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, 2012

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

For the transition period from _____ to _____

Commission file number: 000-51476

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

Delaware	**20-2903526**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
248 Route 25A, No. 2 East Setauket, New York (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, 2012: $0

The aggregate market value of the common stock held by non-affiliates of the registrant as of June 30, 2012 was approximately $10,589,000.

There were 41,583,097 shares of the Company's common stock outstanding on March 11, 2013.

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 is developing new treatments for human cancers for which better therapies are urgently needed. The Company's drug discovery process is based on discerning clues to potential new targets for cancer 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 selects drugs for which there are existing data suggesting that they may affect the altered pathways of the cancer cell and may be given safely to humans. The Company seeks to rapidly arrive at patentable structures through analysis of the literature rather than screening of thousands of structures for activity against a particular biochemical pathway. This approach has led to the development of two classes of drugs, protein phosphatase inhibitors (PTase-i), designated by the Company as the LB-100 series of compounds, and histone deacetylase inhibitors (HDACi), designated by the Company as the LB-200 series of compounds, for the potential 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 the LB-200 series contains compounds which have the potential to be the most effective of this class.

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.

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

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). The research at NINDS is being 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 has now extended to the most common brain tumor of children, medulloblastoma, and to the most common cancer of children, neuroblastoma. Effective treatment of brain tumors depends upon the ability of compounds to penetrate a physiological barrier (blood-brain barrier) which protects the brain from exposure to potentially toxic substances in the blood. Because there is no certainty that the Company's compounds will be active against tumors confined to the brain, the LB-100 compounds have been studied against a variety of common and rare cancer types and have been shown to potentiate the activity of standard anti-cancer drugs in animal models of breast and pancreatic cancer, melanoma, pheochromcytomas and sarcomas. Because the LB-100 compounds appear to exert their ability to improve the effectiveness of different forms of chemotherapy by inhibiting a process upon which most in not all cancer cells types depend 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 (LB-200) under development by the Company is the histone deacetylase inhibitors. Many pharmaceutical companies are also developing drugs of this type, and at least two companies have HDACi approved for clinical use, in both cases for the treatment of a type of lymphoma. Despite this significant competition, the Company has demonstrated that its HDACi have broad activity against many cancer types, have neuroprotective activity, and have anti-fungal activity. In addition, these compounds have low toxicity, making them attractive candidates for development. It appears that one type of molecule has diverse effects, affecting biochemical processes that are fundamental to the life of the cell, whether they are cancer cells, nerve cells, or even fungal cells. The neuroprotective activity of the Company's HDACi has been demonstrated in the test tube in model systems that mimic injury to brain cells such as occurs in stroke and Alzheimer's disease. Potentially, this type of protective activity may have application to a broad spectrum of other chronic neurodegenerative diseases, including Parkinson's Disease and Amytrophic Lateral Sclerosis (ALS, or Lou Gehrig's Disease).

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

The Company filed an IND application with the FDA on April 30, 2012, and on July 24, 2012, the FDA notified the Company that it would allow initiation of a Phase 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 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 II clinical trial of common cancers, a key goal of the initial portion of the Phase I clinical trial will be to demonstrate that the target enzyme of LB-100, protein phosphatase 2A (PP2A), can be inhibited in humans with readily tolerable toxicity. As an anti-cancer drug, LB-100 is likely to be used at maximum tolerable doses, but for the potential treatment of non-malignant diseases, such as acute vascular diseases and metabolic diseases, lower doses may achieve therapeutic benefit by inhibition of the target enzyme, PP2A, thus opening up the possibility of a host of therapeutic applications for LB-100 and related proprietary compounds. The Phase I clinical trial of LB-100 will be carried out by a nationally recognized comprehensive cancer center beginning in the first quarter of 2013. The study is estimated to take from 18 to 30 months and cost approximately $2,000,000.

The next step in the clinical development of LB-100 after the completion of a Phase I clinical trial is to obtain Investigational New Drug (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.

On September 17, 2010, the National Cancer Institute Experimental Therapeutics (NExT) Program Senior Advisory Committee (SAC) approved a collaboration by NCI with the Company for clinical evaluation of LB-100, one of the Company's drug compounds. 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 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. 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 is proceeding with preparation of an IND for a clinical trial of LB-100, which incorporates the toxicity data generated by the NExT program.

The Company believes that it has sufficient funds to meet its operating needs through at least December 31, 2013, and that during this period the Company will be able to initiate its Phase I 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. Accordingly, in late 2013 or early 2014, in order to continue to fund the Company's operations in 2014 and thereafter, it is likely that the Company will be required to raise additional capital.

Intellectual Property

The Company has patent applications in seven major areas. Three of these are joint applications with NIH and include the use of PTase-1 (LB-100 series) in the treatment of glioblastoma multiforme (GBM), the most common and most aggressive brain tumor of adults; the treatment of medulloblastoma, the most common brain tumor of children; the treatment of neuroblastoma, the most common cancer of children; and, on the mechanisms by which the PTase-1 exerts its anticancer effects. The other four areas covered by the applications were filed solely by the Company. These areas cover the structure, synthesis, and utility of the Ptase-1 (LB-100) compounds and separately, for HDACi (LB-200) compounds; the use of the Company's compounds as neuroprotective agents; and, the use of certain of the Company's compounds as tools in the development of human pluripotent (stem cell like) cells for potential use as therapeutic agents.

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 I 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 series (LB-100 and LB-200) 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 needed for the submission of an IND for a 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 patent applications. 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 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 immuno-suppressed 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 will become subject to FDA regulations at such time as it pursues development of 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, 2012, the Company had no full-time employees. Dr. Kovach is a Professor (part-time) in the Department of Preventive Medicine at SUNY, in Stony Brook, New York. He received approvals from the School of Medicine of Stony Brook University and from the New York State Ethics Commission to operate the Company and to hold greater than 5% of the Company's outstanding shares.

The Company's investment commitments in the research efforts pursuant to the CRADA fund two full-time technical assistants who work under the supervision of Dr. Zhuang on the aims of the CRADA. Dr. Kovach devotes approximately 40% of his efforts per year to research planning, and designing and monitoring the research progress under the CRADA. Dr. Kovach's contributions are made outside of his academic responsibilities. He directs, coordinates and manages scientific and business development with the advice of the Company's Board of Directors, the advisory committee, and a consultant with expertise in corporate development. The Company is considering adding another board member with specific expertise in cancer biotechnology development and a Chief Operating Officer, at least part-time, to assist in management once an IND is approved.

Government Regulation

At its present stage of development, the Company's business is not subject to any specific government regulation with respect to its ongoing research and drug development efforts. The Company's only collaborator at present is National Institute of Neurological Diseases and Stroke (NINDS), National Institutes of Health. This collaboration is defined in CRADA 2165 under which NINDS evaluates compounds for their ability to inhibit the growth of brain tumor cells. The NINDS laboratory that is carrying out this activity is a research laboratory that operates in compliance with various federal and state's statutes and regulations, including OSHA. All activities of this laboratory are monitored by the compliance office of NINDS. There are no other regulations affecting the pursuit of the goals of the business.

Studies done under the CRADA are 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 will become subject to the regulations of the FDA when it begins to pursue development of 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 ultimate objective of the CRADA is to identify, characterize, and bring to clinical trial regimens for the treatment of human brain tumors (GBMs). The Company's objective is to be able to initiate a clinical trial in 2012. The first clinical trial would be sponsored by the Company at a U.S. cancer center experienced in such studies. The Company will file and obtain approval from the FDA of an Investigational New Drug Application (IND). At this point, the Company would become subject to FDA regulation as it sought to obtain an IND for clinical evaluation of a therapeutic regimen with the long-range goal of receiving FDA approval of the drug for commercial use. Approval of an IND from the FDA is the process that triggers FDA review and oversight, as federal law requires that a drug be the subject of an approved marketing application before it is transported to clinical investigations, unless exempted. The IND is the means through which the Company would obtain such exemption. During a new drug's early preclinical development, the Company's primary goal is to determine if the product is reasonably safe for initial use in humans, and if the compound exhibits pharmacological activity that justifies commercial development. When a product is identified as a viable candidate for further development, the Company would then focus on collecting the data and information necessary to establish that the product will not expose humans to unreasonable risks when used in limited, early-stage clinical studies. The FDA's role in the development of a new drug begins when the Company, having screened the new molecule for pharmacological activity and acute toxicity potential in animals, tests the drug's diagnostic or therapeutic potential in humans. The legal status of the molecule changes under the Federal Food, Drug, and Cosmetic Act and becomes a new drug subject to specific requirements of the drug regulatory system. Once the IND is submitted, the Company must wait 30 calendar days before initiating any clinical trials. During this time, the FDA has an opportunity to review the IND for safety to assure that research subjects will not be subjected to unreasonable risk.

The first phase of clinical trials, Phase I 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 II trials. Thus, the goal of Phase I studies is to determine the appropriate dose level for evaluation of drug efficacy in patients with the same type of tumor at comparable stages of progression for whom no beneficial treatment is established.

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

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

ITEM 1A RISK FACTORS

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

Risks Related to Business

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

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

- the research methodology used may not be successful in identifying potential product candidates. However, the Company has identified two promising lead candidate compounds which have activity in animal models, one of which, LB-100, is 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 assumption 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 2012 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 meet its operating needs through at least December 31, 2013, and that during this period the Company will be able to initiate its Phase I 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. Accordingly, in late 2013 or early 2014, in order to continue to fund the Company's operations in 2014 and thereafter, it is likely that the Company will be required to raise additional capital.

The amount and timing of future cash requirements will depend on the pace of these programs, particularly the completion of the Phase I trial of LB-100. After completion of the Phase I clinical trial, the next step will be to determine the anti-cancer activity against a particular type of human cancer in Phase II 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 our present collaboration agreement or any 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 are party to a research collaboration agreement and 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 75 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 any of these persons 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 significant weaken our management, harm our ability to compete effectively and harm our business.

Our key personnel are 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 Stony Brook University, New York. He may also become involved in the future with other business opportunities which may become available. Accordingly, our key personnel 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. Dr. Zhengping Zhuang is a full-time employee of NIH. He participates with the Company under a CRADA with NIH that defines the scope of his collaboration, and he does not face a conflict of interest.

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 submitted 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 Lixte, our operating subsidiary, and received shares of our stock in the 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.

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

At present, we conduct basic laboratory activities at the NIH under the CRADA and the preclinical research required for bringing a compound to clinical trial at the 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. No 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

	High	Low
Year Ended December 31, 2011		
First Quarter	$ 0.88	$ 0.35
Second Quarter	$ 0.98	$ 0.88
Third Quarter	$ 0.98	$ 0.65
Fourth Quarter	$ 0.65	$ 0.25

	High	Low
Year Ended December 31, 2012		
First Quarter	$ 0.92	$ 0.50
Second Quarter	$ 0.88	$ 0.65
Third Quarter	$ 0.83	$ 0.50
Fourth Quarter	$ 0.71	$ 0.20

Holders

As of March 11, 2013, there were 41,583,097 shares of our common stock outstanding, held by approximately 92 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, 2012, the most recently completed fiscal year.

Plan Category	Number of Securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column 2)
Equity Compensation Plans Approved by Security Holders	N/A	N/A	N/A
Equity Compensation Plans Not Approved by Security Holders	3,750,000	$ 0.87	1,650,000(1)

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

ITEM 6. SELECTED FINANCIAL DATA

Not Applicable

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

Overview

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".

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 2012 consolidated financial statements, has raised substantial doubt about the Company's ability to continue as a going concern.

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

At December 31, 2012, the Company had not yet commenced any revenue-generating operations. All activity through December 31, 2012 has been related to the Company's formation, capital raising efforts, and research and development activities. As such, the Company has yet to generate any cash flows from operations, and is dependent on debt and equity funding from both related and unrelated parties to finance its operations. Prior to June 30, 2006, the Company's cash requirements were funded by advances from the Company's founder aggregating $92,717.

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

The Company's major focus in 2013 is to initiate a Phase I clinical trial of its lead phosphatase inhibitor, LB-100. The Phase I clinical trial of LB-100 will be carried out by a nationally recognized comprehensive cancer center beginning during the first quarter of 2013. The study is estimated to take from 18 to 30 months and cost approximately $2,000,000.

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

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

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

Recent Accounting Pronouncements

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

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

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

Critical Accounting Policies and Estimates

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

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

Research and Development

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

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

The funds paid to NINDS of the NIH, pursuant to the CRADA effective March 22, 2006, as amended, represented an advance on research and development costs and therefore had future economic benefit. Accordingly, such costs have been charged to expense when they are actually expended by the provider, which is, effectively, as they perform the research activities that they were contractually committed to provide. Absent information that would indicate that a different expensing schedule was more appropriate (such as, for example, from the achievement of performance milestones or the completion of contract work), such advances have been expensed over the contractual service term on a straight-line basis, which, in management's opinion, reflects a reasonable estimate of when the underlying research and development costs were being incurred.

Patent Costs

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

Stock-Based Compensation

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

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

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

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

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

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

Income Taxes

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

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

Plan of Operation

General Overview of Plans

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

The research on brain tumors is proceeding 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, as amended. The research at NINDS continues to be led by Dr. Zhengping Zhuang, an internationally recognized investigator in the molecular pathology of cancer. Dr. Zhuang is aided by two senior research technicians supported by the Company as part of the CRADA. The goal of the CRADA is to develop more effective drugs for the treatment of GBM through the processes required to gain allowance from the Food and Drug Administration ("FDA") for clinical trials. Through a series of amendments, the term of the CRADA has been extended through April 1, 2013.

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

The Company's immediate focus has been to obtain allowance from the FDA to carry a lead compound of the LB-100 series into a Phase I 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. The primary goal of a Phase I clinical trial is to demonstrate the safety of administering a new drug to patients at doses expected to result in therapeutic benefit. If favorable treatment responses are also noted in the Phase I 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 II clinical trial, which, if warranted, is anticipated to follow the Phase I clinical trial.

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

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

Operating Plans

The Company's primary focus is developing new treatments for human cancers for which better therapies are urgently needed. However, the scope of potential applications of the Company's products has expanded to other common non-malignant diseases, including vascular diseases (heart attacks and stroke, diabetes, and genetic diseases in which errors in normal cellular processing lead to loss of functions important to normal cell function, such as Gaucher's disease). This has occurred because the targets selected by the Company have multiple functions in the cell, which when altered result in different disorders that may benefit from treatment with the Company's products. The Company's drug discovery process is based on discerning clues to potential new targets for disease treatments reported in the increasingly large body of literature identifying the molecular variants, which characterize human cancers and other non-cancer disorders. In the past decade, there has been an unprecedented expansion in knowledge of biochemical defects in the cancer cell. The Company selects drugs for which there are existing data suggesting that they may affect the altered pathways of the cancer cell and may be given safely to humans. The Company seeks to rapidly arrive at patentable structures through analysis of the literature rather than screening of thousands of structures for activity against a particular biochemical pathway. This approach has led to the development of two classes of drugs, protein phosphatase inhibitors (PTase-i), designated by the Company as the LB-100 series of compounds, and histone deacetylase inhibitors (HDACi), designated by the Company as the LB-200 series of compounds, for the treatment of cancer. Compounds of both types also have potential use in the prevention and treatment of neurodegenerative diseases. The LB-100 series consists of novel structures, which have the potential to be first in their class, and may be useful in the treatment of not only several types of cancer but also vascular and metabolic diseases. The LB-200 series contains compounds which have the potential to be the most effective in its class and may be useful for the treatment of chronic hereditary diseases, such as Gaucher's disease, in addition to cancer and neurodegenerative diseases. .

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

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

The Company has demonstrated that lead compounds of both series of drugs are active against a broad spectrum of human cancers in cell culture and against several types of human cancers in animal models. The research on new drug treatment was initiated in 2006 with the National Institute of Neurologic Disorders and Stroke (“NINDS”), National Institutes of Health (“NIH”) under a continuing Cooperative Research and Development Agreement (“CRADA”). The research at NINDS is being 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. Effective treatment of brain tumors depends upon the ability of compounds to penetrate a physiological barrier (the blood-brain barrier), which protects the brain from exposure to potentially toxic substances in the blood. Because there is no certainty that the Company’s compounds will be active against tumors confined to the brain, the LB-100 compounds have been studied against a variety of common and rare cancer types and have been shown to potentiate the activity of standard anti-cancer drugs in animal models of breast and pancreatic cancer, melanoma, pheochromcytomas and sarcomas. Because the LB-100 compounds appear to exert their ability to improve the effectiveness of different forms of chemotherapy by inhibiting a process upon which most, if not all, cancer cell types depend on to survive treatment, the Company believes the LB-100 series of compounds may be useful against most, if not all, cancer types.

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

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

The Company filed an IND application with the FDA on April 30, 2012, and on July 24, 2012, the FDA notified the Company that it would allow initiation of a Phase 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 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 II clinical trial of common cancers, a key goal of the initial portion of the Phase I clinical trial will be to demonstrate that the target enzyme of LB-100, protein phosphatase 2A (PP2A), can be inhibited in humans with readily tolerable toxicity. As an anti-cancer drug, LB-100 is likely to be used at maximum tolerable doses, but for the potential treatment of non-malignant diseases, such as acute vascular diseases and metabolic diseases, lower doses may achieve therapeutic benefit by inhibition of the target enzyme, PP2A, thus opening up the possibility of a host of therapeutic applications for LB-100 and related proprietary compounds. The Phase I clinical trial of LB-100 will be carried out by a nationally recognized comprehensive cancer center beginning during the first quarter of 2013. The study is estimated to take from 18 to 30 months and cost approximately $2,000,000.

As a compound moves through the FDA approval process, it becomes an increasingly valuable property, but at a cost of additional investment at each stage. The Company’s approach has been to operate with a minimum of overhead, moving compounds forward as efficiently and inexpensively as possible, and to raise funds to support each of these stages as certain milestones are reached. The allowance of the IND application by the FDA to begin a Phase I 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, 2012.

Years Ended December 31, 2012 and 2011

General and Administrative. 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.

Significant components of the fair value of stock options issued to directors and consultants of $723,554 for the year ended December 31, 2012 were 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.

For the year ended December 31, 2011, general and administrative costs were $533,449, which consisted of the fair value of stock options issued to directors and consultants of $204,898, consulting and professional fees of $200,321, insurance expense of $24,792, officer's salary and related costs of $53,417, stock transfer fees of $9,650, travel and entertainment costs of $16,376, and other operating costs of $23,995.

Beginning March 15, 2011, Dr. Kovach reduced his academic commitment to 60% from 80% in order to devote more time to managing the development of the Company's compounds. Dr. Kovach began receiving compensation of $5,000 per month from the Company at that time.

Research and Development. 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.

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.

For the year ended December 31, 2011, research and development costs were $1,334,801, which consisted of the vested portion of the fair value of stock options issued to a vendor of $982, patent costs of $401,279, third-party contractor costs of $907,540, and consulting fees to a related party of $25,000.

Interest Income. For the year ended December 31, 2012 and 2011, interest income was $8 and $125, 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.

During the year ended December 31, 2011, the Company incurred an expense of $199,839 for the fair value of extending the expiration date of warrants to acquire 273,752 shares of the Company's common stock that were previously issued in connection with a private placement of the Company's common stock in 2006.

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, 2012, the Company incurred a net loss of $3,579,366, as compared to a net loss of $2,067,964 for the year ended December 31, 2011.

Liquidity and Capital Resources – December 31, 2012

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 2012 consolidated financial statements, has raised substantial doubt about the Company's ability to continue as a going concern (see "Going Concern" above").

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

At December 31, 2012, the Company had a working capital surplus of $1,491,858, as compared to working capital surplus of $79,021 at December 31, 2011, an increase in working capital of $1,412,837 for the year ended December 31, 2012. At December 31, 2012, the Company had cash and money market funds aggregating $1,661,256, as compared to $365,430 at December 31, 2011, an increase of $1,295,826 for the year ended December 31, 2012. The increase in working capital and cash during the year ended December 31, 2012 was the result of the cash generated by the Company offering a 25% discount to warrant holders during May and June 2012 as an inducement to exercise their warrants for cash.

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 will be carried out by a nationally recognized comprehensive cancer center beginning in the first quarter of 2013. The study is estimated to take from 18 to 30 months and cost approximately $2,000,000.

The Company believes that it currently has sufficient funds to continue the Phase I clinical trial of LB-100 and fund its operating plans through at least December 31, 2013. Accordingly, in late 2013 or early 2014, in order to continue to fund the Company's operations in 2014 and thereafter, it is likely that the Company will be required to raise additional capital. If cash resources are insufficient to satisfy the Company's cash requirements at that time, the Company would be required to scale back or discontinue its technology and product development programs, 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, 2012, operating activities utilized cash of $1,205,757, as compared to utilizing cash of $1,359,667 for the year ended December 31, 2011, to support the Company's ongoing research and development activities.

Investing Activities. For the year ended December 31, 2012, investing activities consisted of $344,995 being withdrawn from a money market fund. For the year ended December 31, 2011, investing activities consisted of $1,249,877 being withdrawn from a money market fund.

Financing Activities. 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 for cash. For the year ended December 31, 2011, financing activities consisted of $5,000 of proceeds from the exercise of stock options.

Principal Commitments

Effective March 22, 2006, the Company entered into a CRADA, as amended, with the NINDS of the NIH. The CRADA was for a term of 84 months from the effective date and can be unilaterally terminated by either party by providing written notice within 60 days. 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 the 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.

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

On February 5, 2007, the Company entered into a two-year agreement pursuant to which the Company engaged Chem-Master to synthesize a compound designated as LB-100, and any other compound synthesized by Chem-Master pursuant to the Company's request, which have potential use in treating a disease, including, without limitation, cancers such as glioblastomas. Pursuant to the Chem-Master Agreement, the Company agreed to reimburse Chem-Master for the cost of materials, labor, and expenses for other items used in the synthesis process, and also agreed to grant Chem-Master a five-year option to purchase shares of the Company's common stock. The Company has the right to terminate the Chem-Master Agreement at any time during its term upon sixty days prior written notice. On January 29, 2008, the Chem-Master Agreement was amended to extend its term to February 15, 2014, and to expressly provide for the design and synthesis of a new series of compounds designated as LB-300. The Company also periodically enters into other agreements with Chem-Master for other services. During the years ended December 31, 2012 and 2011, the Company incurred expenses of $24,500 and $30,325, respectively, for the costs of materials, labor and expenses related to its agreements with Chem-Master.

On February 2, 2012, the Company entered into an agreement with MRI Global for a series of studies. As of December 31, 2012, work orders for studies having a total estimated cost of $99,000 were in process under this agreement. As of December 31, 2012, the Company had paid $52,000 towards these work orders.

At various times, the Company has entered into agreements with Ash Stevens to conduct various studies. As of December 31, 2012, contracts with a total estimated cost of $62,000 were in process, of which $58,935 had been paid.

On March 17, 2010, the Company engaged Theradex Systems, Inc. ("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 were $163,661 and $720 for the years ended December 31, 2012 and 2011, respectively. 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. The Phase I clinical trial of LB-100 will be carried out by a nationally recognized comprehensive cancer center beginning during the first quarter of 2013, and is estimated to take from 18 to 30 months and cost approximately $2,000,000, with such payments expected to be divided approximately evenly between payments to Theradex for services rendered and payments for pass-through costs for the clinical center, laboratory costs and investigator costs.

The following table sets forth the Company's principal cash obligations and commitments for the next five fiscal years as of December 31, 2012 aggregating $2,353,122, of which $171,057 is included in current liabilities in the consolidated balance sheet at December 31, 2012.

		Payments Due By Year				
	Total	**2013**	**2014**	**2015**	**2016**	**2017**
Research and development contracts	$ 66,405	$ 66,405	$ —	$ —	$ —	$ —
Theradex work order agreement	2,000,000	600,000	1,000,000	400,000	—	—
Patent license agreement	120,000	—	30,000	30,000	30,000	30,000
Liquidated damages payable under registration rights agreement	74,000	74,000		—	—	—
Due to stockholder	92,717	92,717	—	—	—	—
Total	$ 2,353,122	$ 833,122	$ 1,030,000	$ 430,000	$ 30,000	$ 30,000

Off-Balance Sheet Arrangements

At December 31, 2012, 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, 2012 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, 2012.

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 2012 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, 2012. The Board of Directors is comprised of only one class. All of the directors will serve until the next annual meeting of stockholders and until their successors are elected and qualified, or until their earlier death, retirement, resignation or removal. There are no family relationships between or among the directors, executive officers or persons nominated or charged by our Company to become directors or executive officers. The executive officer serves at the discretion of the Board of Directors, and is appointed to serve until the first Board of Directors meeting following the annual meeting of stockholders. The brief descriptions of the business experience of each director and executive officer and an indication of directorships held by each director in other companies subject to the reporting requirements under the Federal securities laws are provided herein below. Also provided are the biographies of the members of the Scientific Advisory Committee.

Our directors and executive officer are as follows:

Name	Age	Position(s) Held with the Registrant
Dr. John S. Kovach	76	Chief Executive Officer, Chief Financial Officer, Director
Dr. Philip F. Palmedo	79	Director
Dr. Mel Sorensen	56	Director
Dr. Robert B. Royds	68	Director
Dr. Kathleen P. Mullinix	68	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 Stony Brook University 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 Stony Brook University 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 Stony Brook University 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 Therpeutics'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. Robert B. Royds

Effective May 2, 2011, the Company elected Dr. Robert B. Royds to its Board of Directors. Dr. Royds is Chairman of the Board and Medical Director of Theradex Systems, Inc., a leading clinical research organization, with research bases in Europe, Australia and Japan. Dr. Royds is responsible for the scientific affairs of Theradex Systems, Inc. Dr. Royds was trained in internal medicine and pharmacology, and he has extensive experience in all stages of the clinical drug development process. Before founding Theradex Systems, Inc., Dr. Royds was Senior Research Physician at Hoffmann-La Roche, Inc., and Associate Director for Clinical Pharmacology International at Merck, Sharp, and Dohme Research Laboratories. Dr. Royds has been a consultant/advisor to the National Institute of Child Health and Development and the National Cancer Institute on issues of clinical trial design and international standardization of data sets of clinical trials of new investigational anti-cancer agents. Dr. Royds has served as the physician-monitor for the Clinical Trials Monitoring Service of the National Cancer Institute since 1979, and has been the Principal Investigator for this contract since 1982.

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, MD

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, MD

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, BS, MS, PhD

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

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

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

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 2012.

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, 2012 and 2011, Dr. Kovach was paid a salary of $60,000 and $47,500, respectively.

Option Grants in 2011 and 2012 - Named Executive Officer

None.

Aggregated Option Exercises in 2011 and 2012 Option Values at December 31, 2011 and at 2012 - Named Executive Officer

None.

Employment Agreements; Compensation

We have not entered into any employment agreements. As of December 31, 2012, 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 and $47,000 for the years ended December 31, 2012 and 2011, respectively. 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 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 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 $21,875 and $25,000 for the years ended December 31, 2012 and 2011, respectively, and $64,583 for the period from August 9, 2005 (inception) to December 31, 2012 (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 Systems, Inc. ("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 were $163,661 and $720 for the years ended December 31, 2012 and 2011, respectively, and $179,587 for the period from August 9, 2005 (inception) to December 31, 2012 (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. The Phase I clinical trial of LB-100 will be carried out by a nationally recognized comprehensive cancer center beginning during the first quarter of 2013, and is estimated to take from 18 to 30 months and cost approximately $2,000,000, with such payments expected to be divided approximately evenly between payments to Theradex for services rendered and payments for pass-through costs for the clinical center, laboratory costs and investigator costs.

Director Compensation

Members of the Board of Directors

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, in conjunction with his appointment as director of the Company, the Company granted to Dr. Mel Sorensen stock options to purchase an aggregate of 200,000 shares of the Company's common stock under the 2007 Plan, exercisable for a period of five years from the date of exercisability at $0.50 per share, vesting 12.5% on January 1, 2009 and 12.5% on the first date of each subsequent quarter. In addition, in connection with Dr. Sorensen acting in an advisory role for a period of one year in connection with the strategic development of the Company's intellectual properties, the Company agreed to pay Dr. Sorensen $40,000, payable in quarterly installments of $10,000 commencing on October 7, 2008. Commencing March 1, 2011, the annual payment was reduced to $25,000. Dr. Sorensen is also eligible to receive a bonus at the sole discretion of the Board of Directors.

Effective May 1, 2011, in conjunction with his election as a director of the Company, Dr. Robert B. Royds was granted stock options to purchase 200,000 shares of the Company's common stock, 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 options vested as to 25,000 shares on May 1, 2011, and a further 25,000 shares vest on the first day of each subsequent quarter until all of the shares are vested.

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.

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	2012	0	0	0	0	0	0	0	0
Director	2011	0	0	0	196,000	0	0	0	196,000
	2010	0	0	0	0	0	0	0	0
Mel Sorensen	2012	0	0	0	0	0	0	21,875	21,875
Director	2011	0	0	0	0	0	0	25,000	25,000
	2010	0	0	0	0	0	0	17,708	17,708
Robert B. Royds	2012	0	0	0	0	0	0	0	0
Director	2011	0	0	0	196,000	0	0	0	196,000
Kathleen P. Mullinix Director	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.

Members of the Scientific Advisory Committee

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.

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

The following table sets forth, as of March 11, 2013, 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 11, 2013, 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 11, 2013, 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.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percent of Class
Officers, Directors and 5% stockholders		
Dr. John S. Kovach 248 Route 25A, No. 2 East Setauket, New York 11733	17,021,786	40.9%
Dr. Philip F. Palmedo 248 Route 25A, No. 2 East Setauket, New York 11733	1,241,020(1)	2.9%
Dr. Mel Sorensen 248 Route 25A, No. 2 East Setauket, New York 11733	200,000(2)	0.5%
Dr. Robert B. Royds 248 Route 25A, No. 2 East Setauket, New York 11733	200,000(2)	0.5%
Dr. Kathleen P. Mullinix 248 Route 25A, No. 2 East Setauket, New York 11733	75,000(5)	0.2%
All officers and directors as a group (four persons)	18,737,806(1)(2)(5)	44.0%
Gil Schwartzberg 269 South Beverly Drive, No. 1315 Beverly Hills, California 90212	7,674,215(3)	17.0%
Debbie Schwartzberg 269 South Beverly Drive, No. 1315 Beverly Hills, California 90212	6,838,845(4)	15.5%
Arthur and Jane Riggs 4852 Saint Andres Avenue La Verne, California 91750	3,000,000(6)	7.2%
Robert and Susan Greenberg 228 Manhattan Beach Boulevard Manhattan Beach, California 90266	3,000,000(7)	7.0%

(1) Consists of 600,000 shares of common stock and warrants to purchase 400,000 shares of common stock owned by the Philip Palmedo Partnership, and 66,020 shares of common stock and options to purchase 175,000 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 200,000 shares of common stock, all of which are immediately exercisable.

(3) Includes 750,000 shares of common stock, options to purchase 2,000,000 shares of common stock, and warrants to purchase 350,000 shares of common stock owned by Mr. Schwartzberg. Also includes 650,000 shares of common stock and warrants to purchase 150,000 shares of common stock owned by the Gil Schwartzberg IRA; 440,215 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 750,000 shares of common stock, options to purchase 2,000,000 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 650,000 shares of common stock and warrants to purchase 150,000 shares of common stock owned by the Gil Schwartzberg IRA, and 440,215 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 75,000 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, 2012.

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, 2012, 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 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 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 $21,875 and $25,000 for the years ended December 31, 2012 and 2011, respectively, and $64,583 for the period from August 9, 2005 (inception) to December 31, 2012 (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 Systems, Inc. ("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 were $163,661 and $720 for the years ended December 31, 2012 and 2011, respectively. 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. The Phase I clinical trial of LB-100 will be carried out by a nationally recognized comprehensive cancer center beginning during the first quarter of 2013, and is estimated to take from 18 to 30 months and cost approximately $2,000,000, with such payments expected to be divided approximately evenly between payments to Theradex for services rendered and payments for pass-through costs for the clinical center, laboratory costs and investigator costs.

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, Royds, 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, 2011 and 2012 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 2011 and 2012.

	2011	2012
Audit Fees[1]	$ 51,368	$ 53,205
Audit-Related Fees[2]	—	—
Tax Fees[3]	6,260	5,804
All Other Fees[4]	—	—
Total	$ 57,628	$ 59,009

(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 13, 2013

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

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

Signature	Title	Date
/s/ JOHN S. KOVACH John S. Kovach	Chief Executive Officer, Chief Financial Officer, Principal Accounting Officer and Director	March 13, 2013
/s/ PHILIP F. PALMEDO Philip F. Palmedo	Director	March 13, 2013
/s/ MEL SORENSEN Mel Sorensen	Director	March 13, 2013
/s/ ROBERT B. ROYDS Robert B. Royds	Director	March 13, 2013
/s/ KATHLEEN P. MULLINIX Kathleen P. Mullinix	Director	March 13, 2013

INDEX TO EXHIBITS

Exhibit Number	Description of Document
2.1	Share Exchange Agreement dated as of June 8, 2006 among the Company, John S. Kovach and Lixte Biotechnology, Inc.[1]
3.1	Certificate of Incorporation, as filed with the Delaware Secretary of State on May 24, 2005.[2]
3.2	Certificate of Amendment of Certificate of Incorporation.[3]
3.2	Bylaws.[2]
10.1	Cooperative Research and Development Agreement (CRADA) between the U.S. Department of Health and Human Services, as represented by National Institute of Neurological Disorders and Stroke of the National Institutes of Health and Lixte Inc., as amended.[4]
10.2	Amendment No. 6 to CRADA.[5]
10.3	Agreement between Lixte Biotechnology Holdings, Inc. and Chem-Master International, Inc. dated as of February 5, 2007.[6]
10.4	Amendment dated January 28, 2008 to Agreement with Chem-Master International, Inc.[7]
10.5	Stock Option Agreement between Lixte Biotechnology Holdings, Inc. and Stephen K. Carter dated September 12, 2007.[8]
10.6	Stock Option Agreement between Lixte Biotechnology Holdings, Inc. and Francis Johnson dated September 12, 2007.[8]
10.7	Stock Option Agreement between Lixte Biotechnology Holdings, Inc. and Gil Schwartzberg dated September 12, 2007.[8]
10.8	Consulting Agreement between Lixte Biotechnology Holdings, Inc. and Gil Schwartzberg dated September 12, 2007.[8]
10.9	Amendment to Consulting Agreement with Gil Schwartzberg dated October 15, 2009.[12]
10.10	Consulting Agreement between Lixte Biotechnology Holdings, Inc. and Francis Johnson dated September 12, 2007.[8]
10.11	Consulting Agreement between Lixte Biotechnology Holdings, Inc. and Pro-Active Capital Group, LLC dated July 27, 2009.[9]
10.12	License Agreement dated as of September 19, 2008 between the Company and the United States Public Health Services.[10]
10.13	Stock Option Agreement between the Company and Mel Sorensen dated October 7, 2008.[11]
10.14	Consulting Agreement between the Company and Mel Sorensen dated October 7, 2008.[11]
10.15	Master Agreement between Lixte Biotechnology Holdings, Inc. and Theradex Systems, Inc. dated January 12, 2010.[12]
31	Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.[12]
32	Officer's Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.[12]

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 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, 2012 and 2011, and
Period from August 9, 2005 (Inception) to December 31, 2012 (Cumulative)

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, 2012 and 2011, 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, 2012 (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, 2012 and 2011, 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, 2012 (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 15, 2013

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

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2012	**2011**
ASSETS		
Current assets:		
Cash	$ 1,655,122	$ 14,301
Money market funds	6,134	351,129
Advances on research and development contract services	51,575	28,983
Prepaid expenses and other current assets	40,179	35,354
Total current assets	1,753,010	429,767
Total assets	$ 1,753,010	$ 429,767
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 80,416	$ 109,341
Research and development contract liabilities	14,019	74,688
Liquidated damages payable under registration rights agreement	74,000	74,000
Due to stockholder	92,717	92,717
Total current liabilities	261,152	350,746
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 and 35,259,142 shares at December 31, 2012 and 2011, respectively	4,158	3,526
Additional paid-in capital	13,064,831	8,073,260
Deficit accumulated during the development stage	(11,577,131)	(7,997,765)
Total stockholders' equity	1,491,858	79,021
Total liabilities and stockholders' equity	$ 1,753,010	$ 429,767

See accompanying notes to consolidated financial statements.

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

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		Period from August 9, 2005 (Inception) to December 31, 2012
	2012	2011	(Cumulative)
Revenues	$ —	$ —	$ —
Costs and expenses:			
General and administrative costs	1,093,614	533,449	5,232,940
Depreciation	—	—	1,909
Research and development costs	1,012,144	1,334,801	4,569,792
Reverse merger costs	—	—	50,000
Total costs and expenses	2,105,758	1,868,250	9,854,641
Loss from operations	(2,105,758)	(1,868,250)	(9,854,641)
Interest income	8	125	27,434
Interest expense	—	—	(2,469)
Fair value of warrant extensions	(1,139,592)	(199,839)	(1,339,431)
Fair value of warrant discount	(334,024)	—	(334,024)
Liquidated damages under registration rights agreement	—	—	(74,000)
Net loss	$ (3,579,366)	$ (2,067,964)	$ (11,577,131)
Net loss per common share – Basic and diluted	$ (0.09)	$ (0.06)	
Weighted average common shares outstanding – Basic and diluted	38,985,832	35,169,406	

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, 2012

	Common Stock		Advances Under Equity	Additional Paid-in	Deficit Accumulated During the Development	Total Stockholders' Equity
	Shares	Amount	Financing	Capital	Stage	(Deficiency)
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, 2012

	Common Stock		Advances Under Equity	Additional Paid-in	Deficit Accumulated During the Development	Total Stockholders' Equity
	Shares	Amount	Financing	Capital	Stage	(Deficiency)
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

See accompanying notes to consolidated financial statements.

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

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		Period from August 9, 2005 (Inception) to December 31, 2012
	2012	2011	(Cumulative)
Cash flows from operating activities:			
Net loss	$ (3,579,366)	$ (2,067,964)	$ (11,577,131)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	—	—	1,909
Stock-based expenses included in general and administrative	723,554	204,898	3,180,975
Stock-based expenses included in research and development	293,450	982	758,484
Fair value of warrant extensions	1,139,592	199,839	1,339,431
Fair value of warrant discount	334,024	—	334,024
Changes in operating assets and liabilities:			
(Increase) decrease in -			
Funds on deposit with law firm	—	50,000	—
Grant receivable	—	116,485	—
Advances on research and development contract services	(22,592)	(18,883)	(51,575)
Prepaid expenses and other current assets	(4,825)	(708)	(40,179)
Increase (decrease) in -			
Accounts payable and accrued expenses	(28,925)	80,996	80,416
Liquidated damages payable under registration rights agreement	—	—	74,000
Research and development contract liabilities	(60,669)	74,688	14,019
Net cash used in operating activities	(1,205,757)	(1,359,667)	(5,885,627)
Cash flows from investing activities:			
(Increase) decrease in money market funds	344,995	1,249,877	(6,134)
Purchase of office equipment	—	—	(1,909)
Net cash provided by (used in) investing activities	344,995	1,249,877	(8,043)
Cash flows from financing activities:			
Proceeds from exercise of stock options	33,333	5,000	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
Net cash provided by financing activities	2,501,583	5,000	7,548,792
Cash:			
Net increase (decrease)	1,640,821	(104,790)	1,655,122
Balance at beginning of period	14,301	119,091	—
Balance at end of period	$ 1,655,122	$ 14,301	$ 1,655,122
Supplemental disclosures of cash flow information:			
Cash paid for -			
Interest	$ —	$ —	$ 2,469
Income taxes	$ —	$ —	$ —
Non-cash financing activities:			
Decrease in advances under equity financing	$ —	$ —	$ 1,200,000
Aggregate exercise price of warrants and options exercised on a cashless basis	$ 109,391	$ 84,207	$ 193,598

See accompanying notes to consolidated financial statements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2012 and 2011, and
Period from August 9, 2005 (Inception) to December 31, 2012 (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. (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".

Operating Plans

The Company's primary focus is developing new treatments for human cancers for which better therapies are urgently needed. However, the scope of potential applications of the Company's products has expanded to other common non-malignant diseases, including vascular diseases (heart attacks and stroke, diabetes, and genetic diseases in which errors in normal cellular processing lead to loss of functions important to normal cell function, such as Gaucher's disease). This has occurred because the targets selected by the Company have multiple functions in the cell, which when altered result in different disorders that may benefit from treatment with the Company's products. The Company's drug discovery process is based on discerning clues to potential new targets for disease treatments reported in the increasingly large body of literature identifying the molecular variants which characterize human cancers and other non-cancer disorders. In the past decade, there has been an unprecedented expansion in knowledge of biochemical defects in the cancer cell. The Company selects drugs for which there are existing data suggesting that they may affect the altered pathways of the cancer cell and may be given safely to humans. The Company seeks to rapidly arrive at patentable structures through analysis of the literature rather than screening of thousands of structures for activity against a particular biochemical pathway. This approach has led to the development of two classes of drugs, protein phosphatase inhibitors (PTase-i), designated by the Company as the LB-100 series of compounds, and histone deacetylase inhibitors (HDACi), designated by the Company as the LB-200 series of compounds, for the treatment of cancer. Compounds of both types also have potential use in the prevention and treatment of neurodegenerative diseases. The LB-100 series consists of novel structures, which have the potential to be first in their class, and may be useful in the treatment of not only several types of cancer but also vascular and metabolic diseases. The LB-200 series contains compounds which have the potential to be the most effective in its class and may be useful for the treatment of chronic hereditary diseases, such as Gaucher's disease, in addition to cancer and neurodegenerative diseases.

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

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

The Company has demonstrated that lead compounds of both series of drugs are active against a broad spectrum of human cancers in cell culture and against several types of human cancers in animal models. The research on new drug treatment was initiated in 2006 with the National Institute of Neurologic Disorders and Stroke ("NINDS"), National Institutes of Health ("NIH") under a continuing Cooperative Research and Development Agreement ("CRADA"). The research at NINDS is being 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. Effective treatment of brain tumors depends upon the ability of compounds to penetrate a physiological barrier (the blood-brain barrier), which protects the brain from exposure to potentially toxic substances in the blood. Because there is no certainty that the Company's compounds will be active against tumors confined to the brain, the LB-100 compounds have been studied against a variety of common and rare cancer types and have been shown to potentiate the activity of standard anti-cancer drugs in animal models of breast and pancreatic cancer, melanoma, pheochromcytomas and sarcomas. Because the LB-100 compounds appear to exert their ability to improve the effectiveness of different forms of chemotherapy by inhibiting a process upon which most, if not all, cancer cell types depend on to survive treatment, the Company believes the LB-100 series of compounds may be useful against most, if not all, cancer types.

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

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

The Company filed an IND application with the FDA on April 30, 2012, and on July 24, 2012, the FDA notified the Company that it would allow initiation of a Phase 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 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 II clinical trial of common cancers, a key goal of the initial portion of the Phase I clinical trial will be to demonstrate that the target enzyme of LB-100, protein phosphatase 2A (PP2A), can be inhibited in humans with readily tolerable toxicity. As an anti-cancer drug, LB-100 is likely to be used at maximum tolerable doses, but for the potential treatment of non-malignant diseases, such as acute vascular diseases and metabolic diseases, lower doses may achieve therapeutic benefit by inhibition of the target enzyme, PP2A, thus opening up the possibility of a host of therapeutic applications for LB-100 and related proprietary compounds. The Phase I clinical trial of LB-100 will be carried out by a nationally recognized comprehensive cancer center beginning in the first quarter of 2013. The study is estimated to take from 18 to 30 months and cost approximately $2,000,000.

As a compound moves through the FDA approval process, it becomes an increasingly valuable property, but at a cost of additional investment at each stage. The Company's approach has been to operate with a minimum of overhead, moving compounds forward as efficiently and inexpensively as possible, and to raise funds to support each of these stages as certain milestones are reached. The allowance of the IND application by the FDA to begin a Phase I 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 2012 consolidated financial statements, has raised substantial doubt about the Company's ability to continue as a going concern.

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

At December 31, 2012, the Company had not yet commenced any revenue-generating operations. All activity through December 31, 2012 has been related to the Company's formation, capital raising efforts, and research and development activities. As such, the Company has yet to generate any cash flows from operations, and is dependent on debt and equity funding from both related and unrelated parties to finance its operations. Prior to June 30, 2006, the Company's cash requirements were funded by advances from the Company's founder aggregating $92,717.

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

The Company's major focus in 2013 is to initiate a Phase I clinical trial of its lead phosphatase inhibitor, LB-100. The Phase I clinical trial of LB-100 will be carried out by a nationally recognized comprehensive cancer center beginning during the first quarter of 2013, and is estimated to take from 18 to 30 months and cost approximately $2,000,000.

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

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

The Company believes that it currently has sufficient funds to initiate the Phase I clinical trial of LB-100 and to continue to fund its operating plans through at least December 31, 2013. Accordingly, in late 2013 or early 2014, in order to continue to fund the Company's operations in 2014 and thereafter, it is likely that the Company will be required to raise additional capital. If cash resources are insufficient to satisfy the Company's cash requirements at that time, the Company would be required to scale back or discontinue its technology and product development programs, 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.

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.

The funds paid to NINDS of the NIH, pursuant to the CRADA effective March 22, 2006, as amended, represented an advance on research and development costs and therefore had future economic benefit. Accordingly, such costs have been charged to expense when they are actually expended by the provider, which is, effectively, as they perform the research activities that they were contractually committed to provide. Absent information that would indicate that a different expensing schedule was more appropriate (such as, for example, from the achievement of performance milestones or the completion of contract work), such advances have been expensed over the contractual service term on a straight-line basis, which, in management's opinion, reflects a reasonable estimate of when the underlying research and development costs were being incurred.

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 $236,784 and $401,279 for the years ended December 31, 2012 and 2011, respectively, and $1,409,397 for the period from August 9, 2005 (inception) to December 31, 2012 (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.

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. Start-up and organization costs were deferred until January 1, 2008. Accordingly, the Company then 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, 2012, 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, 2012, the Company has no accrued interest or penalties related to uncertain tax positions.

Government Grant Under Qualifying Therapeutic Discovery Project

Under the Patient Protection and Affordable Care Act signed into law on March 23, 2010 (the "Act"), the Internal Revenue Service and the Department of Health and Human Services established the qualifying therapeutic discovery project to consider and award certifications for qualified investments by project sponsors. On July 20, 2010, the Company applied for a grant pursuant to the Act based upon qualified investments made in 2009 and 2010. On October 29, 2010, the Company was notified that qualified investments totaling $488,958 had been certified and that a grant in the amount of $244,479 had been awarded to the Company.

The proceeds of the grant were received by the Company in two installments, consisting of $127,994 on November 9, 2010, and $116,485 on February 1, 2011, which were reflected as a receivable at December 31, 2010. For financial statement purposes, the grant of $244,479 was offset against research and development costs in the statement of operations for the year ended December 31, 2010.

Stock-Based Compensation

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

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

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

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

Earnings Per Share

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

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

At December 31, 2012 and 2011, 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.

	2012	2011
Warrants	6,828,800	13,454,552
Stock options	3,750,000	3,250,000
Total	10,578,800	16,704,552

Fair Value of Financial Instruments

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

Use of Estimates

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

Recent Accounting Pronouncements

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

In July 2012, the FASB issued ASU No. 2012-02, Intangibles - Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment. This guidance allows entities the option to first assess qualitative factors to determine whether it is necessary to perform the quantitative impairment test. If the qualitative assessment indicates that it is more-likely-than-not that the fair value of an indefinite-lived intangible asset is less than its carrying amount, the quantitative impairment test is required. Otherwise, no testing is required. The guidance is effective for the Company in the period beginning January 1, 2013. The Company does not expect the adoption of this guidance to have any impact on its 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, 2012, 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, 2010	13,607,426	$ 0.625	
Issued	—	—	
Exercised	(152,874)	0.333	
Expired	—	—	
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	1.41
Warrants exercisable at December 31, 2011	13,284,152	$ 0.608	
Warrants exercisable at December 31, 2012	6,659,840	$ 0.672	1.67

The exercise prices of common stock warrants outstanding and exercisable are as follows at December 31, 2012:

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

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. The intrinsic value of exercisable but unexercised in-the-money common stock warrants at December 31, 2011 was approximately $45,700, based on a fair market value of $0.50 per share on December 31, 2011.

At December 31, 2012, 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.

4. Money Market Funds — Fair Value

Money market funds at December 31, 2012 and 2011 consisted of investments in shares of Morgan Stanley New York Municipal Money Market Trust with market values of $6,134 and $351,129, 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, 2012 and 2011.

	Total	Level 1	Level 2	Level 3
December 31, 2012:				
Money market funds	$ 6,134	$ 6,134	$ —	$ —
December 31, 2011:				
Money market funds	$ 351,129	$ 351,129	$ —	$ —

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, 2012 and 2011, 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 total salary of $60,000 and $47,500 for the years ended December 31, 2012 and 2011, respectively, and $107,500 for the period from August 9, 2005 (inception) to December 31, 2012 (cumulative).

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

On April 7, 2010, the Company entered into an agreement with Dr. Mel Sorensen, a member of the Company's Board of Directors,for consultation and advice regarding the preparation and strategy for obtaining FDA allowance of a clinical trial of the lead compound of the LB-100 series. The initial term of the agreement was for one year and provided for an annual fee of $25,000, payable in two installments of $12,500 on April 15, 2010 and October 15, 2010. On February 18, 2011, the Company's Board of Directors approved a one-year extension of the agreement for an additional annual fee of $25,000, payable in two installments of $12,500 on April 15, 2011 and October 15, 2011. On May 21, 2012, the Company entered into a new agreement with Dr. Mel Sorensen for continuing consultation and advice. The term of the new agreement is for the period from May 21, 2012 to May 31, 2013 and provides for a fee of $25,000, payable in two installments of $12,500 on May 21, 2012 and December 1, 2012. All installments have been paid as due. Consulting and advisory fees charged to operations pursuant to these agreements were $21,875 and $25,000 for the years ended December 31, 2012 and 2011, respectively, and $64,583 for the period from August 9, 2005 (inception) to December 31, 2012 (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 Systems, Inc. ("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 were $163,661 and $720 for the years ended December 31, 2012 and 2011, respectively, and $179,587 for the period from August 9, 2005 (inception) to December 31, 2012 (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. The Phase I clinical trial of LB-100 will be carried out by a nationally recognized comprehensive cancer center beginning during the first quarter of 2013, and is estimated to take from 18 to 30 months and cost approximately $2,000,000, with such payments expected to be divided approximately evenly between payments to Theradex for services rendered and payments for pass-through costs for the clinical center, laboratory costs and investigator costs.

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 $1,017,004 and $205,879 for the years ended December 31, 2012 and 2011, and $3,741,461 for the period from August 9, 2005 (inception) to December 31, 2012 (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, 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.

New transactions during the year ended December 31, 2011 that required an assessment of value pursuant to the Black-Scholes option-pricing model utilized the following inputs: exercise price per share - $0.98 to $1.00; stock price per share – $0.50 to $0.98; expected dividend yield – 0.00%; expected volatility – 294.1 % to 308.8%; average risk-free interest rate – 0.75% to 1.58%; expected life – 5.00 to 6.76 years. For the purpose of assessing value for transactions requiring re-evaluation at December 31, 2011 that were entered into in prior periods, the Black-Scholes option-pricing model utilized the following inputs for the year ended December 31, 2011: exercise price per share - $1.65; stock price per share – $0.35; expected dividend yield – 0.00%; expected volatility – 325.6%; average risk-free interest rate – 2.07%; expected life – 2.00 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 subsequent measurement dates.

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

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

On June 30, 2011, the Company granted to Dr. Palmedo stock options to purchase 200,000 shares of common stock, exercisable for a period of five years from the date of grant at $0.98 per share, which was the fair market value of the Company's common stock on such date. The options vest ratably in equal quarterly installments of 25,000 shares beginning July 1, 2011. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be $196,000 ($0.98 per share). During the years ended December 31, 2012 and 2011, the Company recorded charges to operations of $98,134 and $49,336, 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, 2012 and 2011, the Company recorded a credit to operations of $650 and a charge to operations of $6,293, 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. During the year ended December 31, 2011, the Company recorded a charge to operations of $982 with respect to these options.

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

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

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

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

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

On October 5, 2011, the Company granted to Mr. Schwartzberg stock options to purchase an aggregate of 500,000 shares of common stock, exercisable for a period of the earlier of five years from the grant date or the termination of the consulting agreement at $1.00 per share. One-quarter of the options vested immediately, with the balance vesting in three equal quarterly installments beginning on January 5, 2012. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be $325,000 ($0.65 per share) and was charged to operations ratably from October 5, 2011 through October 4, 2012. During the years ended December 31, 2012 and 2011, the Company recorded charges to operations of $210,410 and $59,589, respectively, 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 ratably from September 12, 2007 through September 12, 2010. On September 12, 2012, options to acquire 100,000 shares expired unexercised.

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

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

Effective May 1, 2011, in connection with his election to the Company's Board of Directors, Dr. Robert B. Royds was granted stock options to purchase 200,000 shares of the Company's common stock, vesting 25,000 shares on May 1, 2011, and 25,000 shares quarterly thereafter until all of the shares are vested, exercisable for a period of five years from each tranche's vesting date, at $0.98 per share, which was the fair market value of the Company's common stock on such date. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $196,000 ($0.98 per share), and is being charged to operations ratably from May 2, 2011 through February 1, 2013. During the years ended December 31, 2012 and 2011, the Company recorded charges to operations of $97,770 and $89,680, respectively, with respect to these options.

Effective September 16, 2012, in connection with her election to the Company's Board of Directors, Dr. Kathleen P. Mullinix was granted stock options to purchase 200,000 shares of the Company's common stock, vesting 25,000 shares on September 16, 2012, and 25,000 shares quarterly thereafter until all of the shares are vested, exercisable for a period of five years from the date of grant at $0.65 per share, which was the fair market value of the Company's common stock on such date. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $118,000 ($0.59 per share), and is being charged to operations ratably from September 16, 2012 through June 16, 2014. During the year ended December 31, 2012, the Company recorded a charge to operations of $31,790 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, 2010	3,540,000	$ 0.794	
Granted	950,000	0.991	
Exercised	(115,015)	0.333	
Expired	(1,124,985)	0.747	
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	3.00
Options exercisable at December 31, 2011	2,587,500	$ 0.856	
Options exercisable at December 31, 2012	3,512,500	$ 0.876	2.91

Total deferred compensation expense for the outstanding value of unvested stock options was approximately $149,700 at December 31, 2012, which is being recognized subsequent to December 31, 2012 over a weighted-average period of approximately twelve months.

The exercise prices of common stock options outstanding and exercisable are as follows at December 31, 2012:

Exercise Prices	Options Outstanding (Shares)	Options Exercisable (Shares)
$ 0.333	300,000	300,000
$ 0.500	200,000	200,000
$ 0.650	700,000	550,000
$ 0.980	450,000	362,500
$ 1.000	2,000,000	2,000,000
$ 1.650	100,000	100,000
	3,750,000	3,512,500

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. The intrinsic value of exercisable but unexercised in-the-money stock options at December 31, 2011 was approximately $83,500, based on a fair market value of $0.50 per share on December 31, 2011.

Outstanding options to acquire 237,500 shares of the Company’s common stock had not vested at December 31, 2012.

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, 2012 and 2011 are summarized below.

	December 31, 2012	December 31, 2011
Start-up and organization costs	$ 63,000	$ 69,000
Research credits	68,000	—
Contingent liability	31,000	31,000
Net operating loss carryforwards	2,421,000	1,912,000
Total deferred tax assets	2,583,000	2,012,000
Valuation allowance	(2,583,000)	(2,012,000)
Net deferred tax assets	$ —	$ —

In assessing the potential realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the Company attaining future taxable income during the periods in which those temporary differences become deductible. As of December 31, 2012 and 2011, 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, 2012 and 2011 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, 2012 and 2011.

	Years Ended December 31,	
	2012	2011
U. S. federal statutory tax rate	(34.0)%	(34.0)%
Non-deductible stock-based compensation	8.6%	3.4%
Non-deductible fair value of warrant extensions	10.8%	3.3%
Non-deductible fair value of warrant discounts	3.2%	—
Adjustment to deferred tax asset	(2.0)%	(4.0)%
Change in valuation allowance	13.4%	31.3%
Effective tax rate	0.0%	0.0%

At December 31, 2012, the Company has available net operating loss carryforwards for federal income tax purposes of approximately $5,835,000 which, if not utilized earlier, expire through 2031.

8. Commitments and Contingencies

Cooperative Research and Development Agreement (CRADA)

Effective March 22, 2006, the Company entered into a CRADA, as amended, with the NINDS of the NIH. The CRADA was for a term of 84 months from the effective date and can be unilaterally terminated by either party by providing written notice within 60 days. 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.

Patent License Agreement

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

Research and Development Contracts

On February 5, 2007, the Company entered into a two-year agreement pursuant to which the Company engaged Chem-Master to synthesize a compound designated as LB-100, and any other compound synthesized by Chem-Master pursuant to the Company's request, which have potential use in treating a disease, including, without limitation, cancers such as glioblastomas. Pursuant to the Chem-Master Agreement, the Company agreed to reimburse Chem-Master for the cost of materials, labor, and expenses for other items used in the synthesis process, and also agreed to grant Chem-Master a five-year option to purchase shares of the Company's common stock. The Company has the right to terminate the Chem-Master Agreement at any time during its term upon sixty days prior written notice. On January 29, 2008, the Chem-Master Agreement was amended to extend its term to February 15, 2014, and to expressly provide for the design and synthesis of a new series of compounds designated as LB-300. The Company also periodically enters into other agreements with Chem-Master for other services. During the years ended December 31, 2012 and 2011, the Company incurred expenses of $24,500 and $30,325, respectively, for the costs of materials, labor and expenses related to its agreements with Chem-Master.

On February 2, 2012, the Company entered into an agreement with MRI Global for a series of studies. As of December 31, 2012, work orders for studies having a total estimated cost of $99,000 were in process under this agreement. As of December 31, 2012, the Company had paid $52,000 towards these work orders.

At various times, the Company has entered into agreements with Ash Stevens to conduct various studies. As of December 31, 2012, contracts with a total estimated cost of $62,000 were in process, of which $58,935 had been paid.

On March 17, 2010, the Company engaged Theradex Systems, Inc. ("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 were $163,661 and $720 for the years ended December 31, 2012 and 2011, respectively. 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. The Phase I clinical trial of LB-100 will be carried out by a nationally recognized comprehensive cancer center beginning during the first quarter of 2013, and is estimated to take from 18 to 30 months and cost approximately $2,000,000, with such payments expected to be divided approximately evenly between payments to Theradex for services rendered and payments for pass-through costs for the clinical center, laboratory costs and investigator costs.

The following table sets forth the Company's principal cash obligations and commitments for the next five fiscal years as of December 31, 2012 aggregating $2,353,122, of which $171,057 is included in current liabilities in the consolidated balance sheet at December 31, 2012.

		Payments Due By Year				
	Total	**2013**	**2014**	**2015**	**2016**	**2017**
Research and development contracts	$ 66,405	$ 66,405	$ —	$ —	$ —	$ —
Theradex work order agreement	2,000,000	600,000	1,000,000	400,000	—	—
Patent license agreement	120,000	—	30,000	30,000	30,000	30,000
Liquidated damages payable under registration rights agreement	74,000	74,000		—	—	—
Due to stockholder	92,717	92,717	—	—	—	—
Total	$ 2,353,122	$ 833,122	$ 1,030,000	$ 430,000	$ 30,000	$ 30,000

MASTER AGREEMENT

between

Lixte Biotechnology Holdings, Inc.

and

Theradex® Systems, Inc.

This Master Agreement (the "Agreement") is made this 12th day of January, 2010 ~~2009~~ (the "Effective Date"), between Lixte Biotechnology Holdings, Inc. (hereinafter "Sponsor"), with its principal place of business at 248 Route 25A No.2, East Setauket, NY 11733 and Theradex® Systems, Inc. (hereinafter "Theradex®"), with its principal place of business at 4365 Route 1 South, Suite 101, Princeton, New Jersey 08540.

WITNESSETH

WHEREAS, Sponsor has now and from time to time in the future may have the desire to engage Theradex® for clinical research services; and

WHEREAS, Theradex® desires to provide such services to Sponsor subject to the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the premises and of the mutual promises and covenants herein contained, the parties hereto agree as follows:

1. SCOPE OF WORK

1.1 General. Theradex® shall use commercially reasonable efforts to provide clinical research services ("Services") to Sponsor as set forth herein, to keep Sponsor advised of the progress of the work, and to provide the Sponsor with such reports, specifications, and the like, as are appropriate to the nature of the Services to be performed hereunder.

1.2 Work Order. Services provided by Theradex® shall be subject to the terms and conditions of this Agreement. All such Services shall be the subject of a work order in substantially the form attached hereto as Attachment A, and as agreed upon and executed by the parties hereto (each, a "Work Order"). Each Work Order shall be attached to this Agreement, incorporated herein by reference, and subject to the terms and conditions set forth herein. Each Work Order shall identify the project and set out a description of the Services, the timeline therefore and the fees to be paid by the Sponsor (the "Fees"). There will be no limit to the number of Work Orders that may be added to this Agreement.

2. LEGAL REQUIREMENTS

2.1 Legal Standard. Theradex® warrants that is and will continue to be in full compliance at all times with all applicable laws and regulations ("Applicable Law"). Should non-compliance of an investigator or study site be discovered during the course of the project, Sponsor will be immediately notified and appropriate action will be taken by Theradex®. Any such action shall be conducted after consultation with Sponsor.

2.2 Use of Debarred Employees. Theradex® shall use its best efforts not to employ, contract with or retain any person directly or indirectly to perform Services under this Agreement if such person is debarred by the FDA under 21 U.S.C. 335a. Upon written request of Sponsor, Theradex® shall, within ten (10) business days of its receipt of such request, provide written confirmation that it has complied with the foregoing obligation. Theradex® agrees to immediately disclose in writing to Sponsor if any employee or agent is debarred, or if any action or investigation is pending or, to the best of Theradex®'s knowledge, threatened, relating to the debarment of Theradex® or any person performing Services pursuant to this Agreement.

2.3 Financial Disclosure. Theradex® shall also provide all information to Sponsor, reasonably requested by Sponsor, necessary to comply with any disclosure requirements of Applicable Law, including any information required to be disclosed in connection with any financial relationship between Sponsor and the investigators involved in the Study.

2.4 FDA/Sponsor Inspection.

(a) During the term of this Agreement, Theradex® agrees to permit representatives of Sponsor and/or of the FDA to examine at any reasonable time during normal business hours (and where applicable make copies of) relevant information and facilities necessary to confirm that the each study (or studies) being conducted pursuant to this Agreement (each, a "Study") is being conducted in compliance with the Study protocol, this Agreement and Applicable Law.

(b) Theradex® shall immediately notify Sponsor if FDA schedules, or, without scheduling, begins an inspection of a Study site, Theradex® or an IRB, in relation to the Sponsor's project. In addition, Theradex® will immediately provide Sponsor copies of any correspondence from or to the FDA or other regulatory authorities related to the Study, including but not limited to any FD-483s or warning letters, as well as any other correspondence with a governmental agency that is reasonably likely to affect the suitability of Theradex® to continue conducting the Study.

(c) Theradex® recognizes that if Sponsor should deem Theradex® to be in default of this Agreement that Theradex® shall have thirty (30) days to correct such default, provided that the correction of such default is within Theradex®'s power.

3. COMPENSATION

Unless otherwise agreed to by the parties hereto, the Fees to be paid to Theradex® for the Services shall be set forth in each Work Order. Payment shall be due and payable in accordance with the schedule set forth therein. Payments shall be made payable to Theradex® Systems, Inc. at the address above. Theradex® will submit to Sponsor a monthly invoice detailing labor and expenses as Services are rendered to Sponsor. Such labor and expenses shall be billed on a time and materials basis. Fees not covered by an individual Work Order will be invoiced separately after execution of a change order. Investigator fees will be invoiced separately from Theradex®'s service costs. Payment will be made by Sponsor within thirty (30) days after Sponsor's receipt of Theradex®'s monthly invoice. If Sponsor contests in good faith, certain elements of any invoice, Sponsor shall evidence the same in writing along with the reasons for such contest within thirty (30) days after the date of invoice. Sponsor and Theradex® will each designate a contact person to address the method in which contested invoice items will be resolved. Except for amounts subject to a bona fide dispute, payment shall be made by Sponsor within thirty (30) days after Sponsor's receipt of Theradex®'s monthly invoice, or as otherwise provided in the applicable Work Order.

4. PATENTS AND INVENTIONS

All rights to any discovery or invention conceived or conceived and reduced to practice in the performance of the Services conducted pursuant to this Agreement shall belong to Sponsor. Theradex® agrees to assign to Sponsor, at the request of Sponsor, the sole and exclusive ownership thereto, upon the payment of applicable fees by Sponsor, if any, incurred by Theradex® in the filing, prosecution, or maintenance of any patent application or patent issuing thereon.

5. CONFIDENTIALITY/PUBLICATIONS

5.1 Confidential Information. For purposes of this Agreement, "Confidential Information" means any information of Sponsor, whether of a technical, business or other nature, including but not limited to, information, documents, data and images which (i) relate to Sponsor's trade secrets, products, promotional material, developments, proprietary rights or business affairs, or (ii) are developed by or compiled by Theradex® pursuant to this Agreement. Confidential Information does not include any information that: (a) Theradex® can prove was known to it prior to the date of this Agreement; (b) Theradex® can prove was lawfully obtained from a third party without any obligation of confidentiality; or (c) is or becomes part of the public domain through no act or violation of any obligation of Theradex®. Theradex® shall not, at any time, without Sponsor's prior written consent, disclose to any third party any of Sponsor's Confidential Information. Theradex® shall use such Confidential Information solely for the performance of its obligations hereunder, and shall keep such information secure, secret and confidential and cause its employees and representatives to keep such information secure, secret and confidential and shall take all reasonable precautions to prevent any unauthorized use or disclosure of the Confidential Information. Notwithstanding the above, if Theradex® is required by law to disclose Confidential Information, Theradex® shall notify Sponsor, and Theradex® and

Sponsor shall agree upon a mutually satisfactory way to disclose such information as necessary and in accordance with Applicable Law. With respect to research subjects' medical records, the parties agree to hold in confidence the identity of the patients in accordance with Applicable Law.

5.2 Return of Information. Upon completion or earlier termination of this Agreement, Theradex® will promptly return to Sponsor, and facilitate return by all investigators, all Confidential Information, and to the extent that Sponsor so requests, Theradex® will destroy all copies of Confidential Information in Theradex®'s possession or under Theradex®'s control, except as otherwise required by Applicable Law.

5.3 Publications. Sponsor's policies and procedures on publications will apply to all investigator publications and presentations regarding a study that is part of the Services.

6. DATA MANAGEMENT

All study data shall be entered into an electronic database that has been validated according to acceptable industry practice. Full audit trails shall be maintained for changes in data entry. Audits of the final databases maintained by Theradex® shall be audited versus case report forms using industry standard techniques. Such audits shall be described in the applicable Work Orders.

7. TERM AND TERMINATION

7.1 Term. The term of this Agreement shall begin on the date first above mentioned and shall end on January 12, 2014, unless sooner terminated in accordance with the terms hereof. The term of this Agreement may be extended upon written agreement by Sponsor and Theradex®.

7.2 Termination.

(a) A Work Order or this Agreement may be terminated (i) by Sponsor at any time in the exercise of its sole discretion upon thirty (30) days prior written notice to Theradex®; (ii) by either party upon the material breach of this Agreement by the other party, which breach continues unremedied for thirty (30) days after delivery to the breaching party by the nonbreaching party of notice of such material breach; or (iii) immediately by either party in the event of the bankruptcy (voluntary or otherwise), insolvency or other similar financial distress of the other party. A termination of the Agreement pursuant to this Section 7.2 shall be deemed a termination of all uncompleted Work Orders.

(b) A Work Order or this Agreement may be terminated by Theradex® at any time in the exercise of its sole discretion upon sixty (60) days prior written notice to Sponsor. Should Theradex® terminate a Work Order or this Agreement pursuant to this Section 7.2(b), Theradex will fully assist Sponsor in transitioning the subject Services to one or more third parties chosen by Sponsor in its sole discretion.

(c) Upon termination or expiration of a Work Order or this Agreement, Theradex® shall (i) promptly terminate all related Services, provided that Theradex® shall not immediately terminate such Services necessary for the responsible treatment of any Study subjects and Sponsor shall continue to pay any and all reasonable fees associated with the provision of such Services and (ii) Theradex® will work with Sponsor to transition such Services to Sponsor or its designee. In the event of termination hereunder, other than as a result of a material breach by Theradex®, the total sums payable by Sponsor pursuant to this Agreement shall be equitably pro-rated for actual work performed up to the date of termination with any unexpended funds previously paid by Sponsor to Theradex® refunded to Sponsor.

8. INSURANCE

Sponsor shall retain product liability insurance for the duration of any such Work Order attached hereto that includes patients be treated. Theradex shall also retain insurance, in the form of professional liability insurance of no less than $5,000,000 for the duration of any Work Order attached hereto. Either party may, at any time receive proof of said insurance within thirty (30) days written notice.

9. TRANSFER OF SPONSOR OBLIGATIONS

Pursuant to 21 CFR 312.52, Sponsor shall identify the obligations it has transferred to Theradex® in the Work Orders. Theradex® agrees to carry out diligently all transferred obligations. Theradex® will undertake the monitoring of the studies to be conducted under the attached Work Orders. Theradex® acknowledges that Sponsor has the right to co-monitor the investigational sites with Theradex® personnel. Theradex® encourages Sponsor to take advantage of the co-monitoring right at the convenience of Sponsor.

10. ADVERSE EVENTS

To the extent appropriate with respect to Services to be delivered in connection with a given Work Order, Theradex® shall have a system to identify and collect all serious adverse drug experiences and unexpected adverse drug experiences (as defined in 21 CFR), which shall include instructing investigators to contact Theradex® and/or Sponsor directly within one (1) day of such an experience. Theradex® will notify Sponsor by telephone within one (1) day of its own receipt of notice of any serious or unexpected adverse drug experiences. Theradex® will promptly thereafter follow-up with written documentation to Sponsor. Theradex® shall notify all investigators of any serious or unexpected adverse drug experiences as required by FDA regulations, if such notification has been delegated to Theradex® in the Work Order(s). Adverse events other than those described above will be submitted by Theradex® in writing on case report forms during the course of the applicable Study. Specific instructions for reporting of serious or unexpected adverse drug experiences, IND safety reports and reporting of adverse events on case report forms shall be contained in the applicable Study protocols.

11. INDEMNIFICATION

(a) Sponsor shall indemnify, defend and hold harmless Theradex® and its employees, officers and directors ("Theradex Indemnitee") against any and all losses, costs, expenses and damages, including but not limited to reasonable attorneys' fees, based on a personal injury allegedly resulting from the use of a Study drug supplied by Sponsor, except to the extent that any such claim is caused solely by a Theradex Indemnitee's own negligence or malpractice, or reckless or intentional misconduct in the administration of the Study drug. Theradex Indemnitee will give Sponsor timely written notice of any such claim served upon a Theradex Indemnitee. Sponsor shall have the right, at its sole expense, to defend same including selection of counsel and control of the proceedings, including reasonable settlement. Theradex® shall fully cooperate and aid in such defense. Sponsor has sole control over the defense and settlement of any such liability, including the sole right to select defense counsel, and in the event such a claim or action is or may be asserted, Theradex® shall have the right to select and to obtain representation by separate legal counsel. If Theradex® exercises such right, all costs and expenses incurred by Theradex® for such separate counsel shall be borne by Theradex®.

(b) Theradex shall indemnify, defend and hold harmless Sponsor and its employees, officers and directors ("Sponsor Indemnitee") against any and all losses, costs, expenses and damages, including but not limited to reasonable attorneys' fees, based on a personal injury allegedly caused solely by Theradex®'s negligence or malpractice, or reckless or intentional misconduct in the administration of the Study drug. Sponsor Indemnitee will give Theradex® timely written notice of any such claim served upon Sponsor Indemnitee. Theradex® shall have the right, at its sole expense, to defend same including selection of counsel and control of the proceedings, including reasonable settlement. Sponsor shall fully cooperate and aid in such defense. Theradex® has sole control over the defense and settlement of any such liability, including the sole right to select defense counsel, and in the event such a claim or action is or may be asserted, Sponsor shall have the right to select and to obtain representation by separate legal counsel. If Sponsor exercises such right, all costs and expenses incurred by Sponsor for such separate counsel shall be borne by Sponsor.

12. LIMITATION OF LIABILITY

Except with respect to liability for a breach of section 4, 5 or 14.12 or a liability indemnifiable pursuant to section 11, neither party shall be liable to the other party under any circumstances for any special, indirect, consequential, or punitive damages, including, but not limited to, loss of profits, loss of business opportunities, or loss of goodwill, even if advised of the possibility of such damages. Except with respect to liability for a breach of section 4, 5 or 14.12 or a liability indemnifiable pursuant to section 11, in no event shall Theradex®'s liability in connection with this agreement exceed an amount equal to the fees paid to Theradex® by sponsor during the six (6) month period immediately preceding the determination of such liability.

13. CONTRACTING; SUBCONTRACTING

All services or materials for which Theradex® contracts, subcontracts or purchases for purposes of this Agreement shall be subject to prior written approval by Sponsor. Theradex® agrees to provide to Sponsor a copy of any such contract for services or materials prior to execution for comment, in particular regarding costs, source, payment schedule, early termination penalties, confidentiality and patent rights.

14. MISCELLANEOUS

14.1 Obligation of Investigators. All investigators and other personnel involved in the conduct of the Study will be informed, by Theradex®, of all of the relevant provisions of this Agreement and the obligations of Theradex® and will be required by Theradex® to comply therewith.

14.2 Publicity. None of the parties shall use the name of any other party for promotional purposes without the prior written consent of the party whose name is proposed to be used, nor shall either party disclose the existence or substance of this Agreement without the other party's prior written consent, except as required by law. Notwithstanding the preceding, the participation of Theradex® in the matters undertaken pursuant to this Agreement may be recognized by Sponsor in publications and promotional materials that may result from the Study and the development of the Study device without the prior approval of Theradex®.

14.3 Governing Law. This Agreement shall be governed by the laws of the State of New Jersey, without regard to its conflicts of laws provisions.

14.4 Independent Contractor. Theradex®, its employees, investigators recruited by Theradex®, and research staff at study sites recruited by Theradex® shall act in the capacity of independent contractors hereunder and not as employees of Sponsor.

14.5 Agreement Modification; Assignment. This Agreement, or any of its Exhibits, may not be altered, amended, or modified except by a written document signed by the parties hereto. Neither party shall assign this Agreement or any of its rights or obligations without the prior written consent of the other party.

14.6 Notice. Any notices given hereunder shall be sent by fax or email, with a confirmation copy sent via first class United States mail or via overnight courier, to the following addresses (or such other address as a party may designate as a notice address in a prior written notice to the other party) and shall be deemed delivered when received as follows:

To: Lixte Biotechnology Holdings, Inc.
248 Route 25A No. 2
East Setauket, NY 11733
Attention: John Kovach
Telephone: ~~516-482-1200~~ 631-942-7959
Fax: 631-982-5050
e-mail: jkovach@lixte.com

To: Theradex® Systems, Inc.
Mailing Address:
CN 5257
Princeton, NJ 08543

Courier address:
4365 Route 1 South , Suite 101
Princeton, NJ 08540
Attention: Margaret Valnoski, President
Telephone: 609-799-7580
Fax: 609-799-4148
e-mail: mvalnoski@Theradex.com

14.7 Counterparts. This Agreement and any Work Order may be executed in two (2) counterparts, each of which will be deemed an original but both of which together will constitute one (1) and the same instrument.

14.8 Survival of Obligations. Notwithstanding expiration or termination of this Agreement for any reason, rights and obligations, which by their nature should survive, will remain in full force and effect. In particular Sections 4, 5, 7.2, 10, 11, 13.3, 13.8 and 13.12 will survive expiration or termination of this Agreement.

14.9 Enforceability. If any of the provisions or a portion of any provision of this Agreement is held to be unenforceable or invalid by a court of competent jurisdiction, the validity and enforceability of the enforceable portion of any such provision and/or the remaining provisions will not be affected thereby.

14.10 Entire Agreement. This Agreement, together with its attachments and Work Orders, is the entire and complete understanding between the parties with respect to its subject

matter. It replaces, supersedes and renders void any and all prior agreements between the parties whether written or oral.

14.11 Conflict of Interest. During the course of Theradex®'s provision of Services hereunder, Theradex® shall not undertake to provide services for any person or organization that substantially hinders, delays and adversely impacts the execution of the Services.

14.12 Non-Solicitation. During the term of this Agreement and for six (6) months thereafter, Sponsor shall not, without the prior written consent of Theradex®, directly or indirectly solicit for employment or contract, attempt to employ or contract with or assist any other entity in employing, contracting with or soliciting for employment or contract any employee, subcontractor or executive who is at that time employed or contracted by Theradex® or who had been employed/contracted by Theradex® within the prior six (6) month period.

14.13 Conflicts. If any of the provisions of this Agreement conflict with any provision of the Study protocol, this Agreement shall take precedence. If any provisions of this Agreement conflict with any provision of a Work Order, the Work Order shall take precedence.

14.14 Waiver. No waiver of any right set forth herein shall be deemed effective unless in writing and signed by the party against whom enforcement of the waiver is sought. If any provision hereof shall be determined to be invalid or unenforceable, such determination shall not affect the validity of the other provisions of this Master Agreement. Waiver by either party or the failure by either party to claim a breach of any provision of this Agreement shall not be deemed to constitute a waiver or estoppel with respect to any subsequent breach of any provision hereof.

14.15 No Third Party Beneficiaries. The provisions set forth in this Agreement are for the sole benefit of the parties hereto and their successors and assigns and they shall not be construed as conferring any rights on any other persons.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

Lixte Biotechnology Holdings, Inc.

By: _____

Name: John S Kovach

Title: President + CEO

Theradex® Systems, Inc.

By: _____
Margaret Valnoski
President

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, 2012 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 13, 2013

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

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

In connection with the filing by Lixte Biotechnology Holdings, Inc. (the "Registrant") of its Annual Report on Form 10-K for the fiscal year ended December 31, 2012 (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 13, 2013

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