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, 2010

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

For the transition period from _____ to _____

Commission file number: 000-51476

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

Indicate by check mark if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B 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, 2010: $0

The aggregate market value of the common stock held by non-affiliates of the registrant as of June 30, 2010 was approximately $4,837,646.

There were 35,077,178 shares of the Company's common stock outstanding on March 15, 2011.

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Introductory Comment

Throughout this Annual Report on Form 10-K, the terms "we," "us," "our," "our company," "Lixte," "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.

GLOSSARY

The following technical terms are used in this Report:

Assay

An assay is a method to determine the presence, absence, or the amount of a particular substance in a sample.Assays of body fluids such as blood and urine can be used to detect specific products (biomarkers) that indicate the presence of a specific type of cancer.

Biomarker

A biomarker is a component of a cell that is uniquely or strongly associated with a particular feature of that cell. The detection of the biomarker in body fluid by anassay indicates that a particular cell is very likely to be present in the body. In this Report, "biomarkers" refer primarily to proteins that are uniquely produced by specific types of cancer cells or that are produced in excess by the cancer cells compared to non-cancer cells of the same tissue or organ.

Cancer

A disease characterized by loss or enhancement of one or more mechanisms that regulate the growth of cells of a specific tissue. Loss of these control mechanisms or gain of abnormal mechanisms in a single cell that put cell growth into overdrive allows that cell to grow, invade local tissue, and to spread to other regions of the body. This spreading of altered cells to distant sites is the process called metastasis.

Cell Growth

Cell growth is the ability of an individual cell to reproduce by dividing into two cells. During normal development and subsequently during the life of the adult, this process is highly controlled. Loss of this control is the distinguishing feature of cancer cells. Although all cancer cells gain the capacity for uncontrolled growth, in most instances they retain many of the highly specialized features (and associated specific molecular components) that were characteristic of the normal tissue before loss of growth control. For example, breast cancer cells and brain cancer cells have lost control of growth and may be unrecognizable by their appearance under the microscope but identifiable by the presence of biomarkers specific to breast or brain cells.

CRADA

A CRADA (Cooperative Research and Development Agreement) is a formal contractual mechanism by which a variety of federal government agencies may agree to work collaboratively with a non-governmental entity to study and advance a particular idea, observation, or process under a defined plan of work.

Gene

A gene is a unit of information that specifies the structure of one or moregene products. Collectively, genes determine the precise composition of all molecules needed for maintenance of the functions of life: reproduction, development, organization, growth and metabolism. Genes are often referred to as units of heredity because they pass on the information necessary for all characteristics of an individual. For mammals like ourselves, one set of genes is received from each parent.

Gene Products

The products of genes are the thousands of different chemical structures, called molecules, needed for development of all cells. Most gene products are proteins. Most proteins are enzymes, molecules that can carry out work such as digesting and utilizing food for energy, signaling the cell to produce other gene products in response to changing conditions in the body, and controlling cell growth. When proteins controlling cell growth are altered, as occurs in all cancers, they become prime candidates forbiomarkers that reveal the presence of cancer.

Glioblastoma Multiforme (GBM)

GBM is the most common and most aggressive type of primary human brain cancer. The name derives from the fact that the brain cell that loses growth control and becomes a brain cancer cell is a glial cell (glioblastoma); as the altered glial cells grow without restraint, they take on many different shapes (multiforme). Recent studies suggest, however, that GBMs may arise from primitive brain stem cells rather than from glial cells.

Metastasis

Metastasis is the process by which cancers acquire the ability to spread to other parts of the body by entry and dissemination through the blood and/or lymph systems. The devastating aspect of metastasis is the ability of the cancer cells to grow in a new environment (new tissue) Examples are the metastasis of breast cancer cells to the brain and liver and prostate cancer cells to bone.

Cure of cancers is much more difficult to achieve after metastasis has occurred. A major goal of our biomarker research is to develop assays for detection of cancers before they have invaded extensively or metastasized, allowing complete removal by surgery.

Mutation

A mutation is a change in one or more building blocks of a gene. Some changes can be tolerated without altering the integrity (function) of the product of the gene but other changes can result in cancer.

For the purposes of the cancer projects described in this memorandum, it is important to distinguish between inherited mutations (inborn mutations) and acquired (environmentally caused) mutations.

Some inborn mutations predispose an individual to development of one or more kinds of cancer. Because these mutations are inherited, they are present in every cell in the body. Such mutations are responsible for the higher frequency of certain cancers in particular families and ethnic groups. Examples are the breast cancer predisposing genes known as BRCA I and BRCA II.

Research on biomarkers, however, is directed at finding the gene products (proteins) of acquired mutations. Acquired mutations that change a single cell to a cancer cell are present ONLY in that cell and cells arising from its uncontrolled cell growth. If the products of the altered genes in these cancer cells are detectable in the body, they may reveal the presence of the cancer at a stage when it is curable by surgery.

Prognosis

Prognosis refers to the likely course of a disease at specific stage of development. For example, a breast or prostate cancer that is not confined to the tissue of origin, e.g. is also present in a lymph node when first detected, has a greater likelihood of recurrence, a worse prognosis, than if it were confined to the tissue of origin.

Thus, the presence of lymph node metastases is an indicator of poor prognosis.

It is hoped that specific biomarkers for cancers will be found that have prognostic value. With assays for such markers, patients with poor prognoses could consider more aggressive treatments before obvious spread of disease and patients with good prognoses could be spared unnecessary treatment.

Proteins

Proteins are molecules that have many functions important to the nature and behavior of the cell. Many proteins are enzymes that regulate and integrate a myriad of biochemical processes essential to life.

Certain enzymes are critical to an integrated system of cellular signaling that regulates cell behavior in response to a constantly changing environment and maintains the specialized nature of different types of cells. It is likely that some biomarkers of cancers have perverted signaling functions that perpetuate the abnormal behavior of the cancer.

Thus, discovery of biomarkers of known function that are unique or overly abundant in specific types of cancers may provide clues as to the biochemical vulnerabilities of these cancers, weaknesses that can be attacked selectively by specific classes of drugs.

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 three and one-half 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 characterizing the molecular variants, which characterize human cancers. In the past decade, there has been an unprecedented expansion in knowledge of biochemical defects in the cancer cell. The Company has assembled a small but intellectually diverse group which uses information about the regulatory pathways altered in cancer cells. 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, 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. The LB-100 series consists of novel structures, which have the potential to be first in their class and the latter group contains compounds, which have the potential to be the most effective of this class. The Company has demonstrated that 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 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. Because of the propensity of malignant melanoma to metastasize to the brain, recent studies have encompassed studying the effectiveness of drugs developed for the treatment of primary brain tumors to the treatment of melanoma as well.

Initial encouraging results of the use of PTase-I (LB-100) against human GBM in a mouse model were published in the Proceedings of the National Academy of Science (Lu et al, June 17, 2009). This report attracted considerable attention including an invitation to submit an article on the novel mechanisms by which this group of compounds increased markedly the anti-cancer activity of standard widely used non-specific chemotherapy drugs, without enhancing toxicity to normal cells. A second article was published in a well-regarded journal, Cell Cycle (Zhuang et al, October 15, 2009). Following this publication, several leading cancer research centers in the United States and elsewhere have initiated studies of the Company's compounds against a variety of other human cancer types, most notably breast cancer and sarcomas. These studies are being done with the Company's compounds provided under agreements, which protect the proprietary nature of the compounds, while allowing significant expansion of the Company's research by academic experts at no additional expense.

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 two companies have an 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 Lixte'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 results of the Company's studies done in conjunction with a neuroscientist carrying out the work under contract were presented at the annual meeting of the Society for Neuroscience, Chicago, Illinois, on October 17, 2009.

The Company's primary goal is to bring one lead compound of the LB-100 series to clinical trial. In late 2009 and early 2010, the Company raised sufficient financial resources to carry out the preclinical studies needed for an application to the FDA to carry out a Phase I trial. The Company has engaged a leading pharmaceutical company, a clinical research organization, and a drug development company specializing in pharmacologic and toxocologic characterization of new anticancer drugs to oversee and carry out all studies necessary for FDA approval to take the compounds into an initial clinical trial.

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 one of the Company's drug compounds, LB-100. This collaboration is a milestone-based approach in which NCI will first confirm studies of the LB-100 compound in an animal model of glioblastoma multiforme, the most common 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.

In addition, the Company is pursuing its collaborative work with the National Institute of Disorders and Stroke (NINDS), National Institutes of Health (NIH) under its ongoing Cooperative Research and Development Agreement (CRADA). This work is focused upon increasing understanding of the mechanisms underlying the effectiveness of the LB-100 series in enhancing the anticancer activity of commonly used standard anticancer drugs. This work has in the past and continues to provide insights as to how to use Lixte's compounds most effectively.

The Company believes that funds on hand should allow the Company to continue operations and to grow its patent portfolio and maintain its applications for international protection of lead compounds of both the LB-100 and LB-200 series without raising additional funds until the first quarter of 2012.

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 Lixte' compounds as neuroprotective agents; and, the use of certain Lixte 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 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.

If compounds of either series are active against glioblastoma multiforme in the clinic, the potential market for such a drug is estimated to be approximately $800 million annually. This estimate is based on the current use and pricing of the drug, Temozolomide. This drug is given to almost every patient with a diagnosis of glioblastoma multiforme, some 40,000 individuals in the United States and Europe annually. The Company's compounds may be used in conjunction with Temozolomide and/or following relapse after treatment with Temozolomide, since unfortunately almost all patients with this disease relapse regardless of therapy with current drugs. If, however, as the experimental data in model systems suggests, the Company's compounds are active against other tumor types and enhance the therapeutic benefit of other standard cancer regimens for common cancers, the Company believes that their potential market could be substantially larger.

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. With present funding, the Company believes it can accomplish this goal. 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) now 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.

The Company's most valuable resource 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 target(s) is expected to be melanoma or glioblastoma multiforme. The Company has had pre-IND discussions with the FDA through the submission of written questions to the FDA, and is proceeding with pre-clinical development of LB-100 in accordance with the written responses of the FDA.

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 on 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. Improved chemotherapy regimens for cancers not curable by surgery or radiation is the primary focus of the Company.

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. Resources permitting, the Company will need collaboration 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, 2010, 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 20% of his efforts per year to research planning and design and monitoring the research progress under the CRADA. Dr. Kovach expects to increase his annual efforts with respect to the Company's business to approximately 40% beginning in March 2011. 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, 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 plan service agreement. 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 treatment 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 hopes to be able to initiate a clinical trial in 2011. 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 well being 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. The duration of a Phase I trial is generally from 4 to 9 months.

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

Please consider the following risk factors together with the other information presented in this Report, including the financial statements and the notes thereto.

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 through pre-clinical evaluation needed for submission of a request (IND) 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 its report on the Company's 2010 consolidated financial statements, have raised substantial doubt about the Company's ability to continue as a going concern. The Company raised $500,000 in November 2009, $1,787,500 in January 2010 (of which $1,200,000 had been advanced to the Company at December 31, 2009), and $500,000 in February 2010, all through the sale of its securities to fund its business activities. In 2010, the Company was successful in competing for funds from the "Qualifying Therapeutic Discovery Grant" program of the federal government. The Company received $244,479 of which $127,994 was paid in October 2010 and $116,405 was paid in February 2011, all in support of the Company's development of LB-100 (LB-1). As a result, the Company believes that its current resources are adequate to fund operations at a minimum through the first quarter of 2012, at a level that will allow the continuation of the Company's two drug development programs currently in process and completion of the initial Phase 1 study of LB-100, including initiation of a Phase I clinical trial if no unexpected delays occur in obtaining FDA approval in 2011.

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 in 2012 to satisfy its future working capital requirements.

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. Continued negative cash flows and lack of liquidity create uncertainty about the Company's ability to fully implement its operating plan beyond the first quarter of 2012. 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 74 years old, and, because of his arrangement with the State University of New York, does not devote his full time to us. The loss of services of Dr. Kovach of 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, also is 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, Dr.Kovach 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. 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. Lixte, 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 would be expected to 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 collaborators may not successfully begin or complete clinical trials in the time periods estimated, if at all. Moreover, if we or our collaborators 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.

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 any patent or patents will be issued. If a third party has also filed a patent application relating to an invention claimed by us or our licensors, we may be required to participate in an interference proceeding declared by the 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 listed on the OTC Market (also referred to as the "Pink Sheets"), an active trading market for the securities does not yet exist and may not exist or be sustained in the future. The OTC Market is an inter-dealer, over-the-counter market that provides significantly less liquidity than the NASD's automated quotation system (the "NASDAQ Stock Market"). Quotes for stocks included on the OTC Market 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 OTC Market 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 4,575,000 shares in private placements in November and December 2009 and February 2010, all of which are currently eligible to be sold under Rule 144.

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

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

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

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

Our principal stockholder has significant influence over our company.

As a result of the Reverse Merger, Dr. John Kovach, our principal stockholder and our Chief Executive Officer, beneficially owns approximately 48.5% 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 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 all laboratory activities at NIH under the CRADA agreement. 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 expected to be needed during the remainder of 2011.

ITEM 3. LEGAL PROCEEDINGS

The Company is not a party to any legal proceedings.

ITEM 4. RESERVED

PART II

ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock trades on the OTC Market (also referred to as the "Pink Sheets") under the symbol "LIXT." There is very limited trading of our stock. 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, 2010		
First Quarter	$ 0.60	$ 0.16
Second Quarter	$ 0.75	$ 0.24
Third Quarter	$ 1.01	$ 0.19
Fourth Quarter	$ 0.75	$ 0.30
Year Ended December 31, 2009		
First Quarter	$ 0.60	$ 0.16
Second Quarter	$ 0.75	$ 0.24
Third Quarter	$ 1.01	$ 0.19
Fourth Quarter	$ 0.75	$ 0.30

Holders

As of February 5, 2011, 35,077,178 shares of our common stock were outstanding, held by approximately 80 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, 2010, 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	400,000	$ 0.42	2,100,000

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. ("Holdings"). 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 has been 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 was listed for trading on the OTC Bulletin Board commencing September 24, 2007 under the symbol "LIXT." It is presently traded on the OTC Market (also referred to as the "Pink Sheets") under the symbol "LIXT.PK".

Recent Developments

On February 1, 2011, the Company received from the Internal Revenue Service a payment of $116,485, representing the final payment under a grant relating to a qualifying investment in a therapeutic discovery project under Section 48D of the Internal Revenue Code for the Company's LB-1 compound. The initial payment of $127,994 under the grant was received in November 2010.

In 2010, Lixte and its CRADA partner, The National Institute of Neurological Disorders and Stroke, NIH, Dr. Zhuang and Dr. Martha Lubet, NCI/Ninos tech transfer specialist, won the 2010 Mid-Atlantic Region Award of Excellence in Technology Transfer for the joint venture in developing drugs for the treatment of brain tumors. The award was made by the Federal Laboratory Consortium, a nationwide network of federal laboratories dedicated to integrating research in federal laboratories into the mainstream of the U.S. economy.

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 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 2010 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 develop additional sources of 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, 2010, the Company had not yet commenced any revenue-generating operations. All activity through December 31, 2010 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.

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 activities in 2011 will consist of continuing drug discovery and development efforts. The Company's primary goal will be to take the Company's LB-100 compound through a Phase I clinical trial by July 1, 2011. The Company raised $500,000 in November 2009, $1,787,500 in January 2010 (of which $1,200,000 had been advanced to the Company at December 31, 2009), and $500,000 in February 2010, all through the sale of its securities to fund its business activities. The Company also received $244,479 from the Internal Revenue Service under its Qualifying Therapeutic Discovery Grant program, consisting of $127,994 on October 29, 2010 and $116,485 on February 1, 2011. As a result, the Company believes that its current resources are adequate to fund operations at a minimum through the first quarter of 2012, at a level that will allow the continuation of the Company's two drug development programs currently in process and completion of the initial Phase I trial of LB-100, if no unexpected delays occur in obtaining FDA approval in 2011.

The amount and timing of future cash requirements will depend on the pace of these programs, in particular, completion of the Phase I trial of LB-100. After completion of the Phase I trial, the next step will be to determine the anti-cancer activity against a particular type of human cancer in Phase II trials. To carry out Phase II trials, the Company anticipates that it will be necessary to raise additional funds in 2012 from a combination of additional debt or equity financings, and/or the sale, licensing or joint venturing of its intellectual properties. 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. Continued negative cash flows and lack of liquidity create significant uncertainty about the Company's ability to fully implement its operating plan beyond the first quarter of 2012, as a result of which the Company may have to reduce the scope of its planned 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.

Recent Accounting Pronouncements

In April 2010, the Financial Accounting Standards Board ("FASB") issued new accounting guidance in applying the milestone method of revenue recognition to research or development arrangements. Under this guidance, management may recognize revenue contingent upon the achievement of a milestone in its entirety, in the period in which the milestone is achieved, only if the milestone meets all of the criteria within the guidance to be considered substantive. The new guidance is effective on a prospective basis for research and development milestones achieved in fiscal years beginning on or after June 15, 2010. Early adoption is permitted; however, adoption of this guidance as of a date other than January 1, 2011 would require the Company to apply this guidance retrospectively effective as of January 1, 2010, and would require disclosure of the effect of this guidance as applied to all previously reported interim periods in the fiscal year of adoption. As the Company plans to implement this guidance prospectively, the effect of this guidance will be limited to future transactions. The Company does not expect that adoption of this guidance will have any impact on its financial position or results of operations, as the Company does not have or currently expect to have any research and development arrangements which will be accounted for under the milestone method.

In January 2010, the FASB issued new accounting guidance which requires new disclosures regarding transfers in and out of Level 1 and Level 2 fair value measurements, as well as requiring presentation on a gross basis of information about purchases, sales, issuances and settlements in Level 3 fair value measurements. The new guidance also clarifies existing disclosures regarding level of disaggregation, inputs and valuation techniques. The new guidance is effective for interim and annual reporting periods beginning after December 15, 2009. Disclosures about purchases, sales, issuances and settlements in the roll forward of activity in Level 3 fair value measurements are effective for fiscal years beginning after December 15, 2010. As this guidance only requires additional disclosure, the Company does not expect that adoption of this guidance will have any impact on its financial position or results of operations.

Management does not believe that any other recently issued, but not yet effective, authoritative guidance, if currently adopted, would have a material effect on the Company's consolidated 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 are expensed as incurred. Research and development expenses 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.

Amounts that become due, pursuant to contractual commitments, on research and development contracts with third parties are recorded as a liability, with the related amount of such contracts recorded as advances on research and development contract services on the Company's balance sheet. Such advances on research and development contract services are expensed over their life 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.

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 share-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 over the vesting period of the awards.

The Company accounts for share-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.

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 Food and Drug Administration ("FDA") approval for clinical trials. The Company has entered into an amendment to the CRADA to extend its term from September 30, 2009 through September 30, 2011.

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 longer-term goal is to secure one or more strategic partnerships with pharmaceutical companies with major programs in cancer, anti-fungal treatments, and/or neuroprotective measures. The Company's immediate focus has shifted to obtaining approval from the FDA to carry a lead compound of the LB-100 series into 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. In addition, the demonstration of clinical benefit would be very important to potential investors and to large pharmaceutical companies looking to add an entirely new approach to their anti-cancer drug portfolios.

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). Studies of the potential neuroprotective effects of homologs of each class of the Company's compounds are continuing under a contract with Southern Research Institute, Birmingham, Alabama.

Plans for 2011 and Beyond

The Company's primary objective is to complete studies needed for a successful application to the FDA for an Investigational New Drug ("IND") for the clinical evaluation of LB-100 by the end of the [second quarter of 2011]. The estimated cost for drug synthesis formulation, pharmacokinetic, and toxicologic studies needed for an IND application is currently estimated to cost approximately $1,200,000. Accordingly, the Company believes that it currently has sufficient capital to fund its operations, including the continued development of the LB-200 series and the sponsorship of a Phase I clinical trial of LB-100.

The critical need for the next step in the clinical development of LB-100 is to obtain IND approval from the FDA to administer the drug to patients. In order to do this, the Company must demonstrate that LB-100 can be administered safely to human beings at a dose and at a frequency that achieves the desired pharmacologic effect, in this case inhibition of a specific enzyme, without being associated with toxicities considered unacceptable. A compound that has a mechanism of action similar to that of LB-100 has been given with safety and benefit to cancer patients outside the United States in the past. This similar compound has a chemical feature which appears to be responsible for most of its toxicity. This feature has been removed from LB-100, making it likely that the Company's compound will be less toxic and, therefore, safer for human use.

With current resources, the Company will further characterize of the anti-cancer and anti-fungal activity of certain homologs of drugs of the LB-200 series. These studies would be done in collaboration with academic partners and with commercial research organizations.

As of March 16, 2011, Dr. Kovach will reduce his academic commitment to 60% from 80% to devote more time to the management of development of the Company's compounds. He will begin receiving compensation of $5,000 per month from the Company at that time.

Results of Operations

The Company is a development stage company and had not commenced revenue-generating operations at December 31, 2010.

Years Ended December 31, 2010 and 2009

General and Administrative Costs. For the year ended December 31, 2010, general and administrative costs were $436,142, which consisted of the fair value of stock options issued to directors and consultants of $160,712, consulting and professional fees of $205,309, insurance expense of $24,500, stock transfer fees of $9,257, travel and entertainment costs of $15,114, and other operating costs of $21,250.

For the year ended December 31, 2009, general and administrative costs were $1,053,611, which consisted of the fair value of restricted common stock and common stock warrants issued to a vendor of $198,000, the vested portion of the fair value of stock options issued to directors and consultants of $547,980, consulting and professional fees of $245,247, insurance expense of $24,019, stock transfer fees of $10,429, travel and entertainment costs of $4,742, and other operating costs of $23,194.

Depreciation. For the years ended December 31, 2010 and 2009, depreciation expense was $-0- and $128, respectively.

Research and Development Costs. For the year ended December 31, 2010, research and development costs were $445,542, which consisted of the vested portion of the fair value of stock options issued to a consultant and a vendor of $67,222, patent costs of $246,185, third-party contractor costs of $358,907, consulting fees to a related party of $17,708, reduced by $244,479 representing the proceeds of a government grant awarded to the Company.

For the year ended December 31, 2009, research and development costs were $496,517, which consisted of the vested portion of the fair value of stock options issued to a consultant and a vendor of $132,933, patent costs of $199,459, and third-party contractor costs of $164,125.

Interest Income. For the years ended December 31, 2010 and 2009, interest income was $1,434 and $155, respectively.

Net loss. For the year ended December 31, 2010, the Company incurred a net loss of $880,250, as compared to a net loss of $1,551,333 for the year ended December 31, 2009.

Liquidity and Capital Resources – December 31, 2010

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 2010 consolidated financial statements, has raised substantial doubt about the Company's ability to continue as a going concern (see "Going Concern" above").

The Company raised $500,000 in November 2009, $1,787,500 in January 2010 (of which $1,200,000 had been advanced to the Company at December 31, 2009), and $500,000 in February 2010, all through the sale of its securities to fund its business activities. The Company also received $244,279 from a federal grant program to support promising biotechnology initiatives. As a result, the Company believes that its current resources are adequate to fund operations at a minimum through the first quarter of 2012, at a level that will allow the continuation of the Company's two drug development programs currently in process and completion of the initial Phase I study of LB-100, if no unexpected delays occur in obtaining FDA approval in 2011.

Operating Activities. For the year ended December 31, 2010, operating activities utilized cash of $936,394, as compared to utilizing cash of $638,440 for the year ended December 31, 2009.

At December 31, 2010, the Company had a working capital surplus of $1,736,266, as compared to $1,301,082 at December 31, 2009.

Investing Activities. For the years ended December 31, 2010 and 2009, investing activities consisted of $1,576,006 and $25,000, respectively, being placed into a money market fund.

Financing Activities. For the year ended December 31, 2010, financing activities provided net cash of $1,087,500, consisting of the gross proceeds from the sale of securities of $2,287,500, less $1,200,000 of advances received through December 31, 2009 For the year ended December 31, 2009, financing activities provided net cash of $2,197,050, consisting of the gross proceeds from the sale of securities of $1,210,000, the proceeds advanced under the private placement pending at December 31, 2009 of $1,200,000, and the proceeds from the issuance of a note payable to a consultant of $100,000, reduced by the payment of private placement offering costs of $112,950 and the repayment of notes payable to a consultant of $200,000.

Principal Commitments

CRADA

Effective March 22, 2006, the Company entered into a CRADA, as amended, with the NINDS of the NIH. The CRADA is for a term of 66 months from the effective date and can be unilaterally terminated by either party by providing written notice within sixty days. The CRADA provides for the collaboration between the parties in the identification and evaluation of agents that target the Nuclear Receptor CoRepressor (N-CoR) pathway for gliomas cell differentiation. The CRADA also provides that NINDS and the Company will conduct research to determine if expression of N-CoR correlates with prognosis in gliomas 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.

Effective as of September 19, 2008, the Company entered into an agreement with the NIH providing the Company with an exclusive license for all patents submitted jointly with the NIH under the CRADA. The agreement provided for an initial payment of $25,000 to 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 agreement also provides for the Company to pay specified royalties based on (i) net sales by the Company and its sub-licensees, (ii) the achievement of certain clinical benchmarks, and (iii) the granting of sublicenses. The Company paid the initial $25,000 obligation on November 10, 2008 and charged the amount to general and administrative costs during the year ended December 31, 2008. As of December 31, 2010, no additional amounts were due pursuant to this agreement.

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-1" (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-3". Pursuant to the Chem-Master Agreement, as amended, the Company reimbursed Chem-Master for the costs of materials, labor and expenses aggregating $11,000 and $59,000 during the years December 31, 2010 and 2009, respectively.

On March 17, 2010, the Company engaged Theradex to assist the Company in bringing LB-100 through the FDA approval process at a total estimated cost of $105,064. As of December 31, 2010, $15,205 had been incurred and work was proceeding under this contract.

On April 15, 2010, the Company entered into an agreement with Ascentage Pharma Group to assist in the pharmacological characterization of the Company's proprietary compounds. As of December 31, 2010, this work had been completed at a total cost of $52,400. Ascentage Pharma Group is an offshoot of Ascenta Therapeutics, of which Dr. Mel Sorensen, a director of the Company, is the President and Chief Executive Officer and a director. Ascentage Pharma Group and Ascenta Therapeutics have a continuing business relationship and certain common shareholders. However, Dr. Sorensen does not have any direct business relationship with or ownership in Ascentage Pharma Group.

During the years ended December 31, 2010 and 2009, the Company has engaged Southern Research Institute to conduct a series of studies. As of December 31, 2010, one such study was in process, having a total estimated cost of $20,200, of which $10,100 had been paid.

Consulting Arrangements

On April 7, 2010, a new agreement was established with Dr. Mel Sorensen providing for consultation and advice over the ensuing twelve month period regarding the preparation and strategy for obtaining FDA approval for the clinical trial of the lead compound of the LB-100 series for an annual fee of $25,000, payable in two installments of $12,500 each due on April 15, 2010 and October 15, 2010. Both installments were paid as due.

The following table sets forth the Company's principal cash obligations and commitments for the next five fiscal years as of December 31, 2010 aggregating $266,676, of which $166,717 is included in current liabilities in the consolidated balance sheet at December 31, 2010.

		Payments Due by Year	
	Total	2011	2012
Research and development contracts	$ 99,959	$ 99,959	$ —
Liquidated damages payable under registration rights agreement	74,000	74,000	—
Due to stockholder	92,717	92,717	—
Total	$ 266,676	$ 266,676	$ —

Off-Balance Sheet Arrangements

At December 31, 2010, 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 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 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 with 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 principal executive and financial officer, has evaluated our internal control over financial reporting as of December 31, 2007 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, and taking into account changes to the business and operating structure of the Company in the intervening years, our management has concluded that our internal control over financial reporting was effective as of December 31, 2010.

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 final rules of the SEC that permanently exempt non-accelerated filers such as the Company from internal control audit requirements, and 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 2010 that materially affected or are reasonably likely to affect our internal controls over financial reports.

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, 2010. 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 Held with the Registrant
Dr. John S. Kovach	74	Chief Executive Officer, Director
Dr. Philip F. Palmedo	76	Director
Dr. Mel Sorensen	53	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 Lixte with the approval of the State University of New York at Stony Brook and the New York State Ethics Commission.

Dr. Philip F. Palmedo

Dr. Palmedo joined our board of directors on June 30, 2006. Dr. Palmedo has had a diversified career as a physicist, entrepreneur, corporate manager. Dr. Palmedo 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. Dr. Palmedo held the position of President and Managing Director until 1991 when Renaissance Technologies Corporation acquired the company. In 2005 he co-founded the quantitative hedge fund, Kepler Asset Management, and serves as Chairman and Managing Director of the firm.

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

Dr. Mel Sorensen

Dr. Sorensen is a medical oncologist who has dedicated his career to clinical cancer research since completing his oncology fellowship at the Mayo Clinic in 1988. Dr. Sorensen joined Ascenta Therapeutics in August 2004 as Board Director, President and Chief Executive Officer. In less than three years, Ascenta was transformed from a 5-person start-up with a single preclinical program into a clinical-stage company with over 65 FTFs and facilities in the US and China and development programs against three distinct targets. Prior to joining Ascenta Therapeutics, he spent approximately seven years each in patient care (St. Louis and Mayo Clinic), the National Cancer Institute and in leadership positions of clinical cancer research in the pharmaceutical industry (Bayer & GSK).

Throughout his career, Dr. Sorensen has been active in fostering public-private collaborations for clinical cancer research, with the National Cancer Institute (NCI) with C-Change, with Friends of Cancer Research (FOCR) and other organizations. He is a frequent speaker and panel participant on optimizing cancer R&D, including presentations at the Woodrow Wilson Center in Washington, D.C. in 2003 ("Confronting Cancer Now"), the 2004 Bioethical Symposium in Tampa, Florida ("Ethial Issues in Large Clinical Trials"), the 2005 Tokyo Pharma Partnering Conference and Shanghai's 2005 Bio-Forum conference, the 2005 Milken Institute's Global Conference ("Biopharmaceuticals: The Innovation Pipeline Race"), BIO 2006 ("Early-Stage Business Models in Cancer"), the March 2007 R&D Readers' Forum ("Biotech R&D Across Borders: The Ascenta Experience") in Philadelphia, and the China 2007 R&D Summit ("Making Innovative Medicines Faster and Cost-Efficiently") in Shanghai.

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, MN. 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., 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 2010.

ITEM 11. EXECUTIVE COMPENSATION

For the fiscal years ended December 31, 2010 and 2009, no individual, including Dr. John Kovach, our current Chief Executive Officer, received any compensation.

Option Grants in 2009 and 2010

None.

Aggregated Option Exercises in 2009 and 2010 Option Values at December 31, 2009 and at 2010

None.

Employment Agreements; Compensation

We have not entered into any employment agreements. As of December 31, 2010, we had no full-time employees. Effective March 15, 2011, Dr. Kovach will begin drawing a salary of $5,000 per month. He 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 share) vesting on September 12, 2008. 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.

In September 2007, the Company entered into a consulting agreement with Francis Johnson 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.

In July 2009, the Company entered into a consulting agreement with Pro-Active Capital Group, LLC ("Pro-Active") to provide consulting services for the Company for a period of 12 months and granted to Pro-Active 150,000 shares of restricted stock and three-year warrants to purchase an aggregate of 150,000 shares with exercise prices as follows: 50,000 shares at $0.75 per share; 50,000 shares at $1.00 per share; and 50,000 shares at $1.25 per share.

Director Compensation

Members of the 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 the vesting date at $0.333 per share, with one-half (100,000 shares) vesting annually on each of September 12, 2008 and 2009. Dr. Carter resigned as a board member on April 20, 2010.

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 Common Stock under the 2007 Plan exercisable for a period of five years from the date of exercisable 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 one-year period 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. On April 7, 2010, the Company entered into a new agreement with Dr. Sorensen providing for consultation and for a one-year period regarding the preparation and strategy for obtaining FDA approval for the clinical trial of the lead compound of the LB-100 series for an annual fee of $25,000, payable in two installments of $12,500 on April 15, 2010 and October 15, 2010. Effective March 1, 2011, this agreement was extended based at an annual payment of $25,000. Dr. Sorensen is also eligible to receive a bonus at the sole discretion of the board of directors.

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	2010	0	0	0	0	0	0	0	0
Director	2009	0	0	0	0	0	0	0	0
	2008	0	0	0	10,332	0	0	0	10,332
Stephen Carter	2010	0	0	0	0	0	0	0	0
Former Director	2009	0	0	0	71,260	0	0	0	71,260
	2008	0	0	0	102.085	0	0	0	102.085
Mel Sorensen	2010	0	0	0	37,398	0	0	17,708(3)	55,106
Director	2009	0	0	0	50,035	0	0	30,000	80,035
	2008	0	0	0	12,568	0	0	10,000	22,568

(1) Consists of grant date fair value calculated pursuant to Black-Scholes option-pricing model recognized as compensation expense in each fiscal year.

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

(3) Of the amount paid to Dr. Sorensen in 2010 of $25,000, $17,708 was charged to operations in 2010, and the balance of $7,292 will be charged to operations in 2011.

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

The following table sets forth, as of March 15, 2011, 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 15, 2011, there were 35,077,178 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 15, 2011, 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	48.5%
Dr. Philip F. Palmedo 248 Route 25A, No. 2 East Setauket, New York 11733	1,390,000(1)	3.9%
Dr. Mel Sorensen 248 Route 25A, No. 2 East Setauket, New York 11733	200,000(2)	0.6%
All officers and directors as a group (three persons)	18,611,786(1)(2)	51.3%
Gil Schwartzberg 269 South Beverly Drive, No. 1315 Beverly Hills, California 90212	7,433,700(3)	18.5%
Dr. Debbie Schwartzberg 269 South Beverly Drive, No. 1315 Beverly Hills, California 90212	6,838,845(4)	17.5%

(1) Includes options to purchase 390,000 shares of common stock and warrants to purchase 600,000 shares of common stock, which are immediately exercisable.

(2) Consists of options to purchase 200,000 shares of common stock, which are immediately exercisable.

(3) Includes 895,000 shares of common stock, options to purchase 2,000,000 shares of common stock, and warrants to purchase 1,000,000 shares of common stock owned directly by Mr. Schwartzberg. Also includes 204,700 shares of common stock owned by Continuum Capital Partners, LP, as to which Mr. Schwartzberg has sole voting, disposition and investment control; 684,000 shares of common stock and warrants to purchase 1,000,000 shares of common stock owned by the Julie Schwartzberg Trust, as to which Mr. Schwartzberg is the co-trustee; and 650,000 shares of common stock and warrants to purchase 1,000,000 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 2,000,000 shares of common stock owned directly by Debbie Schwartzberg, the wife of Mr. Schwartzberg, as to which Mr. Schwartzberg disclaims beneficial ownership or control. Options and warrants are immediately exercisable or within 60 days.

(4) Includes 1,504,845 shares of common stock and warrants to purchase 2,000,000 shares of common stock owned directly by Dr. Schwartzberg. Also includes 684,000 shares of common stock and warrants to purchase 1,000,000 shares of common stock owned by the Julie Schwartzberg Trust, as to which Dr. Schwartzberg is the co-trustee; and 650,000 shares of common stock and warrants to purchase 1,000,000 shares of common stock owned by the David N. Sterling Trust, as to which Dr. Schwartzberg is the co-trustee. Excludes 204,700 shares of common stock owned by Continuum Capital Partners, LP, as to which Mr. Schwartzberg, the husband of Dr. Schwartzberg, has sole voting, disposition and investment control; and 895,000 shares of common stock, options to purchase 2,000,000 shares of common stock, and warrants to purchase 1,000,000 shares of common stock owned directly by Mr. Schwartzberg, as to which Dr. Schwartzberg disclaims beneficial ownership or control. 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, 2010.

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.

Also, in prior years Dr. Kovach had advanced to us an aggregate of $92,717 to meet operating expenses, which has been presented as a current liability at December 31, 2010. Such advances are non-interest bearing and are due on demand.

See "ITEM 11. EXECUTIVE COMPENSATION - Directors Compensation" for disclosure with respect to payments to certain of our directors for services rendered.

(b) Director Independence

The Company considers Drs. Palmedo and Sorensen 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, 2009 and 2010 and for the interim periods in 2009 and 2010. The following table shows the fees that were incurred by us for audit and other services provided by Weinberg & Company, P.C. in fiscal 2009 and 2010.

	2009	2010
Audit Fees[1]	$ 41,401	$ 44,123
Audit-Related Fees[2]	—	—
Tax Fees[3]	2,275	8,585
All Other Fees[4]	2,373	—
Total	$ 46,049	$ 52,708

(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 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

Exhibits -

Exhibit No.	Description
2.1	Share Exchange Agreement dated as of June 8, 2006 among the Company, John S. Kovach and Lixte Biotechnology, Inc!
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]

Exhibit No.	Description
10.14	Consulting Agreement between the Company and Mel Sorensen dated October 7, 2008.[11]
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.

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.

Date: March 28, 2011

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
(Registrant)

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

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

Signature	Title	Date
/s/ John S. Kovach John S. Kovach	Chief Executive Officer, Principal Financial Officer, Principal Accounting Officer and Director	March 28, 2011
/s/ Philip F. Palmedo Philip F. Palmedo	Director	March 28, 2011
/s/ Mel Sorensen Mel Sorensen	Director	March 28, 2011

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, 2010 and 2009, and
Period from August 9, 2005 (Inception) to December 31, 2010 (Cumulative)

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of Lixte Biotechnology Holdings, Inc. and subsidiary (a development stage company) as of December 31, 2010 and 2009, 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, 2010 (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. An audit also includes 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, 2010 and 2009, 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, 2010 (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, 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. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

WEINBERG & COMPANY, P.A.
Los Angeles, California
March 28, 2011

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

CONSOLIDATED BALANCE SHEETS

	December 31, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash	$ 119,091	$ 1,543,991
Money market funds	1,601,006	25,000
Funds on deposit with law firm	50,000	—
Grant receivable	116,485	—
Advances on research and development contract services	10,100	5,000
Prepaid expenses and other current assets	34,646	27,354
Total current assets	1,931,328	1,601,345
Total assets	$ 1,931,328	$ 1,601,345
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 28,345	$ 83,546
Research and development contract liabilities	—	50,000
Liquidated damages payable under registration rights agreement	74,000	74,000
Due to stockholder	92,717	92,717
Total current liabilities	195,062	300,263
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 - 35,077,178 shares and 30,502,178 shares at December 31, 2010 and 2009, respectively	3,508	3,050
Advances under equity financing	—	1,200,000
Additional paid-in capital	7,662,559	5,147,583
Deficit accumulated during the development stage	(5,929,801)	(5,049,551)
Total stockholders' equity	1,736,266	1,301,082
Total liabilities and stockholders' equity	$ 1,931,328	$ 1,601,345

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, 2010
	2010	2009	(Cumulative)
Revenues	$ —	$ —	$ —
Costs and expenses:			
General and administrative costs, including $160,712 and $745,980 of stock-based compensation costs for the years ended December 31, 2010 and 2009, respectively, and $2,252,523 of stock-based compensation costs for the period from August 9, 2005 (inception) to December 31, 2010 (cumulative)	436,142	1,053,611	3,605,876
Depreciation	—	128	1,910
Research and development costs, including $67,222 and $132,933 of stock-based costs for the years ended December 31, 2010 and 2009, respectively, and $464,052 of stock-based costs for the period from August 9, 2005 (inception) to December 31, 2010 (cumulative). Research and development costs include $17,708 to a related party for the year ended December 31, 2010 and for the period from August 9, 2005 (inception) to December 31, 2010 (cumulative). Research and development costs for the year ended December 31, 2010 and for the period from August 9, 2005 (inception) to December 31, 2010 (cumulative) have been reduced by $244,479, representing the proceeds of a government grant related to such costs.	445,542	496,517	2,222,847
Reverse merger costs	—	—	50,000
Total costs and expenses	881,684	1,550,256	5,880,633
Loss from operations	(881,684)	(1,550,256)	(5,880,633)
Interest income	1,434	155	27,301
Interest expense	—	(1,232)	(2,469)
Liquidated damages under registration rights agreement	—	—	(74,000)
Net loss	$ (880,250)	$ (1,551,333)	$ (5,929,801)
Net loss per common share – Basic and diluted	$ (0.03)	$ (0.05)	
Weighted average common shares outstanding – Basic and diluted	34,736,082	29,318,178	

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, 2010

	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 costs	—	—	—	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 costs	250,000	25	—	890,669	—	890,694
Stock-based research and development costs	—	—	—	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 costs	—	—	—	357,987	—	357,987
Stock-based research and development costs	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 costs	150,000	15	—	745,965	—	745,980
Stock-based research and development costs	—	—	—	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
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 costs	—	—	—	160,712	—	160,712
Stock-based research and development costs	—	—	—	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

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, 2010
	2010	2009	(Cumulative)
Cash flows from operating activities:			
Net loss	$ (880,250)	$ (1,551,333)	$ (5,929,801)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	—	128	1,909
Stock-based compensation costs	160,712	745,980	2,252,523
Stock-based research and development costs	67,222	132,933	464,052
Changes in operating assets and liabilities:			
(Increase) decrease in -			
Funds on deposit with law firm	(50,000)	—	(50,000)
Grant receivable	(116,485)	—	(116,485)
Advances on research and development contract services	(5,100)	7,500	(10,100)
Prepaid expenses and other current assets	(7,292)	1,290	(34,646)
Increase (decrease) in -			
Accounts payable and accrued expenses	(55,201)	(24,938)	28,345
Liquidated damages payable under registration rights agreement	—	—	74,000
Research and development contract liabilities	(50,000)	50,000	—
Net cash used in operating activities	(936,394)	(638,440)	(3,320,203)
Cash flows from investing activities:			
Increase in money market funds	(1,576,006)	(25,000)	(1,601,006)
Purchase of office equipment	—	—	(1,909)
Net cash used in investing activities	(1,576,006)	(25,000)	(1,602,915)
Cash flows from financing activities:			
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	—	100,000	200,000
Proceeds advanced under equity financing	—	1,200,000	—
Repayment of notes payable to consultant	—	(200,000)	(200,000)
Cash acquired in reverse merger transaction	—	—	62,500
Gross proceeds from sale of securities	1,087,500	1,210,000	5,331,389
Payment of private placement offering costs	—	(112,950)	(446,147)
Advances received from stockholder	—	—	92,717
Net cash provided by financing activities	1,087,500	2,197,050	5,042,209
Cash:			
Net increase (decrease)	(1,424,900)	1,533,610	119,091
Balance at beginning of period	1,543,991	10,381	—
Balance at end of period	$ 119,091	$ 1,543,991	$ 119,091
Supplemental disclosures of cash flow information:			
Cash paid for -			
Interest	$ —	$ 2,465	$ 2,469
Income taxes	$ —	$ —	$ —
Non-cash financing activities:			
Decrease in advances under equity financing	$ 1,200,000	$ —	$ 1,200,000

See accompanying notes to consolidated financial statements.

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. ("Holdings"). 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 has been 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 was listed for trading on the OTC Bulletin Board commencing September 24, 2007 under the symbol "LIXT". It is presently traded on the OTC Market (also referred to as the "Pink Sheets") under the symbol "LIXT.PK".

Operating Plans

The Company is developing new treatments for human cancers for which better therapies are urgently needed. The Company's drug discovery process based on discerning clues to potential new targets for cancer treatments reported in the increasingly large body of literature characterizing the molecular variants, which characterize human cancers. In the past decade, there has been an unprecedented expansion in knowledge of biochemical defects in the cancer cell. The Company has assembled a small but intellectually diverse group which uses information about the regulatory pathways altered in cancer cells. 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, 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. The LB-100 series consists of novel structures, which have the potential to be first in their class and the latter group contains compounds, which have the potential to be the most effective of this class. The Company has demonstrated that 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 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. Because of the propensity of malignant melanoma to metastasize to the brain, recent studies have encompassed studying the effectiveness of drugs developed for the treatment of primary brain tumors to the treatment of melanoma as well.

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 two companies have an 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 Lixte'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 goal is to bring one lead compound of the LB-100 series to clinical trial. In late 2009 and early 2010, the Company raised sufficient financial resources to carry out the preclinical studies needed for an application to the FDA to carry out a Phase I trial. The Company has engaged a leading pharmaceutical company, a clinical research organization, and a drug development company specializing in pharmacologic and toxocologic characterization of new anticancer drugs to oversee and carry out all studies necessary for FDA approval to take the compounds into an initial clinical trial.

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 one of the Company's drug compounds, LB-100. This collaboration is a milestone-based approach in which NCI will first confirm studies of the LB-100 compound in an animal model of glioblastoma multiforme, the most common 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 Company believes that funds on hand should allow the Company to fund operations and to continue to grow its patent portfolio and maintain its applications for international protection of lead compounds of both the LB-100 and LB-200 series without raising additional funds until the first quarter of 2012.

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 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 2010 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, 2010, the Company had not yet commenced any revenue-generating operations. All activity through December 31, 2010 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 activities in 2011 will consist of continuing drug discovery and development efforts. The Company's primary goal will be to take the Company's LB-100 compound through a Phase I clinical trial by July 1, 2011. The Company raised $500,000 in November 2009, $1,787,500 in January 2010, and $500,000 in February 2010, all through the sale of its securities to fund its business activities. The Company also received $244,479 from the Internal Revenue Service under its Qualifying Therapeutic Discovery Grant program, consisting of $127,994 on October 29, 2010 and $116,485 on February 1, 2011. As a result, the Company believes that its current resources are adequate to fund operations at a minimum through the first quarter 2012 at a level that will allow the continuation of the Company's two drug development programs currently in process and completion of the initial Phase I trial of LB-100, if no unexpected delays occur in obtaining FDA approval in 2011.

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 trial, the next step will be to determine the anti-cancer activity against a particular type of human cancer in Phase II trials. To carry out Phase II trials, the Company anticipates that it will be necessary to raise additional funds in 2012 from a combination of debt or equity financings, and/or the sale, licensing or joint venturing of its intellectual properties. 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. Continued negative cash flows and lack of liquidity create significant uncertainty about the Company's ability to fully implement its operating plan beyond the first quarter of 2012, as a result of which the Company may have to reduce the scope of its planned 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.

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 are expensed as incurred. Research and development expenses 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.

Amounts that become due, pursuant to contractual commitments, on research and development contracts with third parties are recorded as a liability, with the related amount of such contracts recorded as advances on research and development contract services on the Company's balance sheet. Such advances on research and development contract services are expensed over their life 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. 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 $246,185 and $199,459 for the years ended December 31, 2010 and 2009, respectively, and $771,334 for the period from August 9, 2005 (inception) to December 31, 2010 (cumulative). Patent costs are included in research and development costs in the Company's consolidated statements of operations.

Income Taxes

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

The Company has elected to deduct research and development costs on a current basis for federal income tax purposes. 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 new 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. 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. The new accounting rules also provide guidance on de-recognition, classification, interest and penalties on income taxes, accounting in interim periods and requires increased disclosures. The adoption of the new accounting rules did not have a material effect on the Company's financial statements. As of December 31, 2010, 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 2008 and thereafter. The Company's policy is to record interest and penalties on uncertain tax provisions as income tax expense. As of December 31, 2010, 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 installments, consisting of $127,994 on November 9, 2010, and $116,485 on February 1, 2011, which has been reflected as a receivable at December 31, 2010. For financial statement purposes, the grant of $244,479 has been 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 share-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 over the vesting period of the awards.

The Company accounts for share-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, 2010 and 2009, the Company excluded the outstanding securities summarized below, which entitle the holders thereof to acquire shares of common stock, from its calculation of earnings per share, as their effect would have been anti-dilutive.

	December 31,	
	2010	**2009**
Warrants	13,607,426	4,457,426
Stock options	3,540,000	3,540,000
Total	17,147,426	7,997,426

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 April 2010, the Financial Accounting Standards Board ("FASB") issued new accounting guidance in applying the milestone method of revenue recognition to research or development arrangements. Under this guidance, management may recognize revenue contingent upon the achievement of a milestone in its entirety, in the period in which the milestone is achieved, only if the milestone meets all of the criteria within the guidance to be considered substantive. The new guidance is effective on a prospective basis for research and development milestones achieved in fiscal years beginning on or after June 15, 2010. Early adoption is permitted; however, adoption of this guidance as of a date other than January 1, 2011 would require the Company to apply this guidance retrospectively effective as of January 1, 2010, and would require disclosure of the effect of this guidance as applied to all previously reported interim periods in the fiscal year of adoption. As the Company plans to implement this guidance prospectively, the effect of this guidance will be limited to future transactions. The Company does not expect that adoption of this guidance will have any impact on its financial position or results of operations, as the Company does not have or currently expect to have any research and development arrangements which will be accounted for under the milestone method.

In January 2010, the FASB issued new accounting guidance which requires new disclosures regarding transfers in and out of Level 1 and Level 2 fair value measurements, as well as requiring presentation on a gross basis of information about purchases, sales, issuances and settlements in Level 3 fair value measurements. The new guidance also clarifies existing disclosures regarding level of disaggregation, inputs and valuation techniques. The new guidance is effective for interim and annual reporting periods beginning after December 15, 2009. Disclosures about purchases, sales, issuances and settlements in the roll forward of activity in Level 3 fair value measurements are effective for fiscal years beginning after December 15, 2010. As this guidance only requires additional disclosure, the Company does not expect that adoption of this guidance will have any impact on its financial position or results of operations.

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 and Private Placement

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 Holdings, Dr. John S. Kovach ("Seller") and Lixte, Holdings 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 Holdings.

Pursuant to the Exchange, Holdings issued to the Seller 19,021,786 shares of its common stock. Holdings 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.

The Share Exchange Agreement was determined through arms-length negotiations between Holdings, the Seller and Lixte. In connection with the Exchange, the Company paid WestPark Capital, Inc. an aggregate 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 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.

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 accrued six months liquidated damages under the registration rights agreement aggregating approximately $74,000, which has been presented as a current liability for all periods presented. 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, 2010, the registration penalty to the investors had not been paid.

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. 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.

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.

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.

4. Money Market Funds — Fair Value

Money market funds at December 31, 2010 and 2009 consisted of an investment in the Class A Shares of Western Asset New York Municipal Money Market Fund with a market value of $1,601,006 and $25,000, respectively. The stated purpose of this money market fund is to provide income exempt from both regular federal income tax and New York State and New York City personal income tax from a portfolio of high quality short-term municipal obligations selected for liquidity and stability of principal.

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 are 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, 2010 and 2009.

	Total	Level 1	Level 2	Level 3
December 31, 2010:				
Money market funds	$ 1,601,006	$ 1,601,006	$ —	$ —
December 31, 2009:				
Money market funds	$ 25,000	$ 25,000	$ —	$ —

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 and December 31, 2010 and 2009, stockholder advances 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.

Dr. Kovach did not receive any compensation from the Company during the years ended December 31, 2010 and 2009, and for the period from August 9, 2005 (inception) through December 31, 2010 (cumulative), in view of the Company's development stage status and limited resources. 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. Concomitant, Dr. Kovach will reduce his academic commitment from 80% to 60% to devote more time to the Company's activities.

Dr. Kovach is involved in other business activities and may, 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.

6. Notes Payable to Consultant

On October 3, 2008, the Company borrowed $100,000 from Gil Schwartzberg, a consultant to the Company, pursuant to an unsecured demand promissory note with interest at 5% per annum, to fund the Company's short-term working capital requirements. The note, including accrued interest of $834, was repaid on February 7, 2009. An additional interest payment of $851 was made on April 27, 2009.

On September 30, 2009, the Company borrowed $100,000 from Gil Schwartzberg pursuant to an unsecured demand promissory note with interest at 5% per annum, to fund the Company's short-term working capital requirements. The note, including accrued interest of $780, was repaid on November 26, 2009.

Additional transactions between the Company and Gil Schwartzberg are described in Note 8.

7. Common Stock and Preferred Stock

The Company's Certificate of Incorporation provides for authorized capital of 110,000,000 shares, of which 100,000,000 shares consist of common stock with a par value of $0.0001 per share and 10,000,000 shares consist of preferred stock with a par value of $0.0001 per share.

The Company is authorized to issue 10,000,000 shares of preferred stock with such designations, voting and other rights and preferences as may be determined from time to time by the Board of Directors.

8. Stock Options and Warrants

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, 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, 2006, effective with the closing of the Exchange, the Company granted to two members of its Scientific Advisory Committee stock options to purchase an aggregate of 100,000 shares of common stock 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, one of the members resigned from his position and waived his right to his vested stock option to purchase 50,000 shares of common stock.

On June 30, 2006, the fair value of the aforementioned stock options was initially calculated using the following Black-Scholes input variables: stock price - $0.333; exercise price - $0.333; expected life - 5 to 7 years; expected volatility - 150%; expected dividend yield - 0%; risk-free interest rate - 5%. On June 30, 2007, the Black-Scholes input variables utilized to determine the fair value of the aforementioned stock options were stock price - $0.333; exercise price - $0.333; expected life - 4 to 6 years; expected volatility - 150%; expected dividend yield - 0%; risk-free interest rate - 4.5%. On June 30, 2008, the fair value of the aforementioned stock options was calculated using the following Black-Scholes input variables: stock price - $0.30; exercise price - $0.333; expected life - 3 to 5 years; expected volatility - 154.5%; expected dividend yield - 0%; risk-free interest rate - 3.28%.

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) using the following Black-Scholes input variables: stock price on date of grant - $0.333; exercise price - $0.333; expected life - 5 years; expected volatility - 150%; expected dividend yield - 0%; risk-free interest rate - 4.5%. The $31,000 fair value 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 has been reflected as a charge to operations for the period from October 1, 2008 through February 5, 2009. On February 5, 2009, the fair value of this option, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $60,000 ($0.60 per share), which resulted in a charge to operations of $19,143 during the year ended December 31, 2009. The Company granted the second five-year option on February 5, 2009.

On September 30, 2008, the fair value of the aforementioned stock option was initially calculated using the following Black-Scholes input variables: stock price - $0.50; exercise price - $0.333; expected life – 5.35 years; expected volatility – 275.7%; expected dividend yield - 0%; risk-free interest rate – 2.48%. On February 5, 2009, the fair value of the aforementioned stock option was calculated for the stock option revaluation purposes using the following Black-Scholes input variables: stock price - $0.60; exercise price - $0.333; expected life – 5 years; expected volatility – 414.1%; expected dividend yield - 0%; risk-free interest rate – 1.89%.

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, valued at $75,000, and granted an option to purchase 200,000 shares of common stock. The option is 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 fair value of this option, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be $96,000 ($0.48 per share) using the following Black-Scholes input variables: stock price on date of grant - $0.75; exercise price - $1.65; expected life - 5 years; expected volatility - 120.1%; expected dividend yield - 0%; risk-free interest rate - 3.09%.

The fair value of the restricted common stock issued was charged to operations as research and development costs on January 29, 2008. On December 31, 2010, the fair value of the aforementioned stock options was determined to be $68,000 ($0.34 per share) calculated using the following Black-Scholes input variables: stock price - $0.35; exercise price - $1.65; expected life - 2.09 years; expected volatility – 325.4%; expected dividend yield - 0%; risk-free interest rate -1.92%, which resulted in a charge to operations of $18,989 during the year ended December 31, 2010. On December 31, 2009, the fair value of the aforementioned stock options was determined to be $94,000 ($0.47 per share) calculated using the following Black-Scholes input variables: stock price - $0.49; exercise price - $1.65; expected life - 3.09 years; expected volatility – 251.0%; expected dividend yield - 0%; risk-free interest rate - 1.40%, which resulted in a charge to operations of $46,201 during the year ended December 31, 2009..

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. During the year ended December 31, 2009, the Company recorded a charge to operations of $71,260 with respect to these options. Effective April 20, 2010, Dr. Carter resigned as a director for personal reasons. Consequently, pursuant to the stock option agreement, Dr. Carter has twelve months from April 20, 2010 to exercise his stock options to acquire 200,000 shares of the Company's common stock.

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 four years from the 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. 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, 2008, the fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $325,000 ($0.65 per share).

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 four years from the 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 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 is being charged to operations ratably from October 15, 2009 through October 15, 2010. On December 31, 2009, the fair value of the aforementioned stock options was determined to be $245,000 ($0.49 per share) calculated using the following Black-Scholes input variables: stock price - $0.49; exercise price - $1.00; expected life - 4.79 years; expected volatility – 251.0%; expected dividend yield - 0%; risk-free interest rate - 1.40%, which resulted in a charge to operations of $51,685 during the year ended December 31, 2009. On October 15, 2010, the fair value of the aforementioned stock options was determined to be $175,000 ($0.35 per share) calculated using the following Black-Scholes input variables: stock price - $0.35; exercise price - $1.00; expected life - 4.00 years; expected volatility – 325.4%; expected dividend yield - 0%; risk-free interest rate - 1.92%, which resulted in a charge to operations of $123,314 during the year ended December 31, 2010.

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), and is being charged to operations ratably from September 12, 2007 through September 12, 2010. On September 12, 2010, the fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $189,000 ($0.63 per share) which resulted in a charge to operations of $48,233 during the year ended December 31, 2010. On December 31, 2009, the fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $147,000 ($0.49 per share) which resulted in a charge to operations of $67,589 during the year ended December 31, 2009
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On September 12, 2007, the fair value of the aforementioned stock options was initially calculated using the following Black-Scholes input variables: stock price - $1.05; exercise price - $0.333 to $1.00; expected life - 4 to 6 years; expected volatility - 150%; expected dividend yield - 0%; risk-free interest rate - 5%. On October 15, 2009, the fair value of the aforementioned stock options was initially calculated using the following Black-Scholes input variables: stock price - $0.75; exercise price - $1.00; expected life - 5 years; expected volatility – 259.1%; expected dividend yield - 0%; risk-free interest rate – 1.91%. On September 12, 2010, the fair value of the aforementioned stock options was calculated for the stock option revaluation purposes using the following Black-Scholes input variables: stock price - $0.63; exercise price - $0.333; expected life – 4.02 years; expected volatility – 209.6%; expected dividend yield - 0%; risk-free interest rate - 0.52%. On December 31, 2009, the fair value of the aforementioned stock options was calculated for the stock option revaluation purposes using the following Black-Scholes input variables: stock price - $0.48; exercise price - $0.333; expected life - 4.72; expected volatility – 251.0%; expected dividend yield - 0%; risk-free interest rate – 1.40%.

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 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, being that 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 is a medical oncologist with extensive experience in cancer drug development, first at the National Cancer Institute, then at Bayer and GlaxoSmithKline, before becoming President and Chief Executive Officer of a new cancer therapeutics company, Ascenta Therapeutics, in 2004. 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 vests as to 25,000 shares on January 1, 2009, and a further 25,000 shares on the first day of each subsequent calendar quarter until all of the shares are 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 is being charged to operations ratably from October 7, 2008 through October 7, 2010. During the years ended December 31, 2010 and 2009, the Company recorded a charge to operations of $37,398 and $50,035, respectively, with respect to these options.

On October 7, 2008, the fair value of the aforementioned stock options was calculated using the following Black-Scholes input variables: stock price - $0.50; exercise price - $0.50; expected life - 5 years; expected volatility – 275.7%; expected dividend yield - 0%; risk-free interest rate – 2.48%.

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 the Company 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) using the following Black-Scholes input variables: stock price on date of grant - $0.67; exercise price - $0.75 to $1.25; expected life - 3 years; expected volatility – 259.1%; expected dividend yield - 0%; risk-free interest rate - 1.91%. The $198,000 aggregate fair value of the shares and warrants issued was charged to operations as stock-based compensation on July 27, 2009, as the shares and warrants were fully vested and non-forfeitable on the date of issuance.

Additional information with respect to common stock warrants and stock options issued is provided at Notes 3 and 10.

If and when the aforementioned stock options and warrants 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 and 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.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Options and warrants outstanding at December 31, 2008	3,086,626	$ 0.658	
Granted	4,910,800	0.668	
Exercised	—	—	
Cancelled	—	—	
Options and warrants outstanding at December 31, 2009	7,997,426	$ 0.664	
Granted	9,150,000	0.625	
Exercised	—	—	
Cancelled	—	—	
Options and warrants outstanding at December 31, 2010	17,147,426	$ 0.643	2.14
Options and warrants exercisable at December 31, 2009	7,027,026	$ 0.637	
Options and warrants exercisable at December 31, 2010	16,877,026	$ 0.639	2.13

Total deferred compensation expense for the outstanding value of unvested stock options was approximately $1,980 at December 31, 2010, which is being recognized subsequent to December 31, 2010 over a weighted-average period of one month.

Information regarding stock options and warrants outstanding and exercisable is summarized as follows at December 31, 2010:

Exercise Prices	Warrants And Options Outstanding (Shares)	Warrants And Options Exercisable (Shares)
$ 0.333	1,566,626	1,566,626
$ 0.500	7,535,800	7,365,400
$ 0.650	120,000	120,000
$ 0.750	5,625,000	5,625,000
$ 1.000	2,050,000	2,050,000
$ 1.250	50,000	50,000
$ 1.650	200,000	100,000
	17,147,426	16,877,026

The intrinsic value of exercisable but unexercised in-the-money stock options and warrants at December 31, 2010 was $26,633, based on a fair market value of $0.35 per share on December 31, 2010. The intrinsic value of exercisable but unexercised in-the-money stock options and warrants at December 31, 2009 was $230,260, based on a fair market value of $0.49 per share on December 31, 2009.

Outstanding options and warrants to acquire 100,000 shares of the Company's common stock had not vested at December 31, 2010. At December 31, 2010, warrants and options exercisable do not include warrants to acquire 170,400 shares of common stock that are contingent upon the exercise of warrants contained in units sold as part of the third private placement (see Note 3).

9. 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, 2009 and 2008 are summarized below.

	December 31,	
	2010	2009
Start-up and organization costs	$ 76,000	$ 104,000
Contingent liability	31,000	31,000
Net operating loss carryforwards	1,115,000	951,000
Total deferred tax assets	1,222,000	1,086,000
Valuation allowance	(1,222,000)	(1,086,000)
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, 2010 and 2009, 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, 2010 and 2009 due to the losses incurred during such periods. A reconciliation 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, 2010 and 2009 is summarized below.

	Years Ended December 31,	
	2010	2009
U. S. federal statutory tax rate	(34.0)%	(34.0)%
Non-deductible stock-based compensation	8.8%	19.3%
Reduction to operating loss attributed to government grant	9.4%	—
Adjustment to deferred tax asset	3.1%	(1.7)%
Change in valuation allowance	12.6%	16.4%
Other	0.1%	—
Effective tax rate	0.0%	0.0%

At December 31, 2010, the Company has available net operating loss carryforwards for federal income tax purposes of approximately $2,686,000 which, if not utilized earlier, expire in 2029.

10. Commitments and Contingencies

CRADA

Effective March 22, 2006, the Company entered into a CRADA, as amended, with the NINDS of the NIH. The CRADA is for a term of 66 months from the effective date and can be unilaterally terminated by either party by providing written notice within sixty days. The CRADA provides 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 provides that NINDS and the Company will 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 has 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.

Effective as of September 19, 2008, the Company entered into an agreement with the NIH providing the Company with an exclusive license for all patents submitted jointly with the NIH under the CRADA. The agreement provided for an initial payment of $25,000 to 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 agreement also provides for the Company to pay specified royalties based on (i) net sales by the Company and its sub-licensees, (ii) the achievement of certain clinical benchmarks, and (iii) the granting of sublicenses. The Company paid the initial $25,000 obligation on November 10, 2008 and charged the amount to general and administrative costs during the year ended December 31, 2008. As of December 31, 2010, no additional amounts were due pursuant to this agreement.

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-1”, 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-3”. Pursuant to the Chem-Master Agreement, as amended, the Company reimbursed Chem-Master for the costs of materials, labor and expenses aggregating $11,000 and $59,000 during the years December 31, 2010 and 2009, respectively.

On March 17, 2010, the Company engaged Theradex to assist the Company in bringing LB-100 through the FDA approval process at a total estimated cost of $105,064. As of December 31, 2010, $15,205 had been incurred and work was proceeding under this contract.

On April 15, 2010, the Company entered into an agreement with Ascentage Pharma Group to assist in the pharmacological characterization of the Company's proprietary compounds. As of December 31, 2010, this work had been completed at a total cost of $52,400. Ascentage Pharma Group is an offshoot of Ascenta Therapeutics, of which Dr. Mel Sorensen, a director of the Company, is the President and Chief Executive Officer and a director. Ascentage Pharma Group and Ascenta Therapeutics have a continuing business relationship and certain common shareholders. However, Dr. Sorensen does not have any direct business relationship with or ownership in Ascentage Pharma Group.

During the years ended December 31, 2010 and 2009, the Company has engaged Southern Research Institute to conduct a series of studies. As of December 31, 2010, one such study having a total estimated cost of $20,200, of which $10,100 had been paid, was in process.

Consulting Arrangements

On April 7, 2010, a new agreement was established with Dr. Mel Sorensen providing for consultation and advice over the ensuing twelve month period regarding the preparation and strategy for obtaining FDA approval for the clinical trial of the lead compound of the LB-100 series for an annual fee of $25,000, payable in two installments of $12,500 on April 15, 2010 and October 15, 2010. Both installments were paid as due.

The following table sets forth the Company's principal cash obligations and commitments for the next five fiscal years as of December 31, 2010 aggregating $266,676, of which $166,717 is included in current liabilities in the consolidated balance sheet at December 31, 2010.

		Payments Due By Year	
	Total	**2011**	**2012**
Research and development contracts	$ 99,959	$ 99,959	$ —
Liquidated damages payable under registration rights agreement	74,000	74,000	—
Due to stockholder	92,717	92,717	—
Total	$ 266,676	$ 266,676	$ —

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., certify that:

2. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2010 of Lixte Biotechnology Holdings, Inc.;

3. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

4. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

5. 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 report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

6. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: March 28, 2011

By: /s/ JOHN S. KOVACH
Name: John 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, 2010 (the "Annual Report") with the Securities and Exchange Commission, I, John S. Kovach, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

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

Date: March 28, 2011

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