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, 2015

[ ] 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 (State or other jurisdiction of incorporation or organization)	**20-2903526** (I.R.S. Employer Identification Number)
248 Route 25A, No. 2 **East Setauket, New York** (Address of principal executive offices)	**11733** (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, 2015: $200,000

The aggregate market value of the common stock held by non-affiliates of the registrant as of June 30, 2015 was approximately $3,072,615.

There were 45,575,814 shares of the Company's common stock outstanding on March 1, 2016.

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

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

Description of Business

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

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

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

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

The Company has demonstrated that lead compounds of both series of drugs are active against a broad spectrum of human cancers in cell culture and against several types of human cancers in animal models. The research on new drug treatment was initiated in 2006 with the National Institute of 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 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, to prepare an IND application for filing with the FDA.

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

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

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

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

The Company estimates that Part 1 of the Phase 1 clinical trial of LB-100 will now cost a total of approximately $2,200,000 and will be completed by May 31, 2016, as compared to the Company's previous estimate of a total cost of approximately $1,800,000 and a completion date of December 31, 2015. The following factors have contributed to the most recent revisions to the total cost and completion date of this clinical trial: (1) some patients are continuing to receive the study compound longer than is usual for patients with treatment-refractory progressive disease in a Phase 1 clinical trial; (2) the establishment of the MTD required more subjects than the initially planned six patients; and (3) the planned pharmacokinetic studies required more than the initially planned three patients.

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, 2015 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, aggregated $1,660,725, of which $958,896 and $423,108 were incurred during the years ended December 31, 2015 and 2014, respectively, or approximately 46% and 38% of research and development costs for the years ended December 31, 2015 and 2014, respectively.

Publications

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

An article in the December 12, 2011edition 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 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.

On November 6, 2015, it was reported at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, Boston, Massachusetts, that in an ongoing Phase 1 clinical trial, LB-100 was associated with stabilization of a variety of advanced cancers that had been progressing despite extensive prior treatment without dose-limiting toxicity. The authors reporting this development were Vincent Chung, City of Hope, Duarte, California; Donald Richard, Texas Oncology, Tyler, Texas; Fadi Braiteh, Comprehensive Cancer Centers of Nevada, Las Vegas, Nevada; John S. Kovach, Lixte Biotechnology Holdings, Inc. East Setauket, New York; and Aaron Scott Mansfield, May Clinic, Rochester, Minnesota

On January 25, 2016, in the journal Nature Medicine, neuroscientists at the French Institute of Health and Medical Research (Inserm) using a mouse model of depression identified protein phosphatase 2A (PP2A) as a potential pharmacological target for therapy. Administration of LB-100, the Company's proprietary inhibitor of PP2A, rapidly reduced depressive-like symptoms in these conditioned animals.

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.

Patents for the LB-100 series oxabicycloheptanes and -heptenes) and the LB-200 series (histone deacetylase inhibitors; HDACi) have been filed in the United States and internationally under the Patent Cooperation Treaty. Patents for composition of matter and for several uses of both the LB-100 series and the LB-200 series have been issued in the United States, Mexico, Australia Japan, China, the European Patent Office and Eurasian Patent Office.

The Company's portfolio of 26 domestic and international patents issued is summarized below. The Company has additional domestic and international patents pending.

LB-100 Series of Compounds - Phosphatase Inhibitors – Composition and Use in Cancer Treatment
Oxabicycloheptanes and Oxabicycloheptenes, Their Preparation and Use

Patent	Priority Date or International Filing Date (non-U.S. applications)	Issue/Grant Date	Expiration Date
US 7,998,957	02/06/2007	08/16/2011	02/20/2030
US 8,227,473	08/01/2008	07/24/2012	02/20/2030
US 8,426,444 Divisional	02/06/2007	04/23/2013	02/06/2028
US 8,541,458 Divisional	08/01/2008	09/24/2013	08/01/2029
US 8,822,461 Continuation	02/06/2007	09/02/2014	02/20/2030
US 9,079,917 Divisional	02/06/2007	07/14/2015	02/06/2028
AUS 2008214299	02/06/2008	04/24/2014	02/06/2028
PRC ZL200880004292.9	02/06/2008	09/25/2015	02/06/2028
EA (number not assigned)	02/06/2008	Not available	02/06/2028
JAP 5693850	02/06/2008	02/13/2015	02/06/2028
MEX 309985	02/06/2008	05/28/2013	02/06/2028
AUS 2009277031	07/30/2009	05/14/2015	07/30/2029
EA 022311	07/30/2009	12/30/2015	07/30/2029
EU 2307344	07/30/2009	07/02/2015	07/30/2029
JAP 5666443	07/30/2009	12/19/2014	07/30/2029
MEX 324705	07/30/2009	10/21/2014	07/30/2029

LB-200 Series of Compounds – HDAC Inhibitors – Composition and Use in Cancer Treatment

Patent	Priority Date or International Filing Date (non-U.S. applications)	Issue/Grant Date	Expiration Date
US 8,143,445	10/01/2007	03/27/2012	08/23/2029
US 8,455,688 Divisional	10/01/2007	03/21/2012	10/01/2028
AUS 2008307541	10/01/2008	05/28/2015	10/01/2028
PRC ZL200880115815.7	10/01/2008	07/23/2014	10/01/2028
EA 018618	10/01/2008	09/3020/13	10/01/2028
JAP 5730575	10/01/2008	04/17/2015	10/01/2028
MEX 319923	10/01/2008	05/06/2014	10/01/2028

LB-100 and LB-200 Series of Compounds – Use in Treatment of Multiple CNS Diseases
Neuroprotective Agents for the Prevention and Treatment of Neurodegenerative Diseases

Patent	Priority Date or International Filing Date (non-U.S. applications)	Issue/Grant Date	Expiration Date
US 8,058,268	08/01/2008	11/15/2011	01/03/2030
US 8,329,719 Divisional	08/01/2008	12/11/2012	08/01/2029
AUS (number not assigned)	07/29/2009	Not available	07/29/2029

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 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.

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 at some stage of its clinical development. However, the Company would prefer to delay the partnering/licensing decision 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 (i.e., 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. However, by analogy with mechanistically related compounds, there is good reason to believe 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.

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 positioned 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 currently 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 the potential treatment of serious systemic fungal infections and common fungal infections of the skin and nails.

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 and in 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 in 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'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. Additionally, 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 other organizations 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 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; 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, 2015, 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 at Stony Brook ("SUNY – Stony Brook") in Stony Brook, New York. He received approvals from SUNY – Stony Brook and from the New York State Ethics Commission to manage the operations of the Company and to hold greater than 5% of the Company's outstanding shares of common stock.

Dr. Kovach devotes approximately 50% of his efforts per year to the Company, including research planning and management functions. Dr. Kovach's contributions to the Company are made outside of his academic responsibilities at SUNY – Stony Brook. He directs, coordinates and manages the scientific and business development of the Company with the advice of the Company's Board of Directors, the Scientific 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 which 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.

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. 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; 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 significant revenues for several years and there is no assurance that we will ever generate sustainable revenues 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 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 2015 consolidated financial statements, has expressed 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.

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

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 we expect would be integral to our business. These licenses and agreements would 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 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; 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 could affect our ability to achieve revenues and 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. Dr. Kovach is 78 years old, and, with the approval of 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, and would require that we hire a qualified replacement to fill the position of the Chief Executive Officer. 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.

During September 2015, we entered into a Collaboration Agreement with BioPharmaWorks, pursuant to which we engaged BioPharmaWorks to perform certain services for us. Those services include, among other things: (a) assisting us to (i) commercialize our products and strengthen our patent portfolio, (ii) identify large pharmaceutical companies with potential interest in our product pipeline, and (iii) prepare and deliver presentations concerning our products; (b) at the request of the Board of Directors, serving as backup management for up to three months should our Chief Executive Officer and scientific leader be temporarily unable to carry out his duties; (c) being available for consultation in drug discovery and development; and (d) identifying providers and overseeing tasks relating to clinical use and commercialization of new compounds. BioPharmaWorks was founded in 2015 by former Pfizer scientists with extensive multi-disciplinary research and development and drug development experience. The Collaboration Agreement is for an initial term of two years and automatically renews for subsequent annual periods unless terminated by a party not less than 60 days prior to the expiration of the applicable period. We believe that this Collaboration Agreement mitigates, to a certain extent, our reliance on the services of Dr. Kovach, and would allow us the time to replace Dr. Kovach in the event that such a need arose.

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 clinical trial contract for ten years at the Mayo Clinic, Rochester, Minnesota. However, the Company 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 costly. If we and our collaborative partners do not obtain necessary regulatory approvals at each stage of development, 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 costly and lengthy. The time required for FDA and other approvals is uncertain and can typically take 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 complete clinical trials in the time periods estimated, if at all. Moreover, if we, or our collaborative partners, incur unanticipated costs and/or 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 commercial success of our product candidates.

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 United States 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 efforts to implement health care reforms through the Patient Protection and Affordable Care Act (the "ACA"), which became law in 2010, and other measures, 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 the ACA and other 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;
- 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. 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 at that time. 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. 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 United States 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 elsewhere. 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, it is possible that 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. United States patents and patent applications may also be subject to interference proceedings, and United States patents may be subject to reexamination proceedings in the United States 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 would 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 potential 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 re-importation 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 United States Department of Health and Human Services to promulgate regulations allowing drug re-importation 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 re-importation may also attempt to pass legislation that would remove the requirement for the Secretary's certification or allow re-importation under circumstances beyond those anticipated under current law. If legislation is enacted, or regulations issued, allowing the re-importation 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 founder and Chief Executive Officer, 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.

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 20% 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 transaction, 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

The Company's common stock trades on the OTCQB under the symbol "LIXT". There is very limited trading of the Company's common 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. The Company believes that a number of factors, both within and outside its control, could cause the price of the Company's common stock to fluctuate, perhaps substantially. Factors such as the following could have a significant adverse impact on the market price of the Company's common stock:

- The Company's ability to obtain additional financing and, if available, the terms and conditions of the financing;
- The Company's 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 products and services of the Company's competitors;
- Announcements of technological innovations or new products or services by the Company or its competitors;
- United States and foreign governmental regulatory actions;
- The development of litigation against the Company;
- Period-to-period fluctuations in the Company's operating results;
- Changes in estimates of the Company's performance by securities analysts;
- Possible regulatory requirements with respect to the Company's 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;
- The depth and liquidity of the market for the Company's common stock;
- Investor perceptions of the Company; 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, 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

	High	Low
Year Ended December 31, 2015		
First Quarter	$ 0.33	$ 0.15
Second Quarter	$ 0.35	$ 0.15
Third Quarter	$ 0.30	$ 0.16
Fourth Quarter	$ 0.70	$ 0.16

Holders

As of March 1, 2016, there were 45,575,814 shares of the Company's common stock outstanding, held by approximately 90 stockholders of record, including 4,477,036 shares of common stock held by an indeterminate number of beneficial owners of securities whose shares are held in the names of various brokerage firms and clearing agencies.

Dividends

The Company's dividend policy will be determined by its Board of Directors and will depend upon a number of factors, including the Company's financial condition and performance, its cash needs and expansion plans, income tax consequences, and the restrictions that applicable laws and any credit or other contractual arrangements may then impose. The Company has not paid any cash dividends on its common stock to date and at the current time the Company does not anticipate paying a cash dividend on its 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, 2015, 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	7,950,000	$ 0.58	1,950,000(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 a drug discovery company that uses biomarker technology to identify enzyme targets associated with serious common diseases and then designs novel compounds to attack those targets. The Company's product pipeline encompasses two major categories of compounds at various stages of pre-clinical and clinical development that the Company believes have broad therapeutic potential not only for cancer but also for other debilitating and life-threatening diseases.

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

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

Recent Developments

TMU License Agreement

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

Under the TMU License Agreement, TMU will make non-refundable milestone payments to the Company of $200,000 within ninety days from the effective date of December 25, 2015, $50,000 upon the completion of the first Phase 1b/2 clinical trial, $150,000 upon the completion of the first Phase 3 clinical trial, and $200,000 upon the first filing of a New Drug Application ("NDA") with the FDA or a comparable non-United States regulatory authority. During the term of the TMU License Agreement, TMU will also pay earned royalties of 10% on cumulative net sales, and 10% to 15% on non-sale based sub-license income. A Phase 1b/2 clinical trial of LB-100 plus doxorubicin, to be managed and funded by TMU, is expected to commence during the third quarter of 2016.

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

Sale of Series A Convertible Preferred Stock

Effective January 28, 2016, the Series A Convertible Preferred Stock (the "Preferred Stock") Certificate of Designations was amended to increase the number of authorized shares of Preferred Stock to from 175,000 to 350,000. The Company also entered into a Securities Purchase Agreement with the current holder of the Preferred Stock on January 21, 2016, pursuant to which the Company sold an additional 175,000 shares of the Company's Preferred Stock at a per share price of $10.00, representing an aggregate purchase price of $1,750,000, payable $583,333 on closing, $583,333 on or before March 4, 2016, and $583,334 on or before June 3, 2016. This class of Preferred Stock has a dividend per share equal to 1% of the annual net revenue of the Company divided by 175,000, until converted or redeemed. Each share of Preferred Stock may be converted, at the option of the holder, into 12.5 shares of common stock (subject to customary anti-dilution provisions) and the Preferred Stock is subject to mandatory conversion at the conversion rate in the event of a merger or sale transaction resulting in gross proceeds to the Company of at least $21,875,000. If fully converted, the Preferred Stock would convert into 2,187,500 shares of common stock, representing an effective price per common share of $0.80. On the effective date of the transaction, the closing price of the Company's common stock was $0.22 per share. The Company has the right to redeem the Preferred Stock up to the fifth anniversary of the closing date at a price per share equal to $50.00.

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

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

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

At December 31, 2015, the Company had cash and money market funds aggregating $129,376. In January 2016, the Company entered into a agreement to sell additional shares of preferred stock for aggregate cash proceeds of $1,750,000 to be received by June 3, 2016, as a result of which the Company believes that it will have sufficient funds to complete the Phase 1 clinical trial of its lead anti-cancer compound LB-100 and to conduct a Phase 1b/2 clinical trial of LB-100 in myelodysplastic syndrome ("MDS"), as well as to fund the Company's ongoing operating expenses, including maintaining its patent portfolio, through approximately June 30, 2017.

The amount and timing of future cash requirements depend on the pace and design of the Company's clinical trial program. The Company currently plans to attempt to raise an additional approximately $3,000,000 of capital in 2016, likely in the form of equity, to also conduct a Phase 1b/2 clinical trial of LB-100 in combination with a platinum compound in platinum-resistant ovarian cancer and to extend the Company's pre-clinical research to develop oral versions of its lead anti-phosphatase compounds.

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

Recent Accounting Pronouncements

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

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

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

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

In February 2016, the FASB issued Accounting Standards Update No. 2016-02 (ASU 2016-02), Leases (Topic 842). ASU 2016-02 requires a lessee to record a right-of-use asset and a corresponding lease liability, initially measured at the present value of the lease payments, on the balance sheet for all leases with terms longer than 12 months, as well as the disclosure of key information about leasing arrangements. ASU 2016-02 requires recognition in the statement of operations of a single lease cost, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. ASU 2016-02 requires classification of all cash payments within operating activities in the statement of cash flows. Disclosures are required to provide the amount, timing and uncertainty of cash flows arising from leases. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. The Company has not yet evaluated the adoption of ASU 2016-02 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, 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 May 31, 2016.

The Phase 1 clinical trial is currently estimated to cost approximately $2,200,000, with such payments expected to be allocated approximately 60% for services provided by Theradex and approximately 40% for pass-through costs for clinical center laboratory costs and investigator costs over the life of the clinical trial. Total costs charged to operations through December 31, 2015 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, aggregated $1,660,725, of which $958,896 and $423,108 were incurred during the years ended December 31, 2015 and 2014, respectively, or approximately 46% and 38% of research and development costs for the years ended December 31, 2015 and 2014, respectively. 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 ratably over the life of the underlying contracts, unless the achievement of milestones, the completion of contracted work, or other information indicates that a different expensing schedule is more appropriate. The costs of the Phase 1 clinical trial of LB-100 that are being paid through Theradex, the CRO, are recorded and expensed based upon the documentation provided by the CRO.

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

Patent Costs

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

Stock-Based Compensation

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

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

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

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

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

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

Income Taxes

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

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

Plan of Operation

General Overview of Plans

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

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

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

Operating Plans

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

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

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

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

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

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

Effective treatment of brain tumors depends upon the ability of compounds to penetrate a physiological barrier known as the "blood-brain barrier", which protects the brain from exposure to potentially toxic substances in the blood. Because there is no certainty that the Company's compounds will be active against tumors confined to the brain, the LB-100 compounds have been studied against a variety of common and rare cancer types and have been shown to potentiate the activity of standard anti-cancer drugs in animal models of breast and pancreatic cancer, melanoma, 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 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 this clinical trial was to demonstrate that LB-100 can be administered safely to human beings at a dose and at a frequency that achieves the desired pharmacologic effect; in this case, inhibition of a specific enzyme, without being associated with toxicities considered unacceptable. The Phase 1 clinical trial of LB-100 was designed to be conducted in two parts. In Part 1, the maximum tolerable dose ("MTD") of LB-100 was to be determined. In Part 2, the MTD of LB-100, in combination with the standard cytotoxic drug docetaxel (which is a well-established anti-mitotic chemotherapy medication approved by the FDA for the treatment of various cancers), was to be determined.

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

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

As a prelude to determining the therapeutic effectiveness of LB-100 in a subsequent Phase 2 clinical trial of common cancers, a key goal of Part 1 of the Phase 1 clinical trial was to demonstrate that the target enzyme of LB-100, protein phosphatase 2A ("PP2A"), can be inhibited in humans with readily tolerable toxicity. Part 1 of the current Phase 1 clinical trial of LB-100 is now concluding with the entry of three patients into the study to facilitate pharmacokinetic studies to determine the MTD. Two patients have been entered and a third patient will be entered shortly. As an anti-cancer drug, LB-100 is likely to be used at maximum tolerable doses. However, for the potential treatment of non-malignant diseases, such as acute vascular diseases and metabolic diseases, lower doses may achieve therapeutic benefit by inhibition of the target enzyme, PP2A, thus opening up the possibility of a host of therapeutic applications for LB-100 and related proprietary compounds.

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

The costs of the Phase 1 clinical trial of LB-100 are being paid to or through Theradex, the CRO responsible for the clinical development of LB-100. Total costs charged to operations through December 31, 2015 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, aggregated $1,630,725, of which $928,896 and $423,108 were incurred during the years ended December 31, 2015 and 2014, respectively.

The Company had planned to proceed with Part 2 of the Phase 1 clinical trial to determine the toxicity of LB-100 in combination with docetaxel against a specific solid tumor for which single agent docetaxel is indicated. However, two developments have altered this plan. LB-100 appears to have anti-cancer activity in its own right, and second, preclinical studies indicate that LB-100 in combination with cisplatin (a widely used cytotoxic drug) is more active than LB-100 in combination with docetaxel. LB-100 significantly potentiates the standard anti-cancer drug cisplatin in animal models of several tumor types, including hepatocellular cancer and platinum-resistant ovarian cancer. In addition, it has been reported that inhibition of the enzyme-target of LB-100, PP2A, inhibits certain variants of the hematologic disorder known as myelodysplastic syndrome ("MDS"). Accordingly, the Company has decided not to proceed with Part 2 of the Phase 1 clinical trial, and has initiated planning for Phase1b/2 clinical trials in 2016 to evaluate the effectiveness of LB-100 alone for the treatment of MDS and in combination with a platinum compound for the treatment of platinum-resistant ovarian cancer.

The Company estimates that Part 1 of the Phase 1 clinical trial of LB-100 will now cost a total of approximately $2,200,000 and will be completed by May 31, 2016, as compared to the Company's previous estimate of a total cost of approximately $1,800,000 and a completion date of December 31, 2015. The following factors have contributed to the most recent revisions to the total cost and completion date of this clinical trial: (1) some patients are continuing to receive the study compound longer than is usual for patients with treatment-refractory progressive disease in a Phase 1 clinical trial; (2) the establishment of the MTD required more subjects than the initially planned six patients; and (3) the planned pharmacokinetic studies required more than the initially planned three patients.

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

Results of Operations

At December 31, 2015, the Company had not yet commenced any sustainable revenue-generating operations, does not have any positive cash flows from operations, and is dependent on its ability to raise equity capital to fund its operations.

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

	Years Ended December 31,	
	2015	2014
Licensing fee revenue	$ 200,000	$ —
Costs and expenses:		
General and administrative costs	754,440	1,285,173
Research and development costs	2,091,973	1,117,970
Total costs and expenses	2,846,413	2,403,143
Loss from operations	(2,646,413)	(2,403,143)
Interest income	78	66
Fair value of warrant extensions	(34,016)	(302,691)
Fair value of warrant discount	(171,757)	(134,420)
Gain from reversal of registration rights penalty obligation	—	74,000
Net loss	(2,852,108)	(2,766,188)
Dividend on Series A Convertible Preferred Stock	(2,000)	—
Net loss attributable to common stockholders	$ (2,854,108)	$ (2,766,188)
Net loss per common share – basic and diluted	$ (0.06)	$ (0.06)
Weighted average common shares outstanding – basic and diluted	46,793,502	44,405,563

Years Ended December 31, 2015 and 2014

Licensing Revenue . For the year ended December 31, 2015, revenue from licensing fees was $200,000, which consisted of a non-refundable milestone payment pursuant to a License Agreement with Taipei Medical University effective December 25, 2015. The $200,000 licensing fee was due within ninety days from the effective date and was fully earned on the December 25, 2015 effective date. The Company received the $200,000 payment on March 18, 2016. The Company had no revenue during the year ended December 31, 2014.

General and Administrative . For the year ended December 31, 2015, general and administrative costs were $754,440, which consisted of the vested portion of the fair value of common stock and common stock options issued to directors and consultants of $161,715 (including $76,750 of such costs as described at Note 7 to the consolidated financial statements), consulting and professional fees of $414,545, insurance expense of $57,556, officer's salary and related costs of $67,562, stock transfer fees of $10,028, travel and entertainment costs of $15,601, and other operating costs of $27,433.

For the year ended December 31, 2014, general and administrative costs were $1,285,173, which consisted of the fair value of stock options issued to directors and consultants of $775,124, consulting and professional fees of $323,543, 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, and other operating costs of $44,026.

General and administrative costs decreased by $530,733 or 41.3% in 2015 as compared to 2014, primarily as a result of a decrease of $613,409 in stock-based compensation.

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 $732,699 charged to operations for the fair value of stock options to acquire 4,000,000 shares of the Company's common stock that were issued to Gil Schwartzberg on January 28, 2014 for his continuing contributions to the Company's financial strategy.

Research and Development . For the year ended December 31, 2015, research and development costs were $2,091,973, which consisted of the vested portion of the fair value of common stock, and stock options and warrants, of $387,982, patent costs of $565,594, and contractor costs of $1,138,397, including $958,896 to Theradex in connection with the Phase 1 clinical trial of LB-100.

A significant component of the fair value of common stock, and stock options and warrants, of $387,982 for the year ended December 31, 2015 consisted primarily of $324,468 for the fair value of (i) 1,000,000 shares of fully-vested common stock and (ii) stock options and warrants to acquire 1,000,000 shares of the Company's common stock, vesting over the next two years, which were issued to BioPharmaWorks on September 14, 2015.

For the 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, patent costs of $342,625, and contractor costs of $604,296, including $423,108 to Theradex in connection with the Phase 1 clinical trial of LB-100.

A significant component of the fair value of stock options issued to consultants of $171,049 for the year ended December 31, 2014 was $118,650 charged to operations for the fair value of stock options to acquire 500,000 shares of the Company's common stock that were issued to Francis Johnson on June 26, 2014 for his contributions to the Company's compound development activities and $43,500 charged to operations for the fair value of stock options to acquire 1,000,000 shares of the Company's common stock that were assigned to Daniel Von Hoff, a member of the Company's Scientific Advisory Board, by Gil Schwartzberg, a significant stockholder of and consultant to the Company. As Mr. Schwartzberg is considered an affiliate of the Company for accounting and securities purposes, the fair value of the stock options assigned by Mr. Schwartzberg to Mr. Von Hoff for the benefit of the Company were recorded as a contribution to capital and a charge to operations.

Research and development costs increased by $974,003 or 87.1% in 2015 as compared to 2014, as a result of an increase of $216,933 in costs relating to the vested portion of the fair value of stock options, $222,969 in patent costs incurred to protect the Company's patent portfolio, and $534,101 in contractor costs, attributed to an increase of $535,788 to Theradex in connection with the Phase 1 clinical trial of LB-100.

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

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

Fair Value of Warrant Discount . During the year ended December 31, 2015, the Company incurred an expense of $171,757 for the fair value of discounts offered to warrant holders as an inducement for the early exercise of warrants to acquire 2,928,800 shares of common stock. The discounts ranged from $0.25 to $0.375 per share. The subsequent exercise of warrants resulted in the issuance of 1,050,000 shares of common stock and generated net proceeds to the Company of $315,000 in April 2015.

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

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, 2015, the Company incurred a net loss of $2,852,108, as compared to a net loss of $2,766,188 for the year ended December 31, 2014.

Dividends on Series A Convertible Preferred Stock . For the year ended December 31, 2015, dividends accrued on the 175,000 shares of Series A Convertible Preferred Stock outstanding on December 31, 2015 were $2,000. For the year ended December 31, 2014, there were no dividends accrued.

Net Loss Attributable to Common Stockholders . For the year ended December 31, 2015, the Company incurred a net loss attributable to common stockholders of $2,854,108, as compared to a net loss attributable to common stockholders of $2,766,188 for the year ended December 31, 2014.

Liquidity and Capital Resources – December 31, 2015

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 sustainable revenues from operations to date, and does not expect to do so in the foreseeable future. The Company has experienced recurring operating losses and negative operating cash flows since inception, and has financed its working capital requirements during this period primarily through the recurring sale of its equity securities and the exercise of outstanding warrants. As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern (see "Going Concern" above).

At December 31, 2015, the Company had working capital of $312,333 (including a licensing fee receivable of $200,000 and advances on research and development contract services of $207,677), as compared to working capital of $265,862 at December 31, 2014, an increase in working capital of $46,471 for the year ended December 31, 2015. The increase in working capital is primarily the net result of the net proceeds from the sale on March 17, 2015 of 175,000 shares of the Company's non-voting Series A Convertible Preferred Stock at a price per share of $10.00, for an aggregate purchase price of $1,750,000 and $315,000 from the exercise of warrants in April 2015, which resulted in the issuance of 1,050,000 shares of the Company's common stock, which is being utilized to fund the Company's Phase 1 clinical trial and its ongoing operating expenses, including maintaining its patent portfolio. At December 31, 2015, the Company had cash and money market funds aggregating $129,376, as compared to $258,110 at December 31, 2014, a decrease of $128,734 for year ended December 31, 2015.

At December 31, 2015, the Company had advances to Theradex aggregating $185,392, of which $181,510 is expected to be refunded to the Company once the Company's Phase 1 clinical trial of LB-100 is completed in mid-2016.

At December 31, 2015, the Company had cash and money market funds aggregating $129,376. As a result of the Company entering into an agreement in January 2016 to sell additional shares of preferred stock for aggregate cash proceeds of $1,750,000 to be received by June 3, 2016, the Company believes that it has sufficient funds to complete the Phase 1 clinical trial of its lead anti-cancer compound LB-100, to conduct a Phase 1b/2 clinical trial of LB-100 in MDS, and to support its ongoing operating expenses, including maintaining its patent portfolio, through approximately June 30, 2017.

The amount and timing of future cash requirements depend on the pace and design of the Company's clinical trial program. The Company currently plans to attempt to raise an additional approximately $3,000,000 of capital in 2016, likely in the form of equity, to also conduct a Phase 1b/2 clinical trial of LB-100 in combination with a platinum compound in platinum-resistant ovarian cancer and to extend the Company's pre-clinical research to develop oral versions of its lead anti-phosphatase compounds.

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

Operating Activities . For the year ended December 31, 2015, operating activities utilized cash of $2,181,126, as compared to utilizing cash of $1,635,544 for the year ended December 31, 2014, to fund the Company's Phase 1 clinical trial, to support its other ongoing research and development activities, and to fund its other ongoing operating expenses, including maintaining its patent portfolio,

Investing Activities . For the year ended December 31, 2015, investing activities consisted of a decrease in money market funds of $109,604, reflecting withdrawals to meet operating needs. 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.

Financing Activities . For the year ended December 31, 2015, financing activities consisted of $1,750,000 in proceeds received from the sale of 175,000 shares of the Company's non-voting Series A Convertible Preferred Stock at an aggregate purchase price of $1,750,000 on March 17, 2015, less costs of $12,608 associated with the sale, and $315,000 in proceeds received from the exercise of warrants, which resulted in the issuance of 1,050,000 shares of the Company's common stock in April 2015. For the year ended December 31, 2014, financing activities consisted of $1,412,500 in proceeds received from the exercise of warrants for the purchase of 3,900,000 shares of the Company's common stock in April 2014.

Principal Commitments

On September 21, 2012, the Company entered into a work order agreement with Theradex, the CRO responsible for the clinical development of the Company's lead compound, LB-100, to manage and administer the Phase 1 clinical trial of LB-100. The Phase 1 clinical trial of LB-100, which began during April 2013 with the entry of patients into the clinical trial, is being carried out by nationally recognized comprehensive cancer centers, and is estimated to be completed by May 31, 2016. The Phase 1 clinical trial is currently estimated to cost approximately $2,200,000, with such payments expected to be allocated approximately 60% for services provided by Theradex and approximately 40% for pass-through costs for clinical center laboratory costs and investigator costs over the life of the clinical trial. Total costs charged to operations through December 31, 2015 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, aggregated $1,660,725, of which $958,896 and $423,108 were incurred during the years ended December 31, 2015 and 2014, 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 years ended December 31, 2015 and 2014.

Effective January 1, 2014, the Company entered into an Advisory Agreement with Dr. Kathleen P. Mullinix, a member of the Board of Directors of the Company, effective for an initial term of one year through December 31, 2014 to advise on business development matters. The Advisory Agreement provides for annual cash compensation of $25,000. The term of the Advisory Agreement is automatically extended for a term of one year annually unless a notice of intent to terminate is given by either party at least 90 days before the end of the applicable term. Accordingly, the Advisory Agreement was extended for additional terms of one year effective January 1, 2015 and 2016. Consulting and advisory fees charged to operations pursuant to this agreement were $25,000 during the years ended December 31, 2015 and 2014.

On October 7, 2014, the Company entered into an agreement with ProActive Capital Resources Group LLC for strategic advisory, investor relations and public relations services through October 6, 2015. Among other things, the agreement provides for compensation in the form of a monthly fee of $1,500 in cash. Fees charged to operations pursuant to this agreement and other arrangements were $13,500 and $12,000 during the years ended December 31, 2015 and 2014, respectively.

Effective September 14, 2015, the Company entered into a Collaboration Agreement with BioPharmaWorks, pursuant to which the Company engaged BioPharmaWorks to perform certain services for the Company. Those services include, among other things: (a) assisting the Company to (i) commercialize its products and strengthen its patent portfolio, (ii) identify large pharmaceutical companies with potential interest in the Company's product pipeline, and (iii) prepare and deliver presentations concerning the Company's products; (b) at the request of the Board of Directors, serving as backup management for up to three months should the Company's chief executive officer and scientific leader be temporarily unable to carry out his duties; (c) being available for consultation in drug discovery and development; and (d) identifying providers and overseeing tasks relating to clinical use and commercialization of new compounds. BioPharmaWorks was founded in 2015 by former Pfizer scientists with extensive multi-disciplinary research and development and drug development experience. The Collaboration Agreement is for an initial term of two years and automatically renews for subsequent annual periods unless terminated by a party not less than 60 days prior to the expiration of the applicable period. In connection with the Collaboration Agreement, the Company agreed to pay BioPharmaWorks a monthly fee of $10,000, subject to the right of the Company to pay a negotiated hourly rate in lieu of the monthly payment, and agreed to issue to BioPharmaWorks certain equity-based compensation. Fees charged to operations pursuant to this agreement and other arrangements were $52,625 during the year ended December 31, 2015.

The following table sets forth the Company's principal cash obligations and commitments for the next five fiscal years as of December 31, aggregating $713,927, of which $124,050 is included in current liabilities in the Company's consolidated balance sheet at December 31, 2015.

		Payments Due By Year				
	Total	**2016**	**2017**	**2018**	**2019**	**2020**
Research and development contracts	$ 409,703	$ 409,703	$ —	$ —	$ —	$ —
Clinical trial agreements	48,224	48,224	—	—	—	—
Consulting agreements	256,000	166,000	90,000	—	—	—
Total	$ 713,927	$ 623,927	$ 90,000	$ —	$ —	$ —

Off-Balance Sheet Arrangements

At December 31, 2015, 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

The Company's consolidated financial statements and notes thereto and the related report of its 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

The Company maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that the Company files 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 the Company's management, consisting of the Company's 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), the Company carried out an evaluation, under the supervision and with the participation of its management, consisting of the Company's principal executive and financial officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of the end of the most recent fiscal year covered by this report. Based on the foregoing, the Company's principal executive and financial officer concluded that our disclosure controls and procedures are effective to ensure the information required to be disclosed in the Company's 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.

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

Management's Annual Report on Internal Controls Over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) under the Exchange Act. The Company's internal control over financial reporting is designed to ensure that material information regarding the Company's 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.

The Company's management, consisting of its chief executive officer and chief financial officer, has evaluated the Company's internal control over financial reporting as of December 31, 2015 based on the 2013 Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations (COSO) of the Treadway Commission. Based on this assessment, the Company's management has concluded that its internal control over financial reporting was effective as of December 31, 2015.

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 Controls 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, 2015 that materially affected or are reasonably likely to materially 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 the Company as of December 31, 2015. 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 the 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.

The Company's directors and executive officer are as follows:

Name	Age	Position(s) Held with the Registrant
Dr. John S. Kovach	79	President, Chief Executive Officer, Chief Financial Officer and Director
Dr. Philip F. Palmedo	82	Director
Dr. Kathleen P. Mullinix	72	Director

Biographies of Directors and Executive Officers

Dr. John S. Kovach

Dr. John S. Kovach founded the Company in August 2005 and is its President, Chief Executive Officer, Chief Financial Officer and a member of its Board of Directors. He received a B.A. (cum laude) from Princeton University and an M.D. (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 at the National Institute of Arthritis and Metabolic diseases studying control of gene expression in bacterial systems.

Dr. Kovach was recruited to the State University of New York at Stony Brook ("SUNY – Stony Brook") in Stony Brook, New York 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. From 1994 to 2000, Dr. Kovach was Executive Vice President for Medical and Scientific Affairs at the 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, Dr. Kovach 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 School of Medicine of SUNY – 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 the Company's 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 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 H. Lundbeck A/S in 2003. 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") was established effective June 30, 20016 to advise management of the Company in three areas: human molecular pathology; the clinical management of human brain tumors; and medicinal chemistry. The Company's objective is to meet with the Committee as a group annually, with some members participating via telephone conference. The Committee members have been apprised of the Company's 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 such Committee members serve in any management capacity with the Company. The members of the Company's Committee currently 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.

Dr. Von Hoff is currently Physician in Chief, Distinguished Professor and Director of the Clinical Translational Research Division at the 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 is a Fellow of the American College of Physicians.

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 that are now used routinely, including mitoxantrone, fludarabine, paclitaxel, docetaxel, gemcitabine, irinotecan, nelarabine, capecitabine and lapatinib. 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 1,050 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 from 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 in 2004 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

The Company does not presently have an audit committee. The Board of Directors acts in that capacity and has determined that it does not currently have a person qualifying as an audit committee financial expert serving on the Company's Board of Directors.

Code of Ethics

The Company's Board of Directors adopted a code of ethics covering all of the Company's executive officers and key employees. A copy of the Company's 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, except as follows: Philip Palmedo, a director of the Company, did not file a Form 4 with respect to the exercise of warrants to acquire 300,000 shares of the Company's common stock in April 2015.

ITEM 11. EXECUTIVE COMPENSATION

Option Grants in 2014 and 2015 - Named Executive Officer

None.

Aggregated Option Exercises in 2014 and 2015 Option Values at December 31, 2014 and at 2015 - Named Executive Officer

None.

Employment Agreements; Compensation

The Company has not entered into any employment agreements with management. During the years ended December 31, 2014 and 2015, the Company did not have any full-time employees.

During the years ended December 31, 2014 and 2015, the Company paid Dr. John S. Kovach, the Company's Chief Executive Officer and Chief Financial Officer, an annual salary of $60,000. Dr. Kovach currently devotes approximately 50% of his time to his academic commitments at SUNY – Stony Brook, in order to devote sufficient time to the Company's business activities.

Dr. Kovach is not compensated separately for his service on the Company's 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 member of the Company's Board of Directors, 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 vested ratably in equal quarterly installments of 25,000 shares beginning July 1, 2011. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was 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 were 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 stock 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 were 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 stock 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	2015	0	0	0	0	0	0	0	0
Director	2014	0	0	0	0	0	0	0	0
	2013	0	0	0	0	0	0	0	0
Mel Sorensen	2014	0	0	0	0	0	0	0	0
Director (3)	2013	0	0	0	0	0	0	0	0
Robert B. Royds									
Director (4)	2013	0	0	0	0	0	0	0	0
Kathleen P. Mullinix	2015	0	0	0	0	0	0	0	0
Director	2014	0	0	0	0	0	0	0	0
	2013	0	0	0	0	0	0	0	0

(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 stock options vested ratably in equal quarterly installments of 6,250 shares beginning July 1, 2011. The fair value of these stock 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 stock 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 Dr. Daniel D. Von Hoff, M.D., a member of the Company's Scientific Advisory Committee. The stock 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 Dr. 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 stock 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 1, 2016 certain information regarding beneficial ownership of the Company's 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 the Company to own beneficially more than 5% of the Company's outstanding shares of common stock, (ii) each of the Company's directors, and (iii) all directors and executive officers of the Company as a group. As of March 1, 2016, there were 45,575,814 shares of the Company's 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 1, 2016 pursuant to stock 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	9,114,503	20.0%
Dr. Philip F. Palmedo 248 Route 25A, No. 2 East Setauket, New York 11733	1,266,020(1)	2.8%
Dr. Kathleen P. Mullinix 248 Route 25A, No. 2 East Setauket, New York 11733	200,000(2)	0.4%
All officers and directors as a group (three persons)	10,580,523(1)(2)	23.0%
John and Barbara Kovach 2015 Trust Eric J. Forman, Trustee 401 Park Avenue South, 10 th Floor New York, New York 10016	8,000,000(3)	17.6%
Eric J. Forman. 401 Park Avenue South, 10 th Floor New York, New York 10016	8,100,000(4)	17.8%
Gil Schwartzberg 5500 Military Trail, Suite 22 Jupiter, Florida 33458	8,538,697(5)	17.2%
Dr. Debbie Schwartzberg 5500 Military Trail, Suite 22 Jupiter, Florida 33458	6,804,845(6)	14.3%
Dr. Arthur and Jane Riggs 4852 Saint Andres Avenue La Verne, California 91750	9,225,000(7)	18.5%
Robert and Susan Greenberg 228 Manhattan Beach Boulevard Manhattan Beach, California 90266	3,650,000(8)	8.0%

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

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

(3) Consists of 8,000,000 shares of common stock transferred by John Kovach and his wife, Barbara C.H. Kovach, as grantors, to the John and Barbara Kovach 2015 Trust, an irrevocable trust dated July 6, 2015. The primary beneficiaries of the trust are the two adult daughters of John and Barbara Kovach. Eric J. Forman is the trustee of the John and Barbara Kovach 2015 Trust.

(4) Includes 100,000 shares of common stock owned by Eric J. Forman. Mr. Forman is the husband of Julie Schwartzberg, the son-in-law of Gil and Debbie Schwartzberg, and the trustee of the John and Barbara Kovach 2015 Trust. Also includes 8,000,000 shares of common stock owned by the John and Barbara Kovach 2015 Trust, as to which Mr. Forman, as trustee, has voting, disposition and investment control. Excludes 1,150,000 shares of common stock and stock options to purchase 500,000 shares of common stock owned by the Julie Schwartzberg Trust, as to which Julie Schwartzberg is the beneficiary, and as to which Mr. Forman disclaims beneficial ownership or control. All stock options are immediately exercisable or within 60 days.

(5) Includes 800,800 shares of common stock and stock 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; 1,150,000 shares of common stock and stock 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 stock 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 2,004,845 shares of common stock and stock options to purchase 1,000,000 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 stock options are immediately exercisable or within 60 days.

(6) Includes 2,004,845 shares of common stock and stock options to purchase 1,000,000 shares of common stock owned by Ms. Schwartzberg. Also includes 500,000 shares of common stock owned by the Debbie Schwartzberg Family Trust; 1,150,000 shares of common stock and stock 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 stock 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 stock 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 stock options are immediately exercisable or within 60 days.

(7) Includes 4,850,000 shares of common stock and 4,375,000 shares of common stock issuable upon conversion of 350,000 shares of Series A Convertible Preferred Stock owned by the Arthur and Jane Riggs 1990 Revocable Trust. Arthur Riggs and his wife, Jane Riggs, are co-trustees of the trust and share voting and dispositive power over the shares of preferred stock. The shares of Series A Convertible Preferred Stock were acquired on March 17, 2015 and January 15, 2016, are non-voting, and are immediately convertible into common stock.

(8) Consists of 3,650,000 shares of common stock owned by the Greenberg Family Trust dated May 3, 1988. The trust is a revocable trust, and Arthur Greenberg and his wife, Susan Greenberg, are co-trustees of the trust and share voting and dispositive power over the shares of common stock.

Information with respect to securities authorized for issuance under equity compensation plans is provided at “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 the Company as engaged in with persons who were directors, officers or affiliates before and at the time of the transaction, and persons known by the Company to be the beneficial owners of 5% or more of the Company’s common stock during the years ended December 31, 2014 and 2015.

Most office services are provided without charge by Dr. John S. Kovach, the Company's President, Chief Executive Officer and Chief Financial Officer. Such costs were not material to the Company's consolidated 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 the Company and his other business interests. The Company has not formulated a policy for the resolution of such conflicts.

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

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 were non-interest bearing and were due on demand. Effective March 17, 2015, Dr. Kovach converted such advances 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.

On January 28, 2014, the Company approved a second amendment to the Company's consulting agreement with Gil Schwartzberg, a significant stockholder of and consultant to the Company, dated September 12, 2007 to extend it for an additional four years to January 28, 2019 and granted to Mr. Schwartzberg stock options to purchase an additional aggregate of 4,000,000 shares of common stock, exercisable for a period of the earlier of five years from the grant date or the termination of the consulting agreement at $0.50 per share, with one-half of the stock options (2,000,000 shares) vesting immediately and one-half of the stock options (2,000,000 shares) vesting on January 28, 2015. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $596,400 ($0.15 per share) on January 28, 2014, of which $298,200 was attributed to the stock 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 stock options was charged to operations ratably from January 28, 2014 through January 28, 2015. During the years ended December 31, 2015 and 2014, the Company recorded charges to operations of $74,901 and $732,699, respectively, with respect to these stock options.

On June 18, 2014, the Company entered into a sub-lease agreement for shared office space in New York City with the Eric J. Forman Law Office, a party providing legal and consulting services to the Company. The sub-lease was for a term of six months at a base rate of $875 per month and was not renewed upon its expiration in December 2014. Eric J. 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 J. Forman were $48,000 and $46,000 for the years ended December 31, 2015 and 2014, respectively.

On July 15, 2014, Gil Schwartzberg assigned fully-vested stock options to acquire 1,000,000 shares of the Company's common stock to Dr. Daniel D. Von Hoff, M.D., 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 Dr. 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.

See “ITEM 11. EXECUTIVE COMPENSATION - Directors Compensation” for disclosures with respect to compensation (both cash and equity-based) to certain of the Company’s directors for services.

(b) Director Independence

The Company considers Dr. Palmedo and Dr. 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 the Company’s independent registered public accounting firm for the years ended December 31, 2014 and 2015 and for the interim periods in such fiscal years. The following table shows the fees that were incurred by the Company for audit and other services provided by Weinberg & Company, P.C. for the years ended December 31, 2014 and 2015.

	Years Ended December 31,	
	2014	2015
Audit Fees (1)	$ 56,459	$ 66,571
Audit-Related Fees (2)	—	—
Tax Fees (3)	8,260	11,160
All Other Fees (4)	—	—
Total	$ 64,719	$ 77,731

(1) Audit fees represent fees for professional services provided in connection with the audit of the Company’s annual financial statements and the review of its financial statements included in the Company’s Quarterly Reports on Form 10-Q 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 the Company’s 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 the Company’s Board of Directors. The Board of Directors has adopted a pre-approval policy that provides for the pre-approval of all services performed for the Company by its 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 28, 2016

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
(Registrant)

By: */s/ JOHN S. KOVACH*
Name: John S. Kovach
Title: President, Chief Executive Officer and Chief Financial 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	President, Chief Executive Officer and Chief Financial Officer Principal Financial and Accounting Officer and Director	March 28, 2016
/s/ PHILIP F. PALMEDO Philip F. Palmedo	Director	March 28, 2016
/s/ KATHLEEN P. MULLINIX Kathleen P. Mullinix	Director	March 28, 2016

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]
3.3	Certificate of Designations for the Company's Series A Convertible Preferred Stock [14]
3.4	Certificate of Amendment of Certificate of Designations of the Series A Convertible Preferred Stock.*
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	Collaboration Agreement between Lixte Biotechnology Holdings, Inc. and BioPharmaWorks LLC effective September 14, 2015. [15]
10.20	Form of First Warrant to purchase common stock issued to BioPharmaWorks LLC dated September 14, 2015. [15]
10.21	Form of Second Warrant to purchase common stock issued to BioPharmaWorks LLC dated September 14, 2015. [15]
10.22	Advisory Agreement between Lixte Biotechnology Holdings, Inc. and Dr. Fritz Henn effective as of October 28, 2015. [16]

10.23 Stock Option Agreement to purchase common stock issued to Dr. Fritz Henn dated October 28, 2015. [16]

10.24 Exclusive License Agreement between the Company and Taipei Medical University dated December 25, 2015. [17]

31	Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32	Officer's Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document

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

16 Filed as an Exhibit to the Company's Quarterly Report on Form 10-Q, as filed with the Securities and Exchange Commission on November 10, 2015, and incorporated herein by reference.

17 Filed as an Exhibit to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on December 30, 2015, and incorporated herein by reference.

* Filed herewith.

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

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

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

Years Ended December 31, 2015 and 2014

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Consolidated Statements of Operations – Years Ended December 31, 2015 and 2014	F-4
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Notes to Consolidated Financial Statements – Years Ended December 31, 2015 and 2014	F-7

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, 2015 and 2014, 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, 2015 and 2014, 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 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 28, 2016

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2015	**2014**
ASSETS		
Current assets:		
Cash	$ 25,281	$ 44,411
Money market funds	104,095	213,699
License fee receivable	200,000	—
Advances on research and development contract services, including $185,392 and $202,816 from Theradex at December 31, 2015 and 2014, respectively	207,677	231,177
Prepaid expenses and other current assets	60,922	50,012
Total current assets	597,975	539,299
Total assets	$ 597,975	$ 539,299
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 159,076	$ 122,534
Research and development contract liabilities, including $88,162 and $18,436 to Theradex at December 31, 2015 and 2014, respectively	124,566	58,186
Dividend payable on Series A Convertible Preferred Stock	2,000	—
Due to Chairman and major stockholder	—	92,717
Total current liabilities	285,642	273,437
Commitments and contingencies		
Stockholders' equity:		
Series A Convertible Preferred Stock, $0.0001 par value, $10.00 per share stated value, $50.00 per share redemption value; 175,000 shares authorized, issued and outstanding at December 31, 2015; aggregate redemption value of $8,750,000; liquidation preference based on assumed conversion into common shares; 2,187,500 shares of common stock issuable upon conversion	1,750,000	—
Common stock, $0.0001 par value; authorized – 100,000,000 shares; issued and outstanding – 47,875,814 shares and 45,483,097 shares at December 31, 2015 and 2014, respectively	4,787	4,548
Additional paid-in capital	17,129,815	15,979,475
Accumulated deficit	(18,572,269)	(15,718,161)
Total stockholders' equity	312,333	265,862
Total liabilities and stockholders' equity	$ 597,975	$ 539,299

See accompanying notes to consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,	
	2015	**2014**
Licensing fee revenue	$ 200,000	$ —
Costs and expenses:		
General and administrative costs, including $99,901 and $784,598 to related parties for the years ended December 31, 2015 and 2014, respectively	754,440	1,285,173
Research and development costs, including $970,729 and $435,707 to Theradex for the years ended December 31, 2015 and 2014, respectively	2,091,973	1,117,970
Total costs and expenses	2,846,413	2,403,143
Loss from operations	(2,646,413)	(2,403,143)
Interest income	78	66
Fair value of warrant extensions	(34,016)	(302,691)
Fair value of warrant discount	(171,757)	(134,420)
Gain from reversal of registration rights penalty obligation	—	74,000
Net loss	(2,852,108)	(2,766,188)
Dividend on Series A Convertible Preferred Stock	(2,000)	—
Net loss attributable to common stockholders	$ (2,854,108)	$ (2,766,188)
Net loss per common share – basic and diluted	$ (0.06)	$ (0.06)
Weighted average common shares outstanding – basic and diluted	46,793,502	44,405,563

See accompanying notes to consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

Years Ended December 31, 2015 and 2014

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Par Value			
Balance, December 31, 2013	—	$ —	41,583,097	$ 4,158	$ 13,184,081	$ (12,951,973)	$ 236,266
Exercise of warrants	—	—	3,900,000	390	1,412,110	—	1,412,500
Fair value of warrant extensions	—	—	—	—	302,691	—	302,691
Fair value of warrant discounts	—	—	—	—	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
Fair value of warrant extensions	—	—	—	—	34,016	—	34,016
Fair value of warrant discounts	—	—	—	—	171,757	—	171,757
Sale of Series A Convertible Preferred Stock	175,000	1,750,000	—	—	—	—	1,750,000
Costs incurred in connection with sale of Series A Convertible Preferred Stock	—	—	—	—	(12,608)	—	(12,608)
Exercise of warrants	—	—	1,050,000	105	314,895	—	315,000
Conversion of advances due to Chairman and major stockholder into common stock	—	—	92,717	9	92,708	—	92,717
Stock-based compensation expense	—	—	1,250,000	125	549,572	—	549,697
Dividend on Series A Convertible Preferred Stock	—	—	—	—	—	(2,000)	(2,000)
Net loss	—	—	—	—	—	(2,852,108)	(2,852,108)
Balance, December 31, 2015	175,000	$ 1,750,000	47,875,814	$ 4,787	$ 17,129,815	$ (18,572,269)	$ 312,333

See accompanying notes to consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,	
	2015	**2014**
Cash flows from operating activities:		
Net loss	$ (2,852,108)	$ (2,766,188)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense included in -		
General and administrative costs	157,659	775,124
Research and development costs	392,038	171,049
Fair value of warrant -		
Extensions	34,016	302,691
Discounts	171,757	134,420
Changes in operating assets and liabilities:		
(Increase) decrease in -		
Licensing fee receivable	(200,000)	—
Advances on research and development contract services	23,500	(197,297)
Prepaid expenses and other current assets	(10,910)	(7,006)
Increase (decrease) in -		
Accounts payable and accrued expenses	36,542	14,760
Research and development contract liabilities	66,380	10,903
Registration rights penalty obligation	—	(74,000)
Net cash used in operating activities	(2,181,126)	(1,635,544)
Cash flows from investing activities:		
(Increase) decrease in money market funds	109,604	(207,564)
Net cash provided by (used in) investing activities	109,604	(207,564)
Cash flows from financing activities:		
Proceeds from sale of Series A Convertible Preferred Stock	1,750,000	—
Cash payments made for costs incurred in connection with sale of Series A Convertible Preferred Stock	(12,608)	—
Proceeds from exercise of warrants	315,000	1,412,500
Net cash provided by financing activities	2,052,392	1,412,500
Cash:		
Net decrease	(19,130)	(430,608)
Balance at beginning of period	44,411	475,019
Balance at end of period	$ 25,281	$ 44,411
Supplemental disclosures of cash flow information:		
Cash paid for -		
Interest	$ —	$ —
Income taxes	$ —	$ —
Non-cash financing activities:		
Conversion of advances due to Chairman and major stockholder into common stock	$ 92,717	$ —
Accrued dividend on Series A Convertible Preferred Stock	$ 2,000	$ —

See accompanying notes to consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2015 and 2014

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

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

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

Operating Plans

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

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

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

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

The Company'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 this clinical trial was to demonstrate that LB-100 can be administered safely to human beings at a dose and at a frequency that achieves the desired pharmacologic effect; in this case, inhibition of a specific enzyme, without being associated with toxicities considered unacceptable. The Phase 1 clinical trial of LB-100 was designed to be conducted in two parts. In Part 1, the maximum tolerable dose ("MTD") of LB-100 was to be determined. In Part 2, the MTD of LB-100, in combination with the standard cytotoxic drug docetaxel (which is a well-established anti-mitotic chemotherapy medication approved by the FDA for the treatment of various cancers), was to be determined.

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

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

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

The Company estimates that Part 1 of the Phase 1 clinical trial of LB-100 will now cost a total of approximately $2,200,000 and will be completed by May 31, 2016, as compared to the Company's previous estimate of a total cost of approximately $1,800,000 and a completion date of December 31, 2015. The following factors have contributed to the most recent revisions to the total cost and completion date of this clinical trial: (1) some patients are continuing to receive the study compound longer than is usual for patients with treatment-refractory progressive disease in a Phase 1 clinical trial; (2) the establishment of the MTD required more subjects than the initially planned six patients; and (3) the planned pharmacokinetic studies required more than the initially planned three patients.

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

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

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

At December 31, 2015, the Company had cash and money market funds aggregating $129,376. In January 2016, the Company entered into a agreement to sell additional shares of preferred stock for aggregate cash proceeds of $1,750,000 to be received by June 3, 2016 (see Note 4), as a result of which the Company believes that it will have sufficient funds to complete the Phase 1 clinical trial of its lead anti-cancer compound LB-100 and to conduct a Phase 1b/2 clinical trial of LB-100 in MDS, as well as to fund the Company's ongoing operating expenses, including maintaining its patent portfolio, through approximately June 30, 2017.

The amount and timing of future cash requirements will depend on the pace and design of the Company's clinical trial program. The Company currently plans to attempt to raise an additional approximately $3,000,000 of capital in 2016, likely in the form of equity, to also conduct a Phase 1b/2 clinical trial of LB-100 in combination with a platinum compound in platinum-resistant ovarian cancer and to extend the Company's pre-clinical research to develop oral versions of its lead anti-phosphatase compounds.

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

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.

Use of Estimates

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

Cash Concentrations

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

Research and Development

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

Research and development costs are expensed ratably over the life of the underlying contracts, unless the achievement of milestones, the completion of contracted work, or other information indicates that a different expensing schedule is more appropriate. The costs of the Phase 1 clinical trial of LB-100 that are being paid through Theradex, the CRO, are recorded and expensed based upon the documentation provided by the CRO.

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

At December 31, 2015, the Company had advances to Theradex aggregating $185,392, of which $181,510 is expected to be refunded to the Company upon completion of the Company's Phase 1 clinical trial of LB-100 in mid-2016.

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 $565,594 and $342,625 for the years ended December 31, 2015 and 2014, respectively. Patent costs are included in research and development costs in the Company's consolidated statements of operations.

Accounting for Preferred Stock

The Company accounts for preferred stock as either equity or debt, depending on the specific characteristics of the security issued. The Series A Convertible Preferred Stock issued by the Company in March 2015 has been classified in stockholders' equity, as described at Note 4.

Concentration of Risk

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

On September 21, 2012, the Company entered into a work order agreement with Theradex, the CRO responsible for the clinical development of the Company's lead compound, LB-100, to manage and administer the Phase 1 clinical trial of LB-100. The Phase 1 clinical trial of LB-100, which began during April 2013 with the entry of patients into the clinical trial, is being carried out by nationally recognized comprehensive cancer centers, and is estimated to be completed by May 31, 2016.

The Phase 1 clinical trial is currently estimated to cost approximately $2,200,000, with such payments expected to be allocated approximately 60% for services provided by Theradex and approximately 40% for pass-through costs for clinical center laboratory costs and investigator costs over the life of the clinical trial. Total costs charged to operations through December 31, 2015 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, aggregated $1,660,725, of which $958,896 and $423,108 were incurred during the years ended December 31, 2015 and 2014, respectively, or approximately 46% and 38% of research and development costs for the years ended December 31, 2015 and 2014, respectively. Costs pursuant to this agreement are included in research and development costs in the Company's consolidated statements of operations.

Income Taxes

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

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

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

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

The Company accounts for uncertainties in income tax law under a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns as prescribed by GAAP. The tax effects of a position are recognized only if it is "more-likely-than-not" to be sustained by the taxing authority as of the reporting date. If the tax position is not considered "more-likely-than-not" to be sustained, then no benefits of the position are recognized. As of December 31, 2015, the Company had not recorded any liability for uncertain tax positions. In subsequent periods, any interest and penalties related to uncertain tax positions will be recognized as a component of income tax expense.

Stock-Based Compensation

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

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

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

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

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

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

Revenue Recognition

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

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

Comprehensive Income (Loss)

Components of comprehensive income or loss, including net income or loss, are reported in the financial statements in the period in which they are recognized. Comprehensive income or loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income (loss) and other comprehensive income (loss) are reported net of any related tax effect to arrive at comprehensive income (loss). The Company did not have any items of comprehensive income (loss) for the years ended December 31, 2015 and 2014.

Earnings Per Share

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

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

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

At December 31, 2015 and 2014, the Company excluded the outstanding securities summarized below, which entitle the holders thereof to acquire shares of common stock, from its calculation of earnings per share, as their effect would have been anti-dilutive.

	December 31,	
	2015	2014
Series A Convertible Preferred Stock	2,187,500	—
Common stock warrants	—	2,928,800
Common stock options	7,950,000	6,850,000
Total	10,137,500	9,778,800

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.

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

Recent Accounting Pronouncements

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

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

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

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

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

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

Under the TMU License Agreement, TMU will make non-refundable milestone payments to the Company of $200,000 within ninety days from the effective date of December 25, 2015, $50,000 upon the completion of the first Phase 1b/2 clinical trial, $150,000 upon the completion of the first Phase 3 clinical trial, and $200,000 upon the first filing of a New Drug Application ("NDA") with the FDA or a comparable non-United States regulatory authority. During the term of the TMU License Agreement, TMU will also pay earned royalties of 10% on cumulative net sales, and 10% to 15% on non-sale based sub-license income. A Phase 1b/2 clinical trial of LB-100 plus doxorubicin, to be managed and funded by TMU, is expected to commence during the third quarter of 2016.

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

4. Stockholders' Equity

Preferred Stock

The Company has authorized a total of 10,000,000 shares of preferred stock, par value $0.001 per share. On March 17, 2015, the Company filed a Certificate of Designations, Preferences, Rights and Limitations (the "Certificate of Designations") of its Series A Convertible Preferred Stock with the Delaware Secretary of State to amend the Company's certificate of incorporation. The number of shares designated as Series A Convertible Preferred Stock was 175,000 (which are not subject to increase without the written consent of a majority of the holders of the Series A Convertible Preferred Stock or as otherwise set forth in the Certificate of Designations). Accordingly, as of December 31, 2015, 9,825,000 shares of preferred stock were undesignated and may be issued with such rights and powers as the Board of Directors may designate. Effective January 28, 2016, the Series A Convertible Preferred Stock Certificate of Designations was amended to increase the number of authorized shares of Series A Convertible Preferred Stock from 175,000 to 350,000.

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 Stock") at a price per share of $10.00, representing an aggregate purchase price of $1,750,000.

Effective January 28, 2016, the Company entered into a Securities Purchase Agreement with the holder of the Preferred Stock, pursuant to which the Company sold an additional 175,000 shares of Preferred Stock at a price per share of $10.00, representing an aggregate purchase price of $1,750,000, payable $583,333 on closing, $583,333 on or before March 4, 2016, and $583,334 on or before June 3, 2016.

This class of Preferred Stock has a dividend per share equal to 1% of the annual net revenue of the Company divided by 175,000, until converted or redeemed. Each share of Preferred Stock may be converted, at the option of the holder, into 12.5 shares of common stock (subject to customary anti-dilution provisions) and the Preferred Stock is subject to mandatory conversion at the conversion rate in the event of a merger or sale transaction resulting in gross proceeds to the Company of at least $21,875,000. The Preferred Stock has a liquidation preference based on its assumed conversion into shares of common stock.

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

Based on the attributes of the Preferred Stock described above, the Company has determined to account for the Preferred Stock as a permanent component of stockholders' equity. Legal costs of $12,608 incurred with respect to the issuance of the Preferred Stock on March 17, 2015 were charged directly to additional paid-in capital. No costs were incurred with respect to the issuance of the Preferred Stock on January 21, 2016.

Based on the Company's net revenues for the year ended December 31, 2015 of $200,000, the Company has recorded a dividend on the shares of Preferred Stock issued and outstanding at December 31, 2015 of $2,000.

Common Stock

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

See Note 8 for information with respect to the issuance of common stock in connection with various stock-based compensation arrangements.

Common Stock Warrants

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

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

As a result of the January 28, 2014 warrant extension and discount offers, warrants to acquire 3,900,000 shares of the Company's common stock were exercised in April 2014 at exercise prices ranging from $0.25 to $0.375 per share. The exercise of the warrants generated aggregate net proceeds to the Company of $1,412,500.

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

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

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

A summary of warrant activity during the years ended December 31, 2015 and 2014, 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, 2013	6,828,800	$ 0.592	
Issued	—	—	
Exercised	(3,900,000)	0.263	
Expired	—	—	
Warrants outstanding at December 31, 2014	2,928,800	0.592	
Issued	—	—	
Exercised	(1,050,000)	0.300	
Expired	(1,878,800)	0.294	
Warrants outstanding at December 31, 2015	—	$ —	—
Warrants exercisable at December 31, 2014	2,807,840	$ 0.596	
Warrants exercisable at December 31, 2015	—	$ —	—

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

5. Money Market Funds

Money market funds at December 31, 2015 and 2014 consisted of investments in shares of Morgan Stanley New York Municipal Money Market Trust with a market value of $104,095 and $213,699, respectively.

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

The following table presents money market funds at their level within the fair value hierarchy at December 31, 2015 and 2014.

	Total	Level 1	Level 2	Level 3
December 31, 2015:				
Money market funds	$ 104,095	$ 104,095	$ —	$ —
December 31, 2014:				
Money market funds	$ 213,699	$ 213,699	$ —	$ —

6. Related Party Transactions

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

Dr. Kovach was paid a salary of $60,000 for the years ended December 31, 2015 and 2014, 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 Company's 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 J. Forman Law Office, a party providing legal and consulting services to the Company. The sub-lease was for a term of six months at a base rate of $875 per month and was not renewed upon its expiration in December 2014. Eric J. 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 J. Forman were $48,000 and $46,000 for the years ended December 31, 2015 and 2014, respectively.

Effective January 1, 2014, the Company entered into an Advisory Agreement with Dr. Kathleen P. Mullinix, a member of the Board of Directors of the Company, effective for an initial term of one year through December 31, 2014 to advise on business development matters. The Advisory Agreement provided for annual cash compensation of $25,000. The term of the Advisory Agreement was automatically extended for a term of one year annually unless a notice of intent to terminate was given by either party at least 90 days before the end of the applicable term. Accordingly, the Advisory Agreement was extended for additional terms of one year effective January 1, 2015 and 2016. The Company recognized a charge to operations of $25,000 as consulting and advisory fees pursuant to this Advisory Agreement during the years ended December 31, 2015 and 2014, which were 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 and affiliates are described at Note 7. Total stock-based compensation expense relating to directors, officers, affiliates and related parties was $74,901 and $759,598 for the years ended December 31, 2015 and 2014, respectively.

7. Stock-Based Compensation

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

On June 20, 2007, the Board of Directors of the Company approved the 2007 Stock Compensation Plan (the "2007 Plan"), which provides for the granting of awards, consisting of stock options, stock appreciation rights, performance shares, or restricted shares of common stock, to employees and independent contractors, for up to 2,500,000 shares of the Company's common stock, under terms and condition, as determined by the Company's Board of Directors. As of December 31, 2015, unexpired stock options for 550,000 shares were issued and outstanding under the 2007 Plan, and stock options for 1,950,000 were available for issuance under the 2007 Plan.

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

For stock options requiring an assessment of value during the year ended December 31, 2015, the fair value of each stock option award was estimated using the Black-Scholes option-pricing model with the following assumptions:

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

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

Risk-free interest rate	1.15% to 1.75%
Expected dividend yield	0%
Expected volatility	173% to 380%
Expected life	4.0 to 5.0 years

On January 28, 2014, the Company approved a second amendment to the Company's consulting agreement with Gil Schwartzberg, a significant stockholder of and consultant to the Company, dated September 12, 2007 to extend it for an additional four years to January 28, 2019 and granted to Mr. Schwartzberg stock options to purchase an additional aggregate of 4,000,000 shares of common stock, exercisable for a period of the earlier of five years from the grant date or the termination of the consulting agreement at $0.50 per share, with one-half of the stock options (2,000,000 shares) vesting immediately and one-half of the stock options (2,000,000 shares) vesting on January 28, 2015. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $596,400 ($0.15 per share) on January 28, 2014, of which $298,200 was attributed to the stock options that were fully vested on January 28, 2014 and was therefore charged to operations on that date. The remaining unvested portion of the fair value of the stock options was charged to operations ratably from January 28, 2014 through January 28, 2015. During the years ended December 31, 2015 and 2014, the Company recorded charges to operations of $74,901 and $732,699, respectively, with respect to these stock options.

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

On December 24, 2013, the Company entered into an agreement with NDA Consulting Corp. ("NDA") for consultation and advice in the field of oncology research and drug development. As part of the agreement, NDA also agreed to cause its president, Dr. Daniel D. Von Hoff, M.D., to become a member of the Company's Scientific Advisory Committee. In connection with this agreement, NDA was granted stock options to purchase 100,000 shares of the Company's common stock, vesting 25,000 shares on June 24, 2014, and thereafter 25,000 shares annually on June 24, 2015, 2016 and 2017, exercisable for a period of five years from the date of grant at $0.13 per share, which was the fair market value of the Company's common stock on the grant date. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be $12,960 ($0.13 per share), and was charged to operations ratably from December 24, 2013 through June 24, 2017. During the year ended December 31, 2015 and 2014, the Company recorded charges to operations of $9,189 and $8,901 with respect to these stock 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 stock 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 stock options were granted to Mr. Johnson as compensation for his contributions to the Company's compound development activities.

On July 15, 2014, Gil Schwartzberg, a significant stockholder of and consultant to the Company, assigned fully-vested stock options to acquire 1,000,000 shares of the Company's common stock to Dr. Daniel D. Von Hoff, M.D., a member of the Company's Scientific Advisory Committee. The stock 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 Dr. 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 stock options to acquire 500,000 shares were transferred back to Mr. Schwartzberg in February 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 granted stock options to Mr. Robell to purchase 200,000 shares of the Company's common stock, vesting 100,000 shares on October 7, 2014 and 100,000 shares on October 7, 2015, exercisable for a period of five years from the date of grant at $0.50 per share. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $20,000 ($0.10 per share), of which $10,000 is attributed to the stock options fully-vested on October 7, 2014 and was therefore charged to operations on that date. The remaining unvested portion of the fair value of the stock options was charged to operations ratably from October 7, 2014 through October 7, 2015. During the years ended December 31, 2015 and 2014, the Company recorded charges to operations of $10,064 and $15,526, respectively, with respect to these stock options.

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

Effective September 14, 2015, the Company entered into a Collaboration Agreement with BioPharmaWorks LLC ("BioPharmaWorks"), pursuant to which the Company engaged BioPharmaWorks to perform certain services for the Company as described at Note 8. In connection with the Collaboration Agreement, the Company agreed to issue to BioPharmaWorks 1,000,000 fully-vested shares of the Company's common stock, valued at $260,000, based upon the closing price of the Company's common stock of $0.26 per share, on September 14, 2015. Additionally, the Company issued to BioPharmaWorks two options in the form of warrants, to purchase 1,000,000 shares (500,000 shares per warrant) of the Company's common stock. The first warrant will vest on September 14, 2016, and is exercisable for a period of five years from the date of grant at $1.00 per share. The second warrant will vest on September 14, 2017, and is exercisable for a period of five years from the date of grant at $2.00 per share. The fair value of the first and second warrants, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $128,400 ($0.2568 per share) and $127,850 ($0.2557 per share), respectively. During the year ended December 31, 2015, the Company recorded a charge to operations of $324,468 with respect to these common shares and warrants.

On November 28, 2015, the Company entered into a two-year advisory agreement with Dr. Fritz Henn, M.D., Ph.D., for consultation and advice on the development of certain of the Company's products for clinical neurological and neuropsychiatric applications. Dr. Henn is an internationally recognized investigative neuroscientist and psychiatrist. In connection with the advisory agreement, and as sole compensation, Dr. Henn was granted stock options to purchase 200,000 shares of the Company's common stock, with 100,000 shares vesting on November 28, 2015, and 100,000 shares vesting on November 28, 2016. The stock options are exercisable for a period of five years from the grant date at $0.50 per share. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be $103,360 ($0.5168 per share), of which $51,680 is attributed to the options fully-vested on November 28, 2015 and was therefore was charged to operations on that date. The remaining unvested portion of the fair value of the stock options will be charged to operations ratably from November 28, 2015 through November 28, 2016. During the year ended December 31, 2015, the Company recorded a charge to operations of $54,325 with respect to these stock options.

Total stock-based compensation expense was $549,697 and $946,175 for the years ended December 31, 2015 and 2014, respectively.

A summary of stock option activity during the years ended December 31, 2015 and 2014 is presented in the tables below.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Stock options outstanding at December 31, 2013	3,150,000	$ 0.818	
Granted	4,700,000	0.473	
Exercised	—	—	
Expired	(1,000,000)	0.803	
Stock options outstanding at December 31, 2014	6,850,000	0.582	
Granted	1,700,000	1.015	
Exercised	—	—	
Expired	(600,000)	0.942	
Stock options outstanding at December 31, 2015	7,950,000	$ 0.697	2.94
Stock options exercisable at December 31, 2014	4,675,000	$ 0.626	
Stock options exercisable at December 31, 2015	6,800,000	$ 0.586	2.65

Total deferred compensation expense for the outstanding value of unvested stock options was approximately $264,000 at December 31, 2015, which is being recognized subsequent to December 31, 2015 over a weighted-average period of approximately fifteen months.

The exercise prices of stock options outstanding and exercisable are as follows at December 31, 2015:

Exercise Prices	Stock Options Outstanding (Shares)	Stock Options Exercisable (Shares)
$ 0.130	100,000	50,000
$ 0.250	500,000	500,000
$ 0.500	4,400,000	4,300,000
$ 0.650	700,000	700,000
$ 0.980	250,000	250,000
$ 1.000	1,500,000	1,000,000
$ 2.000	500,000	—
	7,950,000	6,800,000

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

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

Outstanding stock options to acquire 1,150,000 shares of the Company's common stock had not vested at December 31, 2015.

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

8. 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, 2015 and 2014 are summarized below.

	December 31,	
	2015	2014
Start-up and organization costs	$ 42,000	$ 49,000
Research credits	181,000	139,000
Contingent liability	—	31,000
Stock-based compensation	938,000	952,000
Net operating loss carryforwards	4,528,000	3,532,000
Total deferred tax assets	5,689,000	4,703,000
Valuation allowance	(5,689,000)	(4,703,000)
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, 2015 and 2014, 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, 2015 and 2014 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, 2015 and 2014.

	Years Ended December 31,	
	2015	2014
U. S. federal statutory tax rate	(34.0)%	(34.0)%
Non-deductible stock-based compensation	—%	0.5%
Non-deductible fair value of warrant extensions	0.4%	3.6%
Non-deductible fair value of warrant discounts	2.0%	1.6%
Expirations related to stock-based compensation	3.3%	5.0%
Adjustment to deferred tax asset	—%	(1.0)%
Change in valuation allowance	28.3%	24.3%
Effective tax rate	0.0%	0.0%

At December 31, 2015, the Company has available net operating loss carryforwards for federal and state income tax purposes of approximately $10,881,000 and $11,042,000, respectively, which, if not utilized earlier, expire through 2035.

9. Commitments and Contingencies

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

Significant agreements and contracts are summarized as follows:

On September 21, 2012, the Company entered into a work order agreement with Theradex, the CRO responsible for the clinical development of the Company's lead 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 May 31, 2016. The Phase 1 clinical trial is currently estimated to cost approximately $2,200,000, with such payments expected to be allocated approximately 60% for services provided by Theradex and approximately 40% for pass-through costs for clinical center laboratory costs and investigator costs over the life of the clinical trial. Total costs charged to operations through December 31, 2015 for services paid to or through Theradex pursuant to this arrangement, which were first incurred in 2013, aggregated $1,660,725, of which $958,896 and $423,108 were incurred during the years ended December 31, 2015 and 2014, 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 also agreed to cause its president, Dr. Daniel D. Von Hoff, M.D., to become a member of the Company's Scientific Advisory Committee. The term of the agreement was for one year and provided for a quarterly cash fee of $4,000. The agreement was automatically renewed on its anniversary date for an additional one-year term. Consulting and advisory fees charged to operations pursuant to this agreement were $16,000 during the years ended December 31, 2015 and 2014.

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

On October 7, 2014, the Company entered into an agreement with ProActive Capital Resources Group LLC for strategic advisory, investor relations and public relations services through October 6, 2015. Among other things, the agreement provided for compensation in the form of a monthly fee of $1,500 in cash. Fees charged to operations pursuant to this agreement and other arrangements were $13,500 and $12,000 during the years ended December 31, 2015 and 2014, respectively.

Effective September 14, 2015, the Company entered into a Collaboration Agreement with BioPharmaWorks, pursuant to which the Company engaged BioPharmaWorks to perform certain services for the Company. Those services include, among other things: (a) assisting the Company to (i) commercialize its products and strengthen its patent portfolio, (ii) identify large pharmaceutical companies with potential interest in the Company's product pipeline, and (iii) prepare and deliver presentations concerning the Company's products; (b) at the request of the Board of Directors, serving as backup management for up to three months should the Company's Chief Executive Officer and scientific leader be temporarily unable to carry out his duties; (c) being available for consultation in drug discovery and development; and (d) identifying providers and overseeing tasks relating to clinical use and commercialization of new compounds. BioPharmaWorks was founded in 2015 by former Pfizer scientists with extensive multi-disciplinary research and development and drug development experience. The Collaboration Agreement is for an initial term of two years and automatically renews for subsequent annual periods unless terminated by a party not less than 60 days prior to the expiration of the applicable period. In connection with the Collaboration Agreement, the Company agreed to pay BioPharmaWorks a monthly fee of $10,000, subject to the right of the Company to pay a negotiated hourly rate in lieu of the monthly payment, and agreed to issue to BioPharmaWorks certain equity-based compensation as described at Note 7. Fees charged to operations pursuant to this Collaboration Agreement and other arrangements were $52,625 during the year ended December 31, 2015.

The following table sets forth the Company's principal cash obligations and commitments for the next five fiscal years as of December 31, aggregating $713,927, of which $124,050 is included in current liabilities in the Company's consolidated balance sheet at December 31, 2015.

		Payments Due By Year				
	Total	2016	2017	2018	2019	2020
Research and development contracts	$ 409,703	$ 409,703	$ —	$ —	$ —	$ —
Clinical trial agreements	48,224	48,224	—	—	—	—
Consulting agreements	256,000	166,000	90,000	—	—	—
Total	$ 713,927	$ 623,927	$ 90,000	$ —	$ —	$ —

10. Subsequent Events

Effective January 28, 2016, the Series A Convertible Preferred Stock (the "Preferred Stock") Certificate of Designations was amended to increase the number of authorized shares of Preferred Stock to from 175,000 to 350,000. The Company also entered into a Securities Purchase Agreement with the current holder of the Preferred Stock on January 21, 2016, pursuant to which the Company sold an additional 175,000 shares of the Company's Preferred Stock at a per share price of $10.00, representing an aggregate purchase price of $1,750,000, payable $583,333 on closing, $583,333 on or before March 4, 2016, and $583,334 on or before June 3, 2016. This class of Preferred Stock has a dividend per share equal to 1% of the annual net revenue of the Company divided by 175,000, until converted or redeemed. Each share of Preferred Stock may be converted, at the option of the holder, into 12.5 shares of common stock (subject to customary anti-dilution provisions) and the Preferred Stock is subject to mandatory conversion at the conversion rate in the event of a merger or sale transaction resulting in gross proceeds to the Company of at least $21,875,000. If fully converted, the Preferred Stock would convert into 2,187,500 shares of common stock, representing an effective price per common share of $0.80. On the effective date of the transaction, the closing price of the Company's common stock was $0.22 per share. The Company has the right to redeem the Preferred Stock up to the fifth anniversary of the closing date at a price per share equal to $50.00.

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

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, 2015 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 28, 2016

By: */s/ JOHN S. KOVACH*
Name: John S. Kovach
Title: President, 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, 2015 (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 28, 2016

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

State of Delaware
Secretary of State
Division of Corporations
Delivered 01:12 PM 01/28/2016
FILED 01:12 PM 01/28/2016
SR 20160452480 - File Number 3974959

STATE OF DELAWARE
CERTIFICATE OF AMENDMENT
OF CERTIFICATE OF DESIGNATIONS
OF THE SERIES A CONVERTIBLE PREFERRED STOCK

Lixte Biotechnology Holdings, Inc. (the "Corporation"), organized and existing under and by virtue of the General Corporation Law of the State of Delaware, does hereby certify:

FIRST: That, pursuant to unanimous consent resolutions of the Board of Directors of the Corporation, resolutions were duly adopted setting forth a proposed amendment to the Certificate of Designations of the Corporation of the Series A Convertible Preferred Stock (the "Certificate of Designations"), declaring said amendment to be advisable and to obtain approval of the holder of all of the shares of the Series A Preferred Stock of the Corporation. The resolution setting forth the proposed amendment is as follows:

RESOLVED, that the Certificate of Designations be amended by changing Section 2 so that, as amended, said Section shall be and read as follows:

> "Section 2. Designation, Amount and Par Value. The series of preferred stock shall be designated as its Series A Convertible Preferred Stock (the "Preferred Stock") and the number of shares so designated shall be 350,000 (which shall not be subject to increase without the written consent of all of the holders of the Preferred Stock (each, a "Holder" and collectively, the "Holders")). Each share of Preferred Stock shall have a par value of $0.0001 per share and a stated value equal to $10.00, subject to increase set forth in Section 3 below (the "Stated Value")."

SECOND: That, thereafter, pursuant to the resolutions of its Board of Directors, by written action, the sole holder of all of the shares of the Series A Preferred Stock of the Corporation consented to the adoption of this Certificate of Amendment.

THIRD: That said amendment was duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, the Corporation has caused this certificate to be signed this 21st day of January, 2016.

Lixte Biotechnology Holdings, Inc.

By: _____
Authorized Officer

Name: John Kovach

Title: President
Print or Type