorships held by each director in other companies subject to the reporting requirements under the Federal securities laws are provided herein below. Also provided are the biographies of the members of the Scientific Advisory Committee.

Our directors and executive officer are as follows:

Name	Age	Position(s) Held with the Registrant
Dr. John S. Kovach	77	Chief Executive Officer, Chief Financial Officer, Director
Dr. Philip F. Palmedo	81	Director
Dr. Kathleen P. Mullinix	70	Director

Biographies of Directors and Executive Officers

Dr. John S. Kovach

Dr. John S. Kovach founded Lixte in August 2005 and is its President and a member of the Board of Directors. He received a BA (cum laude) from Princeton University and an MD (AOA) from the College of Physicians & Surgeons, Columbia University. Dr. Kovach trained in Internal Medicine and Hematology at Presbyterian Hospital, Columbia University and spent six years in the laboratory of Chemical Biology, National Institute of Arthritis and Metabolic diseases studying control of gene expression in bacterial systems.

Dr. Kovach was recruited to SUNY-Stony Brook in 2000 to found the Long Island Cancer Center (now named the Stony Brook University Cancer Center). He is presently a professor (part-time) in the Department of Preventive Medicine at SUNY-Stony Brook in Stony Brook, New York. From 1994 to 2000, Dr. Kovach was Executive Vice President for Medical and Scientific Affairs, City of Hope National Medical Center in Los Angeles, California. His responsibilities included oversight of all basic and clinical research initiatives at the City of Hope. During that time he was also Director of the Beckman Research Center at City of Hope and a member of the Arnold and Mabel Beckman Scientific Advisory Board in Newport Beach, California.

From 1976 to 1994, Dr. Kovach was a consultant in oncology and director of the Cancer Pharmacology Division at the Mayo Clinic in Rochester, Minnesota. During this time, he directed the early clinical trials program for evaluation of new anti-cancer drugs as principal investigator of contracts from the National Cancer Institute. From 1986 to 1994, he was also Chair of the Department of Oncology and Director of the NCI-designated Mayo Comprehensive Cancer Center. During that time, Dr. Kovach, working with a molecular geneticist, Steve Sommer, M.D., Ph.D., published extensively on patterns of acquired mutations in human cancer cells as markers of environmental mutagens and as potential indicators of breast cancer patient prognosis. Dr. Kovach has published over 100 articles on the pharmacology, toxicity, and effectiveness of anti-cancer treatments and on the molecular epidemiology of breast cancer. Dr. Kovach directs the Company with the approval of the State University of New York at Stony Brook and the New York State Ethics Commission.

Dr. Philip F. Palmedo

Philip F. Palmedo, Ph.D., is a physicist, entrepreneur, and corporate manager. Dr. Palmedo joined our board of directors on June 30, 2006. He founded and served as Chairman of the International Resources Group (IRG), an international consultancy in energy, natural resources and economic development. IRG was bought by L3 Communications in 2008. Dr. Palmedo designed and was the first President of the Long Island Research Institute formed by Brookhaven National Laboratory, Cold Spring Harbor Laboratory, and SUNY-Stony Brook to facilitate the commercialization of technologies. In 1988, Dr. Palmedo joined in the formation of Kepler Financial Management, Ltd., a quantitative financial research and trading company. He was President and Managing Director until 1991, when Renaissance Technologies Corporation acquired the company.

Dr. Palmedo served on the boards of Asset Management Advisors, the Teton Trust Company, EHR Investments and C-Quest Capital, and is currently a member of the Board of Directors of the Gyrodyne Corporation of America. He also served on the Board of Trustees of Williams College and of the Stony Brook (University) Foundation, where he chaired the Foundation's Investment Committee.

Dr. Kathleen P. Mullinix

Effective September 16, 2012, the Company elected Kathleen P. Mullinix, Ph.D., to its Board of Directors. Trained as a chemist, Dr. Mullinix is an outstanding scientist and accomplished executive with senior management experience in the commercial, governmental and academic sectors. She was assistant director of the intramural research program at the National Institutes of Health, working with the deputy director for science and the director of NIH on strategic matters concerning the scientific directions of the intramural program from 1979 to 1981. Subsequently, she became vice provost of Columbia University, New York City, and established the Science and Technology Development Office to commercialize the Columbia University's intellectual properties. Dr. Mullinix developed commercialization strategies and negotiated license agreements for Columbia University intellectual property that generated over $2 billion. She founded Synaptic Pharmaceutical Corporation in 1987, and as its President and Chief Executive Officer led the company from its inception as a research-driven biotechnology company to a public pharmaceutical company with over 150 employees. She secured over $80 million from pharmaceutical collaborations and a comparable amount in venture capital and public equity investment. Synaptic Pharmaceutical Corporation was sold to Lundbeck A/S. From 2003 to 2006, Dr. Mullinix was an independent consultant on health sciences and biotechnology, and in 2008 joined WellGen, Inc., a research company at Rutgers University, as Chief Executive Officer, President and Director. She restructured and implemented research strategies to generate intellectual property, moving the company into the New Jersey Economic Development Authority Incubator. Subsequently, she continued her consulting, joining the Office of Technology and Business Development at Mount Sinai School of Medicine in New York in 2009. She became director of that office in 2010 and served until 2012, during which period she was responsible for developing a novel structure and business model to develop research collaborations with pharmaceutical companies and to enhance the intellectual property portfolio.

SCIENTIFIC ADVISORY COMMITTEE

The Scientific Advisory Committee (the "Committee"), which is not part of management, advises us in three areas: human molecular pathology; the clinical management of human brain tumors; and medicinal chemistry. It is planned that the Committee meet as a group annually, with some members participating via telephone conference. Thus far, the Committee has been apprised of our general objectives and several of the specific challenges and leads for developing improved therapies for human brain tumors. The Committee members have not provided specific advice thus far that has modified strategy nor do they serve in any management capacity. The Committee was formalized on June 30, 2006. The members of our Committee are:

Arndt Hartmann, M.D.

Dr. Hartmann is Professor of Pathology, Institute of Pathology, University of Regensburg, Germany. He was trained in Internal Medicine at the University of Jena, Germany, and in molecular genetics of cancer at Mayo Clinic, Rochester, Minnesota. He was subsequently trained in pathology at the University of Regensburg and the University of Basel, Switzerland. His research is focused on methods development in molecular pathology. He has specific expertise in genetic alterations in cancers of the bladder, prostate, kidney and breast.

Ferdinand Hofstadter, M.D.

Dr. Hofstadter is Professor and Director of the Institute of Pathology, University of Regensburg Medical School, Germany. He is Research Dean of the University of Regensburg-Medical Faculty, Chairman of the Managing Board of the Association of German Tumor Centers, Chairman of the German Society for Pathology, a member of the editorial boards of Virchow's Archives and the Journal of Pathology, and a referee for Deutsche Forschungsgesellschaft, the Dr. Mildred Scheel-Stiftung, EU, and the European Research Framework Program.

Iwao Ojima, B.S., M.S., Ph.D.

Professor Ojima is Distinguished Professor of Chemistry and Director, Institute of Chemical Biology and Drug Discovery, SUNY-Stony Brook. He is an internationally recognized expert in medicinal chemistry, including anticancer agents and enzyme inhibitors, development of efficient synthetic methods for organic synthesis by means of organometallic reagents, homogeneous catalysis and organometallic chemistry, peptide and peptide mimetics, beta-lactam chemistry, and organoflourine chemistry at the biomedical interface.

Dr. Ojima is a recipient of the Arthur C. Cope Scholar Award (1994) and the E. B. Hershberg Award (for important discovery of medicinally active substances) (2001) from the American Chemical Society; The Chemical Society of Japan Award (for distinguished achievements) (1999); Outstanding Inventor Award from the Research Foundation of the State University of New York (2002. He is a Fellow of the J.S. Guggenheim Memorial Foundation (1995-), the American Association for the Advancement of Science (1997-), and The New York Academy of Sciences (2000-).

Dr. Ojima is a member of the American Chemical Society, American Association for the Advancement of Science, American Association for Cancer Research, American Peptide Society, the Chemical Society of Japan, the Society of Synthetic Organic Chemistry, Japan, New York Academy of Sciences, and Signa Xi. He has served as a consultant for E. I. du Pont, Eli Lilly, Air Products & Chemicals, Mitsubishi Chem. Inc., Nippon Steel Corp., Life Science Division, Rhone-Poulenc Rorer, ImmunoGen, Inc., Taiho Pharmaceutical Co., Milliken & Co., Aventis Pharma, OSI Pharmaceuticals, Inc. and Mitsubishi Chem. Corp. (current).

Daniel D. Von Hoff, M.D., F.A.C.P.

Dr. Von Hoff is currently Physician in Chief, Distinguished Professor and Director of Clinical Translational Research Division at TGen (Translational Genomics Research Institute) in Phoenix, Arizona. He is also Chief Scientific Officer for US Oncology and for Scottsdale Healthcare's Clinical Research Institute. He holds an appointment as Professor of Medicine, Mayo Clinic, Scottsdale, Arizona.

Dr. Von Hoff's major interest is in the development of new anticancer agents, both in the clinic and in the laboratory. He and his colleagues were involved in the beginning of the development of many of the agents we now use routinely, including mitoxantrone, fludarabine, paclitaxel, docetaxel, gemcitabine, irinotecan, nelarabine, capecitabine, lapatinib and others. At present, he and his colleagues are concentrating on the development of molecularly targeted therapies, particularly for patients with advanced pancreatic cancer.

Dr. Von Hoff has published more than 620 papers, 137 book chapters and over 1050 abstracts. Dr. Von Hoff received the 2010 David A. Karnofsky Memorial Award from the American Society of Clinical Oncology for his outstanding contributions to cancer research leading to significant improvement in patient care.

Dr. Von Hoff was appointed to President Bush's National Cancer Advisory Board in 2004-2010. Dr. Von Hoff is the past President of the American Association for Cancer Research (the world's largest cancer research organization), a Fellow of the American College of Physicians, and a member and past board member of the American Society of Clinical Oncology. He is a founder of ILEX™ Oncology, Inc. (acquired by Genzyme after Ilex had two agents, alemtuzumab and clofarabine, approved by the FDA for patients with leukemia). Dr. Von Hoff is founder and the Editor Emeritus of Investigational New Drugs – The Journal of New Anticancer Agents; and, Editor-in-Chief of Molecular Cancer Therapeutics. He is a co-founder of the AACR/ASCO Methods in Clinical Cancer Research Workshop.

Audit Committee

We do not presently have an audit committee. The Board of Directors acts in that capacity and has determined that we do not currently have a person qualifying as an audit committee financial expert serving on our board.

Code of Ethics

Our Board of Directors adopted a code of ethics covering all of our executive officers and key employees. A copy of our code of ethics will be furnished without charge to any person upon written request. Requests should be sent to: Secretary, Lixte Biotechnology Holdings, Inc., 248 Route 25A, No. 2, East Setauket, New York 11733.

Compliance with Section 16(a) of the Securities Exchange Act of 1934, as Amended:

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires the Company's directors and executive officers and persons who own more than 10% of a registered class of the Company's equity securities to file various reports with the Securities and Exchange Commission concerning their holdings of, and transactions in, securities of the Company. Copies of these filings must be furnished to the Company.

To the Company's knowledge based solely on its review of the copies of the Section 16(a) reports furnished to the Company and written representations to the Company that no other reports were required, the Company believes that all individual filing requirements applicable to the Company's directors and executive officers were complied with under Section 16(a) during 2014.

ITEM 11. EXECUTIVE COMPENSATION

Option Grants in 2013 and 2014 - Named Executive Officer

None.

Aggregated Option Exercises in 2013 and 2014 Option Values at December 31, 2013 and at 2014 - Named Executive Officer

None.

Employment Agreements; Compensation

We have not entered into any employment agreements with management. During the years ended December 31, 2014 and 2013, we did not have any full-time employees.

During the years ended December 31, 2014 and 2013, the Company paid Dr. Kovach, the Company's Chief Executive Officer and Chief Financial Officer, an annual salary of $60,000. Over the past few years, Dr. Kovach has reduced his academic commitment from 80% to 50% in order to devote sufficient time to the Company's business activities.

Dr. Kovach is not compensated separately for his service on the Board of Directors. Dr. Kovach is reimbursed for out-of-pocket expenses.

Any future compensation arrangements will be subject to the approval of the Board of Directors.

Consulting Agreements

See "ITEM 16. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS, AND DIRECTOR INDEPENDENCE – Related Party Transactions" for disclosures with respect to consulting agreements involving directors and related parties.

Board of Director Compensation

On June 30, 2011, the Company granted to Dr. Philip F. Palmedo, a director of the Company, stock options to purchase 200,000 shares of common stock, exercisable for a period of five years from the date of grant at $0.98 per share, which was the fair market value of the Company's common stock on such date. The options vest ratably in equal quarterly installments of 25,000 shares beginning July 1, 2011. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be $196,000 ($0.98 per share).

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. Dr. Royds died on March 23, 2013 and the stock options expired unexercised on March 23, 2014.

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).

DIRECTOR COMPENSATION TABLE

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)	Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)(2)	Total ($)
Philip F. Palmedo	2014	0	0	0	0	0	0	0	0
Director	2013	0	0	0	0	0	0	0	0
	2012	0	0	0	0	0	0	0	0
Mel Sorensen	2014	0	0	0	0	0	0	-	-
Director (3)	2013	0	0	0	0	0	0	10,417	10,417
	2012	0	0	0	0	0	0	21,875	21,875
Robert B. Royds	2013	0	0	0	0	0	0	0	0
Director (4)	2014	0	0	0	0	0	0	0	0
Kathleen P. Mullinix	2014	0	0	0	0	0	0	0	0
Director	2013	0	0	0	0	0	0	0	0
	2012	0	0	0	118,000	0	0	0	118,000

(1) Consists of grant date fair value of option award calculated pursuant to the Black-Scholes option-pricing model.

(2) All other compensation was paid in the form of cash.

(3) Dr. Sorensen resigned from the Company's Board of Directors for personal reasons on April 16, 2014.

(4) Dr. Royds died on March 23, 2013.

Scientific Advisory Committee Compensation

On June 30, 2011, the Company granted to Dr. Iwao Ojima, a member of the Company's Scientific Advisory Committee, 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).

On December 24, 2013, the Company entered into an agreement with NDA Consulting Corp. ("NDA") for consultation and advice in the field of oncology research and drug development. As part of the agreement, NDA agreed to cause its president, Dr. Daniel D. Von Hoff, M.D., to become a member of the Company's Scientific Advisory Committee. In connection with this agreement, NDA was granted stock options to purchase 100,000 shares of the Company's common stock, vesting 25,000 shares on June 24, 2014, and thereafter 25,000 shares annually on June 24, 2015, 2016 and 2017, exercisable for a period of five years from the date of grant at $0.13 per share, which was the fair market value of the Company's common stock on the grant date. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be $12,960 ($0.13 per share).

On July 15, 2014, Gil Schwartzberg, a significant stockholder of and consultant to the Company, assigned fully-vested stock options to acquire 1,000,000 shares of the Company's common stock to Daniel Von Hoff, a member of the Company's Scientific Advisory Committee. The options assigned included options to acquire 500,000 shares that had been previously granted to Mr. Schwartzberg on October 15, 2009, were exercisable at $1.00 per share, and expired on October 15, 2014, and options for 500,000 shares that had been previously granted to Mr. Schwartzberg on October 5, 2011, are exercisable at $1.00 per share, and expire on October 5, 2016. As Mr. Schwartzberg is considered an affiliate of the Company for accounting and securities purposes, the fair value of the stock options assigned by Mr. Schwartzberg to Mr. Von Hoff for the benefit of the Company was recorded as a contribution to capital and a charge to operations. The fair value of the stock options assigned, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $43,500 (average of $0.04 per share). The remaining unexpired options to acquire 500,000 shares were transferred back to Mr. Schwartzberg in February 2015.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth, as of March 20, 2015 certain information regarding beneficial ownership of our common stock (the only class of the Company's voting equity securities issued and outstanding) by (i) each person or entity who is known by us to own beneficially more than 5% of the outstanding shares of common stock, (ii) each of our directors, and (iii) all directors and executive officers as a group. As of March 20, 2015, there were 45,575,814 shares of our common stock issued and outstanding. In computing the number and percentage of shares beneficially owned by a person, shares of common stock that a person has a right to acquire within sixty (60) days of March 20, 2015 pursuant to options, warrants, convertible preferred stock or other rights are counted as outstanding, while these shares are not counted as outstanding for computing the percentage ownership of any other person. Unless otherwise indicated, the address for each stockholder listed in the following table is c/o Lixte Biotechnology Holdings, Inc., 248 Route 25A, No. 2, East Setauket, New York 11733. This table is based upon information supplied by the Company's directors, officers and principal stockholders and reports filed with the Securities and Exchange Commission.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percent of Class
Officers, Directors and 5% stockholders		
Dr. John S. Kovach 248 Route 25A, No. 2 East Setauket, New York 11733	17,114,503[7]	37.6%
Dr. Philip F. Palmedo 248 Route 25A, No. 2 East Setauket, New York 11733	1,266,020[1]	2.7%
Dr. Kathleen P. Mullinix 248 Route 25A, No. 2 East Setauket, New York 11733	200,000[4]	0.4%
All officers and directors as a group (three persons)	18,580,523[1][4][7]	40.2%
Gil Schwartzberg 5500 M ilitary T rail, S uite 22 J upiter, F lorida 33458	8,572,697[2]	17.3%
Dr. Debbie Schwartzberg 5500 M ilitary T rail, S uite 22 J upiter, F lorida 33458	6,838,845[3]	14.2%
Dr. Arthur and Jane Riggs 4852 Saint Andres Avenue La Verne, California 91750	7,037,500[5]	14.7%
Robert and Susan Greenberg 228 Manhattan Beach Boulevard Manhattan Beach, California 90266	3,650,000[6]	8.0%

(1) Consists of 700,000 shares of common stock and warrants to purchase 300,000 shares of common stock owned by the Philip Palmedo Partnership, and 66,020 shares of common stock and options to purchase 200,000 shares of common stock owned by Dr. Palmedo. Dr. Palmedo is the general partner of the Philip Palmedo Partnership and has full voting, disposition and investment control as to such shares. All options and warrants are immediately exercisable or within 60 days.

(2) Includes 800,800 shares of common stock, and options to purchase 3,000,000 shares of common stock owned by Mr. Schwartzberg. Also includes 834,782 shares of common stock owned by the Gil Schwartzberg IRA; 603,115 shares of common stock owned by Continuum Capital Partners, LP, as to which Mr. Schwartzberg has sole voting, disposition and investment control; 1,184,000 shares of common stock and options to purchase 500,000 shares of common stock owned by the Julie Schwartzberg Trust, as to which Mr. Schwartzberg is the co-trustee; and 1,150,000 shares of common stock and options to purchase 500,000 shares of common stock owned by the David N. Sterling Trust, as to which Mr. Schwartzberg is the co-trustee. Excludes 1,504,845 shares of common stock, options to purchase 500,000 shares of common stock, and warrants to purchase 500,000 shares of common stock owned directly by Debbie Schwartzberg, the wife of Mr. Schwartzberg, as to which Mr. Schwartzberg disclaims beneficial ownership or control; and 500,000 shares of common stock by the Debbie Schwartzberg Family Trust. All options and warrants are immediately exercisable or within 60 days.

(3) Includes 1,504,845 shares of common stock, options to purchase 1,000,000 shares of common stock, and warrants to purchase 500,000 shares of common stock owned by Ms. Schwartzberg. Also includes 500,000 shares of common stock owned by the Debbie Schwartzberg Family Trust; 1,184,000 shares of common stock and options to purchase 500,000 shares of common stock owned by the Julie Schwartzberg Trust, as to which Ms. Schwartzberg is the co-trustee; and 1,150,000 shares of common stock and options to purchase 500,000 shares of common stock owned by the David N. Sterling Trust, as to which Ms. Schwartzberg is the co-trustee. Excludes 800,800 shares of common stock, and options to purchase 3,000,000 shares of common stock owned by Mr. Schwartzberg, the husband of Ms. Schwartzberg. Also excludes 834,782 shares of common stock owned by the Gil Schwartzberg IRA, and 603,115 shares of common stock owned by Continuum Capital Partners, LP, as to which Mr. Schwartzberg has sole voting, disposition and investment control. All options and warrants are immediately exercisable.

(4) Consists of options to purchase 200,000 shares of common stock, all of which are immediately exercisable or within 60 days.

(5) Includes 4,850,000 shares of common stock and 2,187,500 shares of common stock issuable upon conversion of 175,000 shares of Series A Convertible Preferred Stock owned by the Arthur and Jane Riggs 1990 Revocable Trust. The shares of Series A Convertible Preferred Stock were issued on March 17, 2015 and are immediately convertible into common stock.

(6) Consists of 3,650,000 shares of common stock owned by the Robert and Susan Greenberg Family Trust.

(7) Includes 92,717 shares of common stock issued upon conversion of amounts owed to Dr. John S. Kovach on March 17, 2015.

Information with respect to securities authorized for issuance under equity compensation plans is provided in "ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS."

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS, AND DIRECTOR INDEPENDENCE

(a) Related Party Transactions

This section describes the material transactions that we have engaged in with persons who were directors, officers or affiliates before and at the time of the transaction, and persons known by us to be the beneficial owners of 5% or more of our common stock during the years ended December 31, 2013 and 2014.

Most office services are provided without charge by Dr. Kovach, our president. Such costs are immaterial to the financial statements and accordingly, have not been reflected therein. Dr. Kovach is involved in other business activities and may, in the future, become involved in other business opportunities that become available, as a result of which he may face a conflict in selecting between us and his other business interests. We have not formulated a policy for the resolution of such conflicts.

As of December 31, 2014, Dr. Kovach had advanced an aggregate of $92,717 to the Company to meet operating expenses, all of which had been advanced at June 30, 2006. Such advances are non-interest bearing and are due on demand. Subsequent to December 31, 2014, Dr. Kovach converted such advances into 92,717 shares of the Company's common stock, reflecting an effective price of $1.00 per share, which was in excess of the quoted market price of the Company's common stock on the date of conversion.

On January 28, 2014, the Company approved a second amendment to the Company's consulting agreement with Gil Schwartzberg, a significant stockholder of and consultant to the Company, dated September 12, 2007 to extend it for an additional four years to January 28, 2019 and granted to Mr. Schwartzberg stock options to purchase an additional aggregate of 4,000,000 shares of common stock, exercisable for a period of the earlier of five years from the grant date or the termination of the consulting agreement at $0.50 per share, with one-half of the options (2,000,000 shares) vesting immediately and one-half of the options (2,000,000 shares) vesting on January 28, 2015. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $596,400 ($0.15 per share) on January 28, 2014, of which $298,200 was attributed to the options fully-vested on January 28, 2014 and as such was charged to operations on that date. The remaining unvested portion of the fair value of the options is being charged to operations ratably from January 28, 2014 through January 28, 2015. During the year ended December 31, 2014, the Company recorded a charge to operations of $434,499 with respect to the remaining unvested portion of the options.

On July 15, 2014, Gil Schwartzberg assigned fully-vested stock options to acquire 1,000,000 shares of the Company's common stock to Daniel Von Hoff, a member of the Company's Scientific Advisory Committee. The options assigned included options to acquire 500,000 shares that had been previously granted to Mr. Schwartzberg on October 15, 2009, were exercisable at $1.00 per share, and expired on October 15, 2014, and options for 500,000 shares that had been previously granted to Mr. Schwartzberg on October 5, 2011, are exercisable at $1.00 per share, and expire on October 5, 2016. As Mr. Schwartzberg is considered an affiliate of the Company for accounting and securities purposes, the fair value of the stock options assigned by Mr. Schwartzberg to Mr. Von Hoff for the benefit of the Company was recorded as a contribution to capital and a charge to operations. The fair value of the stock options assigned, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $43,500 (average of $0.04 per share), and such amount was charged to operations on July 15, 2014. The remaining unexpired options to acquire 500,000 shares were transferred back to Mr. Schwartzberg in February 2015.

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

On September 21, 2012, the Company entered into a work order agreement with Theradex, the CRO responsible for the clinical development of the Company's lead compound, LB-100, to manage and administer the Phase 1 clinical trial of LB-100. Dr. Robert B. Royds, the founder, Chairman of the Board of Directors and Medical Director of Theradex, had been previously appointed to the Company's Board of Directors on May 2, 2011 and died on March 23, 2013. The Phase 1 clinical trial of LB-100, which began during April 2013 with the entry of patients into the clinical trial, is being carried out by nationally recognized comprehensive cancer centers, and is estimated to be completed by June 30, 2016. The Phase 1 clinical trial is currently estimated to cost approximately $2,615,000, with such payments expected to be allocated approximately 60% for services provided by Theradex and approximately 40% for pass-through costs for clinical center laboratory costs and investigator costs. Total costs charged to operations through December 31, 2014 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, totaled $702,255, of which $423,534 and $278,721 were incurred during the years ended December 31, 2014 and 2013, respectively. Costs pursuant to this agreement are included in research and development costs in the Company's consolidated statements of operations.

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

On June 18, 2014, the Company entered into a sub-lease agreement for shared office space in New York City with the Eric Forman Law Office, a party providing legal and consulting services to the Company. The sub-lease was for a term of six months at a base rate of $875 per month and was not renewed upon expiration. Eric Forman is the son-in-law of Gil Schwartzberg, a significant stockholder of and consultant to the Company. Legal and consulting fees charged to operations for services rendered by Eric Forman for the years ended December 31, 2014 and 2013 were $46,000 and $12,000, respectively.

See "ITEM 11. EXECUTIVE COMPENSATION - Directors Compensation" for disclosures with respect to compensation (both cash and equity-based) to certain of our directors for services.

(b) Director Independence

The Company considers Drs. Palmedo and Mullinix to be "independent directors" as such term is defined by the NASDAQ Rules or Rule 10A-3 of the Exchange Act.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Weinberg & Company, P.C. acted as our independent registered public accounting firm for the fiscal years ended December 31, 2013 and 2014 and for the interim periods in such fiscal years. The following table shows the fees that were incurred by us for audit and other services provided by Weinberg & Company, P.C. in fiscal 2013 and 2014.

	2013	2014
Audit Fees [1]	$ 49,664	$ 56,459
Audit-Related Fees [2]	—	—
Tax Fees [3]	10,450	8,260
All Other Fees [4]	—	—
Total	$ 60,114	$ 64,719

(1) Audit fees represent fees for professional services provided in connection with the audit of our annual financial statements and the review of our financial statements included in our Form 10-Q quarterly reports and services that are normally provided in connection with statutory or regulatory filings.

(2) Audit-related fees represent fees for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements and not reported above under “Audit Fees.”

(3) Tax fees represent fees for professional services related to tax compliance, tax advice and tax planning.

(4) All other fees represent fees related to Sarbanes-Oxley compliance work.

All audit related services, tax services and other services rendered by Weinberg & Company, P.C. were pre-approved by our Board of Directors. The Board of Directors has adopted a pre-approval policy that provides for the pre-approval of all services performed for us by our independent registered public accounting firm.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) List of documents filed as part of this report:

(1) Financial Statements

Reference is made to the Index to Financial Statements on page F-1, where these documents are listed.

(2) Financial Statement Schedules

The financial statement schedules have been omitted because the required information is not applicable, or not present in amounts sufficient to require submission of the schedules, or because the information is included in the financial statements or notes thereto.

(3) Exhibits

See (b) below.

(b) Exhibits:

A list of exhibits required to be filed as part of this Annual Report on Form 10-K 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 Section 13 and 15(d) of the Securities Exchange Act of 1934, the Registrant caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: March 27, 2015

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
(Registrant)

By: */s/ JOHN S. KOVACH*
Name: John S. Kovach
Title: Chief Executive Officer

In accordance with the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant in the capacity and on the dates indicated.

Signature	Title	Date
/s/ JOHN S. KOVACH John S. Kovach	Chief Executive Officer, Chief Financial Officer, Principal Accounting Officer and Director	March 27, 2015
/s/ PHILIP F. PALMEDO Philip F. Palmedo	Director	March 27, 2015
/s/ KATHLEEN P. MULLINIX KATHLEEN P. MULLINIX	Director	March 27, 2015

INDEX TO EXHIBITS

Exhibit Number	Description of Document
2.1	Share Exchange Agreement dated as of June 8, 2006 among the Company, John S. Kovach and Lixte Biotechnology, Inc. [1]
3.1	Certificate of Incorporation, as filed with the Delaware Secretary of State on May 24, 2005. [2]
3.2	Certificate of Amendment of Certificate of Incorporation. [3]
3.2	Bylaws. [2]
10.1	Cooperative Research and Development Agreement (CRADA) between the U.S. Department of Health and Human Services, as represented by National Institute of Neurological Disorders and Stroke of the National Institutes of Health and Lixte Inc., as amended. [4]
10.2	Amendment No. 6 to CRADA. [5]
10.3	Agreement between Lixte Biotechnology Holdings, Inc. and Chem-Master International, Inc. dated as of February 5, 2007. [6]
10.4	Amendment dated January 28, 2008 to Agreement with Chem-Master International, Inc. [7]
10.5	Stock Option Agreement between Lixte Biotechnology Holdings, Inc. and Stephen K. Carter dated September 12, 2007. [8]
10.6	Stock Option Agreement between Lixte Biotechnology Holdings, Inc. and Francis Johnson dated September 12, 2007. [8]
10.7	Stock Option Agreement between Lixte Biotechnology Holdings, Inc. and Gil Schwartzberg dated September 12, 2007. [8]
10.8	Consulting Agreement between Lixte Biotechnology Holdings, Inc. and Gil Schwartzberg dated September 12, 2007. [8]
10.9	Amendment to Consulting Agreement with Gil Schwartzberg dated October 15, 2009. [12]
10.10	Consulting Agreement between Lixte Biotechnology Holdings, Inc. and Francis Johnson dated September 12, 2007. [8]
10.11	Consulting Agreement between Lixte Biotechnology Holdings, Inc. and Pro-Active Capital Group, LLC dated July 27, 2009. [9]
10.12	License Agreement dated as of September 19, 2008 between the Company and the United States Public Health Services. [10]
10.13	Stock Option Agreement between the Company and Mel Sorensen dated October 7, 2008. [11]
10.14	Consulting Agreement between the Company and Mel Sorensen dated October 7, 2008. [11]
10.15	Master Agreement between Lixte Biotechnology Holdings, Inc. and Theradex Systems, Inc. dated January 12, 2010. [12]
10.16	Materials Cooperative Research and Development Agreement between Lixte Biotechnology Holdings, Inc. and the National Institute of Neurological Disorders and Stroke dated October 18, 2013. [13]
10.17	Scientific Advisory Board Agreement between Lixte Biotechnology Holdings, Inc. and NDA Consulting Corp. dated December 24, 2013. [13]
10.18	Advisory Agreement between Lixte Biotechnology Holdings, Inc. and Kathleen P. Mullinix dated January 1, 2014. [13]
10.19	Certificate of Designations for the Company's Series A Convertible Preferred Stock. [14]
31	Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. [15]
32	Officer's Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. [15]
101.INS	XBRL Instance Document [15]
101.SCH	XBRL Taxonomy Extension Schema Document [15]
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document [15]
101.LAB	XBRL Taxonomy Extension Label Linkbase Document [15]
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document [15]
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document [15]

1 Filed as an Exhibit to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on July 7, 2006 and incorporated herein by reference.

2 Filed as an Exhibit to the Company's Registration Statement on Form 10-SB, as filed with the Securities and Exchange Commission on August 3, 2005 and incorporated herein by reference.

3 Filed as Appendix A to the Company's Information Statement, as filed with the Securities and Exchange Commission on September 20, 2006 and incorporated herein by reference.

4 Filed as an Exhibit to the Company's Registration on Form SB-2, as filed with the Securities and Exchange Commission on March 13, 2007 and incorporated herein by reference.

5 Filed as an Exhibit to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on August 12, 2009 and incorporated herein by reference.

6 Filed as an Exhibit to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on February 9, 2007 and incorporated herein by reference.

7 Filed as an Exhibit to the Company's Quarterly Report on Form 10-Q, as filed with the Securities and Exchange Commission on May 14, 2008 and incorporated herein by reference.

8 Filed as an Exhibit to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on August 12, 2009 and incorporated herein by reference.

9 Filed as an Exhibit to the Company's Quarterly Report on Form 10-Q, as filed with the Securities and Exchange Commission on November 12, 2009 and incorporated herein by reference.

10 Filed as an Exhibit to the Company's Annual Report on Form 10-K, as filed with the Securities and Exchange Commission on March 31, 2009 and incorporated herein by reference.

11 Filed as an Exhibit to the Company's Quarterly Report on Form 10-Q, as filed with the Securities and Exchange Commission on November 12, 2008 and incorporated herein by reference.

12 Filed as an Exhibit to the Company's Annual Report on Form 10-K, as filed with the Securities and Exchange Commission on March 15, 2013 and incorporated herein by reference.

13 Filed as an Exhibit to the Company's Annual Report on Form 10-K, as filed with the Securities and Exchange Commission on March 21, 2014 and incorporated herein by reference.

14 Filed as an Exhibit to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on March 18, 2015, and incorporated herein by reference.

15 Filed herewith.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
(INCLUDING REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM)

Years Ended December 31, 2014 and 2013

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors
Lixte Biotechnology Holdings, Inc.
East Setauket, New York

We have audited the accompanying consolidated balance sheets of Lixte Biotechnology Holdings, Inc. and subsidiary as of December 31, 2014 and 2013, and the related consolidated statements of operations, stockholders' equity and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that we considered appropriate under the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Lixte Biotechnology Holdings, Inc. and subsidiary as of December 31, 2014 and 2013, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has not generated any revenues from operations to date, and does not expect to do so in the foreseeable future. The Company has experienced recurring operating losses and negative operating cash flows since inception, and has financed its working capital requirements during this period primarily through the recurring sale of its equity securities. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

WEINBERG & COMPANY, P.A.
Los Angeles, California
March 27, 2015

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2014	**2013**
ASSETS		
Current assets:		
Cash	$ 44,411	$ 475,019
Money market funds	213,699	6,135
Advances on research and development contract services	231,177	33,880
Prepaid expenses and other current assets	50,012	43,006
Total current assets	539,299	558,040
Total assets	$ 539,299	$ 558,040
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 122,534	$ 107,774
Research and development contract liabilities, including $18,436 and $34,398 to a related party at December 31, 2014 and 2013, respectively	58,186	47,283
Registration rights penalty obligation	—	74,000
Due to Chairman and major stockholder	92,717	92,717
Total current liabilities	273,437	321,774
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; authorized – 10,000,000 shares; issued – none	—	—
Common stock, $0.0001 par value; authorized – 100,000,000 shares; issued and outstanding – 45,483,097 shares and 41,583,097 shares at December 31, 2014 and 2013, respectively	4,548	4,158
Additional paid-in capital	15,979,475	13,184,081
Accumulated deficit	(15,718,161)	(12,951,973)
Total stockholders' equity	265,862	236,266
Total liabilities and stockholders' equity	$ 539,299	$ 558,040

See accompanying notes to consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,	
	2014	**2013**
Revenues	$ —	$ —
Costs and expenses:		
General and administrative costs, including $784,598 and $115,768 to related parties for the years ended December 31, 2014 and 2013, respectively	1,285,173	494,959
Research and development costs, including $435,707 and $304,102 to related parties for the years ended December 31, 2014 and 2013, respectively	1,117,970	879,886
Total costs and expenses	2,403,143	1,374,845
Loss from operations	(2,403,143)	(1,374,845)
Interest income	66	3
Fair value of warrant extensions	(302,691)	—
Fair value of warrant discount	(134,420)	—
Gain from reversal of registration rights penalty obligation	74,000	—
Net loss	$ (2,766,188)	$ (1,374,842)
Net loss per common share – basic and diluted	$ (0.06)	$ (0.03)
Weighted average common shares outstanding – basic and diluted	44,405,563	41,583,097

See accompanying notes to consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

Years Ended December 31, 2014 and 2013

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance, December 31, 2012	41,583,097	$ 4,158	$ 13,064,831	$ (11,577,131)	$ 1,491,858
Stock-based compensation expense	—	—	119,250	—	119,250
Net loss	—	—	—	(1,374,842)	(1,374,842)
Balance, December 31, 2013	41,583,097	4,158	13,184,081	(12,951,973)	236,266
Exercise of stock warrants	3,900,000	390	1,412,110	—	1,412,500
Fair value of warrant extensions	—	—	302,691	—	302,691
Fair value of warrant discount	—	—	134,420	—	134,420
Stock-based compensation expense	—	—	946,173	—	946,173
Net loss	—	—	—	(2,766,188)	(2,766,188)
Balance, December 31, 2014	45,483,097	$ 4,548	$ 15,979,475	$ (15,718,161)	$ 265,862

See accompanying notes to consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,	
	2014	**2013**
Cash flows from operating activities:		
Net loss	$ (2,766,188)	$ (1,374,842)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense included in -		
General and administrative costs	775,124	119,125
Research and development costs	171,049	125
Fair value of warrant -		
Extensions	302,691	—
Discount	134,420	—
Changes in operating assets and liabilities:		
(Increase) decrease in -		
Advances on research and development contract services	(197,297)	17,695
Prepaid expenses and other current assets	(7,006)	(2,827)
Increase (decrease) in -		
Accounts payable and accrued expenses	14,760	27,358
Research and development contract liabilities	10,903	33,264
Registration rights penalty obligation	(74,000)	—
Net cash used in operating activities	(1,635,544)	(1,180,102)
Cash flows from investing activities:		
Increase in money market funds	(207,564)	(1)
Net cash used in investing activities	(207,564)	(1)
Cash flows from financing activities:		
Proceeds from exercise of warrants	1,412,500	—
Net cash provided by financing activities	1,412,500	—
Cash:		
Net decrease	(430,608)	(1,180,103)
Balance at beginning of period	475,019	1,655,122
Balance at end of period	$ 44,411	$ 475,019
Supplemental disclosures of cash flow information:		
Cash paid for -		
Interest	$ —	$ —
Income taxes	$ —	$ —

See accompanying notes to consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2014 and 2013

1. Organization and Business Operations

Organization and Business

Lixte Biotechnology Holdings, Inc. ("Holdings"), a Delaware corporation, including its wholly-owned Delaware subsidiary, Lixte Biotechnology, Inc. ("Lixte") (collectively, the "Company"), is engaged in research and development activities with respect to anti-cancer treatments and other common non-malignant diseases. The Company's activities are subject to significant risks and uncertainties, including the need to obtain additional financing, as described below.

The Company is considered a development stage company at December 31, 2014, as the Company has not yet commenced any revenue-generating operations, does not have any cash flows from operations, and is dependent on debt and equity funding to finance its operations. In June 2014, as discussed in Note 2, the Financial Accounting Standards Board issued new guidance that removed all incremental financial reporting requirements from generally accepted accounting principles in the United States for development stage entities. The Company early adopted this new guidance effective June 30, 2014, as a result of which all inception-to-date financial information and disclosures have been omitted at December 31, 2014.

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

Operating Plans

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

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

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

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

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

The Company filed an IND application with the FDA on April 30, 2012, and on July 24, 2012, the FDA notified the Company that it would allow initiation of a Phase 1 clinical trial of LB-100. The purpose of the clinical trial is to demonstrate that LB-100 can be administered safely to human beings at a dose and at a frequency that achieves the desired pharmacologic effect; in this case, inhibition of a specific enzyme, without being associated with toxicities considered unacceptable. The Phase 1 clinical trial of LB-100 is divided into two parts: the first part is designed to determine the maximum tolerable dose of LB-100 given alone, and the second part is designed to determine the maximum tolerable dose of LB-100 in combination with a standard widely used anti-cancer drug, docetaxel, a well-established anti-mitotic chemotherapy medication approved by the FDA for the treatment of various cancers.

The Phase 1 clinical trial of LB-100 began in April 2013 with the entry of patients into the clinical trial (NCTO 1837667 at www.clinicaltrials.gov) and was initiated at the City of Hope National Medical Center in Duarte, California, and was extended in December 2013 to include the Mayo Clinic in Rochester, Minnesota, both of which are Comprehensive Cancer Centers designated by the National Cancer Institute. As the accrual of patients was slower than anticipated, in October 2014 the Company entered into a Clinical Research Agreement ("CRA") with US Oncology Research, LLC, a large community-based research network based in Texas, to increase the rate of entry of patients into the ongoing clinical trial by adding four more active clinical oncologic research sites.

The Company originally estimated that the Phase 1 clinical trial of LB-100 would be completed during the quarter ending June 30, 2015 at a total cost of approximately $2,038,000. The Company currently estimates that the first part of the clinical trial will be completed by June 30, 2015, and the second part of the clinical trial will be completed by June 30, 2016, at a total cost of approximately $2,615,000.

The costs of the Phase 1 clinical trial of LB-100 are being paid to or through Theradex, the CRO responsible for the clinical development of LB-100. Total costs charged to operations through December 31, 2014 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, totaled $702,255, of which $423,534 and $278,721 were incurred during the years ended December 31, 2014 and 2013, respectively. The final cost of the clinical trial is variable, depending upon the number of patients needed to be medically screened to determine if they meet the criteria for entry into the clinical trial and ultimately upon the total number of patients entered into the clinical trial to establish the proper doses of the drug for a Phase 2 clinical trial.

The Phase 1 clinical trial of LB-100 is being conducted in two parts. In Part 1, the dose of LB-100 to be administered alone in a subsequent Phase 2 clinical trial is being determined, and in Part 2, the dose of LB-100, in combination with the standard cytotoxic drug docetaxel is being determined. Part 1 of the current clinical trial is anticipated to be concluded in the second quarter of 2015 and Part 2 of the current clinical trial is anticipated to be concluded in the second quarter of 2016.

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

Going Concern

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

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

At December 31, 2014, the Company had not yet commenced any revenue-generating operations. All activity through December 31, 2014 has been related to the Company's capital raising efforts and research and development activities. As such, the Company has yet to generate any cash flows from operations, and is dependent on debt and equity funding from both related and unrelated parties to finance its operations.

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

At December 31, 2014, the Company had cash and money market funds aggregating $258,110. As a result of the Company receiving $1,750,000 from the sale of shares of preferred stock effective March 17, 2015 (see Note 9), the Company believes that it has sufficient funds to complete the ongoing Phase 1 clinical trial of its lead anti-cancer compound LB-100 and to fund its ongoing operating expenses, including maintaining its patent portfolio, through June 30, 2016.

The amount and timing of future cash requirements will depend on the pace of the Company's clinical programs, in particular the completion of the Phase 1 clinical trial of LB-100. The Company expects that it will need to raise additional capital no later than mid-2016, likely in the form of equity, to fund operations, including the continuing costs of its clinical trial program and to maintain its patent portfolio. However, academic investigators have recently published pre-clinical data suggesting that LB-100 alone and/or in combination with standard treatments may be useful in the treatment of two different hematologic cancers. As the single agent dose of LB-100 is expected to be determined by June 30, 2015, the Company may consider raising additional funds during 2015 for the conduct of a Phase 1b/II clinical trial of LB-100 in a hematologic malignancy before the Company completes Part 2 of the current Phase 1 clinical trial.

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

2. Summary of Significant Accounting Policies

Principles of Consolidation

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

Cash Concentrations

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

Research and Development

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

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

Patent Costs

Due to the significant uncertainty associated with the successful development of one or more commercially viable products based on the Company's research efforts and any related patent applications, all patent costs, including patent-related legal and filing fees, are expensed as incurred. Patent costs were $342,625 and $405,582 for the years ended December 31, 2014 and 2013, respectively. Patent costs are included in research and development costs in the Company's consolidated statements of operations.

Concentration of Risk

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

On September 21, 2012, the Company entered into a work order agreement with Theradex, the CRO responsible for the clinical development of the Company's lead compound, LB-100, to manage and administer the Phase 1 clinical trial of LB-100. Dr. Robert B. Royds, the founder, Chairman of the Board of Directors and Medical Director of Theradex, had been previously appointed to the Company's Board of Directors on May 2, 2011 and died on March 23, 2013. The Phase 1 clinical trial of LB-100, which began during April 2013 with the entry of patients into the clinical trial, is being carried out by nationally recognized comprehensive cancer centers, and is estimated to be completed by June 30, 2016. The Phase 1 clinical trial is currently estimated to cost approximately $2,615,000, with such payments expected to be allocated approximately 60% for services provided by Theradex and approximately 40% for pass-through costs for clinical center laboratory costs and investigator costs. Total costs charged to operations through December 31, 2014 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, totaled $702,255, of which $423,534 and $278,721 were incurred during the years ended December 31, 2014 and 2013, respectively, or approximately 38% and 32% of research and development costs for the years ended December 31, 2014 and 2013, respectively. The costs charged to operations for amounts paid to or through Theradex for services relating to the Phase 1 clinical trial of LB-100 are expected to represent a larger percentage of total research and development costs during the fiscal years ending December 31, 2015 and 2016 as compared to prior fiscal years. Costs pursuant to this agreement are included in research and development costs in the Company's consolidated statements of operations (see Note 5).

Income Taxes

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

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

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

The Company is subject to U.S. federal income taxes and income taxes of various state tax jurisdictions. As the Company's net operating losses have yet to be utilized, all previous tax years remain open to examination by Federal authorities and other jurisdictions in which the Company currently operates or has operated in the past. The Company had no unrecognized tax benefits as of December 31, 2014 and 2013 and does not anticipate any material amount of unrecognized tax benefits within the next 12 months.

The Company accounts for uncertainties in income tax law under a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns as prescribed by GAAP. The tax effects of a position are recognized only if it is "more-likely-than-not" to be sustained by the taxing authority as of the reporting date. If the tax position is not considered "more-likely-than-not" to be sustained, then no benefits of the position are recognized. As of December 31, 2014, the Company had not recorded any liability for uncertain tax positions. In subsequent periods, any interest and penalties related to uncertain tax positions will be recognized as a component of income tax expense.

Stock-Based Compensation

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

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

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

The fair value of stock-based compensation is determined utilizing the Black-Scholes option-pricing model, and is affected by several variables, the most significant of which are the life of the equity award, the exercise price of the security as compared to the fair market value of the common stock on the grant date, and the estimated volatility of the common stock over the term of the equity award.

The Company recognizes the fair value of stock-based compensation awards in general and administrative costs and in research and development costs, as appropriate, in the Company's statement of operations.

The Company issues new shares to satisfy stock option exercises.

Comprehensive Income (Loss)

Components of comprehensive income or loss, including net income or loss, are reported in the financial statements in the period in which they are recognized. Comprehensive income or loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income (loss) and other comprehensive income (loss) are reported net of any related tax effect to arrive at comprehensive income (loss). The Company did not have any items of comprehensive income (loss) for the years ended December 31, 2014 and 2013.

Earnings Per Share

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

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

At December 31, 2014 and 2013, the Company excluded the outstanding securities summarized below, which entitle the holders thereof to acquire shares of common stock, from its calculation of earnings per share, as their effect would have been anti-dilutive.

	December 31,	
	2014	**2013**
Common stock warrants	2,928,800	6,828,800
Common stock options	6,850,000	3,150,000
Total	9,778,800	9,978,800

Fair Value of Financial Instruments

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

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

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

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

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

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

Use of Estimates

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

Recent Accounting Pronouncements

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

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

In August 2014, the FASB issued Accounting Standards Update No. 2014-15 (ASU 2014-15), *Presentation of Financial Statements – Going Concern (Subtopic 205-10)* . ASU 2014-15 provides guidance as to management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. In connection with preparing financial statements for each annual and interim reporting period, an entity's management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). Management's evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued (or at the date that the financial statements are available to be issued when applicable). Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or available to be issued). ASU 2014-15 is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The Company is currently evaluating the impact the adoption of ASU 2014-15 on the Company's financial statement presentation and disclosures.

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

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

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.

3. Common Stock and Common Stock Warrants

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

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

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

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

A summary of common stock warrant activity, including warrants to purchase common stock that were issued in conjunction with the Company's private placements, is presented 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, 2012	6,828,800	$ 0.667	
Issued	—	—	
Exercised	—	—	
Expired	—	—	
Warrants outstanding at December 31, 2013	6,828,000	0.667	
Issued	—	—	
Exercised	(3,900,000)	0.263	
Expired	—	—	
Warrants outstanding at December 31, 2014	2,928,800	$ 0.592	0.25
Warrants exercisable at December 31, 2013	6,659,840	$ 0.672	
Warrants exercisable at December 31, 2014	2,807,840	$ 0.596	0.25

The exercise prices of common stock warrants outstanding and exercisable are as follows at December 31, 2014:

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

Based on a fair market value of $0.24 per share on December 31, 2014, there were no exercisable but unexercised in-the-money common stock warrants on that date. Accordingly, there was no intrinsic value attributed to exercisable but unexercised common stock warrants at December 31, 2014.

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

At December 31, 2014, warrants exercisable do not include warrants to acquire 120,960 shares of common stock that are contingent upon the exercise of warrants contained in units sold as part of the third private placement.

Registration Rights Penalty Obligation

In conjunction with 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. 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 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, and the registration statement was declared effective by the Securities and Exchange Commission on May 14, 2007.

In accordance with EITF 00-19-2, "Accounting for Registration Payment Arrangements", 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. As a result, the Company recorded a registration rights penalty obligation under the registration rights agreement aggregating $74,000 at such date. The Company did not make any payments to the investors with respect to the registration rights penalty obligation through December 31, 2014, and it has determined that it is extremely remote that the Company will ever make such payments to the investors. Accordingly, at December 31, 2014, the Company recorded a gain of $74,000 from the reversal of the registration rights penalty obligation in the Company's consolidated statement of operations.

4. Money Market Funds

Money market funds at December 31, 2014 and 2013 consisted of investments in shares of Morgan Stanley New York Municipal Money Market Trust with a market value of $213,699 and $6,135, respectively.

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

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

	Total	Level 1	Level 2	Level 3
December 31, 2014:				
Money market funds	$ 213,699	$ 213,699	$ —	$ —
December 31, 2013:				
Money market funds	$ 6,135	$ 6,135	$ —	$ —

5. Related Party Transactions

Advances from the Company's Chairman and major stockholder, Dr. John Kovach, aggregating $92,717 at December 31, 2014 and 2013 are non-interest bearing and are due on demand, and were included in current liabilities in the Company's consolidated balance sheets. Subsequent to December 31, 2014, such advances were converted into shares of common stock (see Note 9).

Dr. Kovach was paid a salary of $60,000 for the years ended December 31, 2014 and 2013, which amounts are included in general and administrative costs in the Company's consolidated statements of operations.

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

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

On June 18, 2014, the Company entered into a sub-lease agreement for shared office space in New York City with the Eric Forman Law Office, a party providing legal and consulting services to the Company. The sub-lease was for a term of six months at a base rate of $875 per month and was not renewed upon expiration. Eric Forman is the son-in-law of Gil Schwartzberg, a significant stockholder of and consultant to the Company. Legal and consulting fees charged to operations for services rendered by Eric Forman for the years ended December 31, 2014 and 2013 were $46,000 and $12,000, respectively.

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

Periodically, the Company has entered into agreements with Ascentage Pharma Group to conduct various studies. Ascentage Pharma Group is a spin-off of Ascenta Therapeutics, of which Dr. Sorensen is the President and Chief Executive Officer and a director. Ascentage Pharma Group and Ascenta Therapeutics have a continuing business relationship and certain common shareholders. However, Dr. Sorensen does not have any direct business relationship with or ownership in Ascentage Pharma Group.

On September 21, 2012, the Company entered into a work order agreement with Theradex, the CRO responsible for the clinical development of the Company's lead compound, LB-100, to manage and administer the Phase 1 clinical trial of LB-100. Dr. Robert B. Royds, the founder, Chairman of the Board of Directors and Medical Director of Theradex, had been previously appointed to the Company's Board of Directors on May 2, 2011 and died on March 23, 2013. The Phase 1 clinical trial of LB-100, which began during April 2013 with the entry of patients into the clinical trial, is being carried out by nationally recognized comprehensive cancer centers, and is estimated to be completed by June 30, 2016. The Phase 1 clinical trial is currently estimated to cost approximately $2,615,000, with such payments expected to be allocated approximately 60% for services provided by Theradex and approximately 40% for pass-through costs for clinical center laboratory costs and investigator costs. Total costs charged to operations through December 31, 2014 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, totaled $702,255, of which $423,534 and $278,721 were incurred during the years ended December 31, 2014 and 2013, respectively. Costs pursuant to this agreement are included in research and development costs in the Company's consolidated statements of operations.

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

Effective January 1, 2014, the Company entered into an Advisory Agreement with Dr. Kathleen P. Mullinix, a member of the Board of Directors of the Company, effective for an initial term of one year through December 31, 2014 to advise on business development matters. The Advisory Agreement provides for annual cash compensation of $25,000. The term of the Advisory Agreement is automatically extended for a term of one year annually unless a notice of intent to terminate is given by either party at least 90 days before the end of the applicable term. Accordingly, the Advisory Agreement was extended for an additional term of one year effective January 1, 2015. The Company charged $25,000 to operations for services provided under this agreement during the year ended December 31, 2014, which amount was included in general and administrative costs in the Company's consolidated statements of operations.

Stock-based compensation arrangements involving members of the Company's Board of Directors are described at Note 6. Total stock-based compensation expense relating to directors, officers and other related parties was $946,173 and $119,250 for the years ended December 31, 2014 and 2013, respectively.

6. Stock-Based Compensation

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

On June 20, 2007, the Board of Directors of the Company approved the 2007 Stock Compensation Plan (the "2007 Plan"), which provides for the granting of awards, consisting of common stock options, stock appreciation rights, performance shares, or restricted shares of common stock, to employees and independent contractors, for up to 2,500,000 shares of the Company's common stock, under terms and condition, as determined by the Company's Board of Directors. As of December 31, 2014, stock options for 650,000 shares had been issued under the 2007 Plan, and stock options for 1,850,000 were available for issuance under the 2007 Plan.

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

For options granted during the year ended December 31, 2014, the fair value of each option award was estimated using the Black-Scholes option-pricing model with the following assumptions:

Risk-free interest rate	1.15% to 1.75%
Expected dividend yield	0%
Expected volatility	173% to 380%
Expected life	4-5 years

For options granted during the year ended December 31, 2013, the fair value of each option award was estimated using the Black-Scholes option-pricing model with the following assumptions:

Risk-free interest rate	1.51%
Expected dividend yield	0%
Expected volatility	262%
Expected life	5 years

On June 30, 2011, the Company granted to Dr. Philip F. Palmedo, a director of the Company, stock options to purchase 200,000 shares of common stock, exercisable for a period of five years from the date of grant at $0.98 per share, which was the fair market value of the Company's common stock on such date. The options vest ratably in equal quarterly installments of 25,000 shares beginning July 1, 2011. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be $196,000 ($0.98 per share). During the years ended December 31, 2014 and 2013, the Company recorded charges to operations of $-0- and $48,530, respectively, with respect to these options.

On June 30, 2011, the Company granted to Dr. Iwao Ojima, a member of the Company's Scientific Advisory Committee, 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 years ended December 31, 2014 and 2013, the Company charged operations of $-0- and $3,357, respectively, with respect to these options.

On January 28, 2014, the Company approved a second amendment to the Company's consulting agreement with Gil Schwartzberg, a significant stockholder of and consultant to the Company, dated September 12, 2007 to extend it for an additional four years to January 28, 2019 and granted to Mr. Schwartzberg stock options to purchase an additional aggregate of 4,000,000 shares of common stock, exercisable for a period of the earlier of five years from the grant date or the termination of the consulting agreement at $0.50 per share, with one-half of the options (2,000,000 shares) vesting immediately and one-half of the options (2,000,000 shares) vesting on January 28, 2015. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $596,400 ($0.15 per share) on January 28, 2014, of which $298,200 was attributed to the options fully-vested on January 28, 2014 and as such was charged to operations on that date. The remaining unvested portion of the fair value of the options is being charged to operations ratably from January 28, 2014 through January 28, 2015. During the year ended December 31, 2014, the Company recorded a charge to operations of $434,499 with respect to the remaining unvested portion of the options.

Effective May 1, 2011, in connection with his election to the Company's Board of Directors, Dr. Robert B. Royds was granted stock options to purchase 200,000 shares of the Company's common stock, vesting 25,000 shares on May 1, 2011, and 25,000 shares quarterly thereafter until all of the shares are vested, exercisable for a period of five years from each tranche's vesting date, at $0.98 per share, which was the fair market value of the Company's common stock on such date. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $196,000 ($0.98 per share), and was charged to operations ratably from May 2, 2011 through February 1, 2013. During the year ended December 31, 2013, the Company recorded a charge to operations of $8,548 with respect to these options. Dr. Royds died on March 23, 2013 and the stock options expired unexercised on March 23, 2014.

Effective September 16, 2012, in connection with her election to the Company's Board of Directors, Dr. Kathleen P. Mullinix was granted stock options to purchase 200,000 shares of the Company's common stock, vesting 25,000 shares on September 16, 2012, and 25,000 shares quarterly thereafter until all of the shares are vested, exercisable for a period of five years from the date of grant at $0.65 per share, which was the fair market value of the Company's common stock on such date. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $118,000 ($0.59 per share), and was being charged to operations from September 16, 2012 through June 16, 2014. During the years ended December 31, 2014 and 2013, the Company recorded charges to operations of $26,899 and $58,690, respectively, with respect to these options.

On December 24, 2013, the Company entered into an agreement with NDA Consulting Corp. ("NDA") for consultation and advice in the field of oncology research and drug development. As part of the agreement, NDA agreed to cause its president, Dr. Daniel D. Von Hoff, M.D., to become a member of the Company's Scientific Advisory Committee. In connection with this agreement, NDA was granted stock options to purchase 100,000 shares of the Company's common stock, vesting 25,000 shares on June 24, 2014, and thereafter 25,000 shares annually on June 24, 2015, 2016 and 2017, exercisable for a period of five years from the date of grant at $0.13 per share, which was the fair market value of the Company's common stock on the grant date. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be $12,960 ($0.13 per share), and is being charged to operations from December 24, 2013 through June 24, 2017. During the year ended December 31, 2014, the Company recorded a charge to operations of $8,901 with respect to these options.

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

On July 15, 2014, Gil Schwartzberg assigned fully-vested stock options to acquire 1,000,000 shares of the Company's common stock to Daniel Von Hoff, a member of the Company's Scientific Advisory Committee. The options assigned included options to acquire 500,000 shares that had been previously granted to Mr. Schwartzberg on October 15, 2009, were exercisable at $1.00 per share, and expired on October 15, 2014, and options for 500,000 shares that had been previously granted to Mr. Schwartzberg on October 5, 2011, are exercisable at $1.00 per share, and expire on October 5, 2016. As Mr. Schwartzberg is considered an affiliate of the Company for accounting and securities purposes, the fair value of the stock options assigned by Mr. Schwartzberg to Mr. Von Hoff for the benefit of the Company was recorded as a contribution to capital and a charge to operations. The fair value of the stock options assigned, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $43,500 (average of $0.04 per share), and such amount was charged to operations on July 15, 2014. The remaining unexpired stock options to acquire 500,000 shares were transferred back to Mr. Schwartzberg on February 23, 2015.

On October 7, 2014, the Company entered into an Advisory Agreement with Andrew Robell for consultation and advice with respect to identifying and assessing potential licensing and strategic opportunities through September 30, 2016. In connection with the agreement, the Company's Board of Directors granted stock options to Mr. Robell to purchase 200,000 shares of the Company's common stock, vesting 100,000 shares on October 7, 2014 and 100,000 shares on October 7, 2015, exercisable for a period of five years from the date of grant at $0.50 per share. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $20,000 ($0.10 per share), of which $10,000 is attributed to the options fully-vested on October 7, 2014 and as such was charged to operations on that date. The remaining unvested portion of the fair value of the options will be charged to operations ratably from October 7, 2014 through October 7, 2015. During the year ended December 31, 2014, the Company recorded a charge to operations of $15,526 with respect to these options.

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, 2012	3,750,000	$ 0.870	
Granted	100,000	0.130	
Exercised	—	—	
Expired	(700,000)	1.045	
Options outstanding at December 31, 2013	3,150,000	0.818	
Granted	4,700,000	0.473	
Exercised	—	—	
Expired	(1,000,000)	0.803	
Options outstanding at December 31, 2014	6,850,000	$ 0.582	3.57
Options exercisable at December 31, 2013	3,000,000	$ 0.843	
Options exercisable at December 31, 2014	4,675,000	$ 0.626	2.84

Total deferred compensation expense for the outstanding value of unvested stock options was approximately $69,000 at December 31, 2014, which is being recognized subsequent to December 31, 2014 over a weighted-average period of approximately nine months.

The exercise prices of common stock options outstanding and exercisable are as follows at December 31, 2014:

Exercise Prices	Options Outstanding (Shares)	Options Exercisable (Shares)
$ 0.130	100,000	25,000
$ 0.250	500,000	500,000
$ 0.500	4,300,000	2,200,000
$ 0.650	700,000	700,000
$ 0.980	250,000	250,000
$ 1.000	1,000,000	1,000,000
	6,850,000	4,675,000

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

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

Outstanding options to acquire 2,175,000 shares of the Company's common stock had not vested at December 31, 2014.

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

7. Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets as of December 31, 2014 and 2013 are summarized below.

	December 31,	
	2014	2013
Start-up and organization costs	$ 49,000	$ 56,000
Research credits	139,000	95,000
Contingent liability	31,000	31,000
Stock-based compensation	952,000	750,000
Net operating loss carryforwards	3,532,000	2,939,000
Total deferred tax assets	4,703,000	3,871,000
Valuation allowance	(4,703,000)	(3,871,000)
Net deferred tax assets	$ —	$ —

In assessing the potential realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the Company attaining future taxable income during the periods in which those temporary differences become deductible. As of December 31, 2014 and 2013, management was unable to determine if it is more likely than not that the Company's deferred tax assets will be realized, and has therefore recorded an appropriate valuation allowance against deferred tax assets at such dates.

No federal tax provision has been provided for the years ended December 31, 2014 and 2013 due to the losses incurred during such periods. Reconciled below is the difference between the income tax rate computed by applying the U.S. federal statutory rate and the effective tax rate for the years ended December 31, 2014 and 2013.

	Years Ended December 31,	
	2014	**2013**
U. S. federal statutory tax rate	(34.0)%	(34.0)%
Non-deductible stock-based compensation	0.5%	—%
Non-deductible fair value of warrant extensions	3.6%	—%
Non-deductible fair value of warrant discounts	1.6%	—%
Expirations related to stock-based compensation	5.0%	13.8%
Adjustment to deferred tax asset	(1.0)%	(1.3)%
Change in valuation allowance	24.3%	21.5%
Effective tax rate	0.0%	0.0%

At December 31, 2014, the Company has available net operating loss carryforwards for federal income tax purposes of approximately $8,507,000 which, if not utilized earlier, expire through 2033.

8. Commitments and Contingencies

On September 21, 2012, the Company entered into a work order agreement with Theradex, the CRO responsible for the clinical development of the Company's lead compound, LB-100, to manage and administer the Phase 1 clinical trial of LB-100. The Phase 1 clinical trial of LB-100, which began during April 2013 with the entry of patients into the clinical trial, is being carried out by nationally recognized comprehensive cancer centers, and is estimated to be completed by June 30, 2015. The Phase 1 clinical trial is currently estimated to cost approximately $2,615,000, with such payments expected to be allocated approximately 60% for services provided by Theradex and approximately 40% for pass-through costs for clinical center laboratory costs and investigator costs. Total costs charged to operations through December 31, 2014 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, totaled $702,255, of which $423,534 and $278,721 were incurred during the years ended December 31, 2014 and 2013, respectively. Costs pursuant to this agreement are included in research and development costs in the Company's consolidated statements of operations.

On December 24, 2013, the Company entered into an agreement with NDA Consulting Corp. ("NDA") for consultation and advice in the field of oncology research and drug development. As part of the agreement, NDA agreed to cause its president, Dr. Daniel D. Von Hoff, M.D., to become a member of the Company's Scientific Advisory Committee. The term of the agreement is for one year and provides for a quarterly cash fee of $4,000. The agreement was automatically renewed on its anniversary date for an additional one year term. Consulting and advisory fees charged to operations pursuant to this agreement were $16,000 during the year ended December 31, 2014.

Effective January 1, 2014, the Company entered into an Advisory Agreement with Dr. Kathleen P. Mullinix, a member of the Board of Directors of the Company, effective for an initial term of one year through December 31, 2014 to advise on business development matters. The Advisory Agreement provides for annual cash compensation of $25,000. The term of the Advisory Agreement is automatically extended for a term of one year annually unless a notice of intent to terminate is given by either party at least 90 days before the end of the applicable term. Accordingly, the Advisory Agreement was extended for an additional term of one year effective January 1, 2015. The Company charged $25,000 to operations for services provided under this agreement during the year ended December 31, 2014, which amount was included in general and administrative costs in the Company's 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 December 31, 2014 aggregating $1,839,548, of which $150,903 is included in current liabilities in the Company's consolidated balance sheet at December 31, 2014.

		Payments Due By Year				
	Total	2015	2016	2017	2018	2019
Research and development contracts	$ 60,530	$ 60,530	$ —	$ —	$ —	$ —
Clinical trial agreements	1,670,301	1,020,301	650,000	—	—	—
Consulting agreements	16,000	16,000	—	—	—	—
Due to Chairman and major stockholder	92,717	92,717	—	—	—	—
Total	$1,839,548	$1,189,548	$ 650,000	$ —	$ —	$ —

9. Subsequent Events

On March 6, 2015, the Company advised holders of its outstanding common stock purchase warrants that it would extend the expiration date of the warrants, all of which are currently scheduled to expire on March 31, 2015, to April 15, 2015, and that it would reduce the cash exercise prices of the warrants by 50%. Warrants are currently outstanding to acquire a total of 2,928,800 shares of common stock, of which 1,075,000 warrants are exercisable at $0.75 per share and 1,853,800 warrants are exercisable at $0.50 per share. If all of the outstanding warrants are exercised, the Company would receive cash proceeds of $866,575 and the Company would issue 2,928,800 shares of common stock, reflecting an average exercise price of approximately $0.30 per share. The Company expects to record a charge to operations of approximately $200,000 during the three months ending March 31, 2015 with respect to the extension of the warrants and the reduction in the warrant exercise price.

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

Effective March 17, 2015, the Company entered into a Securities Purchase Agreement with a current stockholder of the Company who owned 10.6% of the Company's issued and outstanding shares of common stock immediately prior to the financing transaction, pursuant to which such stockholder purchased 175,000 shares of the Company's non-voting Series A Convertible Preferred Stock (the "Preferred Shares") at a price per share of $10.00, representing an aggregate purchase price of $1,750,000. The Preferred Shares have a dividend of 1% of the annual net revenue of the Company until converted or redeemed. Each of the Preferred Shares may be converted, at the option of the holder, into 12.5 shares of common stock (subject to customary anti-dilution provisions) and the Preferred Shares are subject to mandatory conversion at the conversion rate in the event of a merger or sale transaction resulting in gross proceeds to the Company of at least $21,875,000. If fully converted, the Preferred Shares would convert into 2,187,500 shares of common stock, representing an effective price per share of common stock of $0.80. On the effective date of the transaction, the closing price of the Company's common stock was $0.25 per share. The Company has the right to redeem the Preferred Shares up to the fifth anniversary of the closing date at a price per share equal to $50.00. The Company will account for the Preferred Shares as a component of shareholders' equity.

The following table sets forth the condensed consolidated balance sheet of the Company as of December 31, 2014 on an as reported basis and on an unaudited pro forma basis, giving effect to the sale on March 17, 2015, of 175,000 shares of the Company's Series A Convertible Preferred Stock at a price of $10.00 per share, representing an aggregate purchase price of $1,750,000, and the conversion of $92,717 of advances to the Company by Dr. John Kovach, the Company's Chief Executive Officer, into 92,717 shares of the Company's common stock, also on March 17, 2015.

	Actual - As Reported	Pro Forma - As Adjusted (Unaudited)
ASSETS		
Total current assets	$ 539,299	$ 2,289,299
Total assets	$ 539,299	$ 2,289,299
LIABILITIES AND STOCKHOLDERS' EQUITY		
Total current liabilities	$ 273,437	$ 180,720
Total liabilities	273,437	180,720
STOCKHOLDERS' EQUITY		
Series A convertible preferred stock, $0.0001 par value, $10.00 per share stated value, $50.00 per share redemption value; aggregate dividend equal to 1% of annual net revenue; aggregate redemption value of $8,750,000; liquidation preference based on conversion to common shares; preferred shares authorized: 175,000; preferred shares issued and outstanding: 175,000; common shares issuable upon conversion at 12.5 common shares per share of preferred stock: 2,187,500 shares, as adjusted	—	1,750,000
Common stock, $0.0001 par value, authorized – 100,000,000 shares; issued and outstanding – 45,483,097 shares, as reported, and 45,575,814 shares, as adjusted	4,548	4,557
Additional paid-in capital	15,979,475	16,072,183
Accumulated deficit	(15,718,161)	(15,718,161)
Total stockholders' equity	265,862	2,108,579
Total liabilities and stockholders' equity	$ 539,299	$ 2,289,299

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

I, John S. Kovach, Chief Executive Officer and Chief Financial Officer of Lixte Biotechnology Holdings, Inc. (the "Registrant"), certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2014 of Lixte Biotechnology Holdings, Inc. (the "Annual Report");

2. Based on my knowledge, this Annual 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 Annual Report;

3. Based on my knowledge, the financial statements, and other financial information included in this Annual 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 Annual 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)) for the Registrant and I 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 Annual 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 Annual Report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Annual 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 the Registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: March 27, 2015

By: */s/ JOHN S. KOVACH*
Name: John S. Kovach
Title: Chief Executive Officer and Chief Financial Officer

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

In connection with the filing by Lixte Biotechnology Holdings, Inc. (the "Registrant") of its Annual Report on Form 10-K for the fiscal year ended December 31, 2014 (the "Annual Report") with the Securities and Exchange Commission, I, John S. Kovach, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(i) The Annual Report fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

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

Date: March 27, 2015

By: */s/ JOHN S. KOVACH*
Name: John S. Kovach
Title: Chief Executive Officer and Chief Financial Officer