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, 2008

☐ **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.

(Name of registrant in its charter)

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

Issuer'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 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, 2008: $0

Aggregate market value of the common stock held by non-affiliates of the registrant as of June 30, 2008 was approximately $3,273,177.

There were 28,852,178 shares of the Company's common stock outstanding on March 25, 2009.

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Introductory Comment

Throughout this Annual Report on Form 10-K, the terms "we," "us," "our," "our company," "Company" and "the Registrant" refer to Lixte Biotechnology Holdings, Inc.., a Delaware corporation formerly known as SRKP 7, Inc.

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 prospectus, which would cause actual results to differ before making an investment decision. We are under no duty to update any of these forward-looking statements after the date of this Report or to conform these statements to actual results.

PART I

ITEM 1. DESCRIPTION OF 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 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. Throughout this Report, when we refer to Lixte, we are referring to Lixte Biotechnology, Inc., our operating subsidiary.

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 two 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.

BUSINESS

The Company is developing new treatments for several human cancers for which better treatments are urgently needed. The primary focus is on the most common and most aggressive type of brain cancer of adults, glioblastoma multiforme ("GBM"). The Company, however, has expanded the scope of its drug development program to other cancers of neural tissue (nerve and brain), including medulloblastoma, the most common brain tumor of children, and neuroblastoma, the most common cancer of children, and to several of the most common cancers. The expansion of the scope of the program is based on documentation that each of two distinct types of drugs being developed by the Company inhibits the growth of cell lines of GBM, medulloblastoma, neuroblastoma, and pancreatic cancer in animal models of these diseases and is also active against breast, colon, lung, prostate, ovary, stomach and liver cancer and the major types of leukemias in cell culture. The Company has also recently shown that certain of its compounds are active against fungi that cause life-threatening diseases and other compounds are active against fungi responsible for the majority of skin and nail infections. In addition, the Company found that still other of its compounds affect biochemical pathways such that they may be potentially useful for the treatment of common neurodegenerative diseases such as Alzheimer's disease. These non-cancer applications are under evaluation in collaboration with outside experts.

The research on brain tumors is being conducted 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") initiated on March 22, 2006. The research at NINDS is 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 under the CRADA. The goal of the CRADA is to develop more effective drugs for the treatment of GBM through the steps needed to gain Food and Drug Administration ("FDA") approval for clinical trials. The Company's $200,000 financial obligation due under the CRADA as of March 22, 2007 was paid on June 29, 2007, and funded ongoing research and development activities through June 30, 2008. 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 has agreed to provide additional funding under the CRADA of $200,000, to be paid in four quarterly installments of $50,000 commencing on October 1, 2008.

Patent applications on work done under the CRADA are jointly owned by NIH and Lixte. NIH co-inventors assign their rights to NIH. Under the CRADA, Lixte is entitled to negotiate an exclusive license from NIH to all claims in these patent applications. The Company and NIH concluded negotiations and executed an exclusive license on seven patent filings effective September 19, 2008. Pursuant to the Agreement, PHS has granted an exclusive license of all of PHS' rights in seven patent applications filed by the Company. The majority of these patent applications are related to the use of certain compounds of the Company for the treatment of glioblastoma multiforme, neuroblastoma, and medulloblastoma as well as the potential use of two biomarkers as either diagnostic tests or in assays for the screening of compounds for anti-cancer activity. The Company requested that PHS grant to the Company full rights to these inventions in order to develop processes, methods or marketable products for public use and benefit. The Agreement provides for an initial license fee, minimum annual royalty payments, payments at various milestones in the clinical development of the licensed compounds, and a percentage of net sales of the licensed compounds. The Company has also filed patent applications for intellectual property owned solely by the Company. These applications concern two series of new anti-cancer agents referred to as the LB-100 series and the LB-200 series. The applications include identification of the structure of molecules, their synthesis, and their anti-cancer, anti-fungal, and potential neuroprotective activities. In February 2008, the Company converted provisional patent applications relating to the nature and activity of the LB-100 series of drugs with the filing of a U.S. non-provisional and a PCT patent application and is in the process of converting provisional patent applications for the LB-200 series.

The Company filed five patent applications on August 1, 2008. Two of these filings deal with applications filed earlier jointly with NIH for work done under the CRADA: (1) a filing entering the regional stage of a PCT application involving the use of certain compounds to treat human tumors expressing a biomarker for brain and other human cancers, and (2) an application for the treatment of the pediatric tumors, medulloblastoma (the most common brain tumor in children) and neuroblastoma (a tumor arising from neural cells outside the brain that is the most common cancer of children). The three new patent applications include (1) a joint application with NIH identifying a new biomarker for many common human cancers that when targeted by compounds developed by the Company result in inhibition of growth and death of cancer cells; (2) an application by the Company regarding the structure, synthesis and use of a group of new homologs of its LB-1 compounds; and (3) an application by the Company for the use of certain homologs of its drugs as neuroprotective agents with potential application to common neurodegenerative conditions such as Alzheimer's and Parkinson's diseases.

During 2007, the Company also documented that some of its compounds have activity against several types of fungi that cause serious infections, particularly in immuno-compromised individuals, such as those with HIV-AIDS and those having bone marrow transplantations. This finding extends the potential use of some of Lixte's compounds to the large and important field of therapy of life-threatening mycotic infections.

On April 23, 2008, the Company announced that its CRADA collaborators, Dr. Jie Lu and Dr. Zhengping Zhuang of the Surgical Neurology Branch, NINDS, reported the activity of compound, LB-100, against human glioblastoma multiforme cells in a mouse model of cancer at the Annual Meeting of the American Association of Cancer Research. On August 8, 2008, the Company announced that lead compounds from both the LB-100 and LB-200 series inhibit human pancreatic cancer cells growing in mice. The pancreatic cancer studies are early and there is no evidence that these drugs are able to eliminate pancreatic cancers but rather may slow their growth.

The Company expects that its products will derive directly from the intellectual property generated by its research. Progress to date has borne out this expectation. The development of lead compounds with different mechanisms of action that have now been shown to have activity against brain tumors and several other more common cancers as well as serious fungal infections, originated from the discovery of a biomarker most prominent in GBM. The Company continues to use biomarker discovery to provide insights as to the potential biochemical vulnerabilities of cancers expressing the biomarker.

The Company elected to exercise its right to terminate the second year of an agreement with the University of Regensburg, Germany, for collection of certain numbers of tumors and other biological samples for research programs in the future. Under the agreement, the University of Regensburg will complete ascertainment of 50% of the original number of samples. Lixte estimates that this collection will be sufficient for its needs for the next two to three years. In addition, Lixte has identified a commercial source of such materials that can be purchased in quantities as needed. Cancellation of the second year of the agreement resulted in a saving of Euro 36,000 (about $52,000).

The Company faces several potential challenges to its goal of commercial success. These include raising sufficient capital to fund its business plan, achieving commercially applicable results from its research programs, competition from more established, well-funded companies with competitive technologies, and future competition from companies developing new competitive technologies. Because of these challenges, there is substantial uncertainty as to the Company's ability to fund its operations and continue as a going concern (see "ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS- Going Concern").

The Company expects to participate in clinical trials of new therapies in partnership with an organization experienced in such undertakings. The partnering organization may be either a clinical branch of NIH or a pharmaceutical company with expertise in the conduct of clinical trials. The Company's present position is to take one or more of its new therapies for the treatment of glioblastoma multiforme through pre-clinical evaluation as part of the CRADA with the NINDS of the NIH. After completing pre-clinical evaluation, the Company will consider partnering with the NIH to conduct a Phase I Trial or jointly with the NIH to seek a third party, most probably a large pharmaceutical company, to carry the new therapies into Phase I trials. After completion of Phase I trials, the Company, potentially in partnership with the NIH, would collaborate with the third party to carry new therapies found to be safe for administration to humans in the Phase I trials into Phase II trials.

Phase II trials test the safety and effectiveness, as well as the best estimate of the proper dose of the new therapies, in a group of patients with the same type of cancer at the same stage. For the Company's initial studies, the focus will be brain tumors. The duration of Phase II trials may run from 6 to 24 months. New regimens showing beneficial activity in Phase II trials may then be considered for evaluation in Phase III trials. Phase III trials for the evaluation of new cancer treatments are comparative trials in which the therapeutic benefit of a new regimen is compared to the therapeutic benefit of the best standard regimen in a randomized study.

Whether the Company will participate in or be in a position to participate in any clinical trials will depend upon partnerships and specific licensing agreements. However, in all cases of clinical trial participation, the Company will be subject to FDA regulation. These regulations are specific and form the basis for assessing the potential clinical benefit of new therapeutic regimens while safeguarding the health of patients participating in investigational studies. Even after a drug receives approval from the FDA for sale as a new treatment for a specific disease indication, the sponsors of the drug are subject to reporting potentially adverse effects of the new regimen to the FDA.

Given the progress in identifying two lead compounds with activity in animal models of GBM, medulloblastoma, and neuroblastoma, the Company is devoting its resources to bring the agents to a point at which an Investigational New Drug ("IND") application can be submitted to the FDA for a Phase I clinical trial. One lead compound (LB-100) is the most advanced in the process and the Company plans to be ready for IND submission by [early 2009]. The other lead compound will be selected from among several variants of the LB-200 series that have comparable anti-cancer activity but differ in properties that favor administration by oral or intravenous routes.

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 an assay indicates that a particular cell is very likely to be present in the body. In this memorandum, "**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. GBM is the initial target of Lixte Biotechnology, Inc.

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.

Intellectual Property

The Company filed five patent applications August 1, 2008. Two of these filings deal with applications filed earlier jointly with NIH for work done under the CRADA: (1) a filing entering the regional stage of a PCT application involving the use of certain compounds to treat human tumors expressing a biomarker for brain and other human cancers, and (2) an application for the treatment of the pediatric tumors, medulloblastoma (the most common brain tumor in children) and neuroblastoma (a tumor arising from neural cells outside the brain that is the most common cancer of children). The three new patent applications include: (1) a joint application with NIH identifying a new biomarker for many common human cancers that when targeted by compounds developed by the Company result in inhibition of growth and death of cancer cells; (2) an application by the Company regarding the structure, synthesis and use of a group of new homologs of its LB-1 compounds; and (3) an application by the Company for the use of certain homologs of its drugs as neuroprotective agents with potential application to common neurodegenerative conditions such as Alzheimer's and Parkinson's diseases.

During 2007, the Company also documented that some of its compounds have activity against several types of fungi that cause serious infections, particularly in immuno-compromised individuals, such as those with HIV-AIDS and those having bone marrow transplantations. This finding extends the potential use of some of Lixte's compounds to the large and important field of therapy of life-threatening mycotic infections.

Development of New Drugs

On February 5, 2007, the Company entered into an agreement with Chem-Master International, Inc. pursuant to which we engaged Chem-Master to synthesize the compounds designated the LB-100 series and other compounds subsequently named the LB-2 series pursuant to our request, which have potential use in treating a disease, including, without limitation, cancers such as glioblastomas. Pursuant to the Agreement, we agreed to grant to Chem-Master a five-year option to purchase 100,000 shares of our common stock with an exercise price of $0.333 per share. Additionally, provided that the Agreement is not terminated by us without cause or by any party for cause prior to the second anniversary of the Agreement, we agreed to grant to Chem-Master a five-year option to purchase an additional 100,000 shares of the Company's common stock at $0.333 share. We have agreed to reimburse Chem-Master for the cost of materials, labor and expenses in providing the synthesis.

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 amendment, Lixte issued 100,000 shares of its restricted common stock, valued at $75,000, and granted an option to Chem-Master to purchase 200,000 shares of the Company's common stock.

The Market

Lixte's Anti-cancer Drugs

Lixte has developed 2 series of pharmacologically active drugs, the LB-100 series and the LB-200 series. 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 both series also have activity against human pancreatic cancer in an animal model. Furthermore, lead compounds of the LB-100 and LB-200 series have been shown to enhance the effectiveness of commonly used anti-cancer drugs in model systems. It is hoped, therefore, that some of the compounds, when combined with standard anti-cancer regimens against many tumor types, will improve therapeutic benefit without enhancing toxicity. It remains to be seen whether only therapeutic activity will be enhanced without increased toxicity. However, 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 and drugs of the LB-200 series have only one competing agent in that it has a similar mechanism of action in clinical use.

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 Lixte 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, as experimental data in model systems suggest, the Lixte compounds are active against other tumor types, this will dramatically enhance their value. If the Lixte compounds enhance the therapeutic benefit of other standard cancer regimens for common cancers such as those of the lung and breast, Lixte believes that their potential market is substantial.

Lixte's Diagnostic Biomarkers

Lixte 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 Lixte'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 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.

Marketing Plan

The primary goal of the Company is development of its lead compounds through approval by the FDA for Phase I trials. Once FDA approval is obtained, because of the novelty and spectrum of activity of both types of drugs, the Company believes it is likely it will find a partner in the pharmaceutical industry with interest in these agents. It is also possible that a major company will be interested in licensing the drugs before FDA approval, but the Company would prefer to delay partnering/licensing until the potential value of its products is augmented by demonstrating there is no impediment to clinical evaluation.

Development of biomarkers for diagnostic purposes will require a partner for development. Resources permitting, however, the Company will develop assays for the biomarkers through service contracts and samples of serum and/or cerebrospinal fluid will be analyzed for the biomarker. The goal will be to show that the biomarker(s) is present in a high percentage of samples from patients with the same type of cancer, a requirement for a potentially useful diagnostic test.

Research and Development

Founded as a cancer biomarker company, Lixte has evolved into what is primarily a cancer drug discovery company. This transition was achieved by adding capabilities in medicinal chemistry and pharmacology (including efficient low-cost synthesis of small molecules) to expertise in clinical cancer drug development and molecular and cellular biology. Lixte's current intellectual property includes lead compounds from each of two different types of pharmacological agents. The LB-100 series has the potential to be the first of its type in clinical cancer treatment (first-in-class) and a lead compound from the LB-200 series has the potential to be competitive for best-in-class. Lixte believes that there is only one approved drug with a mechanism of action similar to the LB-200 series in the clinic at present.

Activity of lead compounds from both series has been demonstrated against a broad spectrum of human cancer cell types in cell culture and in animal models including glioblastoma multiforme (the most common and aggressive brain cancer of adults), medulloblastoma (the most common brain cancer of children), neuroblastoma (the most common cancer of children), and pancreatic cancer (a devastating cancer of adults). In addition to anti-cancer activity as single agents, lead compounds of both types enhance the activity of widely used chemotherapeutic drugs. The Lixte compounds are likely to be able to be combined with many standard anti-cancer regimens to enhance therapeutic effectiveness without enhancing toxicity. These features have the potential for generating significant commercial value. Other important features of Lixte's lead compounds are the possibilities that some homologs have neuroprotective, anti-inflammatory, and anti-infective activities. Lixte is initially exploring these potential applications with academic collaborators.

On October 9, 2008, Lixte engaged Southern Research Institute, Birmingham, Alabama, to assess one lead compound from each of its two classes of proprietary pharmacological agents for effects on normal neuronal cells and to determine if the compounds protect normal brain cells from injury in several different models of chemical and traumatic brain injury. The goal is to determine if these agents have promise as drugs potentially useful for the prevention, amelioration, or delay of progression of neurodegenerative diseases such as Alzheimer's disease and other neurological diseases or impairments resulting from trauma and/or other diverse or unknown origins.

Further development of lead compounds from each group 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 human beings safely by routes and at doses resulting in concentration of drug producing anti-cancer activity in animal model systems. Lixte 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.

A secondary objective is to develop sensitive and specific assays for identification of potential therapeutic targets and for the early detection for several common cancers. Most cancers produce abnormal proteins or abnormal amounts of normal proteins. How many of these potential biomarkers are present at detectable concentrations in the blood is not known. Using stringent criteria for biomarker selection, analysis of small numbers of a given type of cancer is sufficient for detection of relevant biomarkers. If potential biomarkers for early diagnosis are discovered for several types of cancer, such as the one already identified for GBMs, we will prioritize their development in the following order: stomach, ovary, prostate, colon, bladder, and kidney.

The Company's most valuable resource, however, 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 neuroblastoma, medulloblastoma, and /or glioblastoma multiforme. The choice will depend in part upon pre-IND discussions with the FDA.

Product Overview

Our products will derive directly from our 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. Lixte 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 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.

We believe that there are four main markets for potential products that may be developed by Lixte.

1. **Improved Anti-Cancer Treatments.** Improved chemotherapy regimens for cancers not curable by surgery or radiation. This 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 is actively evaluating the activity of several compounds against different fungal pathogens.

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 and Parkinson's diseases, 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 determine whether the biomarkers of interest are present in the serum (other fluids) in most if not all of a small number of patients with the same cancer and will explore the interest of a large diagnostic company to undertake clinical development. Development of biomarkers for useful clinical assays is a complex and expensive process.

Product Development

We will become subject to FDA regulations at such time as we pursue development of clinical trials. Additionally, 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.

Competition

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

Employees

As of December 31, 2008, we had no full-time employees. Dr. Kovach is a Professor (part-time) in the Department of Preventive Medicine at State University of New York, 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 our outstanding shares.

Our 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 is monitoring the research progress under the CRADA. Dr. Kovach's contributions are made outside of his academic responsibilities. He directs, coordinates, and manages scientific and business development with the advice of the Company's Board, 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 intends to add 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, our business is not subject to any specific government regulation with respect to its ongoing research and plan service agreement. Our 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.

Our business will become subject to the regulations of the FDA when we begin 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 our CRADA is to identify, characterize, and bring to clinical trial regimens for the treatment of human brain tumors (GBMs). We estimate that we are at least one year from being in a position to begin discussing development of a clinical trial. Such a clinical trial would most likely be conducted by us in association with a pharmaceutical company in association with NIH under the existing CRADA or under a new CRADA or with a pharmaceutical company without association with NIH. In either case, we would be primarily responsible for filing and obtaining approval from the FDA of an Investigational New Drug Application (IND). In the event that we seek to raise sufficient capital to conduct a phase I clinical trial without a partner in the pharmaceutical industry in collaboration with NIH or independently, we would become subject to FDA regulation as we 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 we would obtain such exemption. During a new drug's early preclinical development, our 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, we 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 we, having screened the new molecule for pharmacological activity and acute toxicity potential in animals, want to test its diagnostic or therapeutic potential in humans. At that point, the molecule changes in legal status 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, we 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, the side effects associated with increasing doses, and to gain early evidence of effectiveness. If we were to conduct clinical trials on our own, it is likely that only a Phase I type trial would be done. In such a trial a new investigational drug or combination of drugs is first introduced into humans. For the evaluation of anti-cancer drugs, patients entering such trials are those for whom no means of therapy is known to be associated with benefit. Such studies are closely monitored and require approval from the FDA, including a proposal for the conduct of the clinical trial.

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 our future activities, we 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. We are not able to predict whether any such regulations will be adopted or whether, if adopted, such regulations will apply to our business, or whether we or our collaborators would be able to comply with any applicable regulations.

In addition, as we intend to market our products in international markets, we 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. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. As we are currently in the development stage, we cannot predict the impact on us 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;
- 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 has a stockholders' deficiency at December 31, 2008. As a result, the Company's independent registered public accounting firm, in their report on the Company's 2008 consolidated financial statements, have raised substantial doubt about the Company's ability to continue as a going concern.

Because the Company is currently engaged in research at an early stage, it will likely take a significant amount of time to develop any product or intellectual property capable of generating revenues. As such, the Company's business is unlikely to generate any revenue 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 does not have sufficient resources to fund its operations, including the Company's research activities with respect to its intellectual property, for the next twelve months. In addition, the Company does not have sufficient resources to fully develop and commercialize any products that may arise from its research. Accordingly, the Company needs to raise additional funds in order to satisfy its future working capital requirements.

The Company estimates that it will require minimum funding in calendar 2009 of approximately $750,000 in order to fund operations and continuing drug discovery and to attempt to bring two drugs through the pre-clinical evaluation process needed for submission of an Investigational New Drug ("IND") application. Towards that objective, the Company recently initiated a private placement, which generated net proceeds from two closings in February and March 2009 aggregating approximately $382,000. The Company utilized a portion of such net proceeds to repay a $100,000 short-term note in February 2009. The Company is continuing its efforts in 2009 to raise approximately $500,000 of additional funds under the private placement. There can be no assurances that the Company will have further success in this regard. The amount and timing of future cash requirements will depend on the market's evaluation of the Company's technology and products, if any, and the resources that it devotes to developing and supporting its activities. The Company will need to fund these cash requirements from a combination of additional debt or equity financings, or the sale, licensing or joint venturing of its intellectual properties.

Current 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, 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.

If we are unable to secure licenses to technologies or materials vital to our business, or if the rights to technologies that we have licensed terminate, our commercialization efforts could be delayed or fail.

In February 2006, a provisional patent application was filed covering certain methods and classes of molecules that we expect to be the foundation of our product development and commercialization efforts with respect to human brain tumors that are subject to the CRADA. In February 2007, a PCT international patent covering all countries participating in the Patent Cooperation Treaty was filed and a similar non-provisional patent was filed in the United States, containing all claims in the provisional patent plus additional claims. Any patents resulting from these applications will be jointly owned by us and the U.S. Government. We have executed an agreement with the government granting to us exclusive commercialization rights with respect to those patents. If those licenses terminate and we are unable to renew them, or must renew them only on unfavorable terms, such events could require us to cease providing products or services using such licensed technology and, therefore, would likely result in loss of revenue for our business.

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, as well as the continued availability and contributions of Dr. Zhengping Zhuang and other collaborators at the NIH. In particular, Dr. Kovach is 72 years old, and, because of his arrangement with the State University of New York, does not devote his full time to us, although Dr. Kovach generally devotes a minimum of twenty hours a week to our business. The loss of services of any of these persons could delay or reduce our product development and commercialization efforts. Furthermore, recruiting and retaining qualified scientific personnel to perform future research and development work will be critical to our success. The loss of members of our scientific personnel, or our inability to attract or retain other qualified personnel or advisors, could significant weaken our management, harm our ability to compete effectively and harm our business.

Our key personnel are involved in other business activities and may face a conflict in selecting between their other business interests and our business.

Dr. John Kovach, our Chief Executive Officer, also is a Professor (part-time) in the Department of Preventive Medicine at State University of New York, Stony Brook, New York. He may also become involved in the future with other business opportunities, which may become available. Accordingly, our key personnel may face a conflict in selecting between us and their other business interests. We have not formulated a policy for the resolution of such conflicts. Dr. Zhengping Zhuang is a full-time employee of NIH. He participates with the Company under a CRADA with NIH that defines the scope of his collaboration, and he does not face a conflict of interest.

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

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

Dr. Kovach is experienced in the design and conduct of early clinical cancer trials, having been the lead investigator for a National Cancer Institute Phase I contract for ten years at the Mayo Clinic, Rochester, Minnesota. 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.

Clinical development, including preclinical testing, is a long, expensive and uncertain process. Prior to conducting preclinical studies and clinical trials in humans, we anticipate that the following steps will be taken: Identification of lead compounds in vitro studies, followed by documentation of activity in an animal model of a particular disease entity, and determination of toxicity of the new therapy(s) in an animal system usually consisting of the mouse and often the dog. For new diagnostic tests, pre-clinical studies involve demonstration of recognition of specific endpoints associated with the presence or progression of disease in a manner that suggest relevance to clinical diagnosis and/or assessment of prognosis. It is expected that for us to carry its new treatments to clinical trials, an agreement will be negotiated with (1) NIH to conduct the trial as part of a new CRADA or (2) a pharmaceutical company, most probably in conjunction with NIH as co-inventor of the new therapies. Accordingly, preclinical testing and clinical trials, if any, of our product candidates under development may not be successful. We and our collaborators could experience delays in preclinical or clinical trials of any of our product candidates, obtain unfavorable results in a development program, or fail to obtain regulatory approval for the commercialization of a product. Preclinical studies or clinical trials may produce negative, inconsistent or inconclusive results, and we or our collaborators may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials. The results from early clinical trials may not be statistically significant or predictive of results that will be obtained from expanded, advanced clinical trials.

Furthermore, the timing and completion of clinical trials, if any, of our product candidates depend on, among other factors, the number of patients we will be required to enroll in the clinical trials and the rate at which those patients are enrolled. Any increase in the required number of patients, decrease in recruitment rates or difficulties retaining study participants may result in increased costs, program delays or both.

Also, 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 based on the pending provisional patent application we recently filed. 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 our products were derived from tissue or other samples from a patient without the patient's consent, we could be forced to pay royalties or cease selling our products.

An essential component of our business is our ability to obtain well-characterized tissue and other samples from patients. To that end, on January 5, 2007, we entered into an agreement with the Institute of Pathology at the University of Regensburg in Germany to collect samples of colon, kidney, bladder, stomach, breast, prostate, and ovarian cancers for biomarker discovery programs focused on these cancers. The Agreement has now been terminated. Although we believe that all necessary consents have been and will be obtained from any patient who donates samples for our research purposes, there is a risk that, without our knowledge and through inadvertence or neglect, proper consents will not be obtained from all patients. The responsibility for obtaining the consents is vested in the physicians at the University. If a patient does not give a proper consent and we develop a product using a sample obtained from him or her, we could be forced to pay royalties or to cease selling that product. All tissue samples are de-identified when they are sent to us. We have no way to link any of our studies to an individual patient. Therefore, the risk of an individual patient objecting to development of any product is extremely remote.

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.

To date, we have sought to protect our proprietary position by filing for a Patent Cooperation Treaty patent and a non-provisional patent in the U.S. related to inventions that form the basis of our research arrangements with the NIH and potential pipeline of future products. We also filed new patent applications in the U.S. in February 2007 relating to a lead compound that has activity against glioblastoma multiform cell lines in vitro. We anticipate that we will apply for further patents based on our ongoing research. 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 Bulletin Board, an active trading market for the securities does not yet exist and may not exist or be sustained in the future. The OTC Bulletin Board 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 Bulletin Board 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 Bulletin Board 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, and 999,995 shares in a December 2007 private placement, 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 59% of our outstanding voting stock at the current time. As a result, Dr. Kovach possesses significant influence, giving him the 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. DESCRIPTION OF PROPERTY

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.

ITEM 3. LEGAL PROCEEDINGS

We are not a party to any legal proceedings.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

There were no matters submitted to a vote of the Company's security holders during the quarterly period ended December 31, 2008.

PART II

ITEM5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock trades on the OTC Bulletin Board under the symbol "LIXT." There is very limited trading of our stock on the Bulletin Board. 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 that the Stock began to trade on the Bulletin Board. 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

Year Ended December 31, 2008	High	Low
First Quarter	$ 1.10	$ 0.74
Second Quarter	$ 1.10	$ 0.30
Third Quarter	$ 0.80	$ 0.22
Fourth Quarter	$ 1.10	$ 0.15
Year Ended December 31, 2007		
Third Quarter	$ 1.05	$ 0.75
Fourth Quarter	$ 1.10	$ 0.75

Holders

As of March 25, 2009, we have 28,852,178 shares of our common stock outstanding. As of December 31, 2008, our shares of common stock are 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, 2008, the most recently completed fiscal year.

Plan Category	Number of Securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
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"), 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 and do not include the historical financial results of SRKP. 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.

Lixte was incorporated in Delaware on August 9, 2005 to capitalize on opportunities 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.

The Company is considered a "development stage company" as defined in Statement of Financial Accounting Standards ("SFAS") No. 7, "Accounting and Reporting by Development Stage Enterprises", 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 has selected December 31 as its fiscal year end.

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. Furthermore, the Company has experienced recurring losses and has a stockholders' deficiency at December 31, 2008. As a result, the Company's independent registered public accounting firm, in their report on the Company's 2008 consolidated financial statements, have 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 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, 2008, the Company had not yet commenced any revenue-generating operations. All activity through December 31, 2008 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 revenue 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 does not have sufficient resources to fund its operations, including the Company's research activities with respect to its intellectual property, for the next twelve months. In addition, the Company does not have sufficient resources to fully develop and commercialize any products that may arise from its research. Accordingly, the Company needs to raise additional funds in order to satisfy its future working capital requirements.

The Company estimates that it will require minimum funding in calendar 2009 of approximately $750,000 in order to fund operations and continuing drug discovery and to attempt to bring two drugs through the pre-clinical evaluation process needed for submission of an Investigational New Drug ("IND") application. Towards that objective, the Company recently initiated a private placement, which generated net proceeds from two closings in February and March 2009 aggregating approximately $382,000. The Company utilized a portion of such net proceeds to repay a $100,000 short-term note in February 2009. The Company is continuing its efforts in 2009 to raise approximately $500,000 of additional funds under the private placement. There can be no assurances that the Company will have further success in this regard. The amount and timing of future cash requirements will depend on the market's evaluation of the Company's technology and products, if any, and the resources that it devotes to developing and supporting its activities. The Company will need to fund these cash requirements from a combination of additional debt or equity financings, or the sale, licensing or joint venturing of its intellectual properties.

Current 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, 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 Developments

On January 30, 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.

Each unit consists 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 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 $0.50 per share and 10% of the number of shares issuable upon exercise of warrants issued in the private placement exerciseable at $0.50 per share; and (b) an additional 2% of the number of shares sold in the 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 private placement exerciseable at $0.50 per share.

On February 7, 2009, the Company repaid a $100,000 unsecured demand promissory note, including interest at the rate of 5% per annum, to Gil Schwartzberg, a consultant to the Company.

Adoption of New Accounting Policies in 2008

In September 2006, the Financial Accounting Standards Board ("FASB") issued SFAS No. 157, "Fair Value Measurements" ("SFAS No. 157"), which establishes a formal framework for measuring fair value under Generally Accepted Accounting Principles ("GAAP"). SFAS No. 157 defines and codifies the many definitions of fair value included among various other authoritative literature, clarifies and, in some instances, expands on the guidance for implementing fair value measurements, and increases the level of disclosure required for fair value measurements. Although SFAS No. 157 applies to and amends the provisions of existing FASB and American Institute of Certified Public Accountants ("AICPA") pronouncements, it does not, of itself, require any new fair value measurements, nor does it establish valuation standards. SFAS No. 157 applies to all other accounting pronouncements requiring or permitting fair value measurements, except for: SFAS No. 123R, "Share-Based Payment", and related pronouncements, the practicability exceptions to fair value determinations allowed by various other authoritative pronouncements, and AICPA Statements of Position 97-2 and 98-9 that deal with software revenue recognition. The Company adopted SFAS No. 157 on January 1, 2008.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities" ("SFAS No. 159"), which provides companies with an option to report selected financial assets and liabilities at fair value. The objective of SFAS No. 159 is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. Generally accepted accounting principles have required different measurement attributes for different assets and liabilities that can create artificial volatility in earnings. SFAS No. 159 helps to mitigate this type of accounting-induced volatility by enabling companies to report related assets and liabilities at fair value, which would likely reduce the need for companies to comply with detailed rules for hedge accounting. SFAS No. 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS No. 159 requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of the company's choice to use fair value on its earnings. SFAS No. 159 also requires companies to display the fair value of those assets and liabilities for which the company has chosen to use fair value on the face of the balance sheet. SFAS No. 159 does not eliminate disclosure requirements included in other accounting standards, including requirements for disclosures about fair value measurements included in SFAS No. 157 and SFAS No. 107. The Company adopted SFAS No. 159 on January 1, 2008.

In May 2008, the FASB issued Statement of Financial Accounting Standards No. 162, "The Hierarchy of Generally Accepted Accounting Principles" ("SFAS No. 162"). SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with GAAP. SFAS No. 162 became effective on November 15, 2008.

On October 10, 2008, the FASB issued FASB Staff Position No. 157-3, "Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active" ("FSP FAS No. 157-3"). FSP FAS No. 157-3 clarifies the application of SFAS No. 157, "Fair Value Measurements", in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. FSP FAS No. 157-3 became effective immediately, and includes prior period financial statements that have not yet been issued, and therefore the Company became subject to the provisions of FSP FAS No. 157-3 on October 10, 2008.

The adoption and/or implementation of the aforementioned accounting pronouncements did not have any effect on the Company's consolidated financial statement presentation or disclosures.

Recently Issued Accounting Pronouncements

In December 2007, the FASB issued SFAS No. 141(R), "Business Combinations" ("SFAS No. 141(R)"), which requires an acquirer to recognize in its financial statements as of the acquisition date (i) the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree, measured at their fair values on the acquisition date, and (ii) goodwill as the excess of the consideration transferred plus the fair value of any noncontrolling interest in the acquiree at the acquisition date over the fair values of the identifiable net assets acquired. Acquisition-related costs, which are the costs an acquirer incurs to effect a business combination, will be accounted for as expenses in the periods in which the costs are incurred and the services are received, except that costs to issue debt or equity securities will be recognized in accordance with other applicable GAAP. SFAS No. 141(R) makes significant amendments to other Statements and other authoritative guidance to provide additional guidance or to conform the guidance in that literature to that provided in SFAS No. 141(R). SFAS No. 141(R) also provides guidance as to what information is to be disclosed to enable users of financial statements to evaluate the nature and financial effects of a business combination. SFAS No. 141(R) is effective for financial statements issued for fiscal years beginning on or after December 15, 2008. Early adoption is prohibited. The adoption of SFAS No. 141(R) on January 1, 2009 will affect how the Company accounts for a business combination concluded after December 31, 2008.

In December 2007, the FASB issued SFAS No. 160, “Noncontrolling Interests in Consolidated Financial Statements — an amendment of ARB No. 51” (“SFAS No. 160”), which revises the relevance, comparability, and transparency of the financial information that a reporting entity provides in its consolidated financial statements by establishing accounting and reporting standards that require (i) the ownership interests in subsidiaries held by parties other than the parent be clearly identified, labeled, and presented in the consolidated statement of financial position within equity, but separate from the parent’s equity, (ii) the amount of consolidated net income attributable to the parent and to the noncontrolling interest be clearly identified and presented on the face of the consolidated statement of income, (iii) changes in a parent’s ownership interest while the parent retains its controlling financial interest in its subsidiary be accounted for consistently as equity transactions, (iv) when a subsidiary is deconsolidated, any retained noncontrolling equity investment in the former subsidiary be initially measured at fair value, with the gain or loss on the deconsolidation of the subsidiary being measured using the fair value of any noncontrolling equity investment rather than the carrying amount of that retained investment, and (v) entities provide sufficient disclosures that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS No. 160 amends FASB No. 128 to provide that the calculation of earnings per share amounts in the consolidated financial statements will continue to be based on the amounts attributable to the parent. SFAS No. 160 is effective for financial statements issued for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. Early adoption is prohibited. SFAS No. 160 shall be applied prospectively as of the beginning of the fiscal year in which it is initially applied, except for the presentation and disclosure requirements, which shall be applied retrospectively for all periods presented. The Company does not currently anticipate that the adoption of SFAS No. 160 on January 1, 2009 will have any impact on its consolidated financial statement presentation or disclosures.

In March 2008, the FASB issued SFAS No. 161, “Disclosures about Derivative Instruments and Hedging Activities - an amendment of FASB Statement No. 133” (“SFAS No. 161”). SFAS No. 161 amends and expands the disclosure requirements of SFAS No. 133, “Accounting for Derivative Instruments and Hedging Activities” (“SFAS No. 133”). The objective of SFAS No. 161 is to provide users of financial statements with an enhanced understanding of how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for under SFAS No. 133 and its related interpretations, and how derivative instruments and related hedged items affect an entity’s financial position, financial performance, and cash flows. SFAS No. 161 requires qualitative disclosures about objectives and strategies for using derivatives, quantitative disclosures about fair value amounts of and gains and losses on derivative instruments, and disclosures about credit-risk-related contingent features in derivative agreements. SFAS No. 161 applies to all derivative financial instruments, including bifurcated derivative instruments (and nonderivative instruments that are designed and qualify as hedging instruments pursuant to paragraphs 37 and 42 of SFAS No. 133) and related hedged items accounted for under SFAS No. 133 and its related interpretations. SFAS No. 161 also amends certain provisions of SFAS No. 131. SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. SFAS No. 161 encourages, but does not require, comparative disclosures for earlier periods at initial adoption. The Company does not currently anticipate that the adoption of SFAS No. 161 on January 1, 2009 will have any impact on its consolidated financial statement presentation or disclosures.

In June 2008, the FASB ratified Emerging Issues Task Force (“EITF”) Issue No. 07-05, "Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock" (“EITF 07-05”). EITF 07-05 mandates a two-step process for evaluating whether an equity-linked financial instrument or embedded feature is indexed to the entity's own stock. Warrants that a company issues that contain a strike price adjustment feature, upon the adoption of EITF 07-05, results in the instruments no longer being considered indexed to the company's own stock. Accordingly, adoption of EITF 07-05 will change the current classification (from equity to liability) and the related accounting for such warrants outstanding at that date. EITF 07-05 is effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. The Company does not currently anticipate that the adoption of EITF 07-05 on January 1, 2009 will have any impact on its consolidated financial statement presentation or disclosures.

Management does not believe that any other recently issued, but not yet adopted, accounting pronouncements issued by the FASB (including its Emerging Issues Task Force), the AICPA, and/or the Securities and Exchange Commission will have a material impact on the Company's consolidated financial statement presentation or disclosures in future periods.

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 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 accounts for its research and development contracts in accordance with EITF 07-3, “Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities”.

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 fees, are expensed as incurred.

Stock-Based Compensation

The Company accounts for share-based payments pursuant to SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS No. 123R"), a revision to SFAS No. 123, "Accounting for Stock-Based Compensation". SFAS No. 123R requires that the Company measure the cost of employee services received in exchange for equity awards based on the grant date fair value of the awards, with the cost to be recognized as compensation expense in the Company’s financial statements over the vesting period of the awards.

The Company accounts for stock option and warrant grants issued and vesting to non-employees in accordance with EITF No. 96-18, "Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services", and EITF 00-18, "Accounting Recognition for Certain Transactions involving Equity Instruments Granted to Other Than Employees", whereas the value of the stock compensation is based upon the measurement date as determined 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. In accordance with EITF 96-18, 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.

Income Taxes

The Company accounts for income taxes pursuant to SFAS No. 109, "Accounting for Income Taxes" ("SFAS No. 109"), which establishes financial accounting and reporting standards for the effects of income taxes that result from an enterprise's activities during the current and preceding years. SFAS No. 109 requires 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 is concentrating on developing 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 inhibits the growth of cell lines of breast, colon, lung, prostate, pancreas, ovary, stomach and liver cancer, as well as the major types of leukemias. Activity of lead compounds of both types of drugs was recently demonstrated against human pancreatic cancer cells in a mouse model. Because there is a great need for any kind of effective treatment for pancreatic cancer, this cancer will be studied concomitantly with the primary target of the Company's research program focused on brain cancers.

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 CRADA was extended and is presently scheduled to end on September 30, 2009.

The Company filed five patent applications on August 1, 2008. Two of these patent filings deal with applications filed earlier jointly with NIH for work done under the CRADA as follows: (1) a filing entering the regional stage of a PCT application involving the use of certain compounds to treat human tumors expressing a biomarker for brain and other human cancers; and (2) an application for the treatment of the pediatric tumors, medulloblastoma (the most common brain tumor in children) and neuroblastoma (a tumor arising from neural cells outside the brain that is the most common cancer of children). The three new patent applications include: (1) a joint application with NIH identifying a new biomarker for many common human cancers that when targeted by compounds developed by the Company result in inhibition of growth and death of cancer cells; (2) an application by the Company regarding the structure, synthesis and use of a group of new homologs of its LB-1 compounds; and (3) an application by the Company for the use of certain homologs of its drugs as neuroprotective agents with potential application to common neurodegenerative conditions such as Alzheimer's and Parkinson's diseases.

The Company continues to evaluate compounds for activity against several types of fungi that cause serious infections, particularly in immuno-compromised individuals, such as those with HIV-AIDS, and those having bone marrow transplantations. The Company is also exploring indications that its compounds have against strains of fungi that cause the most common fungal infections of the skin and nails. Discussions are in progress with experts in fungal infections regarding the most reliable methods of assessing the potential of new agents for the management of common fungal diseases.

The Company expects that its products will derive directly from the intellectual property from its research activities. The development of lead compounds with different mechanisms of action that have activity against brain tumors and other common human cancers, as well as against serious fungal infections, originated from the discovery of a biomarker in GBM. The Company will continue to use discovery and/or recognition of molecular variants characteristic of specific human cancers as a guide to drug discovery and potentially new diagnostic tests. Examples of the productivity of this approach to discovery of new therapeutics are: (1) the recent patent application filing for a new biomarker of several common cancers that when targeted by certain of the Company's drugs results in inhibition of growth and death of cancer cells displaying the marker; and (2) the filing of a patent on certain homologs of one group of compounds as potentially useful for the treatment of neurodegenerative diseases.

Plans for 2009 and Beyond

The Company's primary objective is to raise funds to cover ongoing operations and development of its lead compounds for the treatment of brain cancers of adults and neuroblastoma in children and to expand its research to include another devastating human cancer, pancreatic cancer. The Company also wishes to raise sufficient capital to explore, most likely in partnership with a pharmaceutical company, recently discovered activity of some derivatives of its lead drugs for the treatment of fungal diseases and neurodegenerative diseases. In this regard, the Company has made preliminary presentations to several large pharmaceutical companies with respect to one or both of its lead compounds.

The first goal is to initiate preclinical studies of two of its lead compounds required for submission of an application to the FDA for evaluation in clinical trials. The initial target cancers will be glioblastoma multiforme, neuroblastoma and/or medulloblastoma. The final choice will depend in part upon discussions at a pre-IND meeting with the FDA. Subject to the availability of sufficient resources, the Company will also initiate preclinical evaluation of a second compound.

The second goal is further characterization of the fungal activity of certain homologs of drugs of the LB-200 series. These studies will be done in collaboration with academic partners. Recently, the Company confirmed that its lead compound of the LB-200 series is curative of two types of fungi that are representative of the most common skin infections of humans and domestic animals. Cure was achieved by topical application of the drug on a daily basis for 14 days, with no evidence of toxicity.

The Company is also screening other homologs of lead compounds of the LB-100 and LB-200 series for neuroprotective activity in laboratory models of brain cell injury. During October 2008, the Company engaged Southern Research Institute, Birmingham, Alabama, to assess one lead compound from each of two classes of its proprietary pharmacological agents for effects on normal neuronal cells and to determine if the compounds protect normal brain cells from injury in several different models of chemical and traumatic brain injury. The goal is to determine if these agents have promise as potentially useful for the prevention, amelioration or delay of progression of neurodegenerative diseases such as Alzheimer's disease and other neurological diseases or impairments resulting from trauma and/or other diverse or unknown origins. The initial studies in the test tube support the Company's hypothesis that one of its lead compounds appears to have a beneficial effect upon the growth and differentiation of normal brain cells.

Given the progress in identifying two lead compounds with activity in animal models of GBM, the Company is devoting its resources to bring the agents to a point at which an Investigational New Drug ("IND") application can be submitted to the FDA for a Phase I clinical trial. One lead compound (LB-1) is the most advanced in the process and the Company plans to be ready for IND submission in mid-2010. The other lead compound (LB-2.5), which inhibits cancer cells by a mechanism distinct from that of LB-1, is anticipated to complete its evaluation by the end of 2010. If the Company is able to achieve support from and/or partnership with a large pharmaceutical company to co-develop its compounds, this schedule may be accelerated. The drugs are well characterized from the standpoints of activity and mechanism of action. The pre-clinical activity toxicology and pharmacokinetic characterization, which are elements needed for IND submission, could be accomplished quickly with adequate financial resources or by a partner with expertise in characterization of drugs for introduction into the clinic.

On January 29, 2008, the Chem-Master Agreement was amended to extend its term to February 15, 2014, pursuant to which Chem-Master was engaged to synthesize certain compounds, and to expressly provide for the expansion of the Company's drug development program, through consultation with the medicinal chemists at Chem-Master. The Company is exploring the synthesis of additional novel anti-cancer drugs. Several targets for anti-cancer drug development are under consideration. When the next group of compounds is developed, it will be designated as "LB-3", as distinguished from the first two classes of compounds that were designated as "LB-1" and "LB-2". This process is currently in the planning stage and no compounds have been made as yet.

Existing resources will not permit evaluation of activity of the Company's lead drugs against all the common cancers against which the Company's compounds may have anti-cancer activity. Current resources also will not be sufficient to carry out pre-clinical studies necessary to apply to the FDA for approval of drug evaluations in Phase I trials.

The Company estimates that it will require minimum funding in calendar 2009 of approximately $750,000 in order to fund operations and continuing drug discovery and to attempt to bring two drugs through the pre-clinical evaluation process needed for submission of an Investigational New Drug ("IND") application. Towards that objective, the Company recently initiated a private placement, which generated net proceeds from two closings in February and March 2009 aggregating approximately $382,000. The Company utilized a portion of such net proceeds to repay a $100,000 short-term note in February 2009. The Company is continuing its efforts in 2009 to raise approximately $500,000 of additional funds under the private placement. If additional funds in excess of $500,000 are raised in 2009, the detailed characterization of the Company's drugs in preparation for submission of an IND will be initiated. There can be no assurances that the Company will have further success in this regard. The amount and timing of future cash requirements will depend on the market's evaluation of the Company's technology and products, if any, and the resources that it devotes to developing and supporting its activities. The Company will need to fund these cash requirements from a combination of additional debt or equity financings, or the sale, licensing or joint venturing of its intellectual properties.

The Company faces several potential challenges in its efforts to achieve commercial success, including raising sufficient capital to fund its business plan, achieving commercially applicable results of its research programs, competition from more established, well-funded companies with competitive technologies, and future competition from companies that are developing new competitive technologies, some of whom are larger companies with greater capital resources than the Company. Because of these challenges, there is substantial uncertainty as to the Company's ability to fund its operations and continue as a going concern (see "Going Concern" above). Should the Company be unable to raise the required capital on a timely basis, the Company's business plans would be materially adversely affected, and the Company may not be able to continue to conduct operations.

Results of Operations

The Company is a development stage company and had not commenced revenue-generating operations at December 31, 2008.

Years Ended December 31, 2008 and 2007

General and Administrative Expenses. For the year ended December 31, 2008, general and administrative expenses were $664,202, which consisted of stock-based compensation of $357,987, the initial payment of $25,000 made in connection with the Company's exclusive license agreement with NIH, consulting and professional fees of $192,473, insurance expense of $23,821, travel and entertainment costs of $31,221, and other operating costs of $33,700.

For the year ended December 31, 2007, general and administrative expenses were $1,203,722, which consisted of stock-based compensation of $890,444, consulting and professional fees of $248,903, insurance expense of $27,312, travel and entertainment costs of $7,278, and other operating costs of $29,785.

Depreciation. For the years ended December 31, 2008 and 2007, depreciation expense was $615 and $592, respectively.

Research and Development Costs. For the year ended December 31, 2008, research and development costs were $608,733, which consisted of the fair value of restricted common stock issued to a vendor of $75,000, the vested portion of the fair value of stock options issued to a consultant and a vendor of $138,061, patent costs of $164,782, laboratory supplies of $45,750, and other costs of $185,140.

For the year ended December 31, 2007, research and development costs were $454,723, which consisted of the vested portion of the fair value of stock options issued to a vendor of $50,836, patent costs of $94,232, laboratory supplies of $30,895, and other costs of $278,760.

Interest Income. For the year ended December 31, 2008, interest income was $3,261, as compared to interest income of $10,549 for the year ended December 31, 2007.

Net Loss. For the year ended December 31, 2008, the Company incurred a net loss of $1,271,522, as compared to a net loss of $1,648,488 for the year ended December 31, 2007.

Liquidity and Capital Resources - December 31, 2008

The Company's 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 has a stockholders' deficiency at December 31, 2008. 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 profitable operations. The Company's financial statements do not include any adjustments that might result from the outcome of these uncertainties (see "Going Concern" above").

Operating Activities. For the year ended December 31, 2008, operating activities utilized cash of $597,689, as compared to utilizing cash of $702,868 for the year ended December 31, 2007, primarily as a result of a decrease in advances on research and development contract services in 2008, as compared to amounts spent on research and development contract services in 2007 related to an installment payment made under the CRADA in 2007.

The Company had a working capital deficiency of $323,676 at December 31, 2008. At December 31, 2007, the Company had working capital of $376,184, primarily as a result of the sale of the Company's common stock pursuant to a second private placement in December 2007 that generated net proceeds of $531,320.

Investing Activities. There were no investing activities during the year ended December 31, 2008. For the year ended December 31, 2007, investing activities utilized cash of $272 for the purchase of office equipment.

Financing Activities. For the year ended December 31, 2008, financing activities consisted of proceeds from a note payable to a consultant in the amount of $100,000. For the year ended December 31, 2007, financing activities provided net cash of $531,570, consisting of the gross proceeds from the sale of common stock of $650,000, reduced by the payment of private placement offering costs of $118,680.

Principal Commitments

At December 31, 2008, the Company did not have any material commitments for capital expenditures. The Company's principal commitments at December 31, 2008 consisted of $100,000 due on a note payable to a consultant, the liquidated damages payable under the registration rights agreement of $74,000, and the contractual obligations as summarized below.

Effective March 22, 2006, Lixte entered into a CRADA, as amended, with the NINDS of the NIH. The CRADA is for a term of 42 months from the effective date and may 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 provided that NINDS and Lixte will conduct research to determine if expression of N-CoR correlates with prognosis in glioma patients. Pursuant to the CRADA, Lixte 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. However, for the period from October 1, 2008 through September 30, 2009, the Company has 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 installments of $50,000 were paid on September 29, 2008 and March 5, 2009, respectively.

On February 5, 2007, Lixte entered into a two-year 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 Lixte engaged Chem-Master to synthesize a compound designated as "LB-1", and any other compound synthesized by Chem-Master pursuant to Lixte's request, which have potential use in treating a disease, including, without limitation, cancers such as glioblastomas. Pursuant to the Chem-Master Agreement, Lixte 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 100,000 shares of the Company's common stock at an exercise price of $0.333 per share. Lixte 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, the Company has 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. The Company granted the second five-year option on February 5, 2009.

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 amendment, the Company issued 100,000 shares of its restricted common stock and granted an option to purchase 200,000 shares of common stock. The option is exercisable for a period of two years from 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.

Pursuant to the Chem-Master Agreement, the Company reimbursed Chem-Master for the costs of materials, labor, and expenses aggregating $45,750 and $30,150 during the years ended December 31, 2008 and 2007, respectively.

During September 2008, the Company engaged an internet-based investor information service, to enhance awareness of the Company's progress in developing a portfolio of pharmacological agents at an initial cost of $2,500, plus $500 per month for a period of twelve months.

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.

During October 2008, the Company engaged Southern Research Institute, Birmingham, Alabama, to assess one lead compound from each of two classes of its proprietary pharmacological agents for effects on normal neuronal cells and to determine if the compounds protect normal brain cells from injury in several different models of chemical and traumatic brain injury. The goal is to determine if these agents have promise as potentially useful for the prevention, amelioration or delay of progression of neurodegenerative diseases such as Alzheimer's disease and other neurological diseases or impairments resulting from trauma and/or other diverse or unknown origins. The Company agreed to pay a fee not to exceed $50,000 over a four-month period for such services, of which an advance for $12,500 was paid during 2008.

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 CEO of a new cancer therapeutics company, Ascenta Therapeutics, in 2004. Dr. Sorensen is being 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.

Off-Balance Sheet Arrangements

At December 31, 2008, 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 financial statements and notes thereto and the related reports of our independent registered public accounting firms are attached to this Report beginning on page F-1.

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

On December 17, 2008, AJ. Robbins, P.C. ("Robbins") was dismissed as the independent accountant of the Company. The Board of Directors acting in the capacity of an audit committee approved the dismissal of Robbins.

Robbins' reports on the Company's financial statements for the years ended December 31, 2007 and 2006 did not contain any adverse opinion or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles except that the report for both years indicated that the Company is in the development stage and has not commenced operations and its ability to continue as a going concern is dependent upon its ability to develop additional sources of capital and ultimately achieve profitable operations. Accordingly, such report indicated that there was substantial doubt as to the Company's ability to continue as a going concern and that the financial statements did not include any adjustments that might result from the outcome of this uncertainty.

During the years ended December 31, 2007 and 2006 and through December 17, 2008, there were no disagreements with Robbins on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of Robbins, would have caused it to make reference thereto in connection with its reports on the financial statements for such years. During the years ended December 31, 2007 and 2006 and through December 17, 2008, there were no matters that were either the subject of a disagreement as defined in Item 304(a)(1)(iv) of Regulation S-K or a reportable event as described in Item 304(a)(1)(v) of Regulation S-K.

On December 17, 2008, the Company's Board of Directors acting in the capacity of an audit committee engaged Weinberg & Company, P. A. ("Weinberg") as the Company's new independent accountant to act as the principal accountant to audit the Company's financial statements. During the Company's fiscal years ended December 31, 2007 and 2006 and through December 17, 2008, neither the Company, nor anyone acting on its behalf, consulted with Weinberg regarding the application of accounting principles to a specific completed or proposed transaction or the type of audit opinion that might be rendered on the Company's financial statements, and no written report or oral advice was provided that Weinberg concluded was an important factor considered by the Company in reaching a decision as to any such accounting, auditing or financial reporting issue.

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

Management's Annual Report on Internal Control Over Financial Reporting

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

Our management, with the participation of our chief executive officer and chief 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, our management concluded that our internal control over financial reporting was effective as of December 31, 2008.

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

Changes In Internal Control Over Financial Reporting

There were no changes in our internal controls over financial reporting during the fourth quarter of 2008 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, 2008. 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	Positions Held with the Registrant
Dr. John S. Kovach	72	Chief Executive Officer, Chief Financial Officer and Director
Dr. Philip F. Palmedo	74	Director
Dr. Stephen K. Carter	71	Director
Dr. Mel Sorensen	51	Director

Biographies of Directors and Executive Officer:

Dr. John S. Kovach

Dr. John S. Kovach founded Lixte in August 2005 and was 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 Chair of 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 and writer. Dr. Palmedo received his undergraduate degree from Williams College and M.S. and Ph.D. degrees from MIT. He carried out experimental nuclear reactor physics research at MIT, Oak Ridge National Laboratory, the French Atomic Energy Commission Laboratory at Saclay and Brookhaven National Laboratory (BNL). At BNL in 1972 he initiated and was the first head of the Energy Policy Analysis Group. In 1974 he served with the Energy Policy Office of the White House and in the following year initiated the BNL Developing Country Energy Program.

In 1979, Dr. Palmedo founded the International Resources Group, an international professional services firm in energy, environment and natural resources. He served as Chairman and CEO until 1988 and then as Chairman until the company was sold in 2008. In 1985 the company was recognized by Inc. Magazine as one of the 500 fastest growing private companies in the U.S.

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 the end of 1991 when Renaissance Technologies Corporation acquired the company. In 2005 he started a new hedge fund, Kepler Asset Management, and is a Managing Director of the firm.

Dr. Palmedo was the designer and, in 1992, became the first president of the Long Island Research Institute. LIRI was formed by Brookhaven National Laboratory, Cold Spring Harbor Laboratory, and Stony Brook University to facilitate the commercialization of technologies developed in their research and development programs. LIRI guided fledgling companies and started several new high tech entities. In order to provide "zero-stage" financing, LIRI created the Long Island Venture Fund, which evolved into the $250 million Topspin Fund.

Dr. Palmedo served on the boards of Asset Management Advisors and the Teton Trust Company and is currently a member of the Board of Directors of EHR Investments and the Gyrodyne Corporation of America. Dr. Palmedo also served on the Board of Trustees of Williams College and of the Stony Brook (University) Foundation and chaired the Foundation's Investment Committee. He is the founding Chairman of the non-profit Cultural Preservation Fund.

Dr. Palmedo has served as a consultant and advisor to numerous corporations and national and international agencies in science, technology and environmental policy including the MacArthur Foundation, the U.S. National Academy of Sciences, International Atomic Energy Agency, UNIDO, Organization of American States, the Governments of Sweden, Denmark, Dominican Republic, Indonesia, Somalia, Sudan, Egypt and Peru. He is the author of many publications in nuclear reactor physics, energy and environment, and technology and economic development.

Dr. Stephen K. Carter

Dr. Carter joined our Board on September 12, 2007. Dr. Carter is a highly experienced leader and administrator in cancer therapeutics and cancer drug development. For 13 years, he was associated with Bristol-Meyers Co. and Bristol-Meyers Squibb, Co. holding successively the positions of Senior Vice President, Anti-Cancer Research; President, Division of Pharmaceutical Research and Development, and ultimately Senior Vice President, Worldwide Clinical Research and Development, Pharmaceutical Research Institute. Most recently Dr. Carter was Senior Vice President of Clinical and Regulatory Affairs at Sugen, Inc., after serving as Senior Vice President for Research and Development at Boehringer Ingelheim Pharmaceuticals, Inc. Dr. Carter held leadership roles in academia and government including Deputy Director, Division of Cancer Treatment, National Cancer Institute and Director, Northern California Cancer Program.

Dr. Carter is currently a director on the boards of: Cytogen Corporation (NASDAQ:CYTO), Alfacell Corporation (NASDAQ:ACEL), Tapestry Pharmaceuticals, Inc. (NASDAQ:TPPH), Callisto Pharmaceuticals, Inc. (AMEX:KAL), Vion Pharmaceuticals, Inc. (NASDAQ:VION) and Celator.

Dr. Mel Sorensen

Dr. Sorensen joined our Board on October 7, 2008. 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 & 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, DC in 2003 ("Confronting Cancer Now"), the 2004 Bioethical Symposium in Tampa, FL ("Ethial Issues in Large Clinical Trials"), the 2005 Tokyo Pharma Partnering Conference & 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 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 will 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 scientific advisory committee was formalized on June 30, 2006. The members of our Advisory 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 an individual serving on our Board equivalent to an audit committee financial expert.

Code of Ethics

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

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

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

To the Company's knowledge based solely on its review of the copies of the Section 16(a) reports furnished to the Company and written representations to the Company that no other reports were required, the Company believes that all individual filing requirements applicable to the Company's directors and executive officers were complied with under Section 16(a) during 2007 and 2008.

ITEM 11. EXECUTIVE COMPENSATION

For the fiscal years ended December 31, 2008 and 2007, no individual, including Dr. John Kovach, our current Chief Executive Officer, received any compensation. Dr. Kovach will be reimbursed for any out-of-pocket expenses. Any future compensation arrangements will be subject to the approval of the board of directors.

Option Grants in 2007 and 2008

The Company has never issued any options to Management.

Aggregated Option Exercises in 2007 and 2008 Option Values at December 31, 2007 and at 2008

Not Applicable.

Employment Agreements; Management Compensation

We have not entered into any employment agreements. As of December 31, 2008, we had no full-time employees. For the current fiscal year, Dr. Kovach does not anticipate receiving any compensation from us in view of our early stage status. He is reimbursed for any out-of-pocket expenses. Any future compensation arrangements will be subject to the approval of the board of directors.

Director Compensation

Members of the Board of Directors

On June 30, 2006, Dr. Palmedo was granted options to purchase 200,000 shares of common stock at the initial private placement price of $0.333 per share with one third of the options (66,666 shares) vesting on such date and one third vesting annually for two years on the anniversary of that date. On June 30, 2006, Dr. Palmedo also was granted 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 our business plan, 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 $62,000 ($0.31 per share).

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. 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).

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. 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). In addition, in connection with Dr. Sorensen acting in an advisory role for a period of one year in connection with the strategic development of the Company's intellectual properties, the Company has agreed to pay Dr. Sorensen $40,000 payable in quarterly installments of $10,000 commencing on October 7, 2008. Dr. Sorensen is also eligible to receive a bonus at the sole discretion of the board of directors.

DIRECTOR COMPENSATION TABLE

Name	Year	Fees Earned or Paid In Cash ($)	Stock Awards ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)	Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Philip F. Palmedo	2008	0	0	10,332	0	0	0	10,332
Director	2007	0	0	20,668	0	0	0	20,668
	2006	0	0	89,900	0	0	0	89,900
Stephen K. Carter	2008	0	0	102,085	0	0	0	102,085
Director	2007	0	0	30,655	0	0	0	30,655
Mel Sorensen								
Director	2008	10,000	0	12,568	0	0	0	22,568

(1) Represents the portion of the fair market value of options issued to each director for his services as a board member, calculated at the time of issuance pursuant to the Black-Scholes option-pricing model, and charged to operations in each respective fiscal year.

Options to purchase a total of 790,000 shares have been issued to directors at exercise prices ranging from $0.33 to $0.50 per share.

Members of the Scientific Advisory Committee

On June 30, 2006, each member of the Scientific Advisory Committee (SAC), other than Drs. Hartmann and Hofstadter, received options to purchase 50,000 shares of common stock at the initial private placement price of $0.333 per share with one-half of the options (25,000 shares) vesting on the first anniversary of joining the SAC and one-half vesting on the second anniversary.

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

The following table sets forth, as of March 25, 2009, 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 25, 2009, there were 28,852,178 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, 2009, 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	59.0%
Dr. Philip F. Palmedo 248 Route 25A, No. 2 East Setauket, New York 11733	790,000(1)	2.7%
Dr. Stephen K. Carter 248 Route 25A, No. 2 East Setauket, New York 11733	200,000(2)	0.7%
Dr. Mel Sorensen 248 Route 25A, No. 2 East Setauket, New York 11733	100,000(3)	0.3%
All officers and directors as a group (four persons)	18,111,786(1)(2)(3)	60.9%

(1) Includes options to purchase an aggregate of 390,000 shares of common stock and warrants to purchase 200,000 shares of common stock, all of which are immediately exercisable or within six months.

(2) Consists of options to purchase 200,000 shares of common stock which vest within six months.

(3) Consists of options to purchase 100,000 shares of common stock which vest within six months.

Information with respect to securities authorized for issuance under equity compensation plans is provided in "ITEM 5.MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES."

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, 2008.

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. Our officer and director are involved in other business activities and may, in the future, become involved in other business opportunities that become available, such person 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, Dr. Kovach, our President, has advanced to us an aggregate of $92,717 through December 31, 2008 to meet operating expenses. 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, Sorensen and Carter 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

AJ. Robbins, P.C. acted as our independent registered public accounting firm for the fiscal year ended December 31, 2007 and through the interim period ended September 30, 2008. Weinberg & Company, P.C. acted as our independent registered public accounting firm for the fiscal year ended December 31, 2008. The following table shows the fees that were paid or accrued by us for audit and other services provided by AJ. Robbins, P.C. for the 2007 and 2008 fiscal years. As Weinberg & Company, P.A. was retained as the Company's independent registered public accounting firm effective December 17, 2008, such firm did not have any charges for 2008.

	2007	2008
Audit Fees (1)	$ 60,853	**$ 38,760**
Audit-Related Fees (2)	-	**-**
Tax Fees (3)	7,500	**6,000**
All Other Fees	-	**-**
Total	$ 68,353	**$ 44,760**

(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-QSB quarterly reports and services that are normally provided in connection with statutory or regulatory filings for the 2007 and 2008 fiscal years.

(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.

All audit related services, tax services and other services rendered by AJ. Robbins, 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

Exhibit No.	Description
2.1	Share Exchange Agreement dated as of June 8, 2006 among the Company, John S. Kovach and Lixte Biotechnology, Inc.[1]
2.2	Securities Purchase Agreement[3]
2.3	Registration Rights Agreement[3]
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
3.2	Bylaws[2]

Exhibit No.	Description
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	Agreement between Lixte Biotechnology Holdings, Inc. and Chem-Master International, Inc. dated as of February 5, 2007.[6]
10.3	Stock Option Agreement between Lixte Biotechnology Holdings, Inc. and Stephen K. Carter dated September 12, 2007.[7]
10.4	Stock Option Agreement between Lixte Biotechnology Holdings, Inc. and Francis Johnson dated September 12, 2007.[7]
10.5	Stock Option Agreement between Lixte Biotechnology Holdings, Inc. and Gil Schwartzberg dated September 12, 2007.[7]
10.6	Consulting Agreement between Lixte Biotechnology Holdings, Inc. and Gil Schwartzberg dated September 12, 2007.[7]
10.7	Consulting Agreement between Lixte Biotechnology Holdings, Inc. and Mirador Consulting, Inc. dated September 20, 2007.[7]
10.8	Consulting Agreement between Lixte Biotechnology Holdings, Inc. and Francis Johnson dated September 12, 2007.[7]
10.9	Amendment dated as of January 28, 2008 to Agreement with Chem-Master International.
10.10	Amendment 5 to CRADA dated June 2008.[8]
10.11	License Agreement dated as of September 19, 2008 between the Company and the United States Public Health Services.
10.12	Stock Option Agreement between the Company and Mel Sorensen dated October 7, 2008.[9]
10.13	Consulting Agreement between the Company and Mel Sorensen dated October 7, 2008.[10]
31	Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32	Officer's Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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 an Exhibit to the Company's Registration Statement on Form SB-2 as filed with the Securities and Exchange Commission on September 8, 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 Registration Statement on Form SB-2 as filed with the Securities and Exchange Commission on January 11, 2007 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 as filed with the Securities and Exchange Commission on November 11, 2007.

8. Filed as Exhibit to the Company's Quarterly Report as filed with the Securities and Exchange Commission on May 14, 2008

9. Filed as an Exhibit to the Company's Quarterly Report on Form 10-Q as filed with the Securities and Exchange Commission on August 12, 2008

10. 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.

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 30, 2009

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 30, 2009
/s/ Philip F. Palmedo **Philip F. Palmedo**	Director	March 30, 2009
/s/ Stephen K. Carter **Stephen K. Carter**	Director	March 30, 2009
/s/ Mel Sorensen **Mel Sorensen**	Director	March 30, 2009

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

CONSOLIDATED FINANCIAL STATEMENTS

and

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRMS

Years Ended December 31, 2008 and 2007, and
Period from August 9, 2005 (Inception) to December 31, 2008 (Cumulative)

INDEX

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 sheet of Lixte Biotechnology Holdings, Inc. and subsidiary (a development stage company) as of December 31, 2008, and the related consolidated statements of operations, stockholders' equity (deficiency) and cash flows for the year then ended and for the period from August 9, 2005 (Inception) to December 31, 2008 (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 audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit 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 audit 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. An audit includes examining on a test basis, evidence supporting the amounts and disclosures in the financial statements. Accordingly, we express no such opinion. 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 audit provides 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, 2008, and the results of their operations and their cash flows for the year then ended and for the period from August 9, 2005 (Inception) to December 31, 2008 (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. The Company has experienced recurring losses and has a stockholders' deficiency at December 31, 2008. 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 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.
CERTIFIED PUBLIC ACCOUNTANTS

Los Angeles, California
March 6, 2009

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 sheet of Lixte Biotechnology Holdings, Inc. and subsidiary (a development stage company) as of December 31, 2007, and the related consolidated statements of operations and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit 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 audit 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. An audit includes examining on a test basis, evidence supporting the amounts and disclosures in the financial statements. Accordingly, we express no such opinion. 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 audit provides 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, 2007, and the results of their operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company is in the development stage and has not commenced operations. Its ability to continue as a going concern is dependent upon its ability to develop additional sources of capital and ultimately achieve profitable operations. These conditions raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

AJ. ROBBINS, P.C.
CERTIFIED PUBLIC ACCOUNTANTS

Denver, Colorado
March 15, 2008

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

CONSOLIDATED BALANCE SHEETS

	December 31, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 10,381	$ 508,070
Advances on research and development contract services	12,500	88,180
Prepaid expenses and other current assets	28,644	32,117
Total current assets	51,525	628,367
Office equipment , net of accumulated depreciation of $1,782 and $1,167 at December 31, 2008 and 2007, respectively	128	742
Total assets	$ 51,653	$ 629,109
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)		
Current liabilities:		
Accounts payable and accrued expenses	$ 108,484	$ 73,741
Note payable to consultant	100,000	—
Liquidated damages payable under registration rights agreement	74,000	74,000
Research and development contract liabilities	—	11,725
Due to stockholder	92,717	92,717
Total current liabilities	375,201	252,183
Commitments and contingencies		
Stockholders' equity (deficiency):		
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 - 27,932,178 shares and 27,832,178 shares at December 31, 2008 and 2007, respectively	2,793	2,783
Additional paid-in capital	3,171,877	2,600,839
Deficit accumulated during the development stage	(3,498,218)	(2,226,696)
Total stockholders' equity (deficiency)	(323,548)	376,926
Total liabilities and stockholders' equity (deficiency)	$ 51,653	$ 629,109

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, 2008 (Cumulative)
	2008	2007	
Revenues	$ —	$ —	$ —
Costs and expenses:			
General and administrative costs, including $357,987, $890,444 and $1,345,831 of stock-based compensation during the years ended December 31, 2008 and 2007, and the period from August 9, 2005 (inception) to December 31, 2008 (cumulative), respectively	664,202	1,203,722	2,116,123
Depreciation	615	592	1,782
Research and development costs, including $213,061, $50,836 and $263,897 of stock-based compensation during the years ended December 31, 2008 and 2007, and the period from August 9, 2005 (inception) to December 31, 2008 (cumulative), respectively	608,733	454,723	1,280,788
Reverse merger costs	—	—	50,000
Total costs and expenses	1,273,550	1,659,037	3,448,693
	(1,273,550)	(1,659,037)	(3,448,693)
Interest income	3,261	10,549	25,712
Interest expense	(1,233)	—	(1,237)
Liquidated damages under registration rights agreement	—	—	(74,000)
Net loss	$ (1,271,522)	$ (1,648,488)	$ (3,498,218)
Net loss per common share – Basic and diluted	$ (0.05)	$ (0.06)	
Weighted average common shares outstanding - Basic and diluted	27,924,528	26,707,525	

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, 2008

	Common Stock		Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficiency)
	Shares	Amount			
Balance, August 9, 2005 (inception)	—	$ —	$ —	$ —	$ —
Shares issued to founding stockholder	19,021,786	1,902	(402)	—	1,500
Net loss	—	—	—	(16,124)	(16,124)
Balance, December 31, 2005	19,021,786	1,902	(402)	(16,124)	(14,624)
Shares issued in connection with reverse merger transaction	4,005,177	401	62,099	—	62,500
Shares issued in private placement, net of offering costs of $214,517	3,555,220	355	969,017	—	969,372
Stock-based compensation	—	—	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 of $118,680	999,995	100	531,220	—	531,320
Stock-based compensation	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	—	—	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)

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, 2008 (Cumulative)
	2008	2007	
Cash flows from operating activities:			
Net loss	$ (1,271,522)	$ (1,648,488)	$ (3,498,218)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	615	592	1,782
Stock-based compensation	357,987	890,444	1,345,831
Stock-based research and development	213,061	50,836	263,897
Changes in operating assets and liabilities:			
(Increase) decrease in -			
Advances on research and development contract services	75,680	(38,180)	(12,500)
Prepaid expenses and other current assets	3,473	(11,752)	(28,644)
Increase (decrease) in -			
Accounts payable and accrued expenses	34,742	41,955	108,483
Liquidated damages payable under registration rights Agreement	—	—	74,000
Research and development contract liabilities	(11,725)	11,725	—
Net cash used in operating activities	(597,689)	(702,868)	(1,745,369)
Cash flows from investing activities:			
Purchase of office equipment	—	(272)	(1,909)
Net cash used in investing activities	—	(272)	(1,909)
Cash flows from financing activities:			
Proceeds from sale of common stock to consulting firm	—	250	250
Proceeds from sale of common stock to founder	—	—	1,500
Proceeds from note payable to consultant	100,000	—	100,000
Cash acquired in reverse merger transaction	—	—	62,500
Gross proceeds from sale of common stock	—	650,000	1,833,889
Payment of private placement offering costs	—	(118,680)	(333,197)
Advances from stockholder	—	—	92,717
Net cash provided by financing activities	100,000	531,570	1,757,659
Net increase (decrease) in cash	(497,689)	(171,570)	10,381
Cash at beginning of period	508,070	679,640	—
Cash at end of period	$ 10,381	$ 508,070	$ 10,381
Supplemental disclosures of cash flow information:			
Cash paid for - -Interest	$ —	$ —	$ —
Income taxes	$ —	$ —	$ —

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"), 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 and do not include the historical financial results of SRKP. 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.

Lixte was incorporated in Delaware on August 9, 2005 to capitalize on opportunities 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.

The Company is considered a "development stage company" as defined in Statement of Financial Accounting Standards ("SFAS") No. 7, "Accounting and Reporting by Development Stage Enterprises", 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 has selected December 31 as its fiscal year end.

The Company's common stock was listed for trading on the OTC Bulletin Board commencing September 24, 2007.

Operating Plans

The Company is concentrating on developing 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 inhibits the growth of cell lines of breast, colon, lung, prostate, pancreas, ovary, stomach and liver cancer, as well as the major types of leukemias. Activity of lead compounds of both types of drugs was recently demonstrated against human pancreatic cancer cells in a mouse model. Because there is a great need for any kind of effective treatment for pancreatic cancer, this cancer will be studied concomitantly with the primary target of the Company's research program focused on brain cancers.

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 CRADA was extended and is presently scheduled to end on September 30, 2009.

The Company filed five patent applications on August 1, 2008. Two of these patent filings deal with applications filed earlier jointly with NIH for work done under the CRADA as follows: (1) a filing entering the regional stage of a PCT application involving the use of certain compounds to treat human tumors expressing a biomarker for brain and other human cancers; and (2) an application for the treatment of the pediatric tumors, medulloblastoma (the most common brain tumor in children) and neuroblastoma (a tumor arising from neural cells outside the brain that is the most common cancer of children). The three new patent applications include: (1) a joint application with NIH identifying a new biomarker for many common human cancers that when targeted by compounds developed by the Company result in inhibition of growth and death of cancer cells; (2) an application by the Company regarding the structure, synthesis and use of a group of new homologs of its LB-1 compounds; and (3) an application by the Company for the use of certain homologs of its drugs as neuroprotective agents with potential application to common neurodegenerative conditions such as Alzheimer's and Parkinson's diseases.

The Company continues to evaluate compounds for activity against several types of fungi that cause serious infections, particularly in immuno-compromised individuals, such as those with HIV-AIDS, and those having bone marrow transplantations. The Company is also exploring indications that its compounds have against strains of fungi that cause the most common fungal infections of the skin and nails. Discussions are in progress with experts in fungal infections regarding the most reliable methods of assessing the potential of new agents for the management of common fungal diseases.

The Company expects that its products will derive directly from the intellectual property from its research activities. The development of lead compounds with different mechanisms of action that have activity against brain tumors and other common human cancers, as well as against serious fungal infections, originated from the discovery of a biomarker in GBM. The Company will continue to use discovery and/or recognition of molecular variants characteristic of specific human cancers as a guide to drug discovery and potentially new diagnostic tests. Examples of the productivity of this approach to discovery of new therapeutics are: (1) the recent patent application filing for a new biomarker of several common cancers that when targeted by certain of the Company's drugs results in inhibition of growth and death of cancer cells displaying the marker; and (2) the filing of a patent on certain homologs of one group of compounds as potentially useful for the treatment of neurodegenerative diseases.

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. Furthermore, the Company has experienced recurring losses and has a stockholders' deficiency at December 31, 2008. As a result, the Company's independent registered public accounting firm, in their report on the Company's 2008 consolidated financial statements, have 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 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, 2008, the Company had not yet commenced any revenue-generating operations. All activity through December 31, 2008 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 revenue 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 does not have sufficient resources to fund its operations, including the Company's research activities with respect to its intellectual property, for the next twelve months. In addition, the Company does not have sufficient resources to fully develop and commercialize any products that may arise from its research. Accordingly, the Company needs to raise additional funds in order to satisfy its future working capital requirements.

The Company estimates that it will require minimum funding in calendar 2009 of approximately $750,000 in order to fund operations and continuing drug discovery and to attempt to bring two drugs through the pre-clinical evaluation process needed for submission of an Investigational New Drug ("IND") application. Towards that objective, the Company recently initiated a private placement, which generated net proceeds from two closings in February and March 2009 aggregating approximately $382,000. The Company utilized a portion of such net proceeds to repay a $100,000 short-term note in February 2009, as described at Note 10. The Company is continuing its efforts in 2009 to raise approximately $500,000 of additional funds under the private placement. There can be no assurances that the Company will have further success in this regard. The amount and timing of future cash requirements will depend on the market's evaluation of the Company's technology and products, if any, and the resources that it devotes to developing and supporting its activities. The Company will need to fund these cash requirements from a combination of additional debt or equity financings, or the sale, licensing or joint venturing of its intellectual properties.

Current 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, 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 and Cash Equivalents and Concentrations

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. At times, such cash and cash equivalents may 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 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 accounts for its research and development contracts in accordance with EITF 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities".

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. As such, such costs were being charged to expense when they were actually expended by the provider, which is, effectively, as they performed 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 were expensed over the contractual service term on a straight-line basis, which reflected 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 fees, are expensed as incurred. Patent costs were $164,782 and $94,232 for the years ended December 31, 2008 and 2007, respectively, and $325,691 for the period from August 9, 2005 (inception) to December 31, 2008 (cumulative). Patent costs are included in research and development costs in the Company's consolidated statement of operations.

Income Taxes

The Company accounts for income taxes pursuant to SFAS No. 109, "Accounting for Income Taxes" ("SFAS No. 109"), which establishes financial accounting and reporting standards for the effects of income taxes that result from an enterprise's activities during the current and preceding years. SFAS No. 109 requires 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.

For federal income tax purposes, substantially all expenses, except for interest, taxes and research and development, are deemed start-up and organization costs and must be deferred until the Company commences business operations, at which time they may be written off over a 180-month period. The Company has elected to deduct research and development costs on a current basis.

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 FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109, Accounting for Income Taxes" ("FIN 48"). FIN 48 addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under FIN 48, 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. FIN 48 also provides guidance on de-recognition, classification, interest and penalties on income taxes, accounting in interim periods and requires increased disclosures. The adoption of the provisions of FIN 48 did not have a material effect on the Company's financial statements. As of December 31, 2008, 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 2005 and thereafter. The Company's policy is to record interest and penalties on uncertain tax provisions as income tax expense. As of December 31, 2008, the Company has no accrued interest or penalties related to uncertain tax positions.

Stock-Based Compensation

The Company accounts for share-based payments pursuant to SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS No. 123R"), a revision to SFAS No. 123, "Accounting for Stock-Based Compensation". SFAS No. 123R requires that the Company measure the cost of employee services received in exchange for equity awards based on the grant date fair value of the awards, with the cost to be recognized as compensation expense in the Company's financial statements over the vesting period of the awards.

In December 2007, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 110 ("SAB 110"), which expresses the views of the staff regarding the use of a "simplified" method, as discussed in Staff Accounting Bulletin No. 107, in developing an estimate of expected term of "plain vanilla" share options in accordance with SFAS No. 123R. The staff indicated that it will accept a company's election to use the simplified method, regardless of whether the company has sufficient information to make more refined estimates of expected term. SAB 110 was effective January 1, 2008, and did not have a significant impact on the Company's consolidated financial statements.

The Company accounts for stock option and warrant grants issued and vesting to non-employees in accordance with EITF No. 96-18, "Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services", and EITF 00-18, "Accounting Recognition for Certain Transactions involving Equity Instruments Granted to Other Than Employees", whereas the value of the stock compensation is based upon the measurement date as determined 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. In accordance with EITF 96-18, 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 computes earnings per share ("EPS") in accordance with SFAS No. 128, "Earnings per Share" and SEC Staff Accounting Bulletin No. 98. SFAS No. 128 requires companies with complex capital structures to present 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 are the same for all periods presented because all warrants and stock options outstanding are anti-dilutive. The 19,021,786 shares of common stock issued to the founder of Lixte in conjunction with the closing of the reverse merger transaction on June 30, 2006 have been presented as outstanding for all periods presented.

At December 31, 2008 and 2007, 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,	
	2008	2007
Warrants	546,626	546,626
Stock options	2,540,000	2,090,000
Total	3,086,626	2,636,626

Equipment

Equipment is recorded at cost. Depreciation expense is provided on a straight-line basis using estimated useful lives of 3 years. Maintenance and repairs are charged to expense as incurred. When assets are retired or otherwise disposed of, the property accounts are relieved of costs and accumulated depreciation and any resulting gain or loss is credited or charged to operations.

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, prepaid expenses, accounts payable, accrued expenses 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.

Reclassification

During the year ended December 31, 2007, laboratory supplies of $30,894 were reclassified from general and administrative costs to research and development costs. Such reclassification did not have any effect on results of operations.

Adoption of New Accounting Policies in 2008

In September 2006, the FASB issued SFAS No. 157, “Fair Value Measurements” (“SFAS No. 157”), which establishes a formal framework for measuring fair value under Generally Accepted Accounting Principles (“GAAP”). SFAS No. 157 defines and codifies the many definitions of fair value included among various other authoritative literature, clarifies and, in some instances, expands on the guidance for implementing fair value measurements, and increases the level of disclosure required for fair value measurements. Although SFAS No. 157 applies to and amends the provisions of existing FASB and American Institute of Certified Public Accountants (“AICPA”) pronouncements, it does not, of itself, require any new fair value measurements, nor does it establish valuation standards. SFAS No. 157 applies to all other accounting pronouncements requiring or permitting fair value measurements, except for: SFAS No. 123R, “Share-Based Payment”, and related pronouncements, the practicability exceptions to fair value determinations allowed by various other authoritative pronouncements, and AICPA Statements of Position 97-2 and 98-9 that deal with software revenue recognition. The Company adopted SFAS No. 157 on January 1, 2008.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities" ("SFAS No. 159"), which provides companies with an option to report selected financial assets and liabilities at fair value. The objective of SFAS No. 159 is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. Generally accepted accounting principles have required different measurement attributes for different assets and liabilities that can create artificial volatility in earnings. SFAS No. 159 helps to mitigate this type of accounting-induced volatility by enabling companies to report related assets and liabilities at fair value, which would likely reduce the need for companies to comply with detailed rules for hedge accounting. SFAS No. 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS No. 159 requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of the company's choice to use fair value on its earnings. SFAS No. 159 also requires companies to display the fair value of those assets and liabilities for which the company has chosen to use fair value on the face of the balance sheet. SFAS No. 159 does not eliminate disclosure requirements included in other accounting standards, including requirements for disclosures about fair value measurements included in SFAS No. 157 and SFAS No. 107. The Company adopted SFAS No. 159 on January 1, 2008.

In May 2008, the FASB issued Statement of Financial Accounting Standards No. 162, "The Hierarchy of Generally Accepted Accounting Principles" ("SFAS No. 162"). SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with GAAP. SFAS No. 162 became effective on November 15, 2008.

On October 10, 2008, the FASB issued FASB Staff Position No. 157-3, "Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active" ("FSP FAS No. 157-3"). FSP FAS No. 157-3 clarifies the application of SFAS No. 157, "Fair Value Measurements", in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. FSP FAS No. 157-3 became effective immediately, and includes prior period financial statements that have not yet been issued, and therefore the Company became subject to the provisions of FSP FAS No. 157-3 on October 10, 2008.

The adoption and/or implementation of the aforementioned accounting pronouncements did not have any effect on the Company's consolidated financial statement presentation or disclosures.

Recently Issued Accounting Pronouncements

In December 2007, the FASB issued SFAS No. 141(R), "Business Combinations" ("SFAS No. 141(R)"), which requires an acquirer to recognize in its financial statements as of the acquisition date (i) the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree, measured at their fair values on the acquisition date, and (ii) goodwill as the excess of the consideration transferred plus the fair value of any noncontrolling interest in the acquiree at the acquisition date over the fair values of the identifiable net assets acquired. Acquisition-related costs, which are the costs an acquirer incurs to effect a business combination, will be accounted for as expenses in the periods in which the costs are incurred and the services are received, except that costs to issue debt or equity securities will be recognized in accordance with other applicable GAAP. SFAS No. 141(R) makes significant amendments to other Statements and other authoritative guidance to provide additional guidance or to conform the guidance in that literature to that provided in SFAS No. 141(R). SFAS No. 141(R) also provides guidance as to what information is to be disclosed to enable users of financial statements to evaluate the nature and financial effects of a business combination. SFAS No. 141(R) is effective for financial statements issued for fiscal years beginning on or after December 15, 2008. Early adoption is prohibited. The adoption of SFAS No. 141(R) on January 1, 2009 will affect how the Company accounts for a business combination concluded after December 31, 2008.

In December 2007, the FASB issued SFAS No. 160, “Noncontrolling Interests in Consolidated Financial Statements — an amendment of ARB No. 51” (“SFAS No. 160”), which revises the relevance, comparability, and transparency of the financial information that a reporting entity provides in its consolidated financial statements by establishing accounting and reporting standards that require (i) the ownership interests in subsidiaries held by parties other than the parent be clearly identified, labeled, and presented in the consolidated statement of financial position within equity, but separate from the parent’s equity, (ii) the amount of consolidated net income attributable to the parent and to the noncontrolling interest be clearly identified and presented on the face of the consolidated statement of income, (iii) changes in a parent’s ownership interest while the parent retains its controlling financial interest in its subsidiary be accounted for consistently as equity transactions, (iv) when a subsidiary is deconsolidated, any retained noncontrolling equity investment in the former subsidiary be initially measured at fair value, with the gain or loss on the deconsolidation of the subsidiary being measured using the fair value of any noncontrolling equity investment rather than the carrying amount of that retained investment, and (v) entities provide sufficient disclosures that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS No. 160 amends FASB No. 128 to provide that the calculation of earnings per share amounts in the consolidated financial statements will continue to be based on the amounts attributable to the parent. SFAS No. 160 is effective for financial statements issued for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. Early adoption is prohibited. SFAS No. 160 shall be applied prospectively as of the beginning of the fiscal year in which it is initially applied, except for the presentation and disclosure requirements, which shall be applied retrospectively for all periods presented. The Company does not currently anticipate that the adoption of SFAS No. 160 on January 1, 2009 will have any impact on its consolidated financial statement presentation or disclosures.

In March 2008, the FASB issued SFAS No. 161, “Disclosures about Derivative Instruments and Hedging Activities - an amendment of FASB Statement No. 133” (“SFAS No. 161”). SFAS No. 161 amends and expands the disclosure requirements of SFAS No. 133, “Accounting for Derivative Instruments and Hedging Activities” (“SFAS No. 133”). The objective of SFAS No. 161 is to provide users of financial statements with an enhanced understanding of how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for under SFAS No. 133 and its related interpretations, and how derivative instruments and related hedged items affect an entity’s financial position, financial performance, and cash flows. SFAS No. 161 requires qualitative disclosures about objectives and strategies for using derivatives, quantitative disclosures about fair value amounts of and gains and losses on derivative instruments, and disclosures about credit-risk-related contingent features in derivative agreements. SFAS No. 161 applies to all derivative financial instruments, including bifurcated derivative instruments (and nonderivative instruments that are designed and qualify as hedging instruments pursuant to paragraphs 37 and 42 of SFAS No. 133) and related hedged items accounted for under SFAS No. 133 and its related interpretations. SFAS No. 161 also amends certain provisions of SFAS No. 131. SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. SFAS No. 161 encourages, but does not require, comparative disclosures for earlier periods at initial adoption. The Company does not currently anticipate that the adoption of SFAS No. 161 on January 1, 2009 will have any impact on its consolidated financial statement presentation or disclosures.

In June 2008, the FASB ratified Emerging Issues Task Force (“EITF”) Issue No. 07-05, "Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock" (“EITF 07-05”). EITF 07-05 mandates a two-step process for evaluating whether an equity-linked financial instrument or embedded feature is indexed to the entity's own stock. Warrants that a company issues that contain a strike price adjustment feature, upon the adoption of EITF 07-05, results in the instruments no longer being considered indexed to the company's own stock. Accordingly, adoption of EITF 07-05 will change the current classification (from equity to liability) and the related accounting for such warrants outstanding at that date. EITF 07-05 is effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. The Company does not currently anticipate that the adoption of EITF 07-05 on January 1, 2009 will have any impact on its consolidated financial statement presentation or disclosures.

Management does not believe that any other recently issued, but not yet adopted, accounting pronouncements issued by the FASB (including its Emerging Issues Task Force), the AICPA, and/or the Securities and Exchange Commission will have a material impact on the Company's consolidated financial statement presentation or disclosures in future periods.

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.

The fair value of the warrants, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $132,254 ($0.31 per warrant) 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 - 5%.

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.

In accordance with EITF 00-19-2, "Accounting for Registration Payment Arrangements", 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 at December 31, 2008 and 2007. 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, 2008, 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.

The fair value of the warrants, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $115,200 ($0.96 per warrant) using the following Black-Scholes input variables: stock price on date of grant - $1.10; exercise price - $0.65; expected life - 5 years; expected volatility - 118.6%; expected dividend yield - 0%; risk-free interest rate - 4%.

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.

4. Related Party Transactions

Prior to June 30, 2006, the Company's founding stockholder and Chief Executive Officer, Dr. John Kovach, had periodically made advances to the Company to meet operating expenses. Such advances are non-interest-bearing and are due on demand. At December 31, 2008 and 2007, 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, 2008 and 2007, and for the period from August 9, 2005 (inception) through December 31, 2008 (cumulative), in view of the Company's development stage status and limited resources. Any future compensation arrangements will be subject to the approval of the Board of Directors.

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.

5. Note Payable to Consultant

On October 3, 2008, the Company borrowed $100,000 from Gil Schwartzberg, a consultant to the Company (see Note 7), 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 was repaid in full, including accrued interest, on February 7, 2009.

6. 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.

7. 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. During the years ended December 31, 2008 and 2007, the Company recorded a charge to operations of $10,332 and $20,668, respectively, with respect to these options.

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 certain 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. During the years ended December 31, 2008 and 2007, the Company recorded a charge (credit) to operations of $(3,336) and $23,212, respectively, with respect to these options.

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 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 is being charged to operations ratably from September 12, 2007 through September 12, 2009. During the years ended December 31, 2008 and 2007, the Company recorded a charge to operations of $102,085 and $30,655, respectively, with respect to these options.

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 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). During the years ended December 31, 2008 and 2007, the Company recorded a charge to operations of $236,338 and $553,662, respectively, with respect to these options (see Note 5).

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, 2008 and December 31, 2008, the fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $195,000 ($0.65 per share) and $171,000 ($0.57 per share), respectively, which resulted in a charge to operations of $62,342 and $19,836 during the years ended December 31, 2008 and 2007, respectively.

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 September 12, 2008, the fair value of the aforementioned stock options was calculated (for stock options revalued pursuant to EITF 98-16) using the following Black-Scholes input variables: stock price - $0.65; exercise price - $0.333 to $1.00; expected life - 4 years; expected volatility - 275.7%; expected dividend yield - 0%; risk-free interest rate - 2.48%. On December 31, 2008, the fair value of the aforementioned stock options was calculated (for stock options revalued pursuant to EITF 98-16) using the following Black-Scholes input variables: stock price - $0.57; exercise price - $0.333; expected life - 4.72 years; expected volatility - 335%; expected dividend yield - 0%; risk-free interest rate – 1.9%. As the Company's common stock commenced trading on September 24, 2007, the Company was able to utilize such trading date to generate revised volatility factors at September 12, 2008 and December 31, 2008.

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 CEO of a new cancer therapeutics company, Ascenta Therapeutics, in 2004. Dr. Sorensen is being 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 year ended December 31, 2008, the Company recorded a charge to operations of $12,568 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%.

In August 2008, a member of the Scientific Advisory Committee resigned from his position and waived his right to his vested stock option to purchase 50,000 shares of common stock.

Additional information with respect to common stock warrants and stock options issued is provided at Notes 3, 9 and 10. Warrants to purchase common stock that were issued in conjunction with the Company's private placements in 2006, 2007 and 2009 are included in the tables presented below

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 for the years ended December 31, 2007 and 2008 is presented below.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Options and warrants outstanding at December 31, 2006	916,626	$ 0.333	4.51
Granted	1,720,000	0.743	4.35
Exercised	—	—	—
Cancelled	—	—	—
Options and warrants outstanding at December 31, 2007	2,636,626	0.600	4.32
Granted	500,000	0.927	4.71
Exercised	—	—	—
Cancelled	(50,000)	0.333	2.75
Options and warrants outstanding at December 31, 2008	3,086,626	$ 0.658	3.55
Options and warrants exercisable at December 31, 2008	2,286,626	$ 0.641	3.06

The intrinsic value of exercisable but unexercised in-the-money stock options and warrants at December 31, 2008 was $276,490, based on a fair market value of $0.57 per share on December 31, 2008.

Total deferred compensation expense for the outstanding value of unvested stock options was approximately $351,000 at December 31, 2008, which will be recognized subsequent to December 31, 2008 over a weighted-average period of 18.3 months.

Information regarding stock options and warrants outstanding and exercisable at December 31, 2008 is summarized below.

Exercise Prices	Warrants and Options Outstanding (Shares)	Warrants and Options Exercisable (Shares)
$0.333	1,566,626	1,166,626
$0.500	200,000	—
$0.650	120,000	120,000
$1.000	1,000,000	1,000,000
$1.650	200,000	—
	3,086,626	2,286,626

Outstanding options and warrants to acquire 800,000 shares of the Company’s common stock had not vested at December 31, 2008.

8. Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets as of December 31, 2008 and 2007 are summarized below.

	December 31,	
	2008	2007
Start-up and organization costs	$ 411,000	$ 310,000
Contingent liability	31,000	31,000
Net operating loss carryforwards	333,000	170,000
Total deferred tax assets	775,000	511,000
Valuation allowance	(775,000)	(511,000)
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, 2008 and 2007, 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, 2008 and 2007 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, 2008 and 2007 is summarized below.

	Years Ended December 31,	
	2008	2007
U. S. federal statutory tax rate	(34.0)%	(34.0)%
Non-deductible stock-based compensation	15.3%	19.4)%
Adjustment to deferred tax asset	1.7%	—%
Change in valuation allowance	17.0%	14.6%
Effective tax rate	0.0%	0.0%

At December 31, 2008, the Company has available net operating loss carryforwards for federal income tax purposes of approximately $801,000 which, if not utilized earlier, expire in 2027.

9. Commitments and Contingencies

Effective March 22, 2006, the Company entered into a CRADA, as amended, with the NINDS of the NIH. The CRADA was for a term of 42 months from the effective date and could be unilaterally terminated by either party by providing written notice within sixty days. The CRADA provided for the collaboration between the parties in the identification and evaluation of agents that target the Nuclear Receptor CoRepressor (N-CoR) pathway for glioma cell differentiation. The CRADA also provided that NINDS and the Company would conduct research to determine if expression of N-CoR correlates with prognosis in glioma patients. Pursuant to the CRADA, the Company 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. However, for the period from October 1, 2008 through September 30, 2009, the Company has 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.

On January 5, 2007, the Company entered into a Services Agreement with The Free State of Bavaria (Germany) represented by the University of Regensburg (the "University") pursuant to which the Company retained the University to provide to it certain samples of primary cancer tissue and related biological fluids to be obtained from patients afflicted with specified types of cancer. The University also agreed to provide certain information relating to such patients. The Company agreed to pay the University 72,000 Euros in two equal installments. The first installment of 36,000 Euros ($48,902) was paid on March 7, 2007. On January 12, 2008, the Company terminated the Services Agreement in accordance with its terms, as a result of which payment of the second installment of 36,000 Euros was cancelled. The University agreed to deliver 50% of the aforementioned samples under the terminated Services Agreement.

On February 5, 2007, the Company entered into a two-year 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 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 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 during the year ended December 31, 2007, since 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 has not been terminated prior to such date, the Company has 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 is being reflected as a charge to operations for the period from October 1, 2008 through February 5, 2009. On September 30, 2008 and December 31, 2008, the fair value of this option, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $50,000 ($0.50 per share) and $57,000 ($0.57 per share), respectively, which resulted in a charge to operations of $40,857 during the year ended December 31, 2008. 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 December 31, 2008, the fair value of the aforementioned stock option was calculated (for the stock option revalued pursuant to EITF 98-16) using the following Black-Scholes input variables: stock price - $0.57; exercise price - $0.333; expected life – 5.1 years; expected volatility - 335%; expected dividend yield - 0%; risk-free interest rate – 1.9%.

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 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, 2008, the fair value of the aforementioned stock options was determined to be $114,000 ($0.57 per share) calculated using the following Black-Scholes input variables: stock price - $0.57; exercise price - $1.65; expected life - - 4.09 years; expected volatility - 335%; expected dividend yield - 0%; risk-free interest rate - 1.90%, which resulted in a charge to operations of $34,862 during the year ended December 31, 2008.

Pursuant to the Chem-Master Agreement, the Company reimbursed Chem-Master for the costs of materials, labor, and expenses aggregating $45,750 and $30,150 during the years ended December 31, 2008 and 2007, respectively.

On September 12, 2007, the Company entered into two consulting agreements for financial and scientific services. Compensation related to these agreements was primarily in the form of stock options (see Note 7).

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 during the year ended December 31, 2007, since the shares were fully vested and non-forfeitable on the date of issuance. The Company made payments under the Mirador Agreement aggregating $10,000 during 2007. The Mirador Agreement was amended in February 2008, pursuant to which Mirador agreed to forgive all accrued but unpaid monthly fees through February 29, 2008, and the Company agreed to pay Mirador a fee of $2,000 per month for the remaining six months of the Mirador Agreement.

In September 2008, the Company engaged an internet-based investor information service to enhance awareness of the Company's progress in developing a portfolio of pharmacological agents at an initial cost of $2,500, plus $500 per month for a period of twelve months.

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.

During October 2008, the Company engaged Southern Research Institute, Birmingham, Alabama, to assess one lead compound from each of two classes of its proprietary pharmacological agents for effects on normal neuronal cells and to determine if the compounds protect normal brain cells from injury in several different models of chemical and traumatic brain injury. The goal is to determine if these agents have promise as potentially useful for the prevention, amelioration or delay of progression of neurodegenerative diseases such as Alzheimer's disease and other neurological diseases or impairments resulting from trauma and/or other diverse or unknown origins. The Company agreed to pay a fee not to exceed $50,000 over a four-month period for such services, of which an advance of $12,500 was paid during 2008.

10. Subsequent Events

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.

Each unit consists 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. Net cash proceeds to the Company were $269,790.

In conjunction with the first closing of the third private placement of common stock units, the Company issued a total of 157,920 five-year warrants to WestPark Capital, Inc. exercisable at the per unit price of the common stock units sold in the third private placement ($0.50 per unit). 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 will be accounted for as equity and will not be accounted for separately from the common stock and additional paid-in capital accounts. The warrants will not have any accounting impact on the Company's consolidated financial statements.

On February 7, 2009, the Company repaid a $100,000 unsecured demand promissory note, including interest at the rate of 5% per annum, to Gil Schwartzberg, a consultant to the Company.

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.

In conjunction with the second closing of the third private placement of common stock units, the Company issued a total of 31,440 five-year warrants to WestPark Capital, Inc. exercisable at the per unit price of the common stock units sold in the third private placement ($0.50 per unit). 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 will be accounted for as equity and will not be accounted for separately from the common stock and additional paid-in capital accounts. The warrants will not have any 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.

Exhibit 10.11

PUBLIC HEALTH SERVICE

PATENT LICENSE AGREEMENT – *EXCLUSIVE*

COVER PAGE

For PHS internal use only:

License Number:

License Application Number: A-286-2006

Serial Number(s) of Licensed Patent(s) or Patent Application(s):

I. U.S. Provisional Patent Application No. 60/771,163, filed February 6, 2006, entitled "Use of Phosphatases To Treat Glioblastomas" (**HHS** Ref. No. E-123-2006/0-US-01);

II. U.S. Provisional Patent Application No. 60/797,201, filed May 2, 2006, entitled "Use of Phosphatases To Treat Glioblastomas" (**HHS** Ref. No. E-123-2006/1-US-01)

III. U.S. Patent Application Serial No. 11/703,401, filed February 6, 2007, entitled "Use of Phosphatases To Treat Glioblastomas" (**HHS** Ref. No. E-123-2006/0-US-03)

IV. PCT International Application No. PCT/US2007/003095, filed February 6, 2007 entitled "Use of Phosphatases To Treat Glioblastomas" (**HHS** Ref. No. E-123-2006/0-PCT-02)

V. U.S. Provisional Patent Application No. 60/963,307, filed August 3, 2007 entitled "Use of Phosphatases To Treat Neuroblastomas and Medulloblastomas" (**HHS** Ref. No. E-123-2006/2-US-01)

VI. U.S. Provisional Patent Application No. 60/063,970, filed February 6, 2008 entitled "Use of Phosphatases To Treat Neuroblastomas and Medulloblastomas".

VII. U.S. Application in preparation corresponding to Cooper and Dunham Referene No. 4101/79251.

Licensee:

Lixte Biotechnology, Inc.

Cooperative Research and Development Agreement (CRADA) Number (if a subject invention):

CRADA No. 02165 (C-026-2006/0) and Four Amendments

Additional Remarks:

N/A

Public Benefit(s):

Novel methods of treating glioblastomas and other tumors of the central nervous system.
This Patent License Agreement, hereinafter referred to as the "**Agreement**", consists of this Cover Page, an attached **Agreement**, a Signature Page, Appendix A (List of Patent(s) or Patent Application(s)), Appendix B (Fields of Use and Territory), Appendix C (Royalties), Appendix D (Benchmarks and Performance), Appendix E (Commercial Development Plan), Appendix F (Example Royalty Report), and Appendix G (Royalty Payment Options). The Parties to this **Agreement** are:

1) The National Institutes of Health ("**NIH**") or the Food and Drug Administration ("**FDA**"), hereinafter singly or collectively referred to as "**PHS**", agencies of the United States Public Health Service within the Department of Health and Human Services ("**HHS**"); and

2) The person, corporation, or institution identified above or on the Signature Page, having offices at the address indicated on the Signature Page, hereinafter referred to as "**Licensee**".

PHS PATENT LICENSE AGREEMENT – *EXCLUSIVE*

PHS and Licensee agree as follows:

1. BACKGROUND

1.1 In the course of conducting biomedical research, **PHS** investigators made inventions that may have commercial applicability.

1.2 By assignment of rights from **PHS** employees and other inventors, **HHS**, on behalf of the Government, owns intellectual property rights claimed in any United States or foreign patent applications or patents corresponding to the assigned inventions. **HHS** also owns any tangible embodiments of these inventions actually reduced to practice by **PHS**.

1.3 The Secretary of **HHS** has delegated to **PHS** the authority to enter into this **Agreement** for the licensing of rights to these inventions.

1.4 **PHS** desires to transfer these inventions to the private sector through commercialization licenses to facilitate the commercial development of products and processes for public use and benefit.

1.5 Licensee desires to acquire commercialization rights to certain of these inventions in order to develop processes, methods, or marketable products for public use and benefit.

2. DEFINITIONS

2.1 "**Benchmarks**" mean the performance milestones that are set forth in Appendix D.

2.2 "**Commercial Development Plan**" means the written commercialization plan attached as Appendix E.

2.3 "**First Commercial Sale**" means the initial transfer by or on behalf of **Licensee** or its sublicensees of **Licensed Products** or the initial practice of a **Licensed Process** by or on behalf of **Licensee** or its sublicensees in exchange for cash or some equivalent to which value can be assigned for the purpose of determining **Net Sales**.

2.4 "**Government**" means the Government of the United States of America.

2.5 "**Licensed Fields of Use**" means the fields of use identified in Appendix B.

2.6 "**Licensed Patent Rights**" shall mean:

(a) Patent applications (including provisional patent applications and PCT patent applications) or patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing from these applications, divisions, and continuations, and any reissues, reexaminations, and extensions of these patents;

(b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.6(a):

(i) continuations in part of 2.6(a);

(ii) all divisions and continuations of these continuations in part;

(iii) all patents issuing from these continuations in part, divisions, and continuations;

(iv) priority patent application(s) of, and application(s) claiming priority of, 2.6(a); and

(v) any reissues, reexaminations, and extensions of these patents;

(c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.6(a): all counterpart foreign and U.S. patent applications and patents to 2.6(a) and 2.6(b), including those listed in Appendix A; and

(d) **Licensed Patent Rights** shall not include 2.6(b) or 2.6(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in 2.6(a).

2.7 "**Licensed Processes**" means processes which, in the course of being practiced, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.8 "**Licensed Products**" means tangible materials which, in the course of manufacture, use, sale, or importation, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.9 "**Licensed Territory**" means the geographical area identified in Appendix B.

2.10 "Net Sales" means the total gross receipts for sales of **Licensed Products** or practice of **Licensed Processes** by or on behalf of **Licensee** or its sublicensees, and from leasing, renting, or otherwise making **Licensed Products** available to others without sale or other dispositions, whether invoiced or not, less returns and allowances, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade to the extent actually granted. No deductions shall be made for commissions paid to individuals, whether they are with independent sales agencies or regularly employed by **Licensee**, or sublicensees, and on its payroll, or for the cost of collections.

2.11 "**Practical Application**" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under these conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or **Government** regulations available to the public on reasonable terms.

2.12 "**Research License**" means a nontransferable, nonexclusive license to make and to use **Licensed Products** or **Licensed Processes** as defined by the **Licensed Patent Rights** for purposes of research and not for purposes of commercial manufacture or distribution or in lieu of purchase.

2.13 "**Affiliate(s)**" means a corporation or other business entity, which, directly or indirectly, is controlled by, controls, or is under common control with **Licensee**. For this purpose, the term "control" shall mean ownership of more than fifty percent (50%) of the voting stock or other ownership interest of the corporation or other business entity, or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other business entity.

3. GRANT OF RIGHTS

3.1 **PHS** hereby grants and **Licensee** accepts, subject to the terms and conditions of this **Agreement**, an exclusive license under the **Licensed Patent Rights** in the **Licensed Territory** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any **Licensed Products** in the Licensed Fields of Use and to practice and have practiced any **Licensed Processes** in the **Licensed Fields of Use**.

3.2 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of **PHS** other than the **Licensed Patent Rights** regardless of whether these patents are dominant or subordinate to the **Licensed Patent Rights**.

4. SUBLICENSING

4.1 Upon written approval, which shall include prior review of any sublicense agreement by **PHS** and which shall not be unreasonably withheld, Licensee may enter into sublicensing agreements under the **Licensed Patent Rights**.

4.2 **Licensee** agrees that any sublicenses granted by it shall provide that the obligations to **PHS** of Paragraphs 5.1 5.4, 8.1, 10.1, 10.2, 12.5, and 13.8-13.10 of this **Agreement** shall be binding upon the sublicensee as if it were a party to this **Agreement**. **Licensee** further agrees to attach copies of these Paragraphs to all sublicense agreements.

4.3 Any sublicenses granted by **Licensee** shall provide for the termination of the sublicense, or the conversion to a license directly between the sublicensees and **PHS**, at the option of the sublicensee, upon termination of this **Agreement** under Article 13. This conversion is subject to **PHS** approval which will not be unreasonably withheld and contingent upon acceptance by the sublicensee of the remaining provisions of this **Agreement**.

4.4 **Licensee** agrees to forward to **PHS** a complete copy of each fully executed sublicense agreement postmarked within thirty (30) days of the execution of the agreement. To the extent permitted by law, **PHS** agrees to maintain each sublicense agreement in confidence.

5. STATUTORY AND PHS REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

5.1 (a) **PHS** reserves on behalf of the **Government** an irrevocable, nonexclusive, nontransferable, royalty free license for the practice of all inventions licensed under the **Licensed Patent Rights** throughout the world by or on behalf of the **Government** and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement to which the **Government** is a signatory. Prior to the **First Commercial Sale**, **Licensee** agrees to provide **PHS** with reasonable quantities of **Licensed Products** or materials made through the **Licensed Processes** for **PHS** research use; and

(b) In the event that the **Licensed Patent Rights** are Subject Inventions made under a Cooperative Research and Development Agreement ("**CRADA**"), **Licensee** grants to the **Government**, pursuant to 15 U.S.C. §3710a(b)(1)(A), a nonexclusive, nontransferable, irrevocable, paid up license to practice **Licensed Patent Rights** or have **Licensed Patent Rights** practiced throughout the world by or on behalf of the **Government**. In the exercise of this license, the **Government** shall not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of 5 U.S.C. §552(b)(4) or which would be considered as such if it had been obtained from a non Federal party. Prior to the **First Commercial Sale**, **Licensee** agrees to provide **PHS** reasonable quantities of **Licensed Products** or materials made through the **Licensed Processes** for **PHS** research use.

5.2 **Licensee** agrees that products used or sold in the United States embodying **Licensed Products** or produced through use of **Licensed Processes** shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from **PHS**.

5.3 **Licensee** acknowledges that **PHS** may enter into future **CRADA**s under the Federal Technology Transfer Act of 1986 that relate to the subject matter of this Agreement. **Licensee** agrees not to unreasonably deny requests for a Research License from future collaborators with **PHS** when acquiring these rights is necessary in order to make a **CRADA** project feasible. **Licensee** may request an opportunity to join as a party to the proposed **CRADA**.

5.4 (a) In addition to the reserved license of Paragraph 5.1, **PHS** reserves the right to grant **Research Licenses** directly or to require **Licensee** to grant **Research Licenses** on reasonable terms. The purpose of these **Research Licenses** is to encourage basic research, whether conducted at an academic or corporate facility. In order to safeguard the **Licensed Patent Rights**, however, **PHS** shall consult with **Licensee** before granting to commercial entities a Research License or providing to them research samples of materials made through the **Licensed Processes**; and

(b) In exceptional circumstances, and in the event that **Licensed Patent Rights** are Subject Inventions made under a **CRADA**, the **Government**, pursuant to 15 U.S.C. §3710a(b)(1)(B), retains the right to require the **Licensee** to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive sublicense to use the **Licensed Patent Rights** in the **Licensed Field of Use** on terms that are reasonable under the circumstances, or if **Licensee** fails to grant this license, the **Government** retains the right to grant the license itself. The exercise of these rights by the **Government** shall only be in exceptional circumstances and only if the **Government** determines:

(i) the action is necessary to meet health or safety needs that are not reasonably satisfied by **Licensee**;

(ii) the action is necessary to meet requirements for public use specified by Federal regulations, and these requirements are not reasonably satisfied by the **Licensee**; or

(iii) the **Licensee** has failed to comply with an agreement containing provisions described in 15 U.S.C. §3710a(c)(4)(B); and

(c) The determination made by the **Government** under this Paragraph 5.4 is subject to administrative appeal and judicial review under 35 U.S.C. §203(2).

6. ROYALTIES AND REIMBURSEMENT

6.1 **Licensee** agrees to pay **PHS** a noncreditable, nonrefundable license issue royalty as set forth in Appendix C.

6.2 **Licensee** agrees to pay **PHS** a nonrefundable minimum annual royalty as set forth in Appendix C.

6.3 **Licensee** agrees to pay **PHS** earned royalties as set forth in Appendix C.

6.4 **Licensee** agrees to pay **PHS** benchmark royalties as set forth in Appendix C.

6.5 **Licensee** agrees to pay **PHS** sublicensing royalties as set forth in Appendix C.

6.6 A patent or patent application licensed under this Agreement shall cease to fall within the **Licensed Patent Rights** for the purpose of computing earned royalty payments in any given country on the earliest of the dates that:

(a) the application has been abandoned and not continued;

(b) the patent expires or irrevocably lapses, or

(c) the claim has been held to be invalid or unenforceable by an unappealed or unappealable decision of a court of competent jurisdiction or administrative agency.

6.7 No multiple royalties shall be payable because any **Licensed Products** or **Licensed Processes** are covered by more than one of the **Licensed Patent Rights**.

6.8 On sales of **Licensed Products** by **Licensee** to sublicensees or on sales made in other than an arms length transaction, the value of the Net Sales attributed under this Article 6 to this transaction shall be that which would have been received in an arms length transaction, based on sales of like quantity and quality products on or about the time of this transaction.

6.9 **PHS** has not incurred any expenses associated with the preparation, filing, prosecution, and maintenance of the patent applications and patents included within the **Licensed Patent Rights** prior to the effective date of this Agreement.

6.10 With regard to expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and incurred by **PHS** on or after the effective date of this Agreement, **PHS**, at its sole option, may require **Licensee**:

(a) to pay **PHS** on an annual basis, within sixty (60) days of **PHS**' submission of a statement and request for payment, a royalty amount equivalent to these patent expenses incurred during the previous calendar year(s);

(b) to pay these expenses directly to the law firm employed by **PHS** to handle these functions. However, in this event, **PHS** and not **Licensee** shall be the client of the law firm; or

(c) in limited circumstances, **Licensee** may be given the right to assume responsibility for the preparation, filing, prosecution, or maintenance of any patent application or patent included with the **Licensed Patent Rights**. In that event, **Licensee** shall directly pay the attorneys or agents engaged to prepare, file, prosecute, or maintain these patent applications or patents and shall provide **PHS** with copies of each invoice associated with these services as well as documentation that these invoices have been paid.

6.11 **PHS** agrees, upon written request, to provide **Licensee** with summaries of patent prosecution invoices for which **PHS** has requested payment from the **Licensee** under Paragraphs 6.9 and 6.10. **Licensee** agrees that all information provided by **PHS** related to patent prosecution costs shall be treated as confidential commercial information and shall not be released to a third party except as required by law or a court of competent jurisdiction.

6.12 **Licensee** may elect to surrender its rights in any country of the **Licensed Territory** under any of the **Licensed Patent Rights** upon ninety (90) days written notice to **PHS** and owe no payment obligation under Paragraph 6.10 for patent-related expenses incurred in that country after ninety (90) days of the effective date of the written notice.

7. PATENT FILING, PROSECUTION, AND MAINTENANCE

7.1 **Licensee** shall file, prosecute, and maintain patent application(s) relating to the **Licensed Patent Rights** and shall promptly provide to **PHS** all serial numbers and filing dates, together with copies of all these applications, including copies of all Patent Office actions, responses, and all other Patent Office communications. In addition, **Licensee** shall file with Patent Offices a Power of Attorney that names both **Licensee** and **PHS** or names inventors of the **Licensed Patent Rights** who are obligated to assign to**Licensee** or **PHS**. This Power of Attorney shall be filed with every Patent Office involved in prosecuting all patent applications pertaining to **Licensed Patent Rights**. **Licensee** shall consult with **PHS**, when so requested, prior to communicating with any Patent Office with respect to the **Licensed Patent Rights**. **PHS** shall timely provide to **Licensee** or its attorneys any formal document necessary to file, prosecute, and maintain patents and patent applications relating to the **Licensed Patent Rights**.

7.2 **Licensee** shall make an election with respect to foreign filing, upon consultation with **PHS**, including which countries foreign filing shall be done prior to the election, within eight (8) months of any United States filing. If any foreign patent applications are filed, **Licensee** shall promptly provide to **PHS** all serial numbers and filing dates. **Licensee** also shall provide **PHS** copies of foreign patent applications and Patent Office actions. **Licensee** shall consult with **PHS**, when so requested, prior to communication with any Patent Office with respect to the **Licensed Patent Rights**.

7.3 **Licensee** shall promptly record available Assignments of domestic **Licensed Patent Rights** in the United States Patent and Trademark Office and shall promptly provide **PHS** with the original of each recorded Assignment with respect to **PHS**.

7.4 Notwithstanding any other provision of this Agreement, **Licensee** shall not abandon the prosecution of any patent application, including provisional patent applications (except for purposes of filing continuation application(s)) or the maintenance of any patent contemplated by this Agreement, without prior written notice to **PHS**. Upon receiving the written notice, **PHS** may, at its sole option, take over the prosecution of any patent application, or the maintenance of any patent. **Licensee** agrees to furnish written notice to **PHS** as soon as possible after **Licensee**'s decision to abandon prosecution, and **Licensee** will not abandon prosecution within thirty (30) days of a prosecution deadline. **Licensee** shall promptly provide **PHS** with copies of all issued patents under this Agreement.

7.5 **Licensee** shall promptly provide **PHS** with copies of all issued patents under this Agreement.

7.6 In the event that **Licensee** anticipates the possibility of any extraordinary expenditures arising from the preparation, filing, prosecution, licensing, or defense of any patent application or patent contemplated by this Agreement, including, without limitation, interferences, reexaminations, reissues and oppositions, **Licensee** shall provide **PHS** with all relevant information.

8. RECORD KEEPING

8.1 **Licensee** agrees to keep accurate and correct records of **Licensed Products** made, used, sold, or imported and **Licensed Processes** practiced under this Agreement appropriate to determine the amount of royalties due **PHS**. These records shall be retained for at least five (5) years following a given reporting period and shall be available during normal business hours for inspection, at the expense of **PHS**, by an accountant or other designated auditor selected by **PHS** for the sole purpose of verifying reports and royalty payments hereunder. The accountant or auditor shall only disclose to **PHS** information relating to the accuracy of reports and royalty payments made under this Agreement. If an inspection shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then **Licensee** shall reimburse **PHS** for the cost of the inspection at the time **Licensee** pays the unreported royalties, including any additional royalties as required by Paragraph 9.8. All royalty payments required under this Paragraph shall be due within thirty (30) days of the date **PHS** provides **Licensee** notice of the payment due.

8.2 **Licensee** agrees to have an audit of sales and royalties conducted by an independent auditor at least every two (2) years if annual sales of the **Licensed Products** or **Licensed Processes** are over ten (10) million dollars. The audit shall address, at a minimum, the amount of gross sales by or on behalf of **Licensee** during the audit period, terms of the license as to percentage or fixed royalty to be remitted to the **Government**, the amount of royalties owed to the **Government** under this Agreement, and whether the royalties owed have been paid to the **Government** and is reflected in the records of the **Licensee**. The audit shall also indicate the **PHS** license number, product, and the time period being audited. A report certified by the auditor shall be submitted promptly by the auditor directly to **PHS** on completion. **Licensee** shall pay for the entire cost of the audit.

9. REPORTS ON PROGRESS, BENCHMARKS, SALES, AND PAYMENTS

9.1 Prior to signing this **Agreement**, **Licensee** has provided **PHS** with the **Commercial Development Plan** in Appendix E, under which **Licensee** intends to bring the subject matter of the **Licensed Patent Rights** to the point of **Practical Application**. This **Commercial Development Plan** is hereby incorporated by reference into this **Agreement**. Based on this plan, performance **Benchmarks** are determined as specified in Appendix D.

9.2 **Licensee** shall provide written annual reports on its product development progress or efforts to commercialize under the **Commercial Development Plan** for each of the **Licensed Fields of Use** within sixty (60) days after December 31 of each calendar year. These progress reports shall include, but not be limited to: progress on research and development, status of applications for regulatory approvals, manufacturing, sublicensing, marketing, importing, and sales during the preceding calendar year, as well as, plans for the present calendar year. **PHS** also encourages these reports to include information on any of **Licensee**'s public service activities that relate to the **Licensed Patent Rights**. If reported progress differs from that projected in the **Commercial Development Plan** and **Benchmarks**, **Licensee** shall explain the reasons for these differences. In the annual report, **Licensee** may propose amendments to the **Commercial Development Plan**, acceptance of which by **PHS** may not be denied unreasonably. **Licensee** agrees to provide any additional information reasonably required by **PHS** to evaluate **Licensee**'s performance under this Agreement. **Licensee** may amend the **Benchmarks** at any time upon written approval by **PHS**. **PHS** shall not unreasonably withhold approval of any request of **Licensee** to extend the time periods of this schedule if the request is supported by a reasonable showing by **Licensee** of diligence in its performance under the **Commercial Development Plan** and toward bringing the **Licensed Products** to the point of **Practical Application** as defined in 37 CFR §404.3(d). **Licensee** shall amend the **Commercial Development Plan** and **Benchmarks** at the request of **PHS** to address any Licensed Fields of Use not specifically addressed in the plan originally submitted.

9.3 **Licensee** shall report to **PHS** the dates for achieving **Benchmarks** specified in Appendix D and the **First Commercial Sale** in each country in the **Licensed Territory** within thirty (30) days of such occurrences.

9.4 **Licensee** shall submit to **PHS**, within sixty (60) days after each calendar half year ending June 30 and December 31, a royalty report, as described in the example in Appendix F, setting forth for the preceding half year period the amount of the **Licensed Products** sold or **Licensed Processes** practiced by or on behalf of **Licensee** in each country within the **Licensed Territory**, the **Net Sales**, and the amount of royalty accordingly due. With each royalty report, **Licensee** shall submit payment of earned royalties due. If no earned royalties are due to **PHS** for any reporting period, the written report shall so state. The royalty report shall be certified as correct by an authorized officer of **Licensee** and shall include a detailed listing of all deductions made under Paragraph 2.10 to determine **Net Sales** made under Article 6 to determine royalties due.

9.5 **Licensee** agrees to forward semi annually to **PHS** a copy of these reports received by **Licensee** from its sublicensees during the preceding half year period as shall be pertinent to a royalty accounting to **PHS** by **Licensee** for activities under the sublicense.

9.6 Royalties due under Article 6 shall be paid in U.S. dollars and payment options are listed in Appendix G. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day that the payment is due. Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by **Licensee**. The royalty report required by Paragraph 9.4 shall be mailed to **PHS** at its address for Agreement Notices indicated on the Signature Page.

9.7 **Licensee** shall be solely responsible for determining if any tax on royalty income is owed outside the United States and shall pay the tax and be responsible for all filings with appropriate agencies of foreign governments.

9.8 Additional royalties may be assessed by **PHS** on any payment that is more than ninety (90) days overdue at the rate of one percent (1%) per month. This one percent (1%) per month rate may be applied retroactively from the original due date until the date of receipt by **PHS** of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent **PHS** from exercising any other rights it may have as a consequence of the lateness of any payment.

9.9 All plans and reports required by this Article 9 and marked "confidential" by **Licensee** shall, to the extent permitted by law, be treated by **PHS** as commercial and financial information obtained from a person and as privileged and confidential, and any proposed disclosure of these records by the **PHS** under the Freedom of Information Act (FOIA), 5 U.S.C. §552 shall be subject to the predisclosure notification requirements of 45 CFR §5.65(d).

10. PERFORMANCE

10.1 **Licensee** shall use its reasonable commercial efforts to bring the **Licensed Products** and **Licensed Processes** to **Practical Application**. "Reasonable commercial efforts" for the purposes of this provision shall include adherence to the **Commercial Development Plan** in Appendix E and performance of the **Benchmarks** in Appendix D. The efforts of a sublicensee shall be considered the efforts of **Licensee**.

10.2 Upon the **First Commercial Sale**, until the expiration or termination of this Agreement, **Licensee** shall use its reasonable commercial efforts to make **Licensed Products** and **Licensed Processes** reasonably accessible to the United States public.

10.3 **Licensee** agrees, after its **First Commercial Sale**, to make reasonable quantities of **Licensed Products** or materials produced through the use of **Licensed Processes** available on a compassionate use basis to patients, either through the patient's physician(s) or the medical center treating the patient.

10.4 **Licensee** agrees, after its **First Commercial Sale** and as part of its marketing and product promotion, to develop educational materials (e.g., brochures, website, etc.) directed to patients and physicians detailing the **Licensed Products** or medical aspects of the prophylactic and therapeutic uses of the **Licensed Products**.

10.5 **Licensee** agrees to supply, to the Mailing Address for Agreement Notices indicated on the Signature Page, the Office of Technology Transfer, **NIH** with inert samples of the **Licensed Products** or **Licensed Processes** or their packaging for educational and display purposes only.

11. INFRINGEMENT AND PATENT ENFORCEMENT

11.1 **PHS** and **Licensee** agree to notify each other promptly of each infringement or possible infringement of the **Licensed Patent Rights**, as well as, any facts which may affect the validity, scope, or enforceability of the **Licensed Patent Rights** of which either party becomes aware.

11.2 Pursuant to this Agreement and the provisions of Chapter 29 of Title 35, United States Code, **Licensee** may:

(a) bring suit in its own name, at its own expense, and on its own behalf for infringement of presumably valid claims in the **Licensed Patent Rights**;

(b) in any suit, enjoin infringement and collect for its use, damages, profits, and awards of whatever nature recoverable for the infringement; or

(c) settle any claim or suit for infringement of the **Licensed Patent Rights** provided, however, that **PHS** and appropriate **Government** authorities shall have the first right to take such actions; and

(d) If **Licensee** desires to initiate a suit for patent infringement, **Licensee** shall notify **PHS** in writing. If **PHS** does not notify **Licensee** of its intent to pursue legal action within ninety (90) days, **Licensee** shall be free to initiate suit. **PHS** shall have a continuing right to intervene in the suit. **Licensee** shall take no action to compel the **Government** either to initiate or to join in any suit for patent infringement. **Licensee** may request the **Government** to initiate or join in any suit if necessary to avoid dismissal of the suit. Should the **Government** be made a party to any suit, **Licensee** shall reimburse the **Government** for any costs, expenses, or fees which the **Government** incurs as a result of the motion or other action, including all costs incurred by the **Government** in opposing the motion or other action. In all cases, **Licensee** agrees to keep **PHS** reasonably apprised of the status and progress of any litigation. Before **Licensee** commences an infringement action, **Licensee** shall notify **PHS** and give careful consideration to the views of **PHS** and to any potential effects of the litigation on the public health in deciding whether to bring suit.

11.3 In the event that a declaratory judgment action alleging invalidity or non infringement of any of the **Licensed Patent Rights** shall be brought against **Licensee** or raised by way of counterclaim or affirmative defense in an infringement suit brought by **Licensee** under Paragraph 11.2, pursuant to this Agreement and the provisions of Chapter 29 of Title 35, United States Code or other statutes, **Licensee** may:

(a) defend the suit in its own name, at its own expense, and on its own behalf for presumably valid claims in the **Licensed Patent Rights**;

(b) in any suit, ultimately to enjoin infringement and to collect for its use, damages, profits, and awards of whatever nature recoverable for the infringement; and

(c) settle any claim or suit for declaratory judgment involving the **Licensed Patent Rights**-provided, however, that **PHS** and appropriate **Government** authorities shall have the first right to take these actions and shall have a continuing right to intervene in the suit; and

(d) If **PHS** does not notify **Licensee** of its intent to respond to the legal action within a reasonable time, **Licensee** shall be free to do so. **Licensee** shall take no action to compel the **Government** either to initiate or to join in any declaratory judgment action. **Licensee** may request the **Government** to initiate or to join any suit if necessary to avoid dismissal of the suit. Should the **Government** be made a party to any suit by motion or any other action of **Licensee**, **Licensee** shall reimburse the **Government** for any costs, expenses, or fees, which the **Government** incurs as a result of the motion or other action. If **Licensee** elects not to defend against the declaratory judgment action, **PHS**, at its option, may do so at its own expense. In all cases, **Licensee** agrees to keep **PHS** reasonably apprised of the status and progress of any litigation. Before **Licensee** commences an infringement action, **Licensee** shall notify **PHS** and give careful consideration to the views of **PHS** and to any potential effects of the litigation on the public health in deciding whether to bring suit.

11.4 In any action under Paragraphs 11.2 or 11.3 the expenses including costs, fees, attorney fees, and disbursements, shall be paid by **Licensee**. The value of any recovery made by **Licensee** through court judgment or settlement shall be treated as **Net Sales** and subject to earned royalties.

11.5 **PHS** shall cooperate fully with **Licensee** in connection with any action under Paragraphs 11.2 or 11.3. **PHS** agrees promptly to provide access to all necessary documents and to render reasonable assistance in response to a request by **Licensee**.

12. NEGATION OF WARRANTIES AND INDEMNIFICATION

12.1 **PHS** offers no warranties other than those specified in Article 1.

12.2 **PHS** does not warrant the validity of the **Licensed Patent Rights** and makes no representations whatsoever with regard to the scope of the **Licensed Patent Rights**, or that the **Licensed Patent Rights** may be exploited without infringing other patents or other intellectual property rights of third parties.

12.3 **PHS** MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE LICENSED PATENT RIGHTS OR TANGIBLE MATERIALS RELATED THERETO.

12.4 **PHS** does not represent that it shall commence legal actions against third parties infringing the **Licensed Patent Rights**.

12.5 **Licensee** shall indemnify and hold **PHS**, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of:

(a) the use by or on behalf of **Licensee**, its sublicensees, directors, employees, or third parties of any **Licensed Patent Rights**; or

(b) the design, manufacture, distribution, or use of any **Licensed Products**, **Licensed Processes** or materials by **Licensee**, or other products or processes developed in connection with or arising out of the **Licensed Patent Rights**.

12.6 **Licensee** agrees to maintain a liability insurance program consistent with sound business practice.

13. TERM, TERMINATION, AND MODIFICATION OF RIGHTS

13.1 This Agreement is effective when signed by all parties, unless the provisions of Paragraph 14.16 are not fulfilled, and shall extend to the expiration of the last to expire of the **Licensed Patent Rights** unless sooner terminated as provided in this Article 13.

13.2 In the event that **Licensee** is in default in the performance of any material obligations under this Agreement, including but not limited to the obligations listed in Paragraph 13.5, and if the default has not been remedied within ninety (90) days after the date of notice in writing of the default, **PHS** may terminate this Agreement by written notice and pursue outstanding royalties owed through procedures provided by the Federal Debt Collection Act.

13.3 In the event that **Licensee** becomes insolvent, files a petition in bankruptcy, has such a petition filed against it, determines to file a petition in bankruptcy, or receives notice of a third party's intention to file an involuntary petition in bankruptcy, **Licensee** shall immediately notify **PHS** in writing. Furthermore, **PHS** shall have the right to terminate this Agreement immediately upon **Licensee**'s receipt of written notice.

13.4 **Licensee** shall have a unilateral right to terminate this Agreement or any licenses in any country or territory by giving **PHS** sixty (60) days written notice to that effect.

13.5 **PHS** shall specifically have the right to terminate or modify, at its option, this Agreement, subject to paragraph 13.2, if **PHS** determines that the **Licensee**:

(a) is not executing the **Commercial Development Plan** submitted with its request for a license and the **Licensee** cannot otherwise demonstrate to **PHS**' reasonable satisfaction that the **Licensee** has taken, or can be expected to take within a reasonable time, effective steps to achieve **Practical Application** of the **Licensed Products** or **Licensed Processes**;

(b) has not achieved the **Benchmarks** as may be modified under Paragraph 9.2;

(c) has willfully made a false statement of, or willfully omitted a material fact in the license application or in any report required by the license Agreement;

(d) has committed a material breach of a covenant or agreement contained in this Agreement;

(e) is not keeping **Licensed Products** or **Licensed Processes** reasonably available to the public after commercial use commences;

(f) cannot reasonably satisfy unmet health and safety needs; or

(g) cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 5.2 unless waived.

13.6 In making the determination referenced in Paragraph 13.5, **PHS** shall take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by **Licensee** under Paragraph 9.2. Prior to invoking termination or modification of this Agreement under Paragraph 13.5, **PHS** shall give written notice to **Licensee** providing **Licensee** specific notice of, and a ninety (90) day opportunity to respond to, **PHS**' concerns as to the items referenced in 13.5(a)-13.5(g). If **Licensee** fails to alleviate **PHS**' concerns as to the items referenced in 13.5(a)-13.5(g) or fails to initiate corrective action to **PHS**' reasonable satisfaction, **PHS** may terminate this Agreement.

13.7 When the public health and safety so require, and after written notice to **Licensee** providing **Licensee** a sixty (60) day opportunity to respond, **PHS** shall have the right to require **Licensee** to grant sublicenses to responsible applicants, on reasonable terms, in any Licensed Fields of Use under the **Licensed Patent Rights**, unless **Licensee** can reasonably demonstrate that the granting of the sublicense would not materially increase the availability to the public of the subject matter of the **Licensed Patent Rights**. **PHS** shall not require the granting of a sublicense unless the responsible applicant has first negotiated in good faith with **Licensee**.

13.8 **PHS** reserves the right according to 35 U.S.C. §209(d)(3) to terminate or modify this Agreement if it is determined that this action is necessary to meet the requirements for public use specified by federal regulations issued after the date of the license and these requirements are not reasonably satisfied by **Licensee**.

13.9 Within thirty (30) days of receipt of written notice of **PHS**' unilateral decision to modify or terminate this Agreement, **Licensee** may, consistent with the provisions of 37 CFR §404.11, appeal the decision by written submission to the designated **PHS** official. The decision of the designated **PHS** official shall be the final agency decision. **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.

13.10 Within ninety (90) days of expiration or termination of this Agreement under this Article 13, a final report shall be submitted by **Licensee**. Any royalty payments, including those incurred but not yet paid (such as the full minimum annual royalty), and those related to patent expense, due to **PHS** shall become immediately due and payable upon termination or expiration. If terminated under this Article 13, sublicensees may elect to convert their sublicenses to direct licenses with **PHS** pursuant to Paragraph 4.3. Unless otherwise specifically provided for under this Agreement, upon termination or expiration of this Agreement, **Licensee** shall return all **Licensed Products** or other materials included within the **Licensed Patent Rights** to **PHS** or provide **PHS** with certification of the destruction thereof.

14. GENERAL PROVISIONS

14.1 Neither party may waive or release any of its rights or interests in this Agreement except in writing. The failure of the **Government** to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right by the **Government** or excuse a similar subsequent failure to perform any of these terms or conditions by **Licensee**.

14.2 This Agreement constitutes the entire agreement between the parties relating to the subject matter of the **Licensed Patent Rights**, **Licensed Products** and **Licensed Processes**, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this Agreement.

14.3 The provisions of this Agreement are severable, and in the event that any provision of this Agreement shall be determined to be invalid or unenforceable under any controlling body of law, this determination shall not in any way affect the validity or enforceability of the remaining provisions of this Agreement.

14.4 If either party desires a modification to this Agreement, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of the modification. No modification shall be effective until a written amendment is signed by the signatories to this Agreement or their designees.

14.5 The construction, validity, performance, and effect of this Agreement shall be governed by Federal law as applied by the Federal courts in the District of Columbia.

14.6 All Agreement notices required or permitted by this Agreement shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other party at the address designated on the following Signature Page, or to another address as may be designated in writing by the other party. Agreement notices shall be considered timely if the notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

14.7 This Agreement may not be assigned without prior written permission from **PHS** except to an Affiliate, which permission shall not be unreasonably withheld. **Licensee** shall provide **PHS** a minimum of sixty (60) days to grant the written permission. In the event that no response from **PHS** during the sixty (60) day period is received, **Licensee** shall consider the permission granted. **Licensee** shall pay **PHS**, as an additional royalty, one percent (1%) of the fair market value of any consideration received for any assignment of this Agreement within thirty (30) days of the assignment.

14.8 **Licensee** agrees in its use of any **PHS** supplied materials to comply with all applicable statutes, regulations, and guidelines, including **PHS** and **HHS** regulations and guidelines. **Licensee** agrees not to use the materials for research involving human subjects or clinical trials in the United States without complying with 21 CFR Part 50 and 45 CFR Part 46. **Licensee** agrees not to use the materials for research involving human subjects or clinical trials outside of the United States without notifying **PHS**, in writing, of the research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to **PHS** of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of the research or trials.

14.9 **Licensee** acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological material, and other commodities. The transfer of these items may require a license from the appropriate agency of the U.S. **Government** or written assurances by **Licensee** that it shall not export these items to certain foreign countries without prior approval of this agency. **PHS** neither represents that a license is or is not required or that, if required, it shall be issued.

14.10 **Licensee** agrees to mark the **Licensed Products** or their packaging sold in the United States with all applicable U.S. patent numbers and similarly to indicate "Patent Pending" status. All **Licensed Products** manufactured in, shipped to, or sold in other countries shall be marked in a manner to preserve **PHS** patent rights in those countries.

14.11 By entering into this Agreement, **PHS** does not directly or indirectly endorse any product or service provided, or to be provided, by **Licensee** whether directly or indirectly related to this Agreement. **Licensee** shall not state or imply that this Agreement is an endorsement by the **Government**, **PHS**, any other **Government** organizational unit, or any **Government** employee. Additionally, **Licensee** shall not use the names of **NIH**, **FDA**, **PHS**, or **HHS** or the **Government** or their employees in any advertising, promotional, or sales literature without the prior written approval of **PHS**.

14.12 The parties agree to attempt to settle amicably any controversy or claim arising under this Agreement or a breach of this Agreement, except for appeals of modifications or termination decisions provided for in Article 13. **Licensee** agrees first to appeal any unsettled claims or controversies to the designated **PHS** official, or designee, whose decision shall be considered the final agency decision. Thereafter, **Licensee** may exercise any administrative or judicial remedies that may be available.

14.13 Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to 37 CFR Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.

14.14 Any formal recordation of this Agreement required by the laws of any **Licensed Territory** as a prerequisite to enforceability of the Agreement in the courts of any foreign jurisdiction or for other reasons will be carried out by **Licensee** at its expense, and appropriately verified proof of recordation will be promptly furnished to **PHS**.

14.15 Paragraphs 4.3, 8.1, 9.5-9.7, 12.1-12.5, 13.9, 13.10, and 14.13 of this Agreement shall survive termination of this Agreement.

14.16 The terms and conditions of this Agreement shall, at **PHS**' sole option, be considered by **PHS** to be withdrawn from **Licensee**'s consideration and the terms and conditions of this Agreement, and the Agreement itself to be null and void, unless this Agreement is executed by the **Licensee** and a fully executed original is received by **PHS** within sixty (60) days from the date of **PHS** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

PHS PATENT LICENSE AGREEMENT – *EXCLUSIVE*

SIGNATURE PAGE

For **PHS**:

Richard U. Rodriguez. M.B.A. Date
Director, Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

Date

Mailing Address for **Agreement** notices:

Chief, Monitoring & Enforcement Branch, DTDT
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

For **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of **Licensee** made or referred to in this document are truthful and accurate.):

by:

Signature of Authorized Official

Date

John S. Kovach
Printed Name

Chief Executive Officer
Title

I. Official and Mailing Address for **Agreement** notices:

John S. Kovach
Name

Chief Executive Officer
Title

Mailing Address

Lixte Biotechnology, Inc.
248 Route 25A #2
East Setauket, NY 11733

Email Address:

Phone: 631-942-7959
Fax: 631-982-5050

II. Official and Mailing Address for Financial notices (**Licensee's** contact person for royalty payments)

John S. Kovach
Name

Chief Executive Officer
Title

Mailing Address:

Lixte Biotechnology, Inc.
248 Route 25A #2
East Setauket, NY 11733

Email Address:

Phone: 631-942-7959
Fax: 631-982-5050

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) or imprisonment).

APPENDIX A – PATENT(S) OR PATENT APPLICATION(S)

Patent(s) or Patent Application(s):

I. U.S. Provisional Patent Application No. 60/771,163, filed February 6, 2006, entitled "Use of Phosphatases To Treat Glioblastomas" (**HHS** Ref. No. E-123-2006/0-US-01);

II. U.S. Provisional Patent Application No. 60/797,201, filed May 2, 2006, entitled "Use of Phosphatases To Treat Glioblastomas" (**HHS** Ref. No. E-123-2006/1-US-01)

III. U.S. Patent Application Serial No. 11/703,401, filed February 6, 2007, entitled "Use of Phosphatases To Treat Glioblastomas" (**HHS** Ref. No. E-123-2006/0-US-03)

IV. PCT International Application No. PCT/US2007/003095, filed February 6, 2007 entitled "Use of Phosphatases To Treat Glioblastomas" (**HHS** Ref. No. E-123-2006/0-PCT-02)

V. U.S. Provisional Patent Application No. 60/963,307, filed August 3, 2007 entitled "Use of Phosphatases To Treat Neuroblastomas and Medulloblastomas" (**HHS** Ref. No. E-123-2006/2-US-01)

VI. U.S. Provisional Patent Application No. 60/063,970, filed February 6, 2008 entitled "Use of Phosphatases To Treat Neuroblastomas and Medulloblastomas".

VII. U.S. Application in preparation corresponding to Cooper and Dunham Referene No. 4101/79251.

APPENDIX B – LICENSED FIELDS OF USE AND TERRITORY

I. **Licensed Fields of Use:**

(a) Treatment of Glioblastomas and other Central Nervous System (CNS) tumors

II. **Licensed Territory:**

(a) Worldwide

APPENDIX C – ROYALTIES

Royalties:

I. **Licensee** agrees to pay to **PHS** a noncreditable, nonrefundable license issue royalty in the amount of Twenty Five Thousand dollars ($25,000) within sixty (60) days from the effective date of this **Agreement**.

II. **Licensee** agrees to pay **PHS** a nonrefundable minimum annual royalty in the amount of Thirty Thousand ($30,000) on January 1 of each calendar year following the year during which the March 22, 2006 CRADA agreement, as appended, between the parties is terminated and may be credited against any earned royalties due for sales made in that year.

III. **Licensee** agrees to pay **PHS** earned royalties of Four and one-half percent (4.5%) on **Net Sales** by or on behalf of **Licensee** and its sublicensees.

IV. **Licensee** agrees to pay **PHS Benchmark** royalties within thirty (30) days of achieving each **Benchmark**:

(a) Fifty Thousand dollars ($50,000) upon starting Phase I Clinical Trials;

(b) One Hundred Thousand dollars ($100,000) upon starting Phase II Clinical Trials;

(c) Two Hundred Thousand dollars ($200,000) upon starting Phase III Clinical Trials;

(d) Three Hundred Thousand dollars ($300,000) upon filing an IND submission; and

(e) Six Hundred Twenty Five Thousand dollars ($625,000) upon the First Commercial Sale

V. **Licensee** agrees to pay **PHS** additional sublicensing royalties of fifteen percent (15%) on the fair market value of any consideration received for granting each sublicense within sixty (60) days of the execution of each sublicense.

APPENDIX D – BENCHMARKS AND PERFORMANCE

Licensee agrees to the following **Benchmarks** for its performance under this **Agreement** and, within thirty (30) days of achieving a **Benchmark**, shall notify **PHS** that the **Benchmark** has been achieved.

I. Initiation of Phase I Clinical Trials – Est. Second Quarter, 2010

II. Initiation of Phase II Clinical Trials – Est. Second Quarter, 2011

III. Initiation of Phase III Clinical Trials – Est. Third Quarter, 2012

IV. Filing of an IND Submission – Est. Fourth Quarter, 2009

V. First Commercial Sale Expected Timeline – Est. First Quarter, 2015

APPENDIX E – COMMERCIAL DEVELOPMENT PLAN

The ultimate objective of the CRADA is to identify, characterize, and bring to clinical trial regimens for the treatment of human brain tumors (GBMs) and other Central Nervous System (CNS) tumors. Lixte Biotechnology Holdings, Inc., the parent company of **Licensee** will most likely conduct such a clinical trial in association with NINDS.

Licensee is in contact with several large pharmaceutical companies with major programs in development and evaluation of anti-cancer drugs about co-developing one or more phosphatase ligands shown to have anti-cancer activity in vitro and in vivo in the CRADA studies. **Licensee**, however, is prepared to work with NINDS and /or other branches of NIH to develop these compounds through pre-clinical evaluation and clinical testing without the addition of a larger pharmaceutical partner.

To facilitate this approach, NINDS has submitted an application to the NIH RAID PILOT program to be reviewed in the summer of 2008. If approved, NINDS would collaborate with **Licensee** to complete pre-clinical development of one lead compound under the RAID program through to submission of an IND to the FDA for a Phase I trial. The Phase I trial could be done with one of several large academic brain tumor centers in the US, including the surgical neurology branch of NINDS. Following completion of Phase I testing, **Licensee** is committed to supporting Phase II evaluations with or without an additional partner from the pharmaceutical industry.

APPENDIX F – EXAMPLE ROYALTY REPORT

Required royalty report information includes:

- OTT license reference number (L-XXX-200X/0)
- Reporting period
- Catalog number and units sold of each Licensed Product (domestic and foreign)
- Gross Sales per catalog number per country
- Total Gross Sales
- Itemized deductions from Gross Sales
- Total Net Sales
- Earned Royalty Rate and associated calculations
- Gross Earned Royalty
- Adjustments for Minimum Annual Royalty (MAR) and other creditable payments made
- Net Earned Royalty due

Example

Catalog Number	Product Name	Country	Units Sold	Gross Sales (US$)
1	A	US	250	62,500
1	A	UK	32	16,500
1	A	France	25	15,625
2	B	US	0	0
3	C	US	57	57,125
4	D	US	12	1,500
			Total Gross Sales	153,250
			Less Deductions:	
			Freight	3,000
			Returns	7,000
			Total Net Sales	143,250
			Royalty Rate	8%
			Royalty Due	11,460
			Less Creditable Payments	10,000
			Net Royalty Due	**1,460**

APPENDIX G – ROYALTY PAYMENT OPTIONS

NIH/PHS License Agreements

****In order to process payment via Electronic Funds Transfer sender MUST supply the following information:***

Procedure for Transfer of Electronic Funds to NIH for Royalty Payments

Bank Name: Federal Reserve Bank
ABA# 021030004
TREAS NYC
BNF=/AC-75080031
OBI=Licensee Name and OTT Reference Number
Dollar Amount Wired=$$

NOTE: Only U.S. banks can wire directly to the Federal Reserve Bank. Foreign banks cannot wire directly to the Federal Reserve Bank, but must go through an intermediary U.S. bank. Foreign banks may send the wire transfer to the U.S. bank of their choice, who, in turn forwards the wire transfer to the Federal Reserve Bank.

Checks drawn on a U.S. bank account should be sent directly to the following address:

National Institutes of Health (NIH)
P.O. Box 979071
St. Louis, MO 63197-9000

Overnight or courier deliveries should be sent to the following address:

US Bank
Government Lockbox SL-MO-C2GL
1005 Convention Plaza
St. Louis, MO 63101
Phone: 314-418-4087

Checks drawn on a foreign bank account should be sent directly to the following address:

National Institutes of Health (NIH)
Office of Technology Transfer
Royalties Administration Unit
6011 Executive Boulevard
Suite 325, MSC 7660
Rockville, Maryland 20852
Phone: 301-496-7057

All checks should be made payable to "NIH Patent Licensing".

The OTT Reference Number MUST appear on checks, reports and correspondence

Certification of the Principal Executive Officer and Principal 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:

1. I have reviewed this Annual Report on Form 10-K of Lixte Biotechnology Holdings, Inc.;

2. 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;

3. 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;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and 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 that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of 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 30, 2009

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

CERTIFICATIONS OF THE PRINCIPAL EXECUTIVE OFFICERAND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350

In connection with the Annual Report of Lixte Biotechnology Holdings, Inc. (the "Company") on Form 10-K for the year ended December 31, 2008, as filed with the Securities and Exchange Commission (the "Report"), the undersigned does hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of the undersigned's knowledge:

(i) The 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 Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 30, 2009

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