

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

FORM 10-K

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

For the fiscal year ended December 31, 2013

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

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  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  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.

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

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

Issuer's revenues for its fiscal year ended December 31, 2013: \$0

The aggregate market value of the common stock held by non-affiliates of the registrant as of June 30, 2013 was approximately \$3,179,000.

There were 41,583,097 shares of the Company's common stock outstanding on March 7, 2014.

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 formerly known as SRKP 7, Inc., 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 condensed 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

We were organized as a blank check company formed for the purpose of effecting a business combination with an operating business. On June 30, 2006, pursuant to a Share Exchange Agreement dated as of June 8, 2006 among us, Dr. John S. Kovach and Lixte Biotechnology, Inc., we issued 19,021,786 shares of our common stock to Dr. Kovach in exchange for all of the issued and outstanding shares of Lixte Biotechnology, Inc. As a result of this transaction, Lixte Biotechnology, Inc. is now our wholly-owned subsidiary, though from an historical perspective it was deemed to have been the acquirer in the reverse merger and the survivor of the reorganization. On December 7, 2006, we changed our name from SRKP 7, Inc. to Lixte Biotechnology Holdings, Inc.

Lixte was created to capitalize on opportunities for the Company to develop low cost, specific and sensitive tests for the early detection of cancers to better estimate prognosis, to monitor treatment response, and to reveal targets for development of more effective treatments. Over the past several years, however, the Company has evolved into what is now primarily a cancer drug discovery company, using biomarker technology to develop new potentially more effective anti-cancer drugs for life-threatening diseases.

#### DESCRIPTION OF BUSINESS

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

The Company's drug discovery process is based on discerning clues to potential new targets for disease treatments reported in the increasingly large body of literature identifying the molecular variants which characterize human cancers and other non-cancer disorders. In the past decade, there has been an unprecedented expansion in knowledge of biochemical defects in the cancer cell. The Company designs drugs for which there are existing data suggesting that they may affect the altered pathways of the cancer cell and may be given safely to humans. The Company seeks to rapidly arrive at patentable structures through analysis of the literature rather than screening of thousands of structures for activity against a particular biochemical pathway. This approach has led to the development of two classes of drugs for the treatment of cancer, protein phosphatase inhibitors (PTase-i), designated by the Company as the LB-100 series of compounds, and histone deacetylase inhibitors (HDACi), designated by the Company as the LB-200 series of compounds. Compounds of both types also have potential use in the prevention and treatment of neurodegenerative diseases.

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

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

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

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

The second class of drugs under development by the Company, 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 Amyotrophic Lateral Sclerosis (ALS, or Lou Gehrig’s Disease).

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

The Company filed an IND application with the FDA on April 30, 2012, and on July 24, 2012, the FDA notified the Company that it would allow initiation of a Phase I clinical trial of LB-100. The purpose of the clinical trial is to demonstrate that LB-100 can be administered safely to human beings at a dose and at a frequency that achieves the desired pharmacologic effect; in this case, inhibition of a specific enzyme, without being associated with toxicities considered unacceptable.

The Phase I clinical trial of LB-100 began in April 2013 with the entry of patients into the clinical trial (see NCT01837667 at [www.clinicaltrials.gov](http://www.clinicaltrials.gov)) and was initiated at the City of Hope National Medical Center in Duarte, California, and was extended in December 2013 to include the Mayo Clinic in Rochester, Minnesota, both of which are Comprehensive Cancer Centers designated by the National Cancer Institute. The Company estimates that the Phase I clinical trial will be completed within the next 12 to 21 months (sometime between March and December 2015) and will cost a total of approximately \$2,000,000, which will be paid to or through Theradex Systems, Inc. (“Theradex”), the contract research organization (“CRO”) responsible for the clinical development of LB-100. The final cost of the clinical trial is variable, depending upon the number of patients needed to be medically screened to determine if they meet the criteria for entry into the study and ultimately upon the total number of patients entered into the study to establish the proper doses of the drug for Phase 2 clinical trials.

The Phase 1 clinical trial of LB-100 is designed to determine the maximum tolerable dose of LB-100 given alone and then in combination with a standard widely used anti-cancer drug. As a prelude to determining the therapeutic effectiveness of LB-100 in a subsequent Phase 2 clinical trial of common cancers, a key goal of the initial portion of the Phase 1 clinical trial is to demonstrate that the target enzyme of LB-100, protein phosphatase 2A (PP2A), can be inhibited in humans with readily tolerable toxicity. As an anti-cancer drug, LB-100 is likely to be used at maximum tolerable doses, but for the potential treatment of non-malignant diseases, such as acute vascular diseases and metabolic diseases, lower doses may achieve therapeutic benefit by inhibition of the target enzyme, PP2A, thus opening up the possibility of a host of therapeutic applications for LB-100 and related proprietary compounds.

The next step in the clinical development of LB-100 after the completion of a Phase 1 clinical trial is to obtain IND approval from the FDA to administer the drug to patients. In order to do this, the Company must 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. A compound that has a mechanism of action similar to that of LB-100 has been given with safety and benefit to cancer patients outside the United States in the past. This similar compound has a chemical feature which appears to be responsible for most of its toxicity. This feature has been removed from LB-100, making it likely that the Company's compound will be less toxic and, therefore, safer for human use.

### **National Cancer Institute Experimental Therapeutics Program**

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

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

The Company believes that it has sufficient funds to continue with the Phase 1 clinical trial of LB-100 and to fund its operating plans through April 30, 2014. Accordingly, in order to continue to fund the Company's operations in 2014 and thereafter, the Company will need to raise additional capital, likely in the form of equity, aggregating at least \$2,000,000 to fund operations for the next twelve months.

## Publications

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

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

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

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

## Intellectual Property

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

Patents for composition of matter and for several uses of both the LB-100 series (oxabicycloheptanes and -heptenes) and the LB-200 series (histone deacetylase inhibitors; HDACi) have been filed. Patents for the LB-100 series and the LB-200 series have been filed in the U.S. and widely internationally (PCT). International filings are currently all pending.

Issued patents are:

### LB-100 Series Compounds

#### Oxabicycloheptanes and Oxabicycloheptenes, Their Preparation and Use

Patent	Priority Date	Type	Expiration Date
US 7,998,957	Feb 6, 2008	Composition and Use in Cancer Treatment	2/20/2030
US 8,227,473	Aug 1, 2009	Composition and Use in Cancer Treatment	2/20/2030
US 8,426,444 Divisional	Feb 6, 2008	Composition and Use in Cancer Treatment	2/6/2028

LB-200 Series Compounds  
HDAC Inhibitors

US 8,143,445	Oct 1, 2008	Composition and Use in Cancer Treatment	8/23/2029
US 8,455,688 Divisional	Oct 1, 2008	Composition and Use in Cancer Treatment	10/1/2028

LB-100 and LB-200 Series Compounds  
Neuroprotective Agents for the Prevention and Treatment of Neurodegenerative Diseases

US 8,058,268	Aug 1, 2009	Use in Treatment of Multiple CNS Diseases	12/31/2029
US 8,329,719 Divisional	Aug 1, 2009	Use in Treatment of Multiple CNS Diseases	7/29/2029

## The Market

### Anti-Cancer Drugs

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

### Diagnostic Biomarkers

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

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

### Marketing Plan

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

## Research and Development

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

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

## Product Overview

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

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

1. Improved Anti-Cancer Treatments. The primary focus of the Company is improved chemotherapy regimens for cancers not curable by surgery or radiation.
2. Improved Anti-Fungal Treatments. New drug treatments for the management of life-threatening fungal infections in immunosuppressed patients such as those with HIV-AIDS or undergoing bone marrow transplantation are needed due to the constant development of drug resistance in these organisms. More effective and less toxic drugs are also needed for the management of skin and particularly nail fungi that affect tens of millions of people worldwide. The Company has demonstrated the activity of several compounds against different fungal pathogens, and is seeking a partner to develop one lead compound for chemical evaluation.
3. Treatments for Neurodegenerative Diseases. Most experts believe that at present there are no significantly effective drugs available for the delay of progression, as well as prevention, of the common neurodegenerative diseases, including Alzheimer's Disease, Parkinson's Disease, and Amyotrophic Lateral Sclerosis Disease (ALS, or Lou Gehrig's Disease), among a host of rarer chronic diseases of the brain. The Company is exploring mechanisms to evaluate its compounds for these activities with experts in the field, in academic or other not-for-profit settings.
4. Biomarker Assays for Diagnosis, Prognosis, and Assessing Treatment Benefit. Improved assays for biomarkers of specific cancers in the body fluids, primarily blood, for the diagnosis of cancers at stages when cure is possible through surgery and/or radiotherapy. Such assays might also be useful for assessing therapeutic effectiveness of treatment before gross reappearance of disease; and, assays for the molecular classification of otherwise indistinguishable tumor types would be helpful for selection of treatment and also potentially for estimation of prognosis. The Company will need to collaborate with a large diagnostic company to undertake clinical development. Development of biomarkers for useful clinical assays is a complex and expensive process.

## Product Development

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

## Competition

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

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

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

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

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

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

## **Employees**

As of December 31, 2013, the Company had no full-time employees. Dr. Kovach is a Professor (part-time) in the Department of Preventive Medicine at the State University of New York (SUNY) in Stony Brook, New York. He received approvals from the School of Medicine of SUNY-Stony Brook and from the New York State Ethics Commission to operate the Company and to hold greater than 5% of the Company's outstanding shares.

Dr. Kovach devotes approximately 40% of his efforts per year to research planning and management. Dr. Kovach's contributions are made outside of his academic responsibilities. He directs, coordinates and manages the scientific and business development of the Company with the advice of the Company's Board of Directors, the advisory committee, and, from time to time, various consultants with specific expertise.

## **Government Regulation**

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

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

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

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

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

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

## ITEM 1B RISK FACTORS

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

### Risks Related to Business

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

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

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

Although we have identified one potential product candidate in the area of brain tumors, the work needed to demonstrate its commercial viability is at a very early stage. The follow-up research needed to demonstrate the viability of the product is costly and time-consuming and may reveal that the product does not function as expected or that it is otherwise not commercially viable.

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

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

The Company's consolidated financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company is in the development stage and has not generated any revenues from operations to date. Furthermore, the Company has experienced recurring losses and negative operating cash flows since inception, and has financed its working capital requirements through the recurring sale of its equity securities. As a result, the Company's independent registered public accounting firm, in their report on the Company's 2013 consolidated financial statements, have raised substantial doubt about the Company's ability to continue as a going concern.

Because the Company is currently engaged in research at an early stage, it will likely take a significant amount of time to develop any product or intellectual property capable of generating revenues, and even if the Company is able to generate revenues in the future through licensing its technologies or through product sales, there can be no assurance that the Company will be able to generate a profit. The Company does not have sufficient resources to fully develop and commercialize any products that may arise from its research. Accordingly, the Company will need to raise additional funds to do so.

The Company believes that it has sufficient funds to continue with the Phase 1 clinical trial of LB-100 and to fund its operating plans through April 30, 2014. Accordingly, in order to continue to fund the Company's operations in 2014 and thereafter, the Company will need to raise additional capital, likely in the form of equity, aggregating at least \$2,000,000 to fund operations for the next twelve months.

The amount and timing of future cash requirements will depend on the pace of these programs, particularly the completion of the Phase 1 trial of LB-100. After completion of the Phase 1 clinical trial, the next step will be to determine the anti-cancer activity against a particular type of human cancer in Phase 2 clinical trials. Market conditions present uncertainty as to the Company's ability to secure additional funds, as well as its ability to reach profitability. There can be no assurances that the Company will be able to secure additional financing, or obtain favorable terms on such financing if it is available, or as to the Company's ability to achieve positive earnings and cash flows from operations. If cash resources are insufficient to satisfy the Company's liquidity requirements, the Company would be required to scale back or discontinue its technology and product development programs, or obtain funds, if available, through strategic alliances that may require the Company to relinquish rights to certain of its technologies products, or to discontinue its operations entirely.

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

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

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

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

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

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

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

***We may be unable to compete successfully with our competitors.***

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- our ability to provide acceptable evidence of safety and efficacy;
- convenience and ease of administration;
- prevalence and severity of adverse side effects;
- availability of alternative treatments or diagnostic tests;
- cost effectiveness;

- effectiveness of our marketing strategy and the pricing of any product that we may develop;
- publicity concerning our products or competitive products; and
- our ability to obtain third-party coverage or reimbursement.

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

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

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

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

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

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

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

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

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

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

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

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

The following factors are important to our success:

- receiving patent protection for our product candidates;

- preventing others from infringing our intellectual property rights; and
- maintaining our patent rights and trade secrets.

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

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

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

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

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

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

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

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

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

### **Risks Related to Capital Structure**

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

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

- the issuance of new equity securities pursuant to a future offering or acquisition;
- changes in interest rates;
- competitive developments, including announcements by competitors of new products or services or significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;
- variations in quarterly operating results;
- changes in financial estimates by securities analysts;

- the depth and liquidity of the market for our common stock;
- investor perceptions of our company and the medical device industry generally; and
- general economic and other national conditions.

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

Dr. John Kovach, our current Chief Executive Officer, was the former stockholder of our operating subsidiary, and received shares of our stock in a reverse merger. He is currently eligible to sell some of his shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144 promulgated under the Securities Act (“Rule 144”), subject to certain limitations. Rule 144 also permits the sale of securities, without any limitations, by a non-affiliate that has satisfied a six-month holding period. Any substantial sale of common stock pursuant to Rule 144 may have an adverse effect on the market price of our common stock by creating an excessive supply. In this connection, we have sold an aggregate of 3,555,220 shares of common stock in private placements occurring in June and July 2006, 999,995 shares in a December 2007 private placement, and an aggregate of 4,575,000 shares of our common stock in private placements in January and February 2010, all of which are currently eligible to be resold under Rule 144. In addition, during the year ended December 31, 2012, we issued 6,082,000 shares of common stock a result of the exercise of various stock warrants, and during the years ended December 31, 2011 and 2012, we issued 181,964 shares and 241,955 shares of common stock as a result of the exercise of various stock options. There were no issuances of common stock in 2013.

***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.*

As a result of the reverse merger, Dr. John Kovach, our principal stockholder and our Chief Executive Officer, beneficially owns approximately 40.9% of our outstanding voting stock at the current time. As a result, Dr. Kovach possesses significant influence, giving him the practical ability, among other things, to elect all of the members of the Board of Directors and to approve significant corporate transactions. Such stock ownership and control may also have the effect of delaying or preventing a future change in control, impeding a merger, consolidation, takeover or other business combination or discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

*We do not foresee paying cash dividends in the foreseeable future.*

We have not paid any cash dividends on our stock and do not plan to pay cash dividends on our common stock in the foreseeable future.

**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 COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

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

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

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

	<b>High</b>	<b>Low</b>
<b>Year Ended December 31, 2012</b>		
First Quarter	\$ 0.92	\$ 0.50
Second Quarter	\$ 0.88	\$ 0.65
Third Quarter	\$ 0.25	\$ 0.25
Fourth Quarter	\$ 0.70	\$ 0.13

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

## Holders

As of March 7, 2014, there were 41,583,097 shares of our common stock outstanding, held by approximately 88 stockholders of record. This does not include an indeterminate number of beneficial owners of securities whose shares are held in the names of various dealers and clearing agencies.

## Dividends

Our dividend policy will be determined by our Board of Directors and will depend upon a number of factors, including our financial condition and performance, our cash needs and expansion plans, income tax consequences, and the restrictions that applicable laws and our credit arrangements then impose.

## 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, 2013, the most recently completed fiscal year.

<b>Plan Category</b>	<b>Number of Securities to be issued upon exercise of outstanding options, warrants and rights</b>	<b>Weighted average price of outstanding options, warrants and rights</b>	<b>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column 2)</b>
Equity Compensation Plans Approved by Security Holders	N/A	N/A	N/A
Equity Compensation Plans Not Approved by Security Holders (2)	3,150,000	\$ 0.83	1,550,000 (1)

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

(2) Includes option for 200,000 shares exercisable by the estate of Dr. Robert B. Royds, a former director, who died on March 23, 2013.

## ITEM 6. SELECTED FINANCIAL DATA

Not Applicable

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

### **Overview**

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

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

The Company is considered a "development stage company" under current accounting standards, as it has not yet commenced any revenue-generating operations, does not have any cash flows from operations, and is dependent on debt and equity funding to finance its operations.

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

### **Recent Developments**

On January 28, 2014, the Company's Board of Directors extended to June 30, 2014 its outstanding warrants to acquire 1,748,800 shares of the Company's common stock at \$0.50 per share that were issued to investors and the placement agent in connection with offerings that closed on February 10, 2009, March 2, 2009 and April 6, 2009. All other outstanding warrants had previously been extended to June 30, 2014 on September 11, 2012. Included in such 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 scheduled to expire on April 6, 2014.

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).

### **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 is in the development stage and has not generated any revenues from operations to date, and does not expect to do so in the foreseeable future. The Company has experienced recurring operating losses and negative operating cash flows since inception, and has financed its working capital requirements during this period primarily through the recurring sale of its equity securities and the exercise of outstanding warrants. As a result, the Company's independent registered public accounting firm, in its report on the Company's 2013 consolidated financial statements, has raised substantial doubt about the Company's ability to continue as a going concern.

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

At December 31, 2013, the Company had not yet commenced any revenue-generating operations. All activity through December 31, 2013 has been related to the Company's formation, capital raising efforts, and research and development activities. As such, the Company has yet to generate any cash flows from operations, and is dependent on debt and equity funding from both related and unrelated parties to finance its operations. Prior to June 30, 2006, the Company's cash requirements were funded by advances from the Company's founder aggregating \$92,717.

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

The Company's major focus in 2014 is to continue a Phase 1 clinical trial of its lead phosphatase inhibitor, LB-100. The Phase 1 clinical trial of LB-100 began in April 2013 with the entry of patients into the clinical trial, and is being carried out by nationally recognized comprehensive cancer centers. The cost of a clinical trial depends to a considerable extent upon the rate of patient accrual, as well as the number of patients entered into the clinical trial. If screening tests render a patient ineligible for the clinical trial, the screening costs are realized, but patient accrual is not advanced. Accordingly, the costs needed to complete a clinical trial with the planned number of participants may increase under such circumstances.

The Company estimates that the Phase 1 clinical trial will be completed within the next 12 to 21 months (sometime between March and December 2015) and will cost a total of approximately \$2,000,000, which will be paid to or through Theradex, the CRO responsible for the clinical development of LB-100. As of December 31, 2013, the Company has incurred \$278,721 of these clinical trial costs, which have been included in research and development expenses in the statement of operations for the year ended December 31, 2013.

At December 31, 2013, the Company had cash and money market funds aggregating \$481,154. The Company believes that it has sufficient funds to continue with the Phase 1 clinical trial of LB-100 and to fund its operating plans through April 30, 2014. Accordingly, in order to continue to fund the Company's operations in 2014 and thereafter, the Company will need to raise additional capital, likely in the form of equity, aggregating at least \$2,000,000 to fund operations for the next twelve months. Market conditions present uncertainty as to the Company's ability to secure additional funds. There can be no assurances that the Company will be able to secure additional financing on acceptable terms or at all. If cash resources are insufficient to satisfy the Company's ongoing cash requirements, the Company would be required to scale back or discontinue its technology and product development programs and/or clinical trials, or obtain funds, if available (although there can be no certainty), through strategic alliances that may require the Company to relinquish rights to certain of its products, or to discontinue its operations entirely.

The amount and timing of future cash requirements will depend on the pace of the Company's programs, particularly the completion of the Phase 1 clinical trial of LB-100. After completion of the Phase 1 clinical trial, the next step will be to determine the anti-cancer activity of LB-100, in combination with a widely used anti-cancer drug, against a specific type of human cancer in Phase 2 clinical trials. Subject to the availability of funds, the Company intends to continue with its Phase 1 clinical trial of LB-100, continue the two drug development programs currently in process, and expand its patent portfolio, including the maintenance of its applications for international protection of lead compounds of both the LB-100 and LB-200 series.

### **Recent Accounting Pronouncements**

In February 2013, the Financial Accounting Standards Board (the "FASB") issued ASU No. 2013-04, Liabilities (Topic 405): Obligations Resulting from Joint and Several Liability Arrangements for Which the Total Amount of the Obligation Is Fixed at the Reporting Date. This guidance provides direction for the recognition, measurement, and disclosure of obligations resulting from joint and several liability arrangements for which the total amount of the obligation within the scope of this guidance is fixed at the reporting date, except for obligations addressed within existing guidance in U.S. GAAP. The guidance requires an entity to measure those obligations as the sum of the amount the reporting entity agreed to pay on the basis of its arrangement among its co-obligors and any additional amount the reporting entity expects to pay on behalf of its co-obligors. This guidance will become effective for the Company for fiscal years, and interim periods within those years, beginning after December 15, 2013. The Company does not expect the adoption of this guidance to have a material impact on the Company's consolidated financial statements.

In March 2013, the FASB issued ASU No. 2013-05, Foreign Currency Matters (Topic 830). This guidance resolves the diversity in practice relating to financial reporting involving a parent entity's accounting for the cumulative translation adjustment of foreign currency into net income when a parent either sells a part or all of its investment in a foreign entity or no longer holds a controlling financial interest in a subsidiary or group of assets that is a nonprofit activity or a business (other than a sale of in substance real estate or conveyance of oil and gas mineral rights) within a foreign entity. In addition, this guidance resolves the diversity in practice for the treatment of business combinations achieved in stages (sometimes also referred to as step acquisitions) involving a foreign entity. This guidance will become effective for the Company for fiscal years, and interim periods within those years, beginning after December 15, 2013. The Company does not expect the adoption of this guidance to have a material impact on the Company's consolidated financial statements.

In July 2013, the FASB issued ASU 2013-11, Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Loss, or a Tax Credit Carryforward Exists (a consensus the FASB Emerging Issues Task Force). This guidance provides direction on financial statement presentation of unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. The FASB's objective in issuing this guidance was to eliminate diversity in practice resulting from a lack of guidance on this topic in current U.S. GAAP. This guidance applies to all entities with unrecognized tax benefits that also have tax loss or tax credit carryforwards in the same tax jurisdiction as of the reporting date. This guidance will become effective for the Company for fiscal years, and interim periods within those years, beginning after December 15, 2013. The Company does not expect the adoption of this guidance to have a material impact on the Company's consolidated financial statements.

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

### **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. Theradex is an international CRO that provides professional services for the clinical research and development of pharmaceutical compounds. 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 within the next 12 to 21 months (sometime between March and December 2015). The Phase 1 clinical trial is estimated to cost a total of approximately \$2,000,000, with such payments expected to be divided approximately evenly between payments to Theradex for services rendered and payments for pass-through costs for the clinical center's laboratory costs and investigator costs. Total costs charged to operations for services paid to Theradex pursuant to this arrangement, which were first incurred in 2013, were \$278,721 for the year ended December 31, 2013, or approximately 32% of research and development costs for the year ended December 31, 2013. The costs charged to operations for amounts paid to Theradex for services relating to the Phase 1 clinical trial of LB-100 are expected to represent a larger percentage of total research and development costs during the fiscal years ending December 31, 2014 and 2015. Costs pursuant to this agreement are included in research and development costs in the Company's consolidated statements of operations. On May 2, 2011, Dr. Robert B. Royds, the founder, Chairman of the Board and Medical Director of Theradex, was appointed to the Company's Board of Directors. Dr. Royds died on March 23, 2013. The death of Dr. Royds is not expected to have any impact on the management and administration of the Phase 1 clinical trial.

In addition to the above described agreement with Theradex, the Company has also from time to time engaged Theradex to assist the Company in bringing LB-100 through the FDA approval process and to provide other services. Total fees charged to operations for services paid to Theradex pursuant to such engagements were \$14,964 and \$163,661 for the years ended December 31, 2013 and 2012, respectively, or approximately 2% and 16% of research and development costs for the years ended December 31, 2013 and 2012, respectively, and are included in research and development costs in the Company's consolidated statements of operations.

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

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

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

### **Research and Development**

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

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

### **Patent Costs**

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

### **Stock-Based Compensation**

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

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

The Company accounts for stock-based payments to consultants by determining the value of the stock compensation based upon the measurement date at either (a) the date at which a performance commitment is reached or (b) at the date at which the necessary performance to earn the equity instruments is complete.

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

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

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

## **Income Taxes**

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

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

## **Plan of Operation**

### *General Overview of Plans*

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

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

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

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

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

The significant diversity of the potential therapeutic value of the Company's 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. However, the scope of potential applications of the Company's products has expanded to other common non-malignant diseases, including vascular diseases (heart attacks and stroke, diabetes, and genetic diseases, such as Gaucher's disease) in which errors in normal cellular processing lead to loss of functions important to normal cell function. This has occurred because the targets selected by the Company have multiple functions in the cell, which when altered result in different disorders that may benefit by treatment from the Company's products.

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

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

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

The Company has demonstrated that lead compounds of both series of drugs are active against a broad spectrum of human cancers in cell culture and against several types of human cancers in animal models. The research on new drug treatment was initiated in 2006 with the National Institute of 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, pheochromocytomas and sarcomas. Because the LB-100 compounds appear to exert their ability to improve the effectiveness of different forms of chemotherapy and radiation therapy by inhibiting a process upon which most, if not all, cancer cell types depend on to survive treatment, the Company believes the LB-100 series of compounds may be useful against most, if not all, cancer types.

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

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

The Company filed an IND application with the FDA on April 30, 2012, and on July 24, 2012, the FDA notified the Company that it would allow initiation of a Phase 1 clinical trial of LB-100. The purpose of the clinical trial is to demonstrate that LB-100 can be administered safely to human beings at a dose and at a frequency that achieves the desired pharmacologic effect; in this case, inhibition of a specific enzyme, without being associated with toxicities considered unacceptable. The Phase 1 clinical trial of LB-100 is designed to determine the maximum tolerable dose of LB-100 given alone and then in combination with a standard widely use anti-cancer drug. As a prelude to determining the therapeutic effectiveness of LB-100 in a subsequent Phase 2 clinical trial of common cancers, a key goal of the initial portion of the Phase 1 clinical trial will be to demonstrate that the target enzyme of LB-100, protein phosphatase 2A (PP2A), can be inhibited in humans with readily tolerable toxicity. As an anti-cancer drug, LB-100 is likely to be used at maximum tolerable doses, but for the potential treatment of non-malignant diseases, such as acute vascular diseases and metabolic diseases, lower doses may achieve therapeutic benefit by inhibition of the target enzyme, PP2A, thus opening up the possibility of a host of therapeutic applications for LB-100 and related proprietary compounds. The Company estimates that the Phase 1 clinical trial will be completed within the next 12 to 21 months (sometime between March and December 2015) and will cost a total of approximately \$2,000,000, which will be paid to or through Theradex, the CRO responsible for the clinical development of LB-100. As of December 31, 2013, the Company has incurred \$278,721 of these clinical trial costs, which have been included in research and development expenses in the statement of operations for the year ended December 31, 2013.

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

## **Results of Operations**

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

### **Years Ended December 31, 2013 and 2012**

General and Administrative. For the year ended December 31, 2013, general and administrative costs were \$494,959, which consisted of the fair value of stock options issued to directors and consultants of \$119,125, consulting and professional fees of \$211,170, insurance expense of \$37,116, officer's salary and related costs of \$66,952, stock transfer fees of \$6,957, travel and entertainment costs of \$11,574, and other operating costs of \$42,065.

For the year ended December 31, 2012, general and administrative costs were \$1,093,614, which consisted of the fair value of stock options issued to directors and consultants of \$723,554, consulting and professional fees of \$222,708, insurance expense of \$26,200, officer's salary and related costs of \$67,087, stock transfer fees of \$11,313, travel and entertainment costs of \$7,805, and other operating costs of \$34,947.

General and administrative costs decreased by \$598,655 or 54.7% in 2013 as compared to 2012, primarily as a result of a decrease of \$512,384 in stock-based compensation.

A significant component of the fair value of stock options issued to directors and consultants of \$723,554 for the year ended December 31, 2012 was the \$286,100 expense for the fair value of stock options to acquire 500,000 shares of the Company's common stock that were issued to Gil Schwartzberg on September 11, 2012 for his continuing contributions to the Company's financial strategy, and the expense related to stock options previously issued to Gil Schwartzberg and to directors.

Research and Development. For the year ended December 31, 2013, research and development costs were \$879,886, which consisted of the vested portion of the fair value of stock options issued to a vendor of \$125, patent costs of \$405,285, third-party contractor costs of \$464,059, including \$278,721 related to the Phase 1 clinical trial of LB-100 which commenced in April 2013, and consulting fees to a related party of \$10,417.

For the year ended December 31, 2012, research and development costs were \$1,012,144, which consisted of the vested portion of the fair value of stock options issued to a vendor of \$293,450, patent costs of \$236,784, third-party contractor costs of \$460,035, and consulting fees to a related party of \$21,875.

Research and development costs decreased by \$132,258 or 13.1% in 2013 as compared to 2012, primarily as a result of a decrease of \$293,325 in stock-based compensation, offset by an increase of \$168,501 in patent costs.

The fair value of stock options issued to a vendor of \$293,450 for the year ended December 31, 2012 consisted of stock options to acquire 500,000 shares of the Company's common stock that were issued to Chem-Master International, Inc. on September 11, 2012 for its contribution in the pursuit of new projects involving the Company's compounds.

Interest Income. For the year ended December 31, 2013 and 2012, interest income was \$3 and \$8, respectively.

Fair Value of Warrant Extensions. During the year ended December 31, 2012, the Company incurred an expense of \$1,139,592 for the fair value of extending the expiration date of warrants to acquire 5,080,000 shares of the Company's common stock that were purchased by investors as part of the private placement that closed on January 20, 2010 and February 22, 2010.

Fair Value of Warrant Discount. During the year ended December 31, 2012, the Company incurred an expense of \$334,024 for the fair value of discounts offered to warrant holders as an inducement for the early exercise of warrants to acquire 6,082,000 shares of the Company's common stock. The discounts ranged from \$0.125 to \$0.188 per share. The exercise of the warrants generated net proceeds to the Company of \$2,468,250.

Net Loss. For the year ended December 31, 2013, the Company incurred a net loss of \$1,374,842, as compared to a net loss of \$3,579,366 for the year ended December 31, 2012.

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

The Company's consolidated financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company is in the development stage and has not generated any revenues from operations to date, and does not expect to do so in the foreseeable future. The Company has experienced recurring operating losses and negative operating cash flows since inception, and has financed its working capital requirements through the recurring sale of its equity securities. As a result, the Company's independent registered public accounting firm, in its report on the Company's 2013 consolidated financial statements, has raised substantial doubt about the Company's ability to continue as a going concern (see "Going Concern" above).

At December 31, 2013, the Company had a working capital surplus of \$236,266, as compared to working capital surplus of \$1,491,858 at December 31, 2012, a decrease in working capital of \$1,255,592 for the year ended December 31, 2013. At December 31, 2013, the Company had cash and money market funds aggregating \$481,154, as compared to \$1,661,256 at December 31, 2012, a decrease of \$1,180,102 for the year ended December 31, 2013. The decrease in working capital and cash during the year ended December 31, 2013 was the result of cash utilized by the Company in its operating activities.

The Company filed an IND application with the FDA on April 30, 2012, and on July 24, 2012, the FDA notified the Company that it would allow initiation of a Phase 1 clinical trial of LB-100. The purpose of the clinical trial is to demonstrate that LB-100 can be administered safely to human beings at a dose and at a frequency that achieves the desired pharmacologic effect; in this case, inhibition of a specific enzyme, without being associated with toxicities considered unacceptable. The Phase 1 clinical trial of LB-100 began in April 2013 with the entry of patients into the clinical trial, and is being carried out by a nationally recognized comprehensive cancer center. The Company estimates that the Phase 1 clinical trial will be completed within the next 12 to 21 months (sometime between March and December 2015) and will cost a total of approximately \$2,000,000, which will be paid to or through Theradex, the CRO responsible for the clinical development of LB-100. As of December 31, 2013, the Company has incurred \$278,721 of these clinical trial costs, which have been included in research and development expenses in the statement of operations for the year ended December 31, 2013.

The Company believes that it has sufficient funds to continue with the Phase 1 clinical trial of LB-100 and to fund its operating plans through April 30, 2014. Accordingly, in 2014, in order to continue to fund the Company's operations, the Company expects to attempt to raise additional capital. Market conditions present uncertainty as to the Company's ability to secure additional funds. There can be no assurances that the Company will be able to secure additional financing on acceptable terms or at all. If cash resources are insufficient to satisfy the Company's cash requirements at that time, the Company would be required to scale back or discontinue its technology and product development programs and/or clinical trials, or obtain funds, if available, through strategic alliances that may require the Company to relinquish rights to certain of its products, or to discontinue its operations entirely.

Operating Activities. For the year ended December 31, 2013, operating activities utilized cash of \$1,180,102, as compared to utilizing cash of \$1,205,757 for the year ended December 31, 2012, to support the Company's ongoing research and development activities.

Investing Activities. For the year ended December 31, 2013, investing activities consisted of a \$1 increase in money market funds from interest earned during the period. For the year ended December 31, 2012, investing activities consisted of a decrease of \$344,995 in money market funds.

Financing Activities. There were no financing activities during the year ended December 31, 2013. For the year ended December 31, 2012, financing activities consisted of \$33,333 of proceeds from the exercise of stock options and net proceeds of \$2,468,250 resulting from the Company offering a 25% discount to warrant holders during May and June 2012 as an inducement to exercise their warrants.

## **Principal Commitments**

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

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

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

On February 5, 2007, the Company entered into a two-year agreement pursuant to which the Company engaged Chem-Master International, Inc. ("Chem-Master") to synthesize a compound designated as LB-100, and any other compound synthesized by Chem-Master pursuant to the Company's request, which have potential use in treating a disease, including, without limitation, cancers such as glioblastomas. Pursuant to the Chem-Master Agreement, the Company agreed to reimburse Chem-Master for the cost of materials, labor, and expenses for other items used in the synthesis process, and also agreed to grant Chem-Master a five-year option to purchase shares of the Company's common stock. On January 29, 2008, the Chem-Master Agreement was amended to extend its term to February 15, 2014; thereafter, Chem-Master will be engaged as needed. The Company also periodically enters into other agreements with Chem-Master for other services. During the years ended December 31, 2013 and 2012, the Company recorded charges to operations of \$7,275 and \$24,500, respectively, with respect to this agreement.

On September 21, 2012, the Company entered into a work order agreement with Theradex to manage and administer the Phase 1 clinical trial of LB-100. Theradex is an international CRO that provides professional services for the clinical research and development of pharmaceutical compounds. 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 within the next 12 to 21 months (sometime between March and December 2015). The Phase 1 clinical trial is estimated to cost a total of approximately \$2,000,000, with such payments expected to be divided approximately evenly between payments to Theradex for services rendered and payments for pass-through costs for the clinical center's laboratory costs and investigator costs. Total costs charged to operations for services paid to Theradex pursuant to this arrangement, which were first incurred in 2013, were \$278,721 for the year ended December 31, 2013. Costs pursuant to this agreement are included in research and development costs in the Company's consolidated statements of operations. On May 2, 2011, Dr. Robert B. Royds, the founder, Chairman of the Board and Medical Director of Theradex, was appointed to the Company's Board of Directors. Dr. Royds died on March 23, 2013. The death of Dr. Royds is not expected to have any impact on the management and administration of the Phase 1 clinical trial.

In addition to the above described agreement with Theradex, the Company has also from time to time engaged Theradex to assist the Company in bringing LB-100 through the FDA approval process and to provide other services. Total fees charged to operations for services paid to Theradex pursuant to such engagements were \$14,964 and \$163,661 for the years ended December 31, 2013 and 2012, respectively, and \$194,551 for the period from August 9, 2005 (inception) to December 31, 2013 (cumulative), and are included in research and development costs in the Company's consolidated statements of operations.

Periodically, the Company has entered into agreements with Ascentage Pharma Group to conduct various studies. As of December 31, 2013, contracts with a total estimated cost of \$29,025, of which \$17,415 had been paid, were in process. Ascentage Pharma Group is an offshoot of Ascenta Therapeutics, of which Dr. Mel Sorensen, a director of the Company, is the President and Chief Executive Officer and a director. Ascentage Pharma Group and Ascenta Therapeutics have a continuing business relationship and certain common shareholders. However, Dr. Sorensen does not have any direct business relationship with or ownership in Ascentage Pharma Group.

At various times, the Company has entered into agreements with other unrelated vendors to conduct certain required studies. As of December 31, 2013, contracts outstanding with such vendors and in currently process had a total estimated cost of \$104,100, of which \$75,325 had been paid to date.

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 was for one year and provides for a quarterly cash fee of \$4,000. The first such quarterly cash payment was made on January 12, 2014. There were no consulting or advisory fees charged to operations pursuant to this quarterly cash fee prior to January 1, 2014. 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 25,000 shares annually on June 24 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 common stock on the grant date.

The following table sets forth the Company's principal cash obligations and commitments for the next five fiscal years as of December 31, 2013 aggregating \$2,119,565, of which \$213,000 is included in current liabilities in the consolidated balance sheet at December 31, 2013.

	Total	Payments Due By Year				
		2014	2015	2016	2017	2018
Research and development contracts	\$ 40,385	\$ 40,385	\$ —	\$ —	\$ —	\$ —
Theradex work order agreement	1,746,463	1,346,463	400,000	—	—	—
Patent license agreement	150,000	30,000	30,000	30,000	30,000	30,000
Consulting agreement	16,000	16,000	—	—	—	—
Liquidated damages payable under registration rights agreement	74,000	74,000	—	—	—	—
Due to stockholder	92,717	92,717	—	—	—	—
<b>Total</b>	<b>\$ 2,119,565</b>	<b>\$ 1,599,565</b>	<b>\$ 430,000</b>	<b>\$ 30,000</b>	<b>\$ 30,000</b>	<b>\$ 30,000</b>

#### Off-Balance Sheet Arrangements

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

#### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Not Applicable

#### ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

Not Applicable.

#### ITEM 9A(T). CONTROLS AND PROCEDURES

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

## **Management's Annual Report on Internal Control Over Financial Reporting**

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

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

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

### **Changes In Internal Control Over Financial Reporting**

There were no changes in our internal controls over financial reporting during the fourth quarter of 2013 that materially affected or are reasonably likely to affect our internal controls over financial reporting.

### **ITEM 9B. OTHER INFORMATION**

None

### PART III

#### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table and text set forth the names of all directors and executive officer of our Company as of December 31, 2013. The Board of Directors is comprised of only one class. All of the directors will serve until the next annual meeting of stockholders and until their successors are elected and qualified, or until their earlier death, retirement, resignation or removal. There are no family relationships between or among the directors, executive officers or persons nominated or charged by our Company to become directors or executive officers. The executive officer serves at the discretion of the Board of Directors, and is appointed to serve until the first Board of Directors meeting following the annual meeting of stockholders. The brief descriptions of the business experience of each director and executive officer and an indication of directorships held by each director in other companies subject to the reporting requirements under the Federal securities laws are provided herein below. Also provided are the biographies of the members of the Scientific Advisory Committee.

Our directors and executive officer are as follows:

<u>Name</u>	<u>Age</u>	<u>Position(s) Held with the Registrant</u>
Dr. John S. Kovach	77	Chief Executive Officer, Chief Financial Officer, Director
Dr. Philip F. Palmedo	80	Director
Dr. Mel Sorensen	57	Director
Dr. Kathleen P. Mullinix	69	Director

#### **Biographies of Directors and Executive Officer:**

##### ***Dr. John S. Kovach***

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

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

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

***Dr. Philip F. Palmedo***

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

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

***Dr. Mel Sorensen***

Dr. Mel Sorensen is President and Chief Executive Officer of Galera Therapeutics, Inc., a private clinical-stage biotech company with superoxide dismutase mimetic technology. He is also Chairman of Oncofusion Therapeutics, an oncology discovery and development company targeting gene fusions that are thought to drive many common cancers. Oncofusion Therapeutics's technology is based on discoveries from the laboratories of the company's founders at the University of Michigan. Dr. Sorensen joined our board of directors on October 7, 2008.

Prior to Galera Therapeutics, Inc., Dr. Sorensen was President and CEO of Ascenta Therapeutics, an oncology company with apoptosis-triggering small molecules discovered at the University of Michigan. Under his leadership, Ascenta Therapeutics raised nearly \$100 million in private financing, achieved clinical-stage programs against three distinct targets (Bcl-2, HDM2, IAP), managed multiple clinical trials, developed a preclinical subsidiary in China and secured global partnerships for all three programs (with Sanofi, DebioPharm and APGC in China).

A medical oncologist who has dedicated his career to clinical cancer research since completing his oncology fellowship at the Mayo Clinic, Dr. Sorensen has spent seven or more years each in patient care, in academia (at the National Cancer Institute), in leadership positions of clinical cancer research in the pharmaceutical industry (Bayer and GSK), and as CEO or Chairman of private biotech companies. He is an advisor to the Biomarkers Consortium of the National Institutes of Health.

***Dr. Kathleen P. Mullinix***

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

## SCIENTIFIC ADVISORY COMMITTEE

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

### ***Arndt Hartmann, M.D.***

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

### ***Ferdinand Hofstadter, M.D.***

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

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

Professor Ojima is Distinguished Professor of Chemistry and Director, Institute of Chemical Biology and Drug Discovery, SUNY-Stony Brook. He is an internationally recognized expert in medicinal chemistry, including anticancer agents and enzyme inhibitors, development of efficient synthetic methods for organic synthesis by means of organometallic reagents, homogeneous catalysis and organometallic chemistry, peptide and peptide mimetics, beta-lactam chemistry, and organofluorine 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 Sigma Xi. He has served as a consultant for E. I. du Pont, Eli Lilly, Air Products & Chemicals, Mitsubishi Chem. Inc., Nippon Steel Corp., Life Science Division, Rhone-Poulenc Rorer, ImmunoGen, Inc., Taiho Pharmaceutical Co., Milliken & Co., Aventis Pharma, OSI Pharmaceuticals, Inc. and Mitsubishi Chem. Corp. (current).

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

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

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

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

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

#### **Audit Committee**

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

#### **Code of Ethics**

Our Board of Directors adopted a code of ethics covering all of our executive officers and key employees. A copy of our code of ethics will be furnished without charge to any person upon written request. Requests should be sent to: Secretary, Lixte Biotechnology Holdings, Inc., 248 Route 25A, No. 2, 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 2013.

#### **ITEM 11. EXECUTIVE COMPENSATION**

In view of the Company's development stage status and limited resources, Dr. Kovach did not receive any compensation from the Company during 2010 or in prior years. However, on February 18, 2011, the Company's Board of Directors approved a salary to Dr. Kovach of \$5,000 per month beginning March 15, 2011. In connection therewith, Dr. Kovach reduced his academic commitment from 80% to 60% in order to devote more time to the Company's activities. Accordingly, during the years ended December 31, 2013 and 2012, Dr. Kovach was paid a salary of \$60,000.

### **Option Grants in 2012 and 2013 - Named Executive Officer**

None.

### **Aggregated Option Exercises in 2012 and 2013 Option Values at December 31, 2012 and at 2013 - Named Executive Officer**

None.

### **Employment Agreements; Compensation**

We have not entered into any employment agreements. As of December 31, 2013, we had no full-time employees. Effective March 15, 2011, the Board of Directors approved a salary for Dr. Kovach of \$5,000 per month. Dr. Kovach was paid a total salary of \$60,000 during the years ended December 31, 2013 and 2012. Dr. Kovach is also reimbursed for any out-of-pocket expenses. Any future compensation arrangements will be subject to the approval of the Board of Directors.

### **Consulting Agreements**

In September 2007, the Company entered into a consulting agreement with Gil Schwartzberg and granted to Mr. Schwartzberg stock options to purchase an aggregate of 1,000,000 shares of common stock, exercisable for a period of four years from vesting date at \$1.00 per share, with one-half of the options (500,000 shares) vesting immediately and one-half (500,000 shares) vesting on September 12, 2008. On September 12, 2011, the options to acquire 500,000 shares of common stock expired unexercised. On September 12, 2012, the remaining options to acquire 500,000 shares of common stock expired unexercised. The consulting agreement was amended in October 2009 to extend the term to October 2013. In connection with the extension, Mr. Schwartzberg was granted options to purchase an additional 1,000,000 shares at \$1.00 per share, 50% of which vested immediately and 50% vested in October 2010. On October 15, 2013, the options to acquire 500,000 shares of common stock expired unexercised. On October 5, 2011, the Company granted to Mr. Schwartzberg stock options to purchase an aggregate of 500,000 shares of common stock, exercisable for a period of five years from the grant date at \$1.00 per share. One-quarter of the options vested immediately, with the balance vesting in three equal quarterly installments beginning on January 5, 2012. On September 11, 2012, the Company, in recognition of his continuing contributions to its financial strategy, granted to Mr. Schwartzberg stock options to purchase 500,000 shares of common stock at \$1.00 per share, exercisable for a period of the earlier of five years from the date of grant or the termination of the consulting agreement with Mr. Schwartzberg. On January 28, 2014, the consulting agreement was again amended to extend its term to January 28, 2019. In connection with the extension, Mr. Schwartzberg was granted options to purchase an additional 4,000,000 shares at \$0.50 per share, 50% of which vested immediately and 50% vested in January 2015.

On April 7, 2010, the Company entered into an agreement with Dr. Mel Sorensen, a member of the Company's Board of Directors, for consultation and advice regarding the preparation and strategy for obtaining FDA allowance of a clinical trial of the lead compound of the LB-100 series. The initial term of the agreement was for one year and provided for an annual fee of \$25,000, payable in two installments of \$12,500 on April 15, 2010 and October 15, 2010. On February 18, 2011, the Company's Board of Directors approved a one-year extension of the agreement for an additional annual fee of \$25,000, payable in two installments of \$12,500 on April 15, 2011 and October 15, 2011. On May 21, 2012, the Company entered into a new agreement with Dr. Mel Sorensen for continuing consultation and advice. The term of the new agreement is for the period from May 21, 2012 to May 31, 2013 and provides for a fee of \$25,000, payable in two installments of \$12,500 on May 21, 2012 and December 1, 2012. All installments have been paid as due. Consulting and advisory fees charged to operations pursuant to these agreements were \$10,417 and \$21,875 for the years ended December 31, 2013 and 2012, respectively, and \$75,000 for the period from August 9, 2005 (inception) to December 31, 2013 (cumulative), and are included in research and development costs in the Company's consolidated statements of operations.

On March 17, 2010, the Company engaged Theradex to assist the Company in bringing LB-100 through the FDA approval process and to provide other services. Total fees charged to operations for services paid to Theradex pursuant to such engagements were \$14,964 and \$163,661 for the years ended December 31, 2013 and 2012, respectively, and \$194,551 for the period from August 9, 2005 (inception) to December 31, 2013 (cumulative), and are included in research and development costs in the Company's consolidated statements of operations. Dr. Robert B. Royds, the founder, Chairman of the Board and Medical Director of Theradex, was appointed to the Company's Board of Directors on May 2, 2011.

On September 21, 2012, the Company entered into a work order agreement with Theradex to manage and administer the Phase 1 clinical trial of LB-100. Theradex is an international CRO that provides professional services for the clinical research and development of pharmaceutical compounds. 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 within the next 12 to 21 months (sometime between March and December 2015). The Phase 1 clinical trial is estimated to cost a total of approximately \$2,000,000, with such payments expected to be divided approximately evenly between payments to Theradex for services rendered and payments for pass-through costs for the clinical center's laboratory costs and investigator costs. Total costs charged to operations for services paid to Theradex pursuant to this arrangement, which were first incurred in 2013, were \$278,721 for the year ended December 31, 2013. Costs pursuant to this agreement are included in research and development costs in the Company's consolidated statements of operations. On May 2, 2011, Dr. Robert B. Royds, the founder, Chairman of the Board and Medical Director of Theradex, was appointed to the Company's Board of Directors. Dr. Royds died on March 23, 2013. The death of Dr. Royds is not expected to have any impact on the management and administration of the Phase 1 clinical trial.

### ***Board of Director Compensation***

On June 30, 2006, effective with the closing of the Exchange, the Company granted to Dr. Philip Palmedo, an outside director of the Company, stock options to purchase an aggregate of 200,000 shares of common stock, exercisable for a period of five years at \$0.333 per share, with 66,667 shares vesting immediately upon joining the Board of Directors and 66,666 shares vesting annually on each of June 30, 2007 and 2008. On June 30, 2011, these options to acquire 200,000 shares of common stock expired unexercised.

On June 30, 2006, effective with the closing of the Exchange, the Company also granted to Dr. Palmedo additional stock options to purchase 190,000 shares of common stock exercisable for a period of five years at \$0.333 per share for services rendered in developing the business plan for Lixte, all of which were fully vested upon issuance. On June 30, 2011, Dr. Palmedo exercised options to acquire 100,000 shares of common stock, which were part of this grant, on a cashless basis. Such cashless exercise resulted in Dr. Palmedo receiving a net of 66,020 shares of common stock. The remaining options to acquire 90,000 shares of common stock, which were also a part of this grant, expired unexercised on June 30, 2011.

On June 30, 2011, the Company granted to Dr. Palmedo stock options to purchase 200,000 shares of common stock, exercisable for a period of five years from the date of grant at \$0.98 per share, which was the fair market value of the Company's common stock on such date. The options vest ratably in equal quarterly installments of 25,000 shares beginning July 1, 2011.

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

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

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

#### 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 Director	2013	0	0	0	0	0	0	0	0
	2012	0	0	0	0	0	0	0	0
	2011	0	0	0	196,000	0	0	0	196,000
Mel Sorensen Director	2013	0	0	0	0	0	0	10,417	10,417
	2012	0	0	0	0	0	0	21,875	21,875
	2011	0	0	0	0	0	0	25,000	25,000
Robert B. Royds Director	2013	0	0	0	0	0	0	0	0
	2012	0	0	0	0	0	0	0	0
	2011	0	0	0	196,000	0	0	0	196,000
Kathleen P. Mullinix Director	2013	0	0	0	0	0	0	0	0
	2012	0	0	0	118,000	0	0	0	118,000

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

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

#### *Scientific Advisory Committee Compensation*

On June 30, 2006, Iwao Ojima, a member of the Scientific Advisory Committee, received options to purchase 50,000 shares of common stock at the initial private placement price of \$0.333 per share with one-half of the options (25,000 shares) vesting on the first anniversary of joining the Scientific Advisory Committee and one-half vesting on the second anniversary. On June 30, 2011, Dr. Ojima exercised options to acquire 15,015 shares of common stock for a cash payment of \$5,000. Dr. Ojima's remaining options to acquire 34,985 shares of common stock expired unexercised.

On June 30, 2011, the Company granted to Dr. Ojima stock options to purchase 50,000 shares of common stock, exercisable for a period of five years from the date of grant at \$0.98 per share, which was the fair market value of the Company's common stock on such date. The options vest ratably in equal quarterly installments of 6,250 shares each beginning July 1, 2011.

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. 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 25,000 shares annually on June 24 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 common stock on the grant date.

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

The following table sets forth, as of March 7, 2014, certain information regarding beneficial ownership of our common stock by (i) each person or entity who is known by us to own beneficially more than 5% of the outstanding shares of common stock, (ii) each of our directors, and (iii) all directors and executive officers as a group. As of March 7, 2014, there were 41,583,097 shares of our common stock issued and outstanding. In computing the number and percentage of shares beneficially owned by a person, shares of common stock that a person has a right to acquire within sixty (60) days of March 7, 2014, pursuant to options, warrants 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 directors, officers and principal stockholders and reports filed with the Securities and Exchange Commission.

<u>Name and Address of Beneficial Owner</u>	<u>Amount and Nature of Beneficial Ownership</u>	<u>Percent of Class</u>
<b>Officers, Directors and 5% stockholders</b>		
Dr. John S. Kovach 248 Route 25A, No. 2 East Setauket, New York 11733	17,021,786	40.9 %
Dr. Philip F. Palmedo 248 Route 25A, No. 2 East Setauket, New York 11733	1,066,020 <sup>(1)</sup>	2.5 %
Dr. Mel Sorensen 248 Route 25A, No. 2 East Setauket, New York 11733	175,000 <sup>(2)</sup>	0.4 %
Dr. Kathleen P. Mullinix 248 Route 25A, No. 2 East Setauket, New York 11733	175,000 <sup>(5)</sup>	0.4 %
All officers and directors as a group (four persons)	18,437,806 <sup>(1)(2)(5)(8)</sup>	43.6 %
Gil Schwartzberg 269 South Beverly Drive, No. 1315 Beverly Hills, California 90212	9,473,397 <sup>(3)</sup>	21.2 %
Dr. Debbie Schwartzberg 269 South Beverly Drive, No. 1315 Beverly Hills, California 90212	6,838,845 <sup>(4)</sup>	15.5 %
Dr. Arthur and Jane Riggs 4852 Saint Andres Avenue La Verne, California 91750	3,000,000 <sup>(6)</sup>	7.2 %
Robert and Susan Greenberg 228 Manhattan Beach Boulevard Manhattan Beach, California 90266	3,000,000 <sup>(7)</sup>	7.0 %

- (1) Consists of 600,000 shares of common stock and warrants to purchase 200,000 shares of common stock owned by the Philip Palmedo Partnership, and 66,020 shares of common stock and options to purchase 200,000 shares of common stock owned by Dr. Palmedo. Dr. Palmedo is the general partner of the Philip Palmedo Partnership and has full voting, disposition and investment control as to such shares. All options and warrants are immediately exercisable or within 60 days.
- (2) Consists of options to purchase 175,000 shares of common stock, all of which are immediately exercisable.
- (3) Includes 750,800 shares of common stock, options to purchase 3,500,000 shares of common stock, and warrants to purchase 350,000 shares of common stock owned by Mr. Schwartzberg. Also includes 829,782 shares of common stock and warrants to purchase 150,000 shares of common stock owned by the Gil Schwartzberg IRA; 558,815 shares of common stock owned by Continuum Capital Partners, LP, as to which Mr. Schwartzberg has sole voting, disposition and investment control; 1,184,000 shares of common stock and warrants 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 warrants to purchase 500,000 shares of common stock owned by the David N. Sterling Trust, as to which Mr. Schwartzberg is the co-trustee. Excludes 1,504,845 shares of common stock and warrants to purchase 1,500,000 shares of common stock owned directly by Debbie Schwartzberg, the wife of Mr. Schwartzberg, as to which Mr. Schwartzberg disclaims beneficial ownership or control; and 500,000 shares of common stock by the Debbie Schwartzberg Family Trust. All options and warrants are immediately exercisable or within 60 days.
- (4) Includes 1,504,845 shares of common stock and warrants to purchase 1,500,000 shares of common stock owned by Ms. Schwartzberg. Also includes 500,000 shares of common stock owned by the Debbie Schwartzberg Family Trust; 1,184,000 shares of common stock and warrants 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 warrants 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 750,800 shares of common stock, options to purchase 3,500,000 shares of common stock and warrants to purchase 350,000 shares of common stock owned by Mr. Schwartzberg, the husband of Ms. Schwartzberg. Also excludes 829,782 shares of common stock and warrants to purchase 150,000 shares of common stock owned by the Gil Schwartzberg IRA, and 558,815 shares of common stock owned by Continuum Capital Partners, LP, as to which Mr. Schwartzberg has sole voting, disposition and investment control. All options and warrants are immediately exercisable.
- (5) Consists of options to purchase 175,000 shares of common stock, all of which are immediately exercisable or within 60 days.
- (6) Consists of 3,000,000 shares of common stock owned by the Arthur and Jane Riggs 1990 Revocable Trust.
- (7) Includes 2,000,000 shares of common stock and warrants to purchase 1,000,000 shares of common stock owned by the Robert and Susan Greenberg Family Trust. The warrants are immediately exercisable.

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

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

#### **(a) Related Party Transactions**

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

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

As of December 31, 2013, Dr. Kovach had advanced an aggregate of \$92,717 to the Company to meet operating expenses, all of which had been advanced at June 30, 2006. Such advances are non-interest bearing and are due on demand.

In September 2007, the Company entered into a consulting agreement with Gil Schwartzberg and granted to Mr. Schwartzberg stock options to purchase an aggregate of 1,000,000 shares of common stock, exercisable for a period of four years from vesting date at \$1.00 per share, with one-half of the options (500,000 shares) vesting immediately and one-half (500,000 shares) vesting on September 12, 2008. On September 12, 2011, the options to acquire 500,000 shares of common stock expired unexercised. On September 12, 2012, the remaining options to acquire 500,000 shares of common stock expired unexercised. The consulting agreement was amended in October 2009 to extend the term to October 2013. In connection with the extension, Mr. Schwartzberg was granted options to purchase an additional 1,000,000 shares at \$1.00 per share, 50% of which vested immediately and 50% vested in October 2010. On October 15, 2013, the options to acquire 500,000 shares of common stock expired unexercised. On October 5, 2011, the Company granted to Mr. Schwartzberg stock options to purchase an aggregate of 500,000 shares of common stock, exercisable for a period of five years from the grant date at \$1.00 per share. One-quarter of the options vested immediately, with the balance vesting in three equal quarterly installments beginning on January 5, 2012. On September 11, 2012, the Company, in recognition of his continuing contributions to its financial strategy, granted to Mr. Schwartzberg stock options to purchase 500,000 shares of common stock at \$1.00 per share, exercisable for a period of the earlier of five years from the date of grant or the termination of the consulting agreement with Mr. Schwartzberg. On January 28, 2014, the consulting agreement was again amended to extend its term to January 28, 2019. In connection with the extension, Mr. Schwartzberg was granted options to purchase an additional 4,000,000 shares at \$0.50 per share, 50% of which vested immediately and 50% vested in January 2015.

On April 7, 2010, the Company entered into an agreement with Dr. Mel Sorensen, a member of the Company's Board of Directors, for consultation and advice regarding the preparation and strategy for obtaining FDA allowance of a clinical trial of the lead compound of the LB-100 series. The initial term of the agreement was for one year and provided for an annual fee of \$25,000, payable in two installments of \$12,500 on April 15, 2010 and October 15, 2010. On February 18, 2011, the Company's Board of Directors approved a one-year extension of the agreement for an additional annual fee of \$25,000, payable in two installments of \$12,500 on April 15, 2011 and October 15, 2011. On May 21, 2012, the Company entered into a new agreement with Dr. Mel Sorensen for continuing consultation and advice. The term of the new agreement is for the period from May 21, 2012 to May 31, 2013 and provides for a fee of \$25,000, payable in two installments of \$12,500 on May 21, 2012 and December 1, 2012. All installments have been paid as due. Consulting and advisory fees charged to operations pursuant to these agreements were \$10,417 and \$21,875 for the years ended December 31, 2013 and 2012, respectively, and \$75,000 for the period from August 9, 2005 (inception) to December 31, 2013 (cumulative), and are included in research and development costs in the Company's consolidated statements of operations.

On March 17, 2010, the Company engaged Theradex to assist the Company in bringing LB-100 through the FDA approval process and to provide other services. Total fees charged to operations for services paid to Theradex pursuant to such engagements were \$14,964 and \$163,661 for the years ended December 31, 2013 and 2012, respectively, and \$194,551 for the period from August 9, 2005 (inception) to December 31, 2013 (cumulative), and are included in research and development costs in the Company's consolidated statements of operations. Dr. Robert B. Royds, the founder, Chairman of the Board and Medical Director of Theradex, was appointed to the Company's Board of Directors on May 2, 2011.

On September 21, 2012, the Company entered into a work order agreement with Theradex to manage and administer the Phase 1 clinical trial of LB-100. Theradex is an international CRO that provides professional services for the clinical research and development of pharmaceutical compounds. 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 within the next 12 to 21 months (sometime between March and December 2015). The Phase 1 clinical trial is estimated to cost a total of approximately \$2,000,000, with such payments expected to be divided approximately evenly between payments to Theradex for services rendered and payments for pass-through costs for the clinical center's laboratory costs and investigator costs. Total costs charged to operations for services paid to Theradex pursuant to this arrangement, which were first incurred in 2013, were \$278,721 for the year ended December 31, 2013. Costs pursuant to this agreement are included in research and development costs in the Company's consolidated statements of operations. On May 2, 2011, Dr. Robert B. Royds, the founder, Chairman of the Board and Medical Director of Theradex, was appointed to the Company's Board of Directors. Dr. Royds died on March 23, 2013. The death of Dr. Royds is not expected to have any impact on the management and administration of the Phase 1 clinical trial.

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

(b) **Director Independence**

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

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

Weinberg & Company, P.C. acted as our independent registered public accounting firm for the fiscal years ended December 31, 2012 and 2013 and for the interim periods in such fiscal years. The following table shows the fees that were incurred by us for audit and other services provided by Weinberg & Company, P.C. in fiscal 2012 and 2013.

	<b>2012</b>	<b>2013</b>
Audit Fees <sup>(1)</sup>	\$ 53,205	\$ 49,664
Audit-Related Fees <sup>(2)</sup>	—	—
Tax Fees <sup>(3)</sup>	5,804	10,450
All Other Fees <sup>(4)</sup>	—	—
<b>Total</b>	<b>\$ 59,009</b>	<b>\$ 60,114</b>

- (1) Audit fees represent fees for professional services provided in connection with the audit of our annual financial statements and the review of our financial statements included in our Form 10-Q quarterly reports and services that are normally provided in connection with statutory or regulatory filings.
- (2) Audit-related fees represent fees for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements and not reported above under "Audit Fees."
- (3) Tax fees represent fees for professional services related to tax compliance, tax advice and tax planning.
- (4) All other fees represent fees related to Sarbanes-Oxley compliance work.

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

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

A list of exhibits required to be filed as part of this report is set forth in the Index to Exhibits, which is presented elsewhere in this document, and is incorporated herein by reference.

Financial statement schedules – None

## 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.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
(Registrant)

Date: March 21, 2014

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

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ JOHN S. KOVACH</u> John S. Kovach	Chief Executive Officer, Chief Financial Officer, Principal Accounting Officer and Director	March 21, 2014
<u>/s/ PHILIP F. PALMEDO</u> Philip F. Palmedo	Director	March 21, 2014
<u>/s/ MEL SORENSEN</u> Mel Sorensen	Director	March 21, 2014
<u>/s/ KATHLEEN P. MULLINIX</u> Kathleen P. Mullinix	Director	March 21, 2014

## 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. <sup>1</sup>
3.1	Certificate of Incorporation, as filed with the Delaware Secretary of State on May 24, 2005. <sup>2</sup>
3.2	Certificate of Amendment of Certificate of Incorporation. <sup>3</sup>
3.2	Bylaws. <sup>2</sup>
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. <sup>4</sup>
10.2	Amendment No. 6 to CRADA. <sup>5</sup>
10.3	Agreement between Lixte Biotechnology Holdings, Inc. and Chem-Master International, Inc. dated as of February 5, 2007. <sup>6</sup>
10.4	Amendment dated January 28, 2008 to Agreement with Chem-Master International, Inc. <sup>7</sup>
10.5	Stock Option Agreement between Lixte Biotechnology Holdings, Inc. and Stephen K. Carter dated September 12, 2007. <sup>8</sup>
10.6	Stock Option Agreement between Lixte Biotechnology Holdings, Inc. and Francis Johnson dated September 12, 2007. <sup>8</sup>
10.7	Stock Option Agreement between Lixte Biotechnology Holdings, Inc. and Gil Schwartzberg dated September 12, 2007. <sup>8</sup>
10.8	Consulting Agreement between Lixte Biotechnology Holdings, Inc. and Gil Schwartzberg dated September 12, 2007. <sup>8</sup>
10.9	Amendment to Consulting Agreement with Gil Schwartzberg dated October 15, 2009. <sup>12</sup>
10.10	Consulting Agreement between Lixte Biotechnology Holdings, Inc. and Francis Johnson dated September 12, 2007. <sup>8</sup>
10.11	Consulting Agreement between Lixte Biotechnology Holdings, Inc. and Pro-Active Capital Group, LLC dated July 27, 2009. <sup>9</sup>
10.12	License Agreement dated as of September 19, 2008 between the Company and the United States Public Health Services. <sup>10</sup>
10.13	Stock Option Agreement between the Company and Mel Sorensen dated October 7, 2008. <sup>11</sup>
10.14	Consulting Agreement between the Company and Mel Sorensen dated October 7, 2008. <sup>11</sup>
10.15	Master Agreement between Lixte Biotechnology Holdings, Inc. and Theradex Systems, Inc. dated January 12, 2010. <sup>12</sup>
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. <sup>13</sup>
10.17	Scientific Advisory Board Agreement between Lixte Biotechnology Holdings, Inc. and NDA Consulting Corp. dated December 24, 2013. <sup>13</sup>
10.18	Advisory Agreement between Lixte Biotechnology Holdings, Inc. and Kathleen P. Mullinix dated January 1, 2014. <sup>13</sup>
31	Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. <sup>13</sup>
32	Officer's Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. <sup>13</sup>

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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 herewith.

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

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

**Years Ended December 31, 2013 and 2012, and  
Period from August 9, 2005 (Inception) to December 31, 2013 (Cumulative)**

Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets – December 31, 2013 and 2012	F-3
Consolidated Statements of Operations - Years Ended December 31, 2013 and 2012, and Period from August 9, 2005 (Inception) to December 31, 2013 (Cumulative)	F-4
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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 (a development stage company) as of December 31, 2013 and 2012, and the related consolidated statements of operations, stockholders' equity (deficiency) and cash flows for the years then ended and for the period from August 9, 2005 (inception) to December 31, 2013 (cumulative). 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, 2013 and 2012, and the results of their operations and their cash flows for the years then ended and for the period from August 9, 2005 (inception) to December 31, 2013 (cumulative), 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 is in the development stage and has not generated any revenues from operations to date, and does not expect to do so in the foreseeable future. The Company has experienced recurring operating losses and negative operating cash flows since inception, and has financed its working capital requirements during this period primarily through the recurring sale of its equity securities. 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 21, 2014

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

**CONSOLIDATED BALANCE SHEETS**

	<b>December 31,</b>	
	<b>2013</b>	<b>2012</b>
<b>ASSETS</b>		
Current assets:		
Cash	\$ 475,019	\$ 1,655,122
Money market funds	6,135	6,134
Advances on research and development contract services	33,880	51,575
Prepaid expenses and other current assets	43,006	40,179
Total current assets	558,040	1,753,010
Total assets	\$ 558,040	\$ 1,753,010
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 107,774	\$ 80,416
Research and development contract liabilities, including \$34,398 and \$9,679 to a related party at December 31, 2013 and 2012, respectively	47,283	14,019
Liquidated damages payable under registration rights agreement	74,000	74,000
Due to stockholder	92,717	92,717
Total current liabilities	321,774	261,152
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; authorized – 10,000,000 shares; issued – none	—	—
Common stock, \$0.0001 par value; authorized - 100,000,000 shares; issued and outstanding – 41,583,097 shares	4,158	4,158
Additional paid-in capital	13,184,081	13,064,831
Deficit accumulated during the development stage	(12,951,973)	(11,577,131)
Total stockholders' equity	236,266	1,491,858
Total liabilities and stockholders' equity	\$ 558,040	\$ 1,753,010

See accompanying notes to consolidated financial statements.

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

**CONSOLIDATED STATEMENTS OF OPERATIONS**

	<b>Years Ended December 31,</b>		<b>Period from August 9, 2005 (Inception) to December 31, 2013 (Cumulative)</b>
	<b>2013</b>	<b>2012</b>	
Revenues	\$ —	\$ —	\$ —
Costs and expenses:			
General and administrative costs, including \$115,768 and \$724,204 to related parties for the years ended December 31, 2013 and 2012, respectively, and \$2,763,909 for the period from August 9, 2005 to December 31, 2013 (cumulative).	494,959	1,093,614	5,727,899
Depreciation	—	—	1,909
Research and development costs, including \$304,102 and \$185,536 to related parties for the years ended December 31, 2013 and 2012, respectively, and \$548,272 for the period from August 9, 2005 to December 31, 2013 (cumulative).	879,886	1,012,144	5,449,678
Reverse merger costs	—	—	50,000
Total costs and expenses	<u>1,374,845</u>	<u>2,105,758</u>	<u>11,229,486</u>
Loss from operations	(1,374,845)	(2,105,758)	(11,229,486)
Interest income	3	8	27,437
Interest expense	—	—	(2,469)
Fair value of warrant extensions	—	(1,139,592)	(1,339,431)
Fair value of warrant discount	—	(334,024)	(334,024)
Liquidated damages under registration rights agreement	—	—	(74,000)
Net loss	<u>\$ (1,374,842)</u>	<u>\$ (3,579,366)</u>	<u>\$ (12,951,973)</u>
Net loss per common share – Basic and diluted	<u>\$ (0.03)</u>	<u>\$ (0.09)</u>	
Weighted average common shares outstanding – Basic and diluted	<u>41,583,097</u>	<u>38,985,832</u>	

See accompanying notes to consolidated financial statements.

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

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

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

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

(Continued)

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

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

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

	<u>Common Stock</u>		<u>Advances Under Equity Financing</u>	<u>Additional Paid-in Capital</u>	<u>Deficit Accumulated During the Development Stage</u>	<u>Total Stockholders' Equity (Deficiency)</u>
	<u>Shares</u>	<u>Amount</u>				
Shares issued in private placements, net of offering costs	4,575,000	\$ 458	\$(1,200,000)	\$ 2,287,042	\$ —	\$ 1,087,500
Stock-based compensation expense	—	—	—	160,712	—	160,712
Stock-based research and development expense	—	—	—	67,222	—	67,222
Net loss	—	—	—	—	(880,250)	(880,250)
Balance, December 31, 2010	35,077,178	3,508	—	7,662,559	(5,929,801)	1,736,266
Exercise of stock options	181,964	18	—	4,982	—	5,000
Stock-based compensation expense	—	—	—	204,898	—	204,898
Stock-based research and development expense	—	—	—	982	—	982
Fair value of warrant extension	—	—	—	199,839	—	199,839
Net loss	—	—	—	—	(2,067,964)	(2,067,964)
Balance, December 31, 2011	35,259,142	3,526	—	8,073,260	(7,997,765)	79,021
Exercise of stock options	241,955	24	—	33,309	—	33,333
Exercise of stock warrants	6,082,000	608	—	2,467,642	—	2,468,250
Stock-based compensation expense	—	—	—	723,554	—	723,554
Stock-based research and development expense	—	—	—	293,450	—	293,450
Fair value of warrant discount	—	—	—	334,024	—	334,024
Fair value of warrant extensions	—	—	—	1,139,592	—	1,139,592
Net loss	—	—	—	—	(3,579,366)	(3,579,366)
Balance, December 31, 2012	41,583,097	4,158	—	13,064,831	(11,577,131)	1,491,858
Stock-based compensation expense	—	—	—	119,250	—	119,250
Net loss	—	—	—	—	(1,374,842)	(1,374,842)
Balance, December 31, 2013	<u>41,583,097</u>	<u>\$ 4,158</u>	<u>\$ —</u>	<u>\$13,184,081</u>	<u>\$(12,951,973)</u>	<u>\$ 236,266</u>

See accompanying notes to consolidated financial statements.

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

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<b>Years Ended December 31,</b>		<b>Period from August 9, 2005 (Inception) to December 31, 2013 (Cumulative)</b>
	<b>2013</b>	<b>2012</b>	
<b>Cash flows from operating activities:</b>			
Net loss	\$ (1,374,842)	\$ (3,579,366)	\$ (12,951,973)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>			
Depreciation	—	—	1,909
Stock-based compensation expense included in general and administrative costs	119,125	723,554	3,300,100
Stock-based compensation expense included in research and development costs	125	293,450	758,609
Fair value of warrant extensions	—	1,139,592	1,339,431
Fair value of warrant discount	—	334,024	334,024
<b>Changes in operating assets and liabilities:</b>			
<b>(Increase) decrease in -</b>			
Advances on research and development contract services	17,695	(22,592)	(33,880)
Prepaid expenses and other current assets	(2,827)	(4,825)	(43,006)
<b>Increase (decrease) in -</b>			
Accounts payable and accrued expenses	27,358	(28,925)	107,774
Liquidated damages payable under registration rights agreement	—	—	74,000
Research and development contract liabilities	33,264	(60,669)	47,283
<b>Net cash used in operating activities</b>	<b>(1,180,102)</b>	<b>(1,205,757)</b>	<b>(7,065,729)</b>
<b>Cash flows from investing activities:</b>			
(Increase) decrease in money market funds	(1)	344,995	(6,135)
Purchase of office equipment	—	—	(1,909)
<b>Net cash provided by (used in) investing activities</b>	<b>(1)</b>	<b>344,995</b>	<b>(8,044)</b>
<b>Cash flows from financing activities:</b>			
Proceeds from exercise of stock options	—	33,333	38,333
Proceeds from exercise of warrants	—	2,468,250	2,468,250
Proceeds from sale of common stock to consulting firm	—	—	250
Proceeds from sale of common stock to founder	—	—	1,500
Proceeds from issuance of notes payable to consultant	—	—	200,000
Repayment of notes payable to consultant	—	—	(200,000)
Cash acquired in reverse merger transaction	—	—	62,500
Gross proceeds from sale of securities	—	—	5,331,389
Payment of private placement offering costs	—	—	(446,147)
Advances received from stockholder	—	—	92,717
<b>Net cash provided by financing activities</b>	<b>—</b>	<b>2,501,583</b>	<b>7,548,792</b>

(Continued)

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

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

	Years Ended December 31,		Period from August 9, 2005 (Inception) to December 31, 2013 (Cumulative)
	2013	2012	
<b>Cash:</b>			
Net increase (decrease)	\$ (1,180,103)	\$ 1,640,821	\$ 475,019
Balance at beginning of period	1,655,122	14,301	—
Balance at end of period	<u>\$ 475,019</u>	<u>\$ 1,655,122</u>	<u>\$ 475,019</u>
<b>Supplemental disclosures of cash flow information:</b>			
<b>Cash paid for -</b>			
Interest	\$ —	\$ —	\$ 2,469
Income taxes	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>
<b>Non-cash financing activities:</b>			
Decrease in advances under equity financing	\$ —	\$ —	\$ 1,200,000
Aggregate exercise price of warrants and options exercised on a cashless basis	<u>\$ —</u>	<u>\$ 109,391</u>	<u>\$ 193,598</u>

See accompanying notes to consolidated financial statements.

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Years Ended December 31, 2013 and 2012, and  
Period from August 9, 2005 (Inception) to December 31, 2013 (Cumulative)**

**1. Organization and Business Operations**

*Organization*

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

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

The Company is considered a “development stage company” under current accounting standards, as it has not yet commenced any revenue-generating operations, does not have any cash flows from operations, and is dependent on debt and equity funding to finance its operations.

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

*Operating Plans*

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

The Company’s drug discovery process is based on discerning clues to potential new targets for disease treatments reported in the increasingly large body of literature identifying the molecular variants which characterize human cancers and other non-cancer disorders. The Company designs drugs for which there are existing data suggesting that they may affect the altered pathways of the cancer cell and may be given safely to humans. The Company seeks to rapidly arrive at patentable structures through analysis of the literature rather than screening of thousands of structures for activity against a particular biochemical pathway. This approach has led to the development of two classes of drugs for the treatment of cancer, protein phosphatase inhibitors (PTase-i), designated by the Company as the LB-100 series of compounds, and histone deacetylase inhibitors (HDACi), designated by the Company as the LB-200 series of compounds. Compounds of both types also have potential use in the prevention and treatment of neurodegenerative diseases.

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

The Company’s primary objective has been to bring one lead compound of the LB-100 series to clinical trial. In 2012, the Company completed the pre-clinical studies needed to prepare an Investigation New Drug (“IND”) application to the FDA to conduct a Phase 1 clinical trial of LB-100, and engaged Theradex Systems, Inc. (“Theradex”), the contract research organization (“CRO”) responsible for the clinical development of the Company’s lead compound, LB-100, to prepare an IND application for filing with the FDA.

The Company filed an IND application with the FDA on April 30, 2012, and on July 24, 2012, the FDA notified the Company that it would allow initiation of a Phase 1 clinical trial of LB-100. The purpose of the clinical trial is to demonstrate that LB-100 can be administered safely to human beings at a dose and at a frequency that achieves the desired pharmacologic effect; in this case, inhibition of a specific enzyme, without being associated with toxicities considered unacceptable.

The Phase 1 clinical trial of LB-100 began in April 2013 with the entry of patients into the clinical trial (see NCT01837667 at [www.clinicaltrials.gov](http://www.clinicaltrials.gov)) and was initiated at the City of Hope National Medical Center in Duarte, California, and was extended in December 2013 to include the Mayo Clinic in Rochester, Minnesota, both of which are Comprehensive Cancer Centers designated by the National Cancer Institute. The Company estimates that the Phase 1 clinical trial will be completed within the next 12 to 21 months (sometime between March and December 2015) and will cost a total of approximately \$2,000,000, which will be paid to or through Theradex, the CRO responsible for the clinical development of LB-100. As of December 31, 2013, the Company has incurred \$278,721 of these clinical trial costs, which have been included in research and development expenses in the statement of operations for the year ended December 31, 2013. The final cost of the clinical trial is variable, depending upon the number of patients needed to be medically screened to determine if they meet the criteria for entry into the study and ultimately upon the total number of patients entered into the study to establish the proper doses of the drug for Phase 2 clinical trials.

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

### ***Going Concern***

The Company’s consolidated financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company is in the development stage and has not generated any revenues from operations to date, and does not expect to do so in the foreseeable future. The Company has experienced recurring operating losses and negative operating cash flows since inception, and has financed its working capital requirements during this period primarily through the recurring sale of its equity securities and the exercise of outstanding warrants. As a result, the Company’s independent registered public accounting firm, in its report on the Company’s 2013 consolidated financial statements, has raised substantial doubt about the Company’s ability to continue as a going concern.

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

At December 31, 2013, the Company had not yet commenced any revenue-generating operations. All activity through December 31, 2013 has been related to the Company’s formation, capital raising efforts, and research and development activities. As such, the Company has yet to generate any cash flows from operations, and is dependent on debt and equity funding from both related and unrelated parties to finance its operations. Prior to June 30, 2006, the Company’s cash requirements were funded by advances from the Company’s founder aggregating \$ 92,717 .

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

The Company's major focus in 2014 is to continue a Phase 1 clinical trial of its lead phosphatase inhibitor, LB-100. The Phase 1 clinical trial of LB-100 began in April 2013 with the entry of patients into the clinical trial, and is being carried out by nationally recognized comprehensive cancer centers. The cost of a clinical trial depends to a considerable extent upon the rate of patient accrual, as well as the number of patients entered into the clinical trial. If screening tests render a patient ineligible for the clinical trial, the screening costs are realized, but patient accrual is not advanced. Accordingly, the costs needed to complete a clinical trial with the planned number of participants may increase under such circumstances.

The Company estimates that the Phase 1 clinical trial will conclude within the next 12 to 21 months (sometime between March and December 2015) and will cost a total of approximately \$2,000,000, which will be paid to or through Theradex, the CRO responsible for the clinical development of LB-100. As of December 31, 2013, the Company has incurred \$278,721 of these clinical trial costs, which have been included in research and development expenses in the statement of operations for the year ended December 31, 2013.

At December 31, 2013, the Company had cash and money market funds aggregating \$ 481,154. The Company believes that it has sufficient funds to continue with the Phase 1 clinical trial of LB-100 and to fund its operating plans through April 30, 2014. Accordingly, in order to continue to fund the Company's operations in 2014 and thereafter, the Company will need to raise additional capital, likely in the form of equity, aggregating at least \$2,000,000 to fund operations for the next twelve months. Market conditions present uncertainty as to the Company's ability to secure additional funds. There can be no assurances that the Company will be able to secure additional financing on acceptable terms or at all. If cash resources are insufficient to satisfy the Company's ongoing cash requirements, the Company would be required to scale back or discontinue its technology and product development programs and/or clinical trials, or obtain funds, if available (although there can be no certainty), through strategic alliances that may require the Company to relinquish rights to certain of its products, or to discontinue its operations entirely.

The amount and timing of future cash requirements will depend on the pace of the Company's programs, particularly the completion of the Phase 1 clinical trial of LB-100. After completion of the Phase 1 clinical trial, the next step will be to determine the anti-cancer activity of LB-100, in combination with a widely used anti-cancer drug, against a specific type of human cancer in Phase 2 clinical trials. Subject to the availability of funds, the Company intends to continue with its Phase 1 clinical trial of LB-100, continue the two drug development programs currently in process, and expand its patent portfolio, including the maintenance of its applications for international protection of lead compounds of both the LB-100 and LB-200 series.

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

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

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

### ***Cash Concentrations***

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

## ***Research and Development***

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

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

## ***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 \$ 405,285 and \$ 236,784 for the years ended December 31, 2013 and 2012, respectively, and \$ 1,814,682 for the period from August 9, 2005 (inception) to December 31, 2013 (cumulative). Patent costs are included in research and development costs in the Company's consolidated statements of operations.

## ***Royalties***

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

## ***Concentration of Risk***

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

On September 21, 2012, the Company entered into a work order agreement with Theradex, the CRO responsible for the clinical development of the Company's lead compound, LB-100, to manage and administer the Phase 1 clinical trial of LB-100. Theradex is an international CRO that provides professional services for the clinical research and development of pharmaceutical compounds. 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 within the next 12 to 21 months (sometime between March and December 2015). The Phase 1 clinical trial is expected to cost a total of approximately \$2,000,000, with such payments expected to be divided approximately evenly between payments to Theradex for services rendered and payments for pass-through costs for the clinical center's laboratory costs and investigator costs. Total costs charged to operations for services paid to Theradex pursuant to this arrangement, which were first incurred in 2013, were \$278,721 for the year ended December 31, 2013, or approximately 32% of research and development costs for the year ended December 31, 2013. The costs charged to operations for amounts paid to Theradex for services relating to the Phase 1 clinical trial of LB-100 are expected to represent a larger percentage of total research and development costs during the fiscal years ending December 31, 2014 and 2015. Costs pursuant to this agreement are included in research and development costs in the Company's consolidated statements of operations. On May 2, 2011, Dr. Robert B. Royds, the founder, Chairman of the Board and Medical Director of Theradex, was appointed to the Company's Board of Directors. Dr. Royds died on March 23, 2013. The death of Dr. Royds is not expected to have any impact on the management and administration of the Phase 1 clinical trial.

In addition to the above described agreement with Theradex, the Company has also from time to time engaged Theradex to assist the Company in bringing LB-100 through the FDA approval process and to provide other services. Total fees charged to operations for services paid to Theradex pursuant to such engagements were \$14,964 and \$163,661 for the years ended December 31, 2013 and 2012, respectively, or approximately 2% and 16% of research and development costs for the years ended December 31, 2013 and 2012, respectively, and 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.

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

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

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

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

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

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

The Company accounts for stock-based payments to consultants by determining the value of the stock compensation based upon the measurement date at either (a) the date at which a performance commitment is reached or (b) at the date at which the necessary performance to earn the equity instruments is complete.

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

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

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

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

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

	<u>2013</u>	<u>2012</u>
Warrants	6,828,800	6,828,800
Stock options	3,150,000	3,750,000
<b>Total</b>	<u>9,978,800</u>	<u>10,578,800</u>

### ***Fair Value of Financial Instruments***

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

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

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

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

In February 2013, the Financial Accounting Standards Board (the "FASB") issued ASU No. 2013-04, Liabilities (Topic 405): Obligations Resulting from Joint and Several Liability Arrangements for Which the Total Amount of the Obligation Is Fixed at the Reporting Date. This guidance provides direction for the recognition, measurement, and disclosure of obligations resulting from joint and several liability arrangements for which the total amount of the obligation within the scope of this guidance is fixed at the reporting date, except for obligations addressed within existing guidance in U.S. GAAP. The guidance requires an entity to measure those obligations as the sum of the amount the reporting entity agreed to pay on the basis of its arrangement among its co-obligors and any additional amount the reporting entity expects to pay on behalf of its co-obligors. This guidance will become effective for the Company for fiscal years, and interim periods within those years, beginning after December 15, 2013. The Company does not expect the adoption of this guidance to have a material impact on the Company's consolidated financial statements.

In March 2013, the FASB issued ASU No. 2013-05, Foreign Currency Matters (Topic 830). This guidance resolves the diversity in practice relating to financial reporting involving a parent entity's accounting for the cumulative translation adjustment of foreign currency into net income when a parent either sells a part or all of its investment in a foreign entity or no longer holds a controlling financial interest in a subsidiary or group of assets that is a nonprofit activity or a business (other than a sale of in substance real estate or conveyance of oil and gas mineral rights) within a foreign entity. In addition, this guidance resolves the diversity in practice for the treatment of business combinations achieved in stages (sometimes also referred to as step acquisitions) involving a foreign entity. This guidance will become effective for the Company for fiscal years, and interim periods within those years, beginning after December 15, 2013. The Company does not expect the adoption of this guidance to have a material impact on the Company's consolidated financial statements.

In July 2013, the FASB issued ASU 2013-11, Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Loss, or a Tax Credit Carryforward Exists (a consensus the FASB Emerging Issues Task Force). This guidance provides direction on financial statement presentation of unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. The FASB's objective in issuing this guidance was to eliminate diversity in practice resulting from a lack of guidance on this topic in current U.S. GAAP. This guidance applies to all entities with unrecognized tax benefits that also have tax loss or tax credit carryforwards in the same tax jurisdiction as of the reporting date. This guidance will become effective for the Company for fiscal years, and interim periods within those years, beginning after December 15, 2013. The Company does not expect the adoption of this guidance to have a material impact on the Company's consolidated financial statements.

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

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

#### ***Share Exchange Agreement***

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

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

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

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

## *Private Placements*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Warrants outstanding at December 31, 2011	13,454,552	\$ 0.607	
Issued	—	—	
Exercised	(6,355,752)	0.535	
Expired	(270,000)	0.844	
Warrants outstanding at December 31, 2012	6,828,800	0.667	
Issued	—	—	
Exercised	—	—	
Expired	—	—	
Warrants outstanding at December 31, 2013	<u>6,828,800</u>	<u>\$ 0.667</u>	<u>0.67</u>
Warrants exercisable at December 31, 2012	<u>6,659,840</u>	<u>\$ 0.672</u>	
Warrants exercisable at December 31, 2013	<u>6,659,840</u>	<u>\$ 0.672</u>	<u>0.42</u>

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

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

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

Based on a fair market value of \$ 0.25 per share on December 31, 2012, there were no exercisable but unexercised in-the-money common stock warrants on that date. Accordingly, there was no intrinsic value attributed to exercisable but unexercised common stock warrants at December 31, 2012

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

Effective January 28, 2014, the Company entered into various transactions involving its outstanding warrants, as described at Note 9.

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

Money market funds at December 31, 2013 and 2012 consisted of investments in shares of Morgan Stanley New York Municipal Money Market Trust with market values of \$ 6,135 and \$ 6,134 , respectively. The Morgan Stanley New York Municipal Money Market Trust is an open-end fund incorporated in the USA. The Fund's objective is as high level of daily income exempt from federal and New York income tax as is consistent with stability of principal and liquidity. The Fund invests in high quality, short- term municipal obligations that pay interest exempt from federal and NY taxes.

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

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

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

Level 3: unobservable inputs for the asset or liability are only used when there is little, if any, market activity for the asset or liability at the measurement date. Financial assets and liabilities utilizing Level 3 inputs include infrequently-traded non-exchange-based derivatives and commingled investment funds, and are measured using present value pricing models.

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

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

The following table presents money market funds at their level within the fair value hierarchy at December 31, 2013 and 2012.

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

## 5. Related Party Transactions

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

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

In view of the Company's development stage status and limited resources, Dr. Kovach did not receive any compensation from the Company prior to 2011. However, on February 18, 2011, the Company's Board of Directors approved a salary for Dr. Kovach of \$ 5,000 per month beginning March 15, 2011 . Dr. Kovach was paid a salary of \$ 60,000 for the years ended December 31, 2013 and 2012, and \$ 167,500 for the period from August 9, 2005 (inception) to December 31, 2013 (cumulative), 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, he may face a conflict in selecting between the Company and his other business interests. The Company has not yet formulated a policy for the resolution of such potential conflicts.

On April 7, 2010, the Company entered into an agreement with Dr. Mel Sorensen, a member of the Company's Board of Directors, for consultation and advice regarding the preparation and strategy for obtaining FDA allowance of a clinical trial of the lead compound of the LB-100 series. The initial term of the agreement was for one year and provided for an annual fee of \$ 25,000 , payable in two installments of \$ 12,500 on April 15, 2010 and October 15, 2010. On February 18, 2011, the Company's Board of Directors approved a one-year extension of the agreement for an additional annual fee of \$ 25,000 , payable in two installments of \$ 12,500 on April 15, 2011 and October 15, 2011. On May 21, 2012, the Company entered into a new agreement with Dr. Mel Sorensen for continuing consultation and advice. The term of the new agreement was for the period from May 21, 2012 to May 31, 2013 and provided for a fee of \$ 25,000 , payable in two installments of \$ 12,500 on May 21, 2012 and December 1, 2012. All installments have been paid as due. Consulting and advisory fees charged to operations pursuant to these agreements were \$ 10,417 and \$ 21,875 for the years ended December 31, 2013 and 2012, respectively, and \$ 75,000 for the period from August 9, 2005 (inception) to December 31, 2013 (cumulative), and are included in research and development costs in the Company's consolidated statements of operations.

On September 21, 2012, the Company entered into a work order agreement with Theradex to manage and administer the Phase 1 clinical trial of LB-100. Theradex is an international CRO that provides professional services for the clinical research and development of pharmaceutical compounds. 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 within the next 12 to 21 months (sometime between March and December 2015). The Phase 1 clinical trial is estimated to cost a total of approximately \$ 2,000,000 , with such payments expected to be divided approximately evenly between payments to Theradex for services rendered and payments for pass-through costs for the clinical center's laboratory costs and investigator costs. Total costs charged to operations for services paid to Theradex pursuant to this arrangement, which were first incurred in 2013, were \$ 278,721 for the year ended December 31, 2013. Costs pursuant to this agreement are included in research and development costs in the Company's consolidated statements of operations. On May 2, 2011, Dr. Robert B. Royds, the founder, Chairman of the Board and Medical Director of Theradex, was appointed to the Company's Board of Directors. Dr. Royds died on March 23, 2013. The death of Dr. Royds is not expected to have any impact on the management and administration of the Phase 1 clinical trial.

In addition to the above described agreement with Theradex, the Company has also from time to time engaged Theradex to assist the Company in bringing LB-100 through the FDA approval process and to provide other services. Total fees charged to operations for services paid to Theradex pursuant to such engagements were \$ 14,964 and \$ 163,661 for the years ended December 31, 2013 and 2012, respectively, and \$ 194,551 for the period from August 9, 2005 (inception) to December 31, 2013 (cumulative), and 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 was for one year and provides for a quarterly cash fee of \$ 4,000. The first such quarterly cash payment was made on January 12, 2014. There were no consulting or advisory fees charged to operations pursuant to this quarterly cash fee prior to January 1, 2014. 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 25,000 shares annually on June 24 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 common stock on the grant date.

Effective January 1, 2014, the Company entered into an Advisory Agreement with Dr. Kathleen P. Mullinix, a member of the Company's Board of Directors, as described at Note 9.

Stock-based compensation arrangements involving members of the Company's Board of Directors are described at Note 6. Total stock-based compensation expense relating to directors, officers and other related parties was \$ 119,250 and \$ 1,017,004 for the years ended December 31, 2013 and 2012, respectively, and \$ 3,598,461 for the period from August 9, 2005 (inception) to December 31, 2013 (cumulative).

## **6. Stock-Based Compensation**

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

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

New transactions during the year ended December 31, 2013 that required an assessment of value pursuant to the Black-Scholes option-pricing model utilized the following inputs: exercise price per share - \$ 0.13 ; stock price per share - \$0.13; expected dividend yield - 0.00 %; expected volatility - 262.0 %; average risk-free interest rate - 1.51 %; expected life - 5 years. There were no transactions entered into in prior periods that required re-evaluation of assessed value at December 31, 2013.

New transactions during the year ended December 31, 2012 that required an assessment of value pursuant to the Black-Scholes option-pricing model utilized the following inputs: exercise price per share - \$ 0.65 to \$ 1.00 ; stock price per share - \$ 0.65 ; expected dividend yield - 0.00 %; expected volatility - 148.4 %; average risk-free interest rate - 0.78 %; expected life - 5 years. For the purpose of assessing value for transactions requiring re-evaluation at December 31, 2012 that were entered into in prior periods, the Black-Scholes option-pricing model utilized the following inputs for the year ended December 31, 2012: exercise price per share - \$ 0.98 to \$ 1.00 ; stock price per share - \$ 0.25 ; expected dividend yield - 0.00 %; expected volatility - 128.4 %; average risk-free interest rate - 0.24 %; expected life - 3.50 to 4.00 years.

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

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

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

On June 30, 2011, the Company granted to Dr. Palmedo stock options to purchase 200,000 shares of common stock, exercisable for a period of five years from the date of grant at \$ 0.98 per share, which was the fair market value of the Company's common stock on such date. The options vest ratably in equal quarterly installments of 25,000 shares beginning July 1, 2011. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be \$ 196,000 (\$ 0.98 per share). During the years ended December 31, 2013 and 2012, the Company recorded charges to operations of \$ 48,530 and \$ 98,134 , respectively, with respect to these options.

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

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

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

On June 30, 2011, the Company granted to Dr. Ojima stock options to purchase 50,000 shares of common stock, exercisable for a period of five years from the date of grant at \$0.98 per share, which was the fair market value of the Company's common stock on such date. The options vest ratably in equal quarterly installments of 6,250 shares beginning July 1, 2011. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be \$ 49,000 (\$0.98 per share). During the years ended December 31, 2013 and 2012, the Company recorded a charge (credit) to operations of \$ 3,357 and \$(650), respectively, with respect to these options.

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

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

On September 11, 2012, the Company granted to Chem-Master a stock option to purchase 500,000 shares of common stock, exercisable for a period of five years from the date of grant at \$ 0.65 per share, which was the fair market value of the Company’s common stock on such date. The fair value of this option, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$ 293,450 (\$ 0.59 per share), which was charged to operations as research and development costs on September 11, 2012, as the option was fully vested and non-forfeitable on the date of issuance. The option includes cashless exercise provisions.

On June 20, 2007, the Board of Directors of the Company approved the 2007 Stock Compensation Plan (the “2007 Plan”), which provides for the granting of awards, consisting of common stock options, stock appreciation rights, performance shares, or restricted shares of common stock, to employees and independent contractors, for up to 2,500,000 shares of the Company’s common stock, under terms and condition, as determined by the Company’s Board of Directors.

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

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

On October 15, 2009, the Company approved a first amendment to the above described consulting agreement with Gil Schwartzberg to extend it for an additional four years and granted to Mr. Schwartzberg stock options to purchase an additional aggregate of 1,000,000 shares of common stock, exercisable for a period of the earlier of four years from the vesting date or the termination of the consulting agreement at \$ 1.00 per share, with one-half of the options ( 500,000 shares) vesting immediately and one-half (500,000 shares) vesting on October 15, 2010. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$ 750,000 (\$ 0.75 per share) on October 15, 2009, of which \$ 375,000 was attributed to the fully-vested options and was thus charged to operations on October 15, 2009. The remaining unvested portion of the fair value of the options was charged to operations ratably from October 15, 2009 through October 15, 2010. On October 15, 2013, options to acquire 500,000 shares of common stock expired unexercised.

On January 28, 2014, the Company entered into a second amendment to the Company's consulting agreement with Gil Schwartzberg, a consultant and significant shareholder of the Company, as described at Note 9.

On October 5, 2011, the Company granted to Mr. Schwartzberg stock options to purchase an aggregate of 500,000 shares of common stock, exercisable for a period of the earlier of five years from the grant date or the termination of the consulting agreement at \$ 1.00 per share. One-quarter of the options vested immediately, with the balance vesting in three equal quarterly installments beginning on January 5, 2012. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be \$ 325,000 (\$ 0.65 per share) and was charged to operations ratably from October 5, 2011 through October 4, 2012. During the year ended December 31, 2012, the Company recorded a charge to operations of \$ 210,410 with respect to these options.

On September 11, 2012, the Company granted to Mr. Schwartzberg stock options to purchase 500,000 shares of common stock, exercisable for a period of the earlier of five years from the date of grant or the termination of the consulting agreement at \$ 1.00 per share, which was the fair market value of the Company's common stock on such date. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$ 286,100 (\$ 0.57 per share), which was charged to operations on September 11, 2012, as the options were fully vested and non-forfeitable on the date of issuance.

On September 12, 2007, the Company entered into a consulting agreement with Francis Johnson, a co-owner of Chem-Master International, Inc., and granted to Professor Johnson stock options to purchase an aggregate of 300,000 shares of common stock, exercisable for a period of four years from the vesting date at \$ 0.333 per share, with one-third ( 100,000 shares) vesting annually on each of September 12, 2008, 2009 and 2010. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be \$ 300,000 (\$ 1.00 per share). The unvested portion of the fair value of the options was charged to operations from September 12, 2007 through September 12, 2010. On September 12, 2013 and 2012, options to acquire 100,000 shares expired unexercised.

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

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

Effective May 1, 2011, in connection with his election to the Company's Board of Directors, Dr. Robert B. Royds was granted stock options to purchase 200,000 shares of the Company's common stock, vesting 25,000 shares on May 1, 2011, and 25,000 shares quarterly thereafter until all of the shares are vested, exercisable for a period of five years from each tranche's vesting date, at \$ 0.98 per share, which was the fair market value of the Company's common stock on such date. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$196,000 (\$ 0.98 per share), and was charged to operations ratably from May 2, 2011 through February 1, 2013. During the year ended December 31, 2013 and 2012, the Company recorded charges to operations of \$ 8,548 and \$ 97,770 , respectively, with respect to these options. Dr. Royds died on March 23, 2013. As a result of the death of Dr. Royds, pursuant to the stock option agreement, Dr. Royds' executor has twelve months from March 23, 2013 to exercise his stock options to acquire 200,000 shares of the Company's common stock.

Effective September 16, 2012, in connection with her election to the Company's Board of Directors, Dr. Kathleen P. Mullinix was granted stock options to purchase 200,000 shares of the Company's common stock, vesting 25,000 shares on September 16, 2012, and 25,000 shares quarterly thereafter until all of the shares are vested, exercisable for a period of five years from the date of grant at \$ 0.65 per share, which was the fair market value of the Company's common stock on such date. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$ 118,000 (\$ 0.59 per share), and is being charged to operations from September 16, 2012 through June 16, 2014. During the years ended December 31, 2013 and 2012, the Company recorded charges to operations of \$ 58,690 and \$ 31,790 , respectively, with respect to these options.

On December 24, 2013, the Company entered into an agreement with NDA Consulting Corp. ("NDA") for consultation and advice in the field of oncology research and drug development. As part of the agreement, NDA agreed to cause its president, Dr. Daniel D. Von Hoff, M.D., to become a member of the Company's Scientific Advisory Committee . In connection with this agreement, NDA was granted stock options to purchase 100,000 shares of the Company's common stock, vesting 25,000 shares on June 24, 2014, and thereafter 25,000 shares annually on June 24, 2015, 2016 and 2017, exercisable for a period of five years from the date of grant at \$ 0.13 per share, which was the fair market value of the Company's common stock on the grant date. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be \$ 12,960 (\$0.13 per share), and is being charged to operations from December 24, 2013 through June 24, 2017. During the year ended December 31, 2013, the Company recorded a charge to operations of \$ 125 with respect to these options.

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

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

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Options outstanding at December 31, 2011	3,250,000	\$ 0.884	
Granted	1,200,000	0.796	
Exercised	(100,000)	0.333	
Expired	(600,000)	0.889	
Options outstanding at December 31, 2012	3,750,000	0.870	
Granted	100,000	0.130	
Exercised	—	—	
Expired	(700,000)	1.045	
Options outstanding at December 31, 2013	<u>3,150,000</u>	<u>\$ 0.818</u>	<u>2.62</u>
Options exercisable at December 31, 2012	<u>3,512,500</u>	<u>\$ 0.876</u>	
Options exercisable at December 31, 2013	<u>3,000,000</u>	<u>\$ 0.843</u>	<u>2.52</u>

Total deferred compensation expense for the outstanding value of unvested stock options was approximately \$ 40,000 at December 31, 2013, which is being recognized subsequent to December 31, 2013 over a weighted-average period of approximately seventeen months.

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

Exercise Prices	Options Outstanding (Shares)	Options Exercisable (Shares)
\$ 0.130	100,000	—
\$ 0.333	200,000	200,000
\$ 0.500	200,000	200,000
\$ 0.650	700,000	650,000
\$ 0.980	450,000	450,000
\$ 1.000	1,500,000	1,500,000
	<u>3,150,000</u>	<u>3,000,000</u>

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

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

Outstanding options to acquire 150,000 shares of the Company's common stock had not vested at December 31, 2013.

## 7. Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets as of December 31, 2013 and 2012 are summarized below.

	December 31,	
	2013	2012
Start-up and organization costs	\$ 56,000	\$ 63,000
Research credits	95,000	68,000
Contingent liability	31,000	31,000
Net operating loss carryforwards	2,939,000	2,421,000
Total deferred tax assets	3,121,000	2,583,000
Valuation allowance	(3,121,000)	(2,583,000)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

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, 2013 and 2012, 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, 2013 and 2012 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, 2013 and 2012.

	Years Ended December 31,	
	2013	2012
U. S. federal statutory tax rate	(34.0)%	(34.0)%
Non-deductible stock-based compensation	2.9 %	8.6 %
Non-deductible fair value of warrant extensions	— %	10.8 %
Non-deductible fair value of warrant discounts	— %	3.2 %
Adjustment to deferred tax asset	(1.3)%	(2.0)%
Change in valuation allowance	32.4 %	13.4 %
Effective tax rate	<u>0.0 %</u>	<u>0.0 %</u>

At December 31, 2013, the Company has available net operating loss carryforwards for federal income tax purposes of approximately \$ 7,099,000 which, if not utilized earlier, expire through 2032 .

## **8. Commitments and Contingencies**

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

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

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

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

### ***Materials Cooperative Research and Development Agreement (M-CRADA)***

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.

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

On February 5, 2007, the Company entered into a two-year agreement pursuant to which the Company engaged Chem-Master to synthesize a compound designated as LB-100, and any other compound synthesized by Chem-Master pursuant to the Company’s request, which have potential use in treating a disease, including, without limitation, cancers such as glioblastomas. Pursuant to the Chem-Master Agreement, the Company agreed to reimburse Chem-Master for the cost of materials, labor, and expenses for other items used in the synthesis process, and also agreed to grant Chem-Master a five-year option to purchase shares of the Company’s common stock. On January 29, 2008, the Chem-Master Agreement was amended to extend its term to February 15, 2014; thereafter, Chem-Master will be engaged as needed. The Company also periodically enters into other agreements with Chem-Master for other services. During the years ended December 31, 2013 and 2012, the Company recorded charges to operations of \$ 7,275 and \$ 24,500 , respectively, with respect to this agreement.

On September 21, 2012, the Company entered into a work order agreement with Theradex to manage and administer the Phase 1 clinical trial of LB-100. Theradex is an international CRO that provides professional services for the clinical research and development of pharmaceutical compounds. 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 within the next 12 to 21 months (sometime between March and December 2015). The Phase 1 clinical trial is estimated to cost a total of approximately \$ 2,000,000, with such payments expected to be divided approximately evenly between payments to Theradex for services rendered and payments for pass-through costs for the clinical center's laboratory costs and investigator costs. Total costs charged to operations for services paid to Theradex pursuant to this arrangement, which were first incurred in 2013, were \$ 278,721 for the year ended December 31, 2013. Costs pursuant to this agreement are included in research and development costs in the Company's consolidated statements of operations. On May 2, 2011, Dr. Robert B. Royds, the founder, Chairman of the Board and Medical Director of Theradex, was appointed to the Company's Board of Directors. Dr. Royds died on March 23, 2013. The death of Dr. Royds is not expected to have any impact on the management and administration of the Phase 1 clinical trial.

In addition to the above described agreement with Theradex, the Company has also from time to time engaged Theradex to assist the Company in bringing LB-100 through the FDA approval process and to provide other services. Total fees charged to operations for services paid to Theradex pursuant to such engagements were \$ 14,964 and \$ 163,661 for the years ended December 31, 2013 and 2012, respectively, and \$ 194,551 for the period from August 9, 2005 (inception) to December 31, 2013 (cumulative), and are included in research and development costs in the Company's consolidated statements of operations.

Periodically, the Company has entered into agreements with Ascentage Pharma Group to conduct various studies. As of December 31, 2013, contracts with a total estimated cost of \$ 29,025, of which \$ 17,415 had been paid, were in process. Ascentage Pharma Group is an offshoot of Ascenta Therapeutics, of which Dr. Mel Sorensen, a director of the Company, is the President and Chief Executive Officer and a director. Ascentage Pharma Group and Ascenta Therapeutics have a continuing business relationship and certain common shareholders. However, Dr. Sorensen does not have any direct business relationship with or ownership in Ascentage Pharma Group.

At various times, the Company has entered into agreements with other unrelated vendors to conduct certain required studies. As of December 31, 2013, contracts outstanding with such vendors and in currently process had a total estimated cost of \$ 104,100, of which \$ 75,325 had been paid.

### *Consulting Agreement*

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 first such quarterly cash payment was made on January 12, 2014. There were no consulting or advisory fees charged to operations prior to January 1, 2014. 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.

The following table sets forth the Company's principal cash obligations and commitments for the next five fiscal years as of December 31, 2013 aggregating \$ 2,119,565, of which \$ 213,000 is included in current liabilities in the consolidated balance sheet at December 31, 2013.

	<b>Total</b>	<b>Payments Due By Year</b>				
		<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
Research and development contracts	\$ 40,385	\$ 40,385	\$ —	\$ —	\$ —	\$ —
Theradex work order agreement	1,746,463	1,346,463	400,000	—	—	—
Patent license agreement	150,000	30,000	30,000	30,000	30,000	30,000
Consulting agreement	16,000	16,000	—	—	—	—
Liquidated damages payable under registration rights agreement	74,000	74,000	—	—	—	—
Due to stockholder	92,717	92,717	—	—	—	—
<b>Total</b>	<b>\$ 2,119,565</b>	<b>\$ 1,599,565</b>	<b>\$ 430,000</b>	<b>\$ 30,000</b>	<b>\$ 30,000</b>	<b>\$ 30,000</b>

## 9 . Subsequent Events

Effective January 1, 2014, the Company entered into an Advisory Agreement with Dr. Kathleen P. Mullinix, a member of the Board of Directors of the Company, effective for an initial term of one year through December 31, 2014 to advise on business development matters. The initial term and any subsequent one year term shall be automatically extended on an annual basis unless a notice of intent to terminate is given by either party at least 90 days before the end of the applicable term. The Advisory Agreements provides for compensation of \$25,000 annually, payable in two installments of \$12,500, with the first payment due on January 31, 2014 and the second payment due on July 1, 2014.

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

On January 28, 2014, the Company's Board of Directors extended to June 30, 2014 its 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 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 fair value of the warrant 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 will be charged to operations on January 28, 2014. The fair value of the warrant extensions were 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 aggregate fair value of the warrant discounts, 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 will be charged to operations on January 28, 2014. The fair value of the warrant extensions were 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 %.

NATIONAL INSTITUTES OF HEALTH

**MATERIALS COOPERATIVE RESEARCH  
AND DEVELOPMENT AGREEMENT**

This Materials Cooperative Research and Development Agreement (“M-CRADA”) has been adopted for use by the Institutes and Centers (“ICs”) of the National Institutes of Health (“NIH”) for transfers of essential research material(s) from collaborators (hereinafter “Collaborator Research Material”) not otherwise reasonably available for NIH research. It consists of a copy of the NIH Model M-CRADA, a Signature Page, a Contacts Page, and a Summary Page. The research plan (“Research Plan”) is attached as Appendix A and all changes to this model agreement are collected in Appendix B. Appendices A and B are incorporated herein by reference. This M-CRADA involves no exchange of personnel or of any resources other than as described in Appendix A. This M-CRADA is made under authority of the Federal Technology Transfer Act, 15 U.S.C. § 3710a, and is governed by its terms.

1. Lixte Biotechnology Holdings, Inc., hereinafter referred to as “Collaborator”, agrees to transfer to NIH’s investigator, Richard J. Youle, Ph.D., the following “Collaborator Research Material”: certain compounds proprietary to Collaborator, as listed under Appendix A.
2. This Collaborator Research Material will be used solely in connection with the Research Plan by NIH’s investigator in his/her laboratory under suitable containment conditions.
  - 2(a). Are the Collaborator Research Materials of human origin?  
 Yes  
 No
  - 2(b). If Yes in 2(a), were the Collaborator Research Materials collected according to 45 CFR Part 46, “Protection of Human Subjects?”  
 Yes (Please provide Assurance Number: \_\_\_\_\_)  
 No
3. In all oral presentations or written publications concerning the Research Plan, NIH will acknowledge Collaborator’s contribution of this Collaborator Research Material unless requested otherwise. To the extent permitted by law and unless otherwise directed by a court or administrative body of competent jurisdiction, each Party agrees to treat in confidence, for a period of three (3) years from the date of the disclosure, any of the disclosing Party’s written information about this Collaborator Research Material that is stamped “confidential” or any of the disclosing Party’s oral information about this Collaborator Research Material that is identified in writing as being confidential within ten (10) days of the oral disclosure, except for:
  - (a) information that is publicly known or that becomes publicly available from public sources;
  - (b) information that has been made available by the disclosing Party to others without a confidentiality obligation;

- (c) information that is already known by the receiving Party, or information that is independently created or compiled by the receiving Party without reference to or use of the provided information; or
- (d) information that relates to potential hazards or cautionary warnings associated with the production, handling, or use of the subject matter of the Research Plan.

NIH may publish or otherwise publicly disclose the results of the research, but if Collaborator has given confidential information to NIH such public disclosure may be made only after Collaborator has had thirty (30) days to review the proposed disclosure to determine if it contains any confidential information, except when a shortened time period under court order or the Freedom of Information Act pertains.

- 4. This Collaborator Research Material represents a significant investment on the part of Collaborator and is considered proprietary to Collaborator. NIH's investigator therefore agrees to retain control over this Collaborator Research Material, and further agrees not to transfer the Collaborator Research Material to other people not under her or his direct supervision without advance written approval of Collaborator. Collaborator reserves the right to distribute the Collaborator Research Material to others and to use it for its own purposes.
- 5. This Collaborator Research Material is provided as a service to the research community. **IT IS BEING SUPPLIED TO NIH WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.** Collaborator makes no representations that the use of the Collaborator Research Material will not infringe any patent or proprietary rights of third parties. It is the intention of NIH that Collaborator not be liable for any claims or damages arising from NIH's use of the Collaborator Research Material; however, no indemnification is provided or intended.
- 6. The NIH shall promptly report to Collaborator in writing each Subject Invention and any patent applications filed thereon resulting from the research conducted under this M-CRADA that is reported to NIH by its employees. Collaborator agrees to keep all information provided to Collaborator confidential until the information is published or the patent issues. "Subject Invention" means any invention, conceived or first actually reduced to practice under this M-CRADA, that is or may be patentable under 35 U.S.C. § 101 or § 161, protectable under 7 U.S.C. § 2321, or otherwise protectable by other types of U.S. or foreign intellectual property rights.
- 7. With respect to Government intellectual property rights to any Subject Invention made solely by an NIH employee(s) or jointly with Collaborator for which a patent or other intellectual property application is filed, NIH hereby grants to the Collaborator an exclusive option to elect an exclusive or nonexclusive commercialization license. The license will be substantially in the form of the appropriate model Public Health Service (PHS) license agreement and will fairly reflect the nature of the Subject Invention, the relative contributions of the Parties to the Subject Invention and the M-CRADA, a plan for the development and marketing of the Subject Invention, the risks incurred by Collaborator, and the costs of subsequent research and development needed to bring the Subject Invention to the marketplace. The field of use of the license will not exceed the scope of the Research Plan. This option does not apply to Subject Inventions conceived prior to the effective date of this M-CRADA that are reduced to practice under this M-CRADA, if prior to that reduction to practice, NIH has filed a patent application on the Subject Invention and has licensed it or offered to license it to a third party.

8. To exercise the option of Paragraph 7, Collaborator must submit a written notice to the PHS Patenting and Licensing Contact identified on the Contacts Information Page (and provide a copy to the NIH Contact for M-CRADA Notices) within three (3) months after the Collaborator receives written notice from NIH that the patent application has been filed. The written notice exercising this option will include a completed "Application for License to Public Health Service Inventions" and will initiate a negotiation period that expires nine (9) months after the exercise of the option. If NIH has not responded in writing to the last proposal by Collaborator within this nine (9) month period, the negotiation period will be extended to expire one (1) month after PHS so responds, during which month Collaborator may accept in writing the final license proposal of NIH. In the absence of Collaborator's exercise of the option, or upon election of a nonexclusive license, NIH will be free to license the Subject Invention to others. These time periods may be extended at the sole discretion of NIH upon good cause shown in writing by Collaborator.
9. Pursuant to 15 U.S.C. § 3710a(b)(1)(A), for Subject Inventions made under this M-CRADA by a NIH employee(s) or jointly by such employee(s) and employees of the Collaborator under this M-CRADA, and licensed to Collaborator, the Collaborator grants to the Government a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government. In the exercise of such license, the Government shall not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of 5 U.S.C. § 552(b)(4) or which would be considered as such if it had been obtained from a non-Federal party.
10. Pursuant to 15 U.S.C. § 3710a(b)(2), for Subject Inventions made solely by Collaborator employees under this M-CRADA, the Collaborator grants to the Government, a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government for research or other Government purposes.
11. Pursuant to 15 U.S.C. § 3710a(b)(1)(B), if NIH grants an exclusive license to a Subject Invention made wholly by NIH employees or jointly with a Collaborator under this M-CRADA, the Government shall retain the right to require the Collaborator to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive sublicense to use the invention in Collaborator's licensed field of use on terms that are reasonable under the circumstances; or if the Collaborator fails to grant such a license, to grant the license itself. The exercise of such rights by the Government shall only be in exceptional circumstances and only if the Government determines (i) the action is necessary to meet health or safety needs that are not reasonably satisfied by Collaborator, (ii) the action is necessary to meet requirements for public use specified by Federal regulations, and such requirements are not reasonably satisfied by the Collaborator; or (iii) the Collaborator has failed to comply with an agreement containing provisions described in 15 U.S.C. § 3710a(c)(4)(B). The determination made by the Government under this paragraph is subject to administrative appeal and judicial review under 35 U.S.C. § 203(b).

12. Any dispute arising under this M-CRADA that is not disposed of by agreement of the Principal Investigators shall be submitted jointly to the signatories of this M-CRADA. If the signatories are unable to jointly resolve the dispute within thirty (30) days after notification thereof, the Assistant Secretary for Health (or his/her designee or successor) shall propose a resolution. Nothing in this article shall prevent any Party from pursuing any additional administrative remedies that may be available and, after exhaustion of such administrative remedies, pursuing all available judicial remedies.
13. The illegality or invalidity of any provisions of this M-CRADA shall not impair, affect or invalidate the other provisions of this M-CRADA.
14. Neither this M-CRADA nor any rights or obligations of any Party hereunder shall be assigned or otherwise transferred by either Party without the prior written consent of the other Party.
15. All notices pertaining to or required by this M-CRADA will be in writing, signed by an authorized representative of the notifying Party, and delivered by first class, registered, or certified mail, or by an express/overnight commercial delivery service, prepaid and properly addressed to the other Party at the address designated on the Contacts Information Page, or to any other address designated in writing by the other Party. Notices will be considered timely if received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Notices regarding the exercise of license options will be made pursuant to Paragraph 8. Either Party may change its address by notice given to the other Party in the manner set forth above.
16. By entering into this M-CRADA, the Government does not directly or indirectly endorse any product or service that is or will be provided, whether directly or indirectly related to either this M-CRADA or to any patent or other intellectual property license or agreement that implements this M-CRADA by Collaborator, its successors, assignees, or licensees. Collaborator will not in any way state or imply that the Government or any of its organizational units or employees endorses any product or service. Each Party agrees to provide proposed press releases that reference or rely upon the work under this M-CRADA to the other Party for review and comment at least seven (7) days prior to publication. Either Party may disclose the Summary Page to the public without the approval of the other Party.
17. Either NIH or Collaborator may unilaterally terminate this M-CRADA at any time by providing written notice at least sixty (60) days before the desired termination date.
18. This M-CRADA constitutes the entire agreement between the Parties concerning the subject matter of this M-CRADA and supersedes any prior understanding or written or oral agreement.
19. The construction, validity, performance and effect of this M-CRADA will be governed by U.S. federal law, as applied by the federal courts in the District of Columbia. If any provision in this M-CRADA conflicts with or is inconsistent with any U.S. federal law or regulation, then the U.S. federal law or regulation will preempt that provision.

20. This M-CRADA shall be effective upon execution by the Parties. The term of this M-CRADA is twelve (12) months from execution. When the Research Plan is completed or twelve (12) months has elapsed, whichever occurs first, or the M-CRADA is terminated, the Collaborator Research Material will be disposed of as directed by Collaborator.
21. The provisions of Articles 3, 5-12 and 14 shall survive the termination of this M-CRADA.

**SIGNATURES BEGIN ON THE NEXT PAGE**

NIH M-CRADA  
Page 5 of 10

Agreement Ref. No. 2013-0167  
*Confidential*

MODEL ADOPTED 2006  
Revised August 1, 2012

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**SIGNATURE PAGE**

**ACCEPTED AND AGREED**

BY EXECUTING THIS M-CRADA, EACH PARTY REPRESENTS THAT ALL STATEMENTS MADE HEREIN ARE TRUE, COMPLETE, AND ACCURATE TO THE BEST OF ITS KNOWLEDGE. COLLABORATOR ACKNOWLEDGES THAT IT MAY BE SUBJECT TO CRIMINAL, CIVIL, OR ADMINISTRATIVE PENALTIES FOR KNOWINGLY MAKING A FALSE, FICTITIOUS, OR FRAUDULENT STATEMENT OR CLAIM.

FOR NIH (IC):

/s/ Walter J. Kovoshetz for Dr. S Landis  
Signature

9/24/2013  
Date

WJ Kovoshetz, Deputy Director/NINDS  
Story C. Landis, Ph.D.  
Director, National Institute of Neurological Disorders and Stroke

FOR COLLABORATOR:

/s/ John S. Kovach  
Signature

10/18/2013  
Date

John S. Kovach, M.D.  
President, Lixte Biotechnology Holdings, Inc.

**CONTACTS PAGE**

M-CRADA Notices

For IC:

Laurie Arrants  
Technology Development Coordinator  
Building 31, Room 8A52  
31 Center Drive, MSC 2540  
Bethesda, MD 20892  
Tel: 301-435-3112  
Fax: 301-496-0296

For Collaborator:

John S. Kovach, M.D.  
248 Route 25A No. 2  
East Setauket, NY 11733  
Tel: 631-942-7959  
Fax: 631-982-5050

Patenting and Licensing

For NIH:

Division Director, Division of Technology  
Development and Transfer  
NIH Office of Technology Transfer  
6011 Executive Boulevard, Suite 325  
Rockville, Maryland 20852-3804  
Tel: 301-496-7057  
Fax: 301-402-0220

For Collaborator (if separate from above):

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
Tel:  
Fax:

**Delivery of Materials Identified In Article 1**

**For IC:**

IC Contact: Richard J. Youle, Ph.D.  
IC Address: SNB, Bldg 35, Room 2C-917, 35 Convent Drive, MSC 3704, Bethesda, MD 20892-3704  
IC Phone Number: 301-496-6628  
IC Fax: 301-402-0380  
IC contact e-mail YouleR@ninds.nih.gov

**For Collaborator: same as for M-CRADA notices**

Collaborator Contact:  
Collaborator Address:  
Collaborator Phone Number:  
Collaborator Fax:  
Collaborator contact e-mail:

## SUMMARY PAGE

EITHER PARTY MAY, WITHOUT FURTHER CONSULTATION OR PERMISSION,  
RELEASE THIS SUMMARY PAGE TO THE PUBLIC.

TITLE OF M-CRADA: Characterization of Proprietary Compounds from Lixte Biotechnology Holdings, Inc.

NIH Institute/Center (IC) IC Principal Investigator: National Institute of Neurological Disorders and Stroke Richard J. Youle, Ph.D.

Collaborator: Lixte Biotechnology Holdings, Inc.  
Collaborator Principal Investigator: John S. Kovach, M.D.

TERM OF M-CRADA: Four (4) years from the Effective Date.

### ABSTRACT OF THE RESEARCH PLAN:

The Surgical Neurology Branch of the National Institute of Neurological Disorders and Stroke of the National Institutes of Health will conduct research characterizing a variety of compounds proprietary to Lixte Biotechnology Holdings, Inc., under a Materials Cooperative Research and Development Agreement. The research will examine the compounds' potential for anti-cancer activity, reducing neurologic deficit due to ischemia and brain injury, and stabilizing catalytic function of misfolded proteins for inborn brain diseases.

**APPENDIX A**  
**RESEARCH PLAN**

Background

Lixte Biotechnology Holdings, Inc.'s primary emphasis is on developing drugs for cancer but its proprietary compounds also have potential for treating a variety of other diseases. The Surgical Neurology Branch (SNB) has experience in researching brain tumors, neurological brain injury, and inborn diseases affecting the brain, such as Gaucher's disease, von Hippel-Lindau, and neurofibromatosis type II.

Overall Goal. The SNB would like to examine the Collaborator's compounds' potential for anti-cancer activity, reduction of neurologic deficit due to ischemia and brain injury, and stabilization of the catalytic function of misfolded proteins for inborn brain diseases.

Research

The SNB will characterize proprietary compounds from the Collaborator, including but not limited to the following seven: LB-100, LB-102, LB-113, LB-153, LB-157, LB-201, and LB-205.

Collaborator may provide additional proprietary compounds to the SNB if the parties mutually agree in advance and the transfer is documented in writing.

The SNB may study one or more of the above compounds in *in vitro* and *in vivo* (animal models) for the following effects:

- promoting anti-cancer activity alone or in combination with standard anti-cancer drugs and/or radiation for the treatment of primary brain tumors and secondary (metastatic) brain tumors; specific cancers may include astrocytic tumors, oligodendroglial tumors, medulloblastoma, meningeal tumors, hemangioblastomas, and brain metastatic tumors
- overcoming or mitigating the physiological phenomenon of multi-drug resistance, particularly of cancer cells to anti-cancer drugs
- reducing neurological deficit due to cerebral ischemia and traumatic brain injury
- stabilizing the catalytic function of misfolded proteins due to genetic variants responsible for inborn diseases affecting the brain, such as Gaucher's disease, von Hippel-Lindau diseases and neurofibromatosis 2

**APPENDIX B**

**EXCEPTIONS OR MODIFICATIONS TO THIS M-CRADA**

Additions are noted as underline and deletions are noted as ~~strikeout~~.

Modify Article 20 as follows:

Article 20. This M-CRADA shall be effective upon execution by the Parties. The term of this M-CRADA is forty-eight ~~twelve~~ (~~48~~ ~~12~~) months from execution. When the Research Plan is completed or forty-eight ~~twelve~~ (~~48~~ ~~12~~) months has elapsed, whichever occurs first, or the M-CRADA is terminated, the Collaborator Research Material will be disposed of as directed by Collaborator.

NIH M-CRADA  
Page 10 of 10

Agreement Ref. No. 2013-0167  
*Confidential*

MODEL ADOPTED 2006  
Revised August 1, 2012

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## SCIENTIFIC ADVISORY BOARD AGREEMENT

THIS AGREEMENT (the “Agreement”) is made and entered into this 24th day of December, 2013 (the “Effective Date”) between Lixte Biotechnology Holdings, Inc., 248 Route 25A No. 2, East Setauket, New York 11733 (hereinafter referred to as the “Company”), and NDA Consulting Corp., an Arizona corporation, with offices at 9977 N. 90th Street, Suite 175, Scottsdale, Arizona 85258 (hereinafter referred to as the “Consultant”).

WHEREAS, the Company wishes to engage the Consultant to serve the Company as an Advisor for Clinical Development and provide this service for the compensation and otherwise in accordance with the terms and conditions contained in this Agreement.

NOW, THEREFORE, in consideration of the foregoing, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, accepted and agreed to, the Company and the Consultant, intending to be legally bound, agree to the terms set forth below.

### 1. TERM.

(a) The initial term of this Agreement is one (1) year from the Effective Date. The initial term will be extended for successive terms of one (1) year on each anniversary date of the Effective Date, unless the Agreement is terminated as provided below. This Agreement may be renewed or extended for any period as may be mutually agreed by the parties.

(b) This Agreement may be cancelled by either party for any reason by providing written notice to the other party not less than thirty (30) days prior to the end of the initial term or any successive one (1) year term. Upon termination, Consultant shall return to the Company or destroy all Concepts and Ideas and Confidential Information (as defined in Section 5 below) and copies thereof.

(c) In the event Dr. Von Hoff accepts an invitation from the Company to become Principal Investigator in a clinical trial conducted by the Company, this Agreement shall immediately terminate and no further Services will be provided by Consultant pursuant to this Agreement.

### 2. SERVICES.

(a) Consultant agrees to cause its President, Dr. Von Hoff to be a member of and advise the Company’s SAB in the field of oncology research and drug development under the terms and conditions herein provided (the “Services”). The Services shall only be performed by Dr. Von Hoff personally and may not be assigned, subcontracted or otherwise delegated without the prior written consent of the Company

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(b) The Consultant represents and warrants to the Company that it is under no contractual or other restrictions or obligations which are inconsistent with the execution of this Agreement, or which will interfere with the performance of its duties. Consultant represents and warrants that the execution and performance of this Agreement will not violate any policies or procedures of any other person or entity for which it performs consulting services concurrently with those performed herein.

### 3. COMPENSATION.

(a) Subject to the provisions hereof, the Company shall pay the Consultant four thousand dollars (\$4,000) per calendar quarter, for providing the Services to the Company (the “Consulting Fee”) for up to a cumulative amount of 4 hours per quarter. As additional compensation, the Company shall provide Dr. Von Hoff a grant of options to purchase an aggregate of shares of Lixte with the options vesting as follows: 25,000 options vesting six, eighteen, thirty, and forty two months after the date of this agreement so long as Dr. Von Hoff is continuing as Advisor for Clinical Development on those dates. The options shall be for five years.

(b) The Consulting Fee shall be paid within thirty (30) days of the receipt by the Company of the Consultant’s invoice for Services. The grant of stock or stock options shall be made to Dr. Von Hoff as soon as practicable after the Effective Date.

(c) The Consultant shall be entitled to reimbursement of two hundred fifty dollars (\$250) per hour for travel time (not to exceed one thousand five hundred dollars (\$1,500) per day) on approved Company business. The Consultant shall also be entitled to prompt reimbursement for preapproved, actual travel and out-of-pocket business expenses incurred in the performance of its Services. The Company shall reimburse Consultant within thirty (30) days of receipt by the Company of the Consultant’s statements or receipts for such expenses. For air travel of three (3) hours or more, Consultant shall be entitled to First Class Airfare.

(d) Unless otherwise notified by the Consultant, the Company shall make payment of the Consulting Fee and reimbursement of travel and out-of-pocket expenses in the name of the Consultant and send the payments directly to:

NDA Consulting Corp.  
c/o MCS Biotech Resources, LLC  
9977 N. 90th Street, Suite 175  
Scottsdale, AZ 85258

Stock or stock options issued in the name of Dr. Von Hoff shall be sent to the same address.

(e) The Consultant agrees that all Services rendered will be as an independent contractor and that this Agreement does not create an employer-employee, agency, joint venture, or partnership relationship between the Consultant and the Company. The Consultant shall have no right to receive any employee benefits, including, but not limited to, health and accident insurance, retirement, life insurance, sick leave and/or vacation. The Consultant agrees to pay all taxes, including self-employment taxes due in respect of the Consulting Fee and to indemnify the Company in the event the Company is required to pay any such taxes as a direct result of actions taken by the Consultant.

#### 4. COMPANY OBLIGATIONS.

(a) The Company shall provide the Consultant with all information and materials that are necessary to enable Consultant to perform the Services. The Company acknowledges and agrees that such information and materials will be used, and the accuracy and completeness of such information and materials relied upon, by the Consultant as the basis for providing the Services.

(b) Company agrees that Consultant's services are provided without representation or warranty of any kind. Company acknowledges that drug development carries inherent risks and that no particular work product or business result is guaranteed under this Agreement. Except with respect to Section 5, the Company agrees that Consultant's monetary liability for any breach of this Agreement shall in no event exceed the amount of cash compensation paid to Consultant under this Agreement. Company hereby releases Consultant from any monetary liability to the extent it may exceed such amount. In addition, Company agrees to indemnify, defend and hold Consultant harmless from and against any losses, costs, claims, damages, liabilities or expense (including reasonable attorneys' and professional fees and other expenses of litigation) (collectively, "Liabilities") arising directly or indirectly out of or in connection with third party claims, suits, actions, demands or judgments, relating to services provided by Consultant under this Agreement.

(c) The Company agrees not to use the Consultant's name in any publications or other written material, or otherwise use Consultant's name in any manner whatsoever unless, in each case, the Company obtains the prior written consent of the Consultant. Unless otherwise notified by Consultant, all such requests should be directed to:

MCS Biotech Resources, LLC  
9977 N. 90th Street, Suite 175  
Scottsdale, AZ 85258  
Telephone number: (480) 268-2000  
Facsimile number: (480) 268-2001

#### 5. PROPRIETARY RIGHTS.

(a) Definitions. For the purpose of this Section 5, the terms set forth below shall have the following meanings:

(i) Concept and Ideas. For the purpose of this Agreement, “Concepts and Ideas” shall mean those concepts and ideas disclosed by the Company to the Consultant or which are first developed by the Consultant during the course of the performance of Services hereunder and which relate to the Company’s past, present, or prospective business activities, services, and products, all of which shall remain the sole and exclusive property of the Company. The Consultant shall have no publication rights and all of the same shall belong exclusively to the Company.

(ii) Confidential Information. For the purposes of this Agreement, “Confidential Information” shall mean and collectively include all information relating to the business, plans and/or technology of the Company including, but not limited to technical information, including inventions, methods, plans, processes, specifications, characteristics, assays, raw data, scientific pre-clinical or clinical data, records, databases, formulations, clinical protocols, equipment design, know-how, experience, and trade secrets.

Notwithstanding the foregoing, the term “Confidential Information” shall not include any information which: (x) can be demonstrated to have already been publicly known or available or generally known in the trade or business of the Company prior to the date of the disclosure to the Consultant, (y) can be demonstrated to have been rightfully in the possession of the Consultant prior to the disclosure of such information to the Consultant, or (z) is required to be disclosed by Consultant as a matter of law or by a judicial or governmental order or requirement.

(b) Non-Disclosure to Third Parties. Except as may be required for the Consultant to perform the Services, the Consultant shall not, at any time now or in the future, directly or indirectly, use, publish, disseminate or otherwise disclose any Confidential Information or Concepts and Ideas to any third party without the prior written consent of the Company.

(c) Patents. The Consultant agrees that the Company is and shall remain the exclusive owner of the Confidential Information and Concepts and Ideas. Any interest in patents, patent applications, inventions, technological innovations, trade names, trademarks, service marks, copyrights, copyrightable works, developments, discoveries, designs, processes, formulas, know-how, data and analysis which the Consultant may develop as a direct result of rendering Services to the Company under this Agreement (collectively the “Developments”), shall: (i) promptly be brought to the attention of the Company by the Consultant and (ii) belong exclusively to the Company. No license or conveyance of any such rights to the Consultant is granted or implied under this Agreement.

(d) Assignment. The Consultant hereby assigns and, to the extent any such assignment cannot be made at present, hereby agrees to assign to the Company any Developments. The Consultant will execute all documents and perform all lawful acts, which the Company considers reasonably necessary or advisable to secure its rights hereunder.

In the event the company is unable for any reason to secure the Consultant’s signature to any document required to apply for or execute any patent, copyright or other application with respect to any Developments, the Consultant hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as the Consultant’s attorneys-in-fact to act for and on behalf of the Consultant, for the sole purpose of executing and filing any such document.

6. **EQUITABLE RELIEF.** The Consultant agrees that any breach of Section 5 above by it would cause irreparable damage to the Company and that, in the event of such breach, the Company shall have, in addition to any and all remedies of law, the right to an injunction, specific performance or other equitable relief to prevent the violation or threatened violation of the Consultant's obligations hereunder.

7. **WAIVER.** Any waiver by either party of a breach of any provision of this Agreement shall not operate or be construed as a waiver of any subsequent breach of the same or any other provision hereof. All waivers by either party shall be in writing.

8. **SEVERABILITY; REFORMATION.** If a court or other lawful authority finds any provision of this Agreement to be invalid and unenforceable, the remaining provisions are severable, and will not be affected by that finding. If a court or lawful authority finds any provision of this Agreement to be excessively broad as to duration, geographical scope, activity or subject matter, that provision will be construed to make it enforceable to the extent possible under the applicable law then in effect.

9. **ASSIGNMENT.** The Company shall have the right to assign its rights and obligations under this Agreement to a related party, which assumes the Company's obligations hereunder. The Consultant shall not have the right to assign its rights or obligations under this Agreement without the prior written consent of the Company, which consent shall not be unreasonably withheld.

10. **HEADINGS.** Headings and subheadings are for convenience only and shall not be deemed to be a part of this Agreement.

11. **AMENDMENTS.** This Agreement may be amended or modified, in whole or in part, only by an instrument in writing signed by all parties hereto.

12. **NOTICES.** Any notices or other communications required hereunder shall be in writing and shall be deemed effective when (a) hand-delivered with receipt acknowledged, (b) delivered by a nationally recognized overnight delivery service with receipt acknowledged, (c) sent by confirmed facsimile, or (d) three (3) days after mailing, by certified or registered first class mail, postage prepaid, return receipt requested; in each case, addressed to the parties at their addresses specified in the preamble of this Agreement or to such other address as a party hereto shall designate upon written notice to the other party.

13. **COUNTERPARTS.** This Agreement may be executed in two or more counterparts, each of which shall constitute an original and all of which shall be deemed a single agreement.

14. GOVERNING LAW. This Agreement shall be construed in accordance with and governed for all purposes by the laws of the State of Arizona.

15. SURVIVAL. The provision of Sections 3, 4, 5, 6, 8 and 14 of this Agreement shall survive the expiration of the Term or the termination of this Agreement. This Agreement supersedes all prior agreements, written or oral, between the Company and the Consultant relating to the subject matter of this Agreement.

EXECUTED, under seal, effective as of the Effective Date.

Lixte Biotechnology Holdings, Inc.

/s/ John S. Kovach  
John S. Kovach, M.D.

NDA Consulting Corp.

Daniel D. Von Hoff, M.D.  
President

Federal ID Tax Number 26-0348104

## ADVISORY AGREEMENT

This ADVISORY AGREEMENT (this “Agreement”), is entered into effective as of January 1, 2014, by and between Lixte Biotechnology Holdings, Inc., a Delaware corporation (the “Company”), and Kathleen Mullinix (“Advisor”).

### RECITALS

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

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

### AGREEMENT

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

1. Engagement. The Company hereby agrees that, commencing on January 1, 2014 (the “Effective Date”), the Company shall engage Advisor and Advisor hereby accepts such engagement with the Company, upon the terms and subject to the conditions hereinafter set forth.
2. Term. The initial term of Advisor’s engagement under this Agreement (the “Initial Term”) shall commence on the Effective Date and, subject to the provisions of Section 6, shall continue until December 31, 2014. The Initial Term and any subsequent one year term (each a “Term”) shall automatically be extended on an annual basis unless a Notice of Intent to Terminate is given by either party at least 90 days before the end of the applicable Term.
3. Services. Advisor shall advise on business development.
4. No Authority to Bind. Except as directed and authorized by the Chief Executive Officer of the Company in writing, Advisor shall not execute or agree to any contract, agreement or instrument on behalf of the Company.
5. Compensation. The Company shall pay to Advisor the sum of \$25,000 payable in two installments of \$12,500 with the first installment payable on January 31, 2014 and the second installment payable on July 1, 2014.
6. Termination. The Company may terminate this Agreement at any time “for cause” upon delivery of written notice to Advisor, in which case such termination shall be effective immediately upon Advisor’s receipt of the written notice.

“Cause” shall mean:

- (a) Advisor is convicted of, or pleads *nolo contendere* (no contest) to, any crime (whether or not involving the Company) constituting a felony in the jurisdiction involved; or
- (b) Advisor is in material breach of any provision of this Agreement or any other agreement with the Company, or willfully fails to or refuses to comply with the lawful directives of the Chief Executive Officer or the Board in the performance of her duties under this Agreement (other than a failure caused by temporary disability).

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

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

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

- (a) is or hereafter becomes generally available to the public other than by reason of any default with respect to a confidentiality obligation under this Agreement; or
- (b) was already known to the recipient as evidenced by prior written documents in its possession; or
- (c) is disclosed to the recipient by a third party who is not in default of any confidentiality obligation to the disclosing party hereunder; or
- (d) is developed by or on behalf of the receiving party, without reliance on confidential information received hereunder as evidenced by written documents in its possession; or
- (e) has been approved in writing by one party for publication by the other party; or
- (f) is required to be disclosed in compliance with applicable laws or regulations.

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

- (a) Solicit any employee of the Company to terminate her employment with the Company, or employ any such individual during her employment with the Company and for a period of six months after such individual terminates her employment with the Company;
- (b) Solicit any distributor or customer, or prospective distributor or customer, of the Company to terminate her relationship with the Company, or accept any business from any such distributor or customer, or prospective distributor or customer, of the Company; or
- (c) Make any public statement, comment or remark that disparages the integrity or competence of a Company officer, director, employee, or shareholder, that disparages any product or service of the Company, or that is reasonably likely to cause injury to the relationships between the Company and any existing or prospective distributor, client, contractual counterparty, supplier, customer, employee, consultant or other business associate of the Company. Likewise, the Company agrees that it shall not make any public statement, comment or remark that disparages the integrity or competence of Advisor.

9. Status as Advisor.

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

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

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

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

10. Miscellaneous.

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

If to the Company to:

Lixte, Inc.  
6 Tinker Lane  
East Setauket, New York 11733  
Attn: John Kovach, M.D.

Phone: (631) 751-2882  
Fax: (631) 982-5050  
Email: kovach1329@yahoo.com

If to Advisor:

1050 Fifth Avenue  
New York, New York 10028  
Phone:  
Fax:  
e-mail:

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

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

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

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

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

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

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

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

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

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

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

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

By: \_\_\_\_\_

Name: John Kovach

Its: President

\_\_\_\_\_  
Kathleen Mullinix

**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, 2013 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 21, 2014

By: /s/ JOHN S. KOVACH

Name: John S. Kovach

Title: Chief Executive Officer and Chief Financial Officer

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**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, 2013 (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 21, 2014

By: /s/ JOHN S. KOVACH

Name: John S. Kovach

Title: Chief Executive Officer and Chief Financial Officer

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