# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 10-KSB

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

For the fiscal year ended December 31, 2007

□ 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 small business issuer in its charter)

**Delaware** (State or other jurisdiction of incorporation or organization)

248 Route 25A, No. 2 East Setauket, New York (Address of principal executive offices) **20-2903526** (I.R.S. Employer Identification Number)

> 11733 (Zip Code)

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

Securities registered under Section 12(g) of the Act: Common Stock, \$0.0001 par value.

Check whether the issuer is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act.

Check whether the issuer (1) 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  $\boxtimes$  No  $\square$ 

Issuer's telephone number: (631) 942-7959

Check 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-KSB or any amendment to this Form 10-KSB.

Indicate by check mark whether the 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, 2007: \$0

Aggregate market value of the common stock held by non-affiliates of the Issuer as of March 15, 2008 was approximately \$9,729,352.

There were 27,832,178 shares of the Company's common stock outstanding on March 15, 2008.

Transitional Small Business Disclosure Format: Yes 🗖 No 🖾

#### Introductory Comment

Throughout this Annual Report on Form 10-KSB, 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 10K-SB (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.

# Business

The Company is concentrating on discovering biomarkers for common cancers for which better diagnostic and therapeutic measures are needed. For each of these diseases, a biomarker that would enable identification of the presence of cancer at a stage curable by surgery could possibly save thousands of lives annually. In addition, biomarkers specific to these diseases may also provide clues as to processes (biological pathways) that characterize specific cancer types and that may be vulnerable to drug treatment targeted to the activity of the biomarker.

The Company is currently focusing on developing new treatments for the most common and most aggressive type of brain cancer of adults, glioblastoma multiforme ("GBM"). 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.

The research on brain tumors is proceeding in collaboration with the National Institute of Neurological Disorders and Stroke ("NINDS") of the National Institutes of Health ("NIH") under a Cooperative Research and Development Agreement ("CRADA") entered into on March 22, 2006, as amended. The research at NINDS continues to be led by Dr. Zhengping Zhuang, an internationally recognized investigator in the molecular pathology of cancer. Dr. Zhuang is aided by two senior research technicians supported by the Company as part of the CRADA. The goal of the CRADA is to develop more effective drugs for the treatment of GBM through the processes required to gain Food and Drug Administration ("FDA") approval for clinical trials. The Company's contribution to the CRADA has been \$200,000 annually for two years. The CRADAis presently scheduled to end June 30, 2008, with current discussions exploring a several month extension supported by funds remaining from the original agreement, followed by a potential one-year extension at a cost of \$200,000.

The Company has filed a series of patent applications jointly with NIH covering certain methods of treatment of brain tumors of adults and children. On February 14, 2007, provisional patent applications were converted to a U.S. non-provisional patent and a patent cooperation treaty application on behalf of the Company and NIH.

Patent applications filed with NIH are jointly owned by NIH and Lixte. All NIH co-inventors assigned 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 is continuing its negotiations on the details of the terms under which NIH will provide an exclusive license and anticipates finalizing terms of the agreement with the NIH in mid-2008.

The Company has also filed patent applications for intellectual property owned solely by the Company. These applications identify two series of new anti-cancer agents referred to as the LB-1 series and the LB-2 series. The applications include identification of the structure of molecules, their synthesis, and their activity against GBM, medulloblastoma, and more recently, the common cancers and leukemias as mentioned above. At the present time, the efficacies of the LB-1 and LB-2 series are based on activity in cell culture and in animal models of GBM and medulloblastoma. The Company is in the process of documenting the activities of both series of drugs against the more common tumor types in animal models.

In February 2008, the Company converted provisional patents relating to the nature and activity of the LB-1 series of drugs with the filing of a U.S. non-provisional and a PCT patent application.

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.

The Company expects that its products will derive directly from the intellectual property from its research activities. 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 much more common human cancers, as well as serious fungal infections, originated from its original focus on a biochemical defect 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.

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).

During 2008, the Company will also start to make public presentations of some of its data at national and international scientific meetings. A presentation was made at the First International Drug Discovery and Development Meeting, in Dubai, UAE, in February 2008, and a presentation will be made at the Annual Meeting of the American Association of Cancer Research in San Diego, California, in April 2008.

The Company had planned to begin its own analyses of tumor types other than GBM for new biomarkers by late 2008. However, in order to do this, the Company would need to establish and operate an independent laboratory. The creation and operation of such a laboratory for two years is estimated to cost approximately \$2,000,000. Accordingly, the Company is deferring plans to open and staff an independent laboratory until the full intellectual property value of its initial lead compounds for treatment of brain tumors is determined.

A goal of the Company is to continue the synthesis of new compounds that target other components of molecular pathways already identified by the Company and its CRADA partner to be vulnerable to attack by small molecule drugs, and to explore the vulnerability of additional potential new targets revealed through the molecular characterization of the effects of the Company's lead compounds.

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, 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 by early 2009. 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 2009.

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.

## GLOSSARY

The following technical terms are used in this Report:

#### Assay

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

### Biomarker

A <u>biomarker</u> 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 <u>assay</u> indicates that a particular cell is very likely to be present in the body. In this Report, "**biomarkers**" refer primarily to <u>proteins</u> 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 <u>cell growth</u> 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 <u>metastasis</u>.

### Cell Growth

<u>Cell growth</u> 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 <u>but identifiable</u> by the presence of biomarkers specific to breast or brain cells.

### CRADA

A <u>CRADA</u> (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 more gene 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 <u>cell growth</u>. When proteins controlling cell growth are altered, as occurs in all cancers, they become prime candidates for <u>biomarkers</u> that reveal the presence of cancer.

### Glioblastoma Multiforme (GBM)

<u>GBM</u> 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. <u>GBM</u> is the initial target of Lixte.

# 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 <u>mutation</u> 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 <u>biomarkers</u>, 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

<u>Prognosis</u> 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**

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 except the United States was filed containing all claims in the provisional patent plus additional claims. A non-provisional patent application with the same claims was filed in the United States. The PCT application and the non-provisional application include data supporting the original claims in the provisional patent and a number of new claims, including evidence that several drugs mentioned in the provisional patent may mimic the activity of the lead drugs named in the provisional patent, and do, in fact, have anti-tumor activity against human glioblastoma cell lines.



Both February patent 2007 filings, the PCT application and the non-provisional application, fall under the CRADA agreement with NINDS of the NIH. As such, we are entitled to obtain an exclusive license to such claims as specified in the standard NIH CRADA. In addition, patents resulting from these applications will be jointly owned by Lixte and the U.S. Government. The terms of the license (including term and royalty) is subject to continuing negotiations between us and NINDS of the NIH in the future.

The Company has also filed patent applications for intellectual property owned solely by the Company. These applications identify two series of new anti-cancer agents referred to as the LB-1 series and the LB-2 series. The applications include identification of the structure of molecules, their synthesis, and their activity against GBM, medulloblastoma, and more recently, the common cancers and leukemias as mentioned above. At the present time, the efficacies of the LB-1 and LB-2 series are based on activity in cell culture and in animal models of GBM and medulloblastoma. The Company is in the process of documenting the activities of both series of drugs against the more common tumor types in animal models.

In February 2008, the Company converted provisional patents relating to the nature and activity of the LB-1 series of drugs with the filing of a U.S. non-provisional and a PCT patent application.

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.

The Company expects that its products will derive directly from the intellectual property from its research activities. 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 much more common human cancers, as well as serious fungal infections, originated from its original focus on a biochemical defect 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.

# Access to Clinical Materials

On January 5, 2007, Lixte entered into a Services Agreement with The Free State of Bavaria (Germany) represented by the University of Regensburg (the "University") pursuant to which Lixte 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. Lixte 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, Lixte 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.

To date, the cancers studied by us are those of brain cancers and, to a lesser extent, breast and kidney cancers, and all such studies have been done at the NIH under the CRADA. All brain cancer cell lines and human tumor cells were provided by NIH.

#### Access to Chemical Compounds

On February 5, 2007, we entered into an agreement with Chem-Master International, Inc. pursuant to which we engaged Chem-Master to synthesize the compound designated LB-1 and any other compound synthesized by Chem-Master pursuant to our request, which has 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 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.

### The Market

We believe that a sensitive, specific, reasonably priced assay for the detection of any common human cancer at an early stage could save thousands of lives annually, reduce health care costs, and generate significant income.

## Brain Cancer

The most malignant type of brain cancer, GBM, although less common than stomach, breast and prostate cancers, is almost invariably fatal. Typically, survival after surgery and radiation is only 12 to 18 months. A biomarker reflecting disease progression and, most importantly, providing a method to develop more specific and effective treatments of GBM would be an important discovery.

### Stomach Cancer

We believe that stomach cancer (gastric cancer) is a target for biomarker identification because of its high prevalence in certain of the world's population, particularly in Asia. Since gastric cancer is uncommon in the West, development of new diagnostics and treatments is not a priority for many pharmaceutical and diagnostic companies, providing a special opportunity for us.

Current screening for gastric cancer entails passing a tube into the stomach (gastroscopy) and sampling of suspicious areas. The invasive nature and cost of gastroscopy with sedation limits systematic screening of large numbers of individuals at risk. We believe that a blood test for the early detection of stomach cancer could save many lives and significantly reduce health care costs in countries with a high prevalence of the disease.

### **Ovarian** Cancer

Although ovarian cancer is much less common than breast cancer, cancer of the ovary is responsible for the death of almost half as many women who die from breast cancer. Less than 50% of women are cured of ovarian cancer because the disease is almost always in an advanced stage before it produces symptoms. Yet, if ovarian cancer is found early, the cure rate is 90% or better. A blood test for screening women at risk (all women who are 50 or older) is urgently needed.

# Marketing Plan

Once a biomarker has been identified, depending on the projected cost for evaluation, we expect to either conduct the initial assessment using our resources or seek partners in industry for clinical development. If we have the resources, we prefer to generate evidence of clinical value on our own to maximize financial value of the product.



If we do not have the resources needed to develop the clinical potential of a given biomarker ourselves, we intend to try to find partners in large diagnostic and/or pharmaceutical companies. These companies are increasingly dependent upon new biomarkers discovered by academic groups and small biotechnology companies to maintain a pipeline of promising drugs and new diagnostic tools.

We believe that the molecular approaches that led to the discovery of the biomarker for GBMs (and the subject of the Provisional Patent Application) could also lead to the discovery of equally promising new biomarkers for other cancers. If discovered and developed, the challenge will be to decide which products to license early and which to carry into clinical evaluation without a pharmaceutical company partner.

### **Research and Development**

Our primary 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 currently known.

There are four steps in our biomarker detection and validation process:

### 1. Tissue Acquisition

The acquisition of well-characterized cancer tissue and blood samples from cancer patients and control individuals is the most critical step to success. We believe that our recently terminated agreement with the Institute of Pathology at the University of Regensburg in Germany has provided us with the clinical samples needed for our program. We understand that these samples were collected under the regulatory requirements of the European Union and of the Office of Protection of Research Subjects in the United States. Those regulations require that each patient be fully informed about the process, the use of the samples, and any attendant risks. Though there is a negligible medical risk related to the collection of the samples for Lixte's purposes, the consent form points out that the tissue is not needed for clinical purposes and that the research done will not affect the patient's care in any way.

The consent specifies further that the samples will be used to develop diagnostic tests and/or treatments for cancer that may have commercial value and that the participants will not be entitled to any of the financial benefits from the product's development. All samples are coded and the privacy of all participants is assured because personal identifiers are never shared with us by the University of Regensburg. Obtaining consent is the responsibility of the collaborating institution, but all consent processes and forms will be jointly approved by the collaborating institution and by us.

Under the CRADA, any tissue that might be studied at NIH must meet the requirements of the Office of Protection of Research Subjects in the United States. Before any samples collected by us would be used under the CRADA, the informed consent process pertaining to the samples, including determination that anonymization of the samples was carried out, would be reviewed with NIH and deemed acceptable with respect to the requirements of NIH.

## 2. Tissue Processing

For maximum efficiency in detecting biomarkers, cancer cells must be isolated from a complex matrix of normal cells and other structural elements of tissue in which the cancer has arisen under conditions that do not alter potential biomarkers. The procedures used minimize destruction and alteration of cell components. Once processed, preparations can be transported without compromising their integrity.

# 3. Detection and Identification of Biomarkers

The search for molecular elements with features unique to a specific cancer type is accomplished using highly reproducible physical techniques. These techniques are not proprietary but involve technologies used in sequences that are not obvious. The most prominent biomarkers for each tumor type are identified by mass spectrometric sequencing. We will select for patenting and clinical evaluation biomarkers present at high frequency in all cancers of the same type.

### 4. Development of Assays for Biomarkers in the Blood

Whether to develop an assay for selected biomarkers is an important decision point. Assay development is an expensive component of the discovery process but also an essential step in establishing commercial value. For each cancer type, we expect to screen sera of affected and unaffected persons for the five most promising biomarkers of known sequence for which patent protection seems achievable. Maximum value of the product for diagnostics is achieved by demonstrating the presence of specific biomarkers in the serum of patients harboring the cancer of interest and their absence in the sera of patients without the cancer.

Biomarkers not useful for diagnostic assays may still have significant value as markers of prognosis and/or as drug targets. For example, although it is not yet clear whether the new biomarker discovered by Dr. Zhuang will serve as a useful diagnostic assay for GBMs, that biomarker is nevertheless valuable because it was demonstrated to provide a tool for identification of new drug combinations active against GBMs in vitro.

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. If a particularly compelling opportunity arises, we have the flexibility to quickly direct resources to maximize chances of developing a clinically useful product.

# **Product Overview**

Our products will derive directly from our intellectual property consisting of our Provisional Patent Application and other patents we anticipate will arise from our research activities. Those patents are expected to cover biomarkers uniquely associated with specific types of cancer that may provide the bases for assays suitable for cancer detection and patents on methods to identify drugs that inhibit growth of specific tumor types and combinations of drugs as potential therapeutic agents for the treatment of specific cancers.

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

1. Improved Cancer Treatments. Improved chemotherapy regimens for cancers not curable by surgery or radiation;

2. Diagnostic Assays. Improved assays of body fluids, primarily blood, for the diagnosis of cancers at stages when cure is possible through surgery and/or radiotherapy;

3. Estimation of Prognosis. Improved methods for estimation of prognosis by molecular sub-classification of histologically indistinguishable tumor subtypes; and

4. Assessment of Therapeutic Effectiveness. Improved methods to assess therapeutic effectiveness by monitoring with biomarker assays persistence or reappearance of cancer during and after treatment and during drug development.

Each market is discussed below.

### 1. Improved Cancer Treatments

We will seek to develop improved therapeutic regimens when biomarkers provide insight into pathways vulnerable to chemical and/or immunological attack. Some tumor biomarkers have specific (enzymatic) functions and are "drugable," that is, their function can be altered pharmacologically. For example, the identification of the biomarker specific to regulation of GBMs has led to development of an assay for screening compounds for anti-GBM activity.

### 2. Diagnostic Assays

We intend to work under the CRADA with NINDS to assess the clinical potential of the new biomarker for GBM. Using the approach developed by Dr. Zhuang to identify markers for GBM and for other rare tumors, we also intend to initiate searches for biomarkers in other common cancers for which there is no highly specific and sensitive blood test for early detection. The initial focus, in addition to GBMs, is ovarian and gastric cancer. For these diseases, a reliable blood test for their detection at an early surgically curable stage would save many lives. If we are successful in increasing our resources, research will likely be extended to the identification of biomarkers for stomach and ovarian cancer, and subsequently to biomarkers for breast, prostate, colon, bladder and kidney cancers.

### 3. Estimation of Prognosis

There is a wide spectrum of aggressiveness and responsiveness to drug treatments for many cancers that are clinically indistinguishable with present methods of classification. Judgment of the aggressiveness of most cancers is currently based on their morphologic appearance under the microscope and, for some tumors, on a few molecular features such as hormone receptors associated with breast cancers. There are few biomarkers sufficiently reliable to predict the prognosis of a given cancer patient so that treatment intensity can be adjusted with confidence toward less or more toxic regimens.

### 4. Assessment of Therapeutic Effectiveness

We believe that specific and sensitive biomarkers for any human cancer are in great demand by pharmaceutical companies and by the National Cancer Institute as aids to drug development and to the development of targeted drug treatment. In addition, we believe that biomarkers that reflect disease progression and regression during initial clinical evaluation of new therapeutic agents could greatly reduce the cost of new drug development. To assess the effectiveness of a specific treatment, it would be less expensive and more efficient to monitor the appearance and disappearance of a biomarker in the blood than to monitor the course of disease by radiological imaging.

### **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. This would cause our revenues to decline and affect our ability to achieve profitability.

## Employees

As of December 31, 2007, we had no full-time employees. Dr. Kovach is a Professor in the Department of Preventive Medicine at SUNY, in Stony Brook, New York. He received approvals from the School of Medicine of Stony Brook University and from the New York State Ethics Commission to operate the Company (or to serve as CEO of 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 technical assistants who work under the supervision of Dr. Zhuang on the objectives of the CRADA. Dr. Kovach devotes approximately 30 hours per week with respect to his activities involving the Company, including research planning and design and monitoring of the research progress under the CRADA. Dr. Kovach's contributions are made outside of his academic responsibilities.

### Properties

At present, we conduct all laboratory activities at NIH under the CRADA. We also collected and stored samples of human tumors other than brain cancers under a service agreement with the University of Regensburg, Germany, which was terminated in January 2008. 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.

### **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) of the National Institutes of Health (NIH). 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 the OSHA. All activities of this laboratory are monitored by the compliance office of NINDS.

We negotiated a service agreement with Regensburg University, Germany for access to "waste" samples of various human cancers and serum and urine from individuals with cancers. The collection, preparation, storage, and transfer of these materials are subject to the investigational review board of the University, which operates under the requirements of the Free State of Bavaria. The materials are anonymized by the personnel by the University of Regensburg so that the business has no way to link clinical samples to any individuals. This process is in compliance with the requirements of the CRADA and with FDA regulations concerning the study of clinical material. This agreement was terminated on January 12, 2008.

There are no other regulations affecting the pursuit of the goals of the business. In the future, if and when we develop an independent laboratory, that laboratory would be subject to the same regulations that apply to any laboratory carrying out research on biological samples. Should we develop an independent laboratory, it will engage a compliance expert to formally assess the status of the laboratory with respect to federal occupational and environmental regulations and also those regulations of the state in which the laboratory is located as these regulations pertain to the operation of the laboratory.

In the future, we anticipate that as part of the CRADA with NINDS lead compounds identified as active in vitro by the NINDS laboratory will be assessed for activity in animal models (mouse/rat) of human brain tumors. Such activities by NINDS and the business would be carried out in compliance with all 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.

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 are use to 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 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. Acquisition 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 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 a

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 anticancer 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 on the basis of animal studies to cause any toxicity. No more than three patients are entered at a given dose and 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 plan high 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 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.

### 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.

# 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. If we do not generate revenues and achieve profitability, we will be forced to cease or substantially curtail our operations and you may lose your entire investment.

Because we are currently engaged in research at a very early stage, significant time may be required to develop any product or intellectual property capable of generating revenues. As such, our business is unlikely to generate any revenue in the next several years and may never do so. Even if we are able to generate revenues in the future through licensing our technologies or through product sales, there is no assurance that our revenues will exceed our expenses. Should we fail to achieve profitability, you may lose your entire investment.

We will need to raise additional funds in the future and these funds may not be available on acceptable terms or at all.



The funds we raised in the private placements will not be sufficient to fully develop and commercialize any products that may arise from our research. We will also need to raise additional funds in order to satisfy our future liquidity requirements. In the near term, we expect to require approximately \$3,000,000 of additional funding to enable us to develop our lead compounds to a point allowing for submission of an IND to the FDA to institute Phase I trials. Additionally, the amount and timing of future cash requirements will depend on market acceptance of our products, if any, and the resources we devote to developing and supporting our products. We will need to fund these cash requirements from a combination of debt or equity financings and the sale, licensing or joint venturing of our intellectual properties. Current market conditional funds, as well as our ability to reach profitability. There can be no assurances that we will be able to secure additional financing, or obtain favorable terms on such financing if it is available, or as to our ability to achieve positive cash flow from operations. Continued negative cash flows and lack of liquidity create significant uncertainty about our ability to fully implement our operating plan and we may have to reduce the scope of our planned operations. If cash and cash equivalents are insufficient to satisfy our liquidity requirements, we would be required to scale back or discontinue our product development program, or obtain funds if available through strategic alliances that may require us to relinquish rights to certain of our technologies or discontinue our operations.

### Our auditors have included a going concern assumption in their opinion.

The opinion of our auditors regarding our financial statements includes concerns about our ability to continue as a going concern in view of the fact that we are in the development stage and have not generated revenues from operations. All activity through December 31, 2007 related to our formation, capital raising efforts and initial research and development activities. As such, we have yet to generate any cash flows from operations, and are essentially dependent on debt and equity funding from both related parties to finance our operations. Prior to June 30 2006, cash requirements for Lixte, our operating subsidiary, were funded by advances from Dr. John Kovach, Lixte's founder, our current Chief Executive Officer. On June 30, 2006, we completed an initial closing of a private placement, selling 1,973,869 shares of common stock at a price of \$0.333 per share and receiving net proceeds of \$446,433. On December 12, 2007, we completed another private placement, selling 999,995 shares of common stock at a price of \$0.65 per share and receiving net proceeds of \$531,320.

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

Based on the proceeds received from the December 2007 private placement, we may not have sufficient resources to completely fund our planned operations for the next twelve months. We do not have sufficient resources to fully develop and commercialize any products that may arise from our research. We will need to raise approximately \$3,000,000 of additional funds in order to satisfy our near-term working capital requirements. Additionally, the amount and timing of future cash requirements will depend on market acceptance of our products, if any, and the resources that we devote to developing and supporting our products. We will need to fund these cash requirements from a combination of debt or equity financings and the sale, licensing or joint venturing of our intellectual properties.

Current market conditions present uncertainty as to our ability to secure additional funds, as well as our ability to reach profitability. There can be no assurances that we will be able to secure additional financing, or obtain favorable terms on such financing if it is available, or as to our ability to reach profitability. There can be no assurances that we will be able to secure additional financing, or obtain favorable terms on such financing if it is available, or as to our ability to achieve positive cash flow from operations. Continued negative cash flows and lack of liquidity create significant uncertainty about our ability to fully implement our operating plan and we may have to reduce the scope of our planned operations. If cash and cash equivalents are insufficient to satisfy our liquidity requirements, we would be required to scale back or discontinue our product development program, or obtain funds if available through strategic alliances that may require us to relinquish rights to certain of our technologies or discontinue our operations.



# 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 U.S. 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 are negotiating with the government on the terms of exclusive commercialization rights with respect to those patents. However, should we be unable to reach such an agreement, or should we be unable to reach such an agreement in the future pertaining to other technologies owned by the government or third parties, this could harm our businesses. Additionally, if those 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 71 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 approximately 30 hours per week to our business activities. 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 in the Department of Preventive Medicine at Stony Brook University, New York. He may also become involved in the future with other business opportunities, which may become available. Accordingly, our key personnel may face a conflict in selecting between us and their other business interests. We have not formulated a policy for the resolution of such conflicts. Dr. Zhengping Zhuang is a full-time employee of NIH. Under a formal agreement with the NIH, he participates with the Company under a CRADA that defines the scope of his collaboration, and he therefore 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 new treatments to clinical trials, an agreement will be negotiated with NIH to conduct the trial as part of a new CRADA or 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 will be unsuccessful and the market price of our common stock will substantially decline.

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 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. For example, legislation was enacted on December 8, 2003, which provides a new Medicare prescription drug benefit beginning in 2006 and mandates other reforms. While we cannot predict the full effects of the implementation of this new legislation or whether any legislative or regulatory proposals affecting our business will be adopted, the implementation of this legislation or announcement or adoption of these 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 of Regensburg. 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 re-examination 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 costeffectiveness 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. 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, our common stock was not publicly traded until recently. On September 24, 2007, our common stock commenced trading on the OTC Bulletin Board, although there has been very limited trading activity to date. In addition, the NASD limits quotations on the OTC Bulletin Board to securities of issuers that are current in their reports filed with the Securities and Exchange Commission. The NASD also periodically proposes rule changes that could have an impact on the market for out stock. 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 sole 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 this prospectus or Rule 144 could 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, all of which are currently eligible to be sold under Rule 144, and 999,995 shares in a December 2007 private placement, all of which will be eligible to be sold under Rule 144 on June 12, 2008.



### 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 of 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 \$2,000,000, if in business more than a continuous three years, or with average revenues of less than \$6,000,000 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 their 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 61% of our outstanding voting stock. 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 2. DESCRIPTION OF PROPERTY**

At present, we conduct all laboratory activities at NIH under the CRADA. 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, 2007.

## ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Since September 21, 2007, our common stock has traded on the OTC Bulletin Board under the symbol "LIXT." There is very limited trading of our stock on the Bulletin Board, and it should not be deemed to be an "established trading market". 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 bysecurities 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;
- 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 traded on the OTC Bulletin Board. Such quotations reflect prices between dealers in securities and do not include any retail mark-up, mark-down or commissions, and may not necessarily represent actual transactions.

High		Low
\$ 1.05	\$	0.75
\$ 1.10	\$	0.75
	\$ 1.05	\$ 1.05 \$

### Holders

As of December 31, 2007, we currently have 27,832,178 shares of our common stock outstanding. As of December 31, 2007, our shares of common stock are held by approximately 66 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. We do not currently plan to pay cash dividends on our common stock in the foreseeable future.

# Sales of Unregistered Securities

On February 5, 2007, in connection with an agreement with Chem-Master International, Inc., we agreed to issue to Chem-Master a five-year option to purchase 100,000 shares of our Common Stock at an exercise price of \$0.333 per share and an additional five-year option to purchase 100,000 shares at the same exercise price subject to certain conditions. The option was issued pursuant to Section 4(2) of the Securities Act of 1933, as amended.

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 shares were issued pursuant to Section 4(2) of the Securities Act of 1933, as amended.

On September 12, 2007, the Company entered into a consulting agreement with Gil Schwartzberg and granted to Mr. Schwartzberg stock options to purchase an aggregate of 1,000,000 shares of common stock, exercisable for a period of four years from vesting date at \$1.00 per share, with one-half of the options (500,000 shares) vesting immediately and one-half (500,000 shares) vesting on September 12, 2008. The shares were issued pursuant to Section 4(2) of the Securities Act of 1933, as amended.

On September 12, 2007, the Company entered into a consulting agreement with Francis Johnson and granted to Professor Johnson stock options to purchase an aggregate of 300,000 shares of common stock, exercisable for a period of four years from 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 shares were issued pursuant to Section 4(2) of the Securities Act of 1933, as amended.

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, Lixte agreed to sell Mirador 250,000 shares of the Company's restricted common stock for \$250 (\$0.001 per share). The shares were issued pursuant to Section 4(2) of the Securities Act of 1933, as amended.

On December 12, 2007, we sold 999,995 shares of common stock to accredited investors in a private placement at a per share price of \$0.65. We paid to WestPark Capital, Inc., as placement agent, a commission of 10% and a non-accountable fee of 4% of the gross proceeds and issued five year warrants to purchase 120,000 shares of common stock in connection with the private placements. All of the issues were accredited investors and the securities were issued pursuant to Section 4(2) of the Securities Act of 1933, as amended, and Regulation D promulgated thereunder. The issues also represented that they were acquiring the securities for their own account and a legend was placed on the stock certificates.

# 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, 2007, the most recently completed fiscal year.

Plan Category	Number of Securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column 2)
Equity Compensation Plans Approved by Security Holders	200,000	\$ 0.333	2,300,000
Equity Compensation Plans Not Approved by Security Holders	N/A	N/A	N/A

### ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

### 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. 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.

Unless the context indicates otherwise, SRKP and Lixte are hereinafter referred to as the "Company". On December 7, 2006, the Company amended its Certificate of Incorporation to change its name from SRKP 7, Inc. to Lixte Biotechnology Holdings, Inc. ("Holdings").

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. 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 financial statements do not include any adjustments that might result from the outcome of these uncertainties (see "Liquidity and Capital Resources - December 31, 2007 - Going Concern").

#### **Recent Developments**

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.

### Adoption of New Accounting Policies

In December 2006, the FASB issued FSP EITF 00-19-2, "Accounting for Registration Payment Arrangements" ("EITF 00-19-2"), which addresses an issuer's accounting for registration payment arrangements. EITF 00-19-2 specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with FASB No. 5, "Accounting for Contingencies". EITF 00-19-2 further clarifies that a financial instrument subject to a registration payment arrangement should be accounted for in accordance with other applicable generally accepted accounting principles without regard to the contingent obligation to transfer consideration payment arrangements that are entered into or modified subsequent to the date of issuance of EITF 00-19-2. For registration payment arrangements and financial instruments subject to those arrangements that were entered into prior to the issuance of EITF 00-19-2, EITF 00-19-2 is effective for financial statements issued for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. Early adoption of EITF 00-19-2 for interim or annual periods for which financial statements or interim reports have not been issued is permitted. The Company chose to early adopt EITF 00-19-2 effective December 31, 2006.

Effective 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 should be 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, 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, 2007, no liability for unrecognized tax benefits was required to be recorded.

The Company files income tax returns in the U.S. federal jurisdiction and various states. The Company is subject to U.S. federal or state income tax examinations by tax authorities for years after 2004.

The Company's policy is to record interest and penalties on uncertain tax provisions as income tax expense. As of December 31, 2007, the Company has no accrued interest or penalties related to uncertain tax positions.

### **Recent Accounting Pronouncements**

In September 2006, the FASB issued Statement of Financial Accounting Standards 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. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company is currently assessing the potential effect of SFAS No. 157 on its financial statements.

In February 2007, the FASB issued Statement of Financial Accounting Standards 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. SFAS No. 159's objective 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 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 company 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 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 also requires companies to disclosure requirements included in other accounting standards, including requirements for disclosures about fair value measurements included in SFAS No. 157 and SFAS No. 107. SFAS No. 159 is effective as of the beginning of a company's first fiscal year beginning after November 15, 2007. Early adoption is permitted as of the beginning of the previous fiscal year provided the company makes that choice in the first 120 days of that fiscal year and also elects to apply the provisions of SFAS

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, if any, upon adoption of SFAS No. 141(R).

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 p

### **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.

### 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

Effective January 1, 2006, the Company adopted 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.

### **Income Taxes**

The Company accounts for income taxes pursuant to Statement of Financial Accounting Standards 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 discovering biomarkers for common cancers for which better diagnostic and therapeutic measures are needed. For each of these diseases, a biomarker that would enable identification of the presence of cancer at a stage curable by surgery could possibly save thousands of lives annually. In addition, biomarkers specific to these diseases may also provide clues as to processes (biological pathways) that characterize specific cancer types and that may be vulnerable to drug treatment targeted to the activity of the biomarker.

The Company is currently focusing on developing new treatments for the most common and most aggressive type of brain cancer of adults, glioblastoma multiforme ("GBM"). 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.

The research on brain tumors is proceeding in collaboration with the National Institute of Neurological Disorders and Stroke ("NINDS") of the National Institutes of Health ("NIH") under a Cooperative Research and Development Agreement ("CRADA") entered into on March 22, 2006, as amended. The research at NINDS continues to be led by Dr. Zhengping Zhuang, an internationally recognized investigator in the molecular pathology of cancer. Dr. Zhuang is aided by two senior research technicians supported by the Company as part of the CRADA. The goal of the CRADA is to develop more effective drugs for the treatment of GBM through the processes required to gain Food and Drug Administration ("FDA") approval for clinical trials. The Company's contribution to the CRADA has been \$200,000 annually for two years. The CRADA is presently scheduled to end June 30, 2008, with current discussions exploring a several month extension supported by funds remaining from the original agreement, followed by a potential one-year extension at a cost of \$200,000.

The Company has filed a series of patent applications jointly with NIH covering certain methods of treatment of brain tumors of adults and children. On February 6, 2007, provisional patent applications were converted to a U.S. non-provisional patent and a patent cooperation treaty application on behalf of the Company and NIH.

Patent applications filed with NIH are jointly owned by NIH and Lixte. All NIH co-inventors assigned 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 is continuing its negotiations on the details of the terms under which NIH will provide an exclusive license and anticipates finalizing terms of the agreement with the NIH in mid-2008.

The Company has also filed patent applications for intellectual property owned solely by the Company. These applications identify two series of new anti-cancer agents referred to as the LB-1 series and the LB-2 series. The applications include identification of the structure of molecules, their synthesis, and their activity against GBM, medulloblastoma, and more recently, the common cancers and leukemias as mentioned above. At the present time, the efficacies of the LB-1 and LB-2 series are based on activity in cell culture and in animal models of GBM and medulloblastoma. The Company is in the process of documenting the activities of both series of drugs against the more common tumor types in animal models.

In February 2008, the Company converted provisional patents relating to the nature and activity of the LB-1 series of drugs with the filing of a U.S. non-provisional and a PCT patent application.

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.

The Company expects that its products will derive directly from the intellectual property from its research activities. 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 much more common human cancers, as well as serious fungal infections, originated from its original focus on a biochemical defect 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.

The Company elected to exert 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 "Liquidity and Capital Resources - December 31, 2007 - Going Concern" below).

Plans for the Next 12 Months

The Company has three major goals for the next 12 months.

The first goal is to evaluate lead compounds of the LB-1 and LB-2 series for effectiveness in a rat model of brain cancer in which drugs are administered systemically or by direct infusion into the diseased area of the brain. The latter method of administration is called "convection administration". These studies will be done by the Company's partner at NIH that has substantial expertise in the evaluation of the treatment of brain diseases. In addition, under the CRADA, the effectiveness of drugs of each series given in combination with each other and in combination with the standard drug used clinically for the treatment of GBM will be studied.

The second goal is to evaluate the anti-cancer activity of lead compounds from the LB-1 and LB-2 series against a series of common human cancers. Lung and pancreatic cancer will be the first of this group to be studied in an animal model because there is an urgent need for better drug for the treatment of these almost uniformly fatal cancers. These studies are being done independently of NIH and are therefore not part of the CRADA.

The Company will seek the interest of NIH in supporting development of one or two lead compounds from the LB-1 series through pre-clinical studies necessary to receive FDA approval to take the drugs into Phase I clinical trials. The NIH offers opportunities for academic laboratories, including laboratories at NIH with a for-profit partner, to seek NIH support and expertise in expediting development of particularly promising new compounds as anti-cancer drugs. The Company will also explore the potential interest of two or more major pharmaceutical companies in collaborating in the development of one or more of its lead compounds through Phase I clinical trials of their anti-cancer activity.

The third goal is to assess the interest of pharmaceutical companies in collaborating with the Company or in licensing from the Company rights to some of its lead compounds as anti-fungal drugs. Certain molecular pathways essential for growth by cancer cells are also used by microorganisms, including fungi. Anti-fungal therapy is an additional potentially large market for the Company's compounds, but one in which outside expertise will be necessary to plan efficient assessment and development of their potential value. Management is engaging in discussions with contract research organizations with the expertise to determine the magnitude of anti-fungal activity in animal models of the most important fungal infections in humans.

The Company expects to complete its explorations of interest in collaboration with NIH and pharmaceutical companies by mid-2008. At that time, a decision will be made as to where to place emphasis on the Company's research and development of compounds of the LB-1 and LB-2 series. Depending upon the interest of NIH and/or pharmaceutical companies to support development of one or more of its products, the Company will adjust the estimate of its financial requirements discussed below for the next year of operation. The Company has sufficient financial resources to carry out the approaches described above through 2008.

Existing resources, however, will not permit evaluation of activity of the Company's lead drugs against many of 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 the cost of pre-clinical development by outsourcing to a leading clinical research organization at \$1,000,000 per drug. Thus, additional financing will need to be completed by late 2008 to give the Company the ability to accelerate drug development in the absence of a partner. Management is currently planning to proceed with pre-clinical development of one lead compound from the LB-1 and LB-2 series at a cost of \$2,000,000, extend the CRADA with NIH at a cost of \$200,000 for one additional year, and increase the Company's research in assessing new anti-cancer compounds being created with its collaborating chemists. Accordingly, management will be seeking to raise approximately \$3,000,000 in 2008 for expansion of the Company's intellectual property and to capitalize on its initial successes in anti-cancer drug development by bringing at least one compound to clinical evaluation in 2009.

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 program, competition from more established, well-funded companies with competitive technologies, and future competition from companies that are developing competitive technologies, some of whom are larger companies with greater capital resources than the Company. There is substantial uncertainty as to the Company's ability to fund its operations and continue as a going concern (see "Liquidity and Capital Resources - December 31, 2007 - Going Concern"). Should the Company be unable to raise the required capital on a timely basis, the Company's business plans would be materially adversely effected.

During 2008, the Company will also start to make public presentations of some of its data at national and international scientific meetings. A presentation was made at the First International Drug Discovery and Development Meeting, in Dubai, UAE, in February 2008, and a presentation will be made at the Annual Meeting of the American Association of Cancer Research in San Diego, California, in April 2008.

The Company had planned to begin its own analyses of tumor types other than GBM for new biomarkers by late 2008. However, in order to do this, the Company would need to establish and operate an independent laboratory. The creation and operation of such a laboratory for two years is estimated to cost approximately \$2,000,000. The Company is deferring plans to open and staff an independent laboratory until the full intellectual property value of its initial lead compounds for treatment of brain tumors is determined.

#### Plans Beyond the Next 12 Months

A goal of the Company is to continue the synthesis of new compounds that target other components of molecular pathways already identified by the Company and its CRADA partner to be vulnerable to attack by small molecule drugs, and to explore the vulnerability of additional potential new targets revealed through the molecular characterization of the effects of the Company's lead compounds.

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, 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 by early 2009. 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 2009.

#### Results of Operations - Years Ended December 31, 2007 and 2006

The Company is a development stage company and had not commenced revenue-generating operations at December 31, 2007.

General and Administrative Expenses. For the year ended December 31, 2007, general and administrative expenses were \$1,234,616, which consisted of stock-based compensation of \$890,444, consulting and professional fees of \$248,903, insurance expense of \$27,312, laboratory supplies of \$30,895, filing fees of \$11,164, and other operating costs of \$25,898. For the year ended December 31, 2006, general and administrative expenses were \$268,951, which consisted of stock-based compensation of \$97,400, consulting and professional fees of \$140,814, insurance expense of \$8,385, laboratory supplies of \$555, filing fees of \$4,799, and other operating costs of \$16,998.

Depreciation. For the years ended December 31, 2007 and 2006, depreciation expense was \$592 and \$462, respectively.

Research and Development Costs. For the year ended December 31, 2007, research and development costs were \$423,829, including \$50,836 for the vested portion of the fair value of stock options issued to a consultant and the fair value of a five-year stock option to purchase 100,000 shares of the Company's common stock at \$0.333 per share issued to Chem-Master International, Inc. on February 5, 2007 that was fully vested and non-forfeitable on the date of issuance. Research and development costs were \$180,569 for the year ended December 31, 2006. For the years ended December 31, 2007 and 2006, research and development costs included patent costs of \$94,232 and \$30,469, respectively.

Reverse Merger Costs. In conjunction with the reverse merger transaction completed on June 30, 2006, WestPark Capital, Inc. was paid an aggregate cash fee of \$50,000, which was charged to operations during the year ended December 31, 2006.

Interest Income. For the year ended December 31, 2007, interest income was \$10,549, as compared to interest income of \$11,898 for the year ended December 31, 2006.

Liquidated Damages Under Registration Rights Agreement. 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 closing of 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 SEC. 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, 2007 and 2006. No further registration penalty accrual was required at December 31, 2007, as the Company's registration statement on Form SB-2 was declared effective by the Securities and Exchange Commission on May 14, 2007. The Company will continue to review the status of the registration statement at each quarter end in the future and record further liquidated damages under the registration rights agreement as necessary. At December 31, 2007, the registration penalty to the investors was still due and payable.

Net Loss. For the year ended December 31, 2007, the Company incurred a net loss of \$1,648,488, as compared to a net loss of \$562,084 for the year ended December 31, 2006.

### Liquidity and Capital Resources - December 31, 2007

### **Going Concern**

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.

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.

The Company is currently devoting its efforts to research and development related to specific cancer biomarkers for early detection, estimation of prognosis, monitoring response to treatment, and development of targeted therapeutic agents. The Company is seeking to exploit this opportunity through execution of its business plan and the development of related patents.

At December 31, 2007, the Company had not yet commenced any revenue-generating operations. All activity through December 31, 2007 related to the Company's formation, capital raising efforts and initial research and development activities. As such, the Company has yet to generate any cash flows from operations, and is essentially 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 Lixte's founder. On June 30, 2006, the Company completed an initial closing of a private placement, selling 1,973,869 shares of common stock at a price of \$0.333 per share and receiving net proceeds of \$522,939. On July 27, 2006, the Company completed a second closing of the private placement, selling 1,581,351 shares of common stock at a price of \$0.333 per share and receiving net proceeds of \$446,433. On December 12, 2007, the Company completed a second private placement, selling 999,995 shares of common stock at a price of \$0.65 per share and receiving net proceeds of \$531,320.

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 such revenues will exceed its expenses.

The Company current resources may not be sufficient to fully fund all of the Company's planned operations for the next twelve months. The Company does not have sufficient resources to fully develop and commercialize any products that may arise from its research. Accordingly, the Company will need to raise additional funds in order to satisfy its future working capital requirements. The Company expects that the net proceeds from the second private placement which closed in December 2007 of approximately \$531,000 will be adequate to fund the Company's updated and revised 2008 operating budget. Thereafter, the Company currently estimates that it will require approximately \$3,000,000 of additional funding to finance future operations by late 2008, including the costs of the pre-clinical evaluation and submission to the FDA of two lead compounds in 2009. The amount and timing of future cash requirements will depend on the market's evaluation of the Company's technology and products, and the resources that the Company devotes to developing and supporting its activities. The Company anticipates funding these cash requirements from a combination of debt or equity financings and 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 its ability to achieve positive cash flow 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.

Operating Activities. For the year ended December 31, 2007, operating activities utilized cash of \$702,868, as compared to utilizing cash of \$443,451 for the year ended December 31, 2006, primarily as a result of increased expenditures for both general and administrative and research and development activities in 2007 as compared to 2006.

The Company had working capital of \$376,184 at December 31, 2007, 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. For the years ended December 31, 2007 and 2006, investing activities utilized cash of \$272 and \$498, respectively, for the purchase of office equipment.

<u>Financing Activities</u>. 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. For the year ended December 31, 2006, financing activities provided net cash of \$1,118,643, consisting of the gross proceeds from the sale of common stock of \$1,183,889, the cash acquired in the reverse merger transaction of \$62,500, and advances from stockholder of \$86,771, reduced by the payment of private placement offering costs of \$214,517.

#### **Principal Commitments**

At December 31, 2007, the Company did not have any material commitments for capital expenditures. The Company had paid its second and final installment due under the CRADA of \$200,000 on June 29, 2007. The Company's principal commitments at December 31, 2007 consisted of the liquidated damages payable under the registration rights agreement of \$74,000 and the contractual obligations as summarized below.

On January 5, 2007, Lixte entered into a Services Agreement with The Free State of Bavaria (Germany) represented by the University of Regensburg (the "University") pursuant to which Lixte 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. Lixte 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, Lixte 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, Lixte entered into a two-year agreement (the "Chem-Master Agreement") with Chem-Master International, Inc. ("Chem-Master") 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 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.

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, Lixte 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 Company made payments under the Mirador Agreement aggregating \$10,000 during 2007. The Mirador Agreement was amended in February 2008 such that Mirador forgave 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.

## **Off-Balance Sheet Arrangements**

At December 31, 2007, the Company did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

### **ITEM 7. FINANCIAL STATEMENTS**

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

## ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not Applicable.

1.

## **ITEM 8A. 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.

There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

### 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, 2007.

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.

## **ITEM 8B. OTHER INFORMATION**

None

## ITEM 9. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16H OF THE EXCHANGE ACT

The following table and text set forth the names of all directors and executive officer of our Company as of December 31, 2007. 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 Company				
Dr. John S. Kovach	71	Chief Executive Officer, Chief Financial Officer, Director				
Dr. Philip F. Palmedo	73	Director				
Dr. Stephen K. Carter	70	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 a Professor in the Department of Preventive Medicine at Stony Brook University in Stony Brook, New York. From 1994 to 2000, Dr. Kovach was Executive Vice President for Medical and Scientific Affairs, City of Hope National Medical Center in Los Angeles, California. His responsibilities included oversight of all basic and clinical research initiatives at the City of Hope. During that time, he was also Director of the Beckman Research Center at City of Hope and a member of the Arnold and Mabel Beckman Scientific Advisory Board in Newport Beach, California.

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

### **Chief Executive Officer**

Leadership and management of our Company is provided by Dr. Kovach, with the advice of the Board of Directors and the Scientific Advisory Committee. The activities to date have been confined to achieving the goals of the CRADA through the collaborative arrangement of the Company by which Dr. Kovach and Dr. Zhuang, aided by two full-time technical personnel, are pursuing development of lead compounds for the treatment of malignant brain tumors. During this period of time, Dr. Kovach has also been supervising the collection of the clinical samples needed to validate the biomarker observations regarding GBMs and to be able to extend the discovery process to ovarian and stomach cancers. The Company intends to seek an extension of the CRADA for an additional year. Depending on various factors, including raising approximately \$3,000,000 of new funding during 2008, the Company may recruit a full-time chief executive officer to manage the Company's business affairs, as well as a part-time chief financial officer.

#### 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 since that time has remained as chairman. In 1985, the company was recognized by Inc. Magazine as one of the 500 fastest growing private companies in the United States.

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 Carter

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 has 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 member of the board of directors 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, a privately-held biopharmaceutical company.

## SCIENTIFIC ADVISORY COMMITTEE

The Scientific Advisory 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 members have 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 Scientific Advisory Committee are:

#### Arndt Hartmann, MD

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

#### Ferdinand Hofstadter, MD

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

#### Stefan Madajewicz, MD, PhD

Dr. Madajewicz is Professor of Medicine. For the past 15 years, he has been Director of Cancer Clinical Trials and for the past 10 years, Chief, Neoplastic Diseases at SUNY-Stony Brook. Dr. Madajewicz is a Fellow, American College of Physicians, and a member of the American Society of Clinical Oncology, American Association for Cancer Research, European Society of Medical Oncology, an affiliate of the Eastern Cooperative Oncology Group, and member of the National Surgical Adjuvant Breast and Bowel Project. He is recognized as an outstanding cancer clinician and for the design of clinical trials, particularly the evaluation of new drugs in the treatment of cancers of the gastrointestinal tract and brain.

### 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 anti-cancer 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); and Outstanding Inventor Award from the Research Foundation of the State University of New York (2002. He is a Fellow of the J.S. Guggenheim Memorial Foundation (1995-), the American Association for the Advancement of Science (1997-), and The New York Academy of Sciences (2000-).

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

#### Audit Committee

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

#### **Code of Ethics**

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

#### **Director Independence**

The Company considers Dr. Palmedo and Dr. Carter to be independent directors according to applicable standards.

### 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.

## **ITEM 10. EXECUTIVE COMPENSATION**

For the fiscal years ended December 31, 2007 and 2006, no individual, including Dr. John Kovach, our current Chief Executive Officer, received any compensation. Dr. Kovach is reimbursed for any out-of-pocket expenses. Any future compensation arrangements will be subject to the approval of the Board of Directors.

#### Option Grants to Officers in 2006 and 2007

None.

#### Aggregate Option Exercises in 2006 and 2007; Option Values at December 31, 2007

None; not applicable.

#### **Employment Agreements; Compensation**

We have not entered into any employment agreements. As of December 31, 2007, 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 will be reimbursed for any out-of-pocket expenses. Any future compensation arrangements will be subject to the approval of the Board of Directors.

### **Consulting Agreements**

On September 12, 2007, the Company entered into a consulting agreement with Gil Schwartzberg and granted to Mr. Schwartzberg stock options to purchase an aggregate of 1,000,000 shares of common stock, exercisable for a period of four years from vesting date at \$1.00 per share, with one-half of the options (500,000 shares) vesting immediately and one-half (500,000 shares) vesting on September 12, 2008. 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 these options is being charged to operations ratably from September 12, 2007 through September 12, 2008. During the year ended December 31, 2007, the Company recorded a charge to operations of \$553,662 with respect to these options.

On September 12, 2007, the Company entered into a consulting agreement with Francis Johnson and granted to Professor Johnson stock options to purchase an aggregate of 300,000 shares of common stock, exercisable for a period of four years from 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 December 31, 2007, the fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$198,000 (\$0.66 per share), which resulted in a charge to operations of \$19,836 during the year ended December 31, 2007.

#### **Director Compensation**

#### Members of the Board of Directors

On June 30, 2006, effective with the closing of the Exchange, the Company granted to Dr. Philip Palmedo, an outside director of the Company, stock options to purchase an aggregate of 200,000 shares of common stock, exercisable for a period of five years at \$0.333 per share, with 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 is being charged to operations ratably from July 1, 2006 through June 30, 2008. During the years ended December 31, 2007 and 2006, the Company recorded a charge to operations of \$20,668 and \$31,000, 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 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, which resulted in a charge to operations of \$30,655 during the year ended December 31, 2007. Any additional outside member of the Board of Directors will generally receive options to purchase 200,000 shares of common stock at the fair market value as of the date of the grant, with one third of the options (66,666 shares) vesting immediately upon joining the board and one third vesting annually for two years on the anniversary of that date.

## DIRECTOR COMPENSATION TABLE

	Non-Equity								
						Incentive	Non-Qualified		
				Stock	Option	Plan	Deferred	All Other	
				Awards	Awards	Compensation	Compensation	Compensation	
Name and Principal Position	Year	Salary (\$)	Bonus (\$)	(\$)	(\$)	(\$)	Earnings (\$)	(\$)	Total (\$)
Philip F. Palmedo	2007	0	0	0	0	0	0	0	0
Director	2006	0	0	0	120,900	0	0	0	120,900
Stephen Carter	2007	0	0	0	204,000	0	0	0	204,000
51									

Director

#### Members of the Scientific Advisory Committee

On June 30, 2006, each member of the Scientific Advisory Committee, other than Dr. Hartmann and Dr. 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 committee and one-half vesting on the second anniversary.

Accordingly, on June 30, 2006, 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 initially determined to be \$31,000 (\$0.31 per share), and is being charged to operations ratably from July 1, 2006 through June 30, 2008. On December 31, 2007 and 2006, the fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$63,000 (\$0.63 per share) and \$30,000 (\$0.30 per share), respectively, which resulted in a charge to operations of \$23,212 and \$7,500 during the years ended December 31, 2007 and 2006, respectively.

#### Aggregated Option Exercises in 2006 and 2007; Option Values at December 31, 2007

There were no option exercises in 2006 or 2007.

The value of vested and unvested unexercised in-the-money stock options held by our Officers and Directors at December 31, 2007 was \$134,830 and \$111,200, respectively, which was calculated by determining the difference between the weighted average exercise price of the stock options of \$0.333 per share and the market price for the Company's common stock of \$0.75 per share at December 31, 2007.

## ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth, as of March 15, 2008, certain information regarding beneficial ownership of our common stock by (i) each person or entity who is known by us to own beneficially more than 5% of the outstanding shares of common stock, (ii) each of our directors, and (iii) all directors and executive officers as a group. As of March 15, 2008, there were 27,832,178 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, 2008, 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	61.15%
Dr. Philip F. Palmedo 248 Route 25A, No. 2 East Setauket, New York 11733	390,000 <sup>(1)</sup>	1.4%
Dr. Stephen K. Carter 248 Route 25A, No. 2		
East Setauket, New York 11733	100,000 <sup>(2)</sup>	_
All Officers and Directors as a group (three persons)	17,511,786 <sup>(1) (2)</sup>	62.9%

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

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

## ITEM 12. CERTAIN RELATIONSHIPS AND 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, 2007.

Most office services are provided without charge by our president, Dr. John Kovach. Such costs are immaterial to the financial statements and accordingly, have not been reflected therein. Our officer and directors are involved in other business activities and may, in the future, become involved in other business opportunities that become available, and 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 has advanced to us an aggregate of \$92,717 through December 31, 2007 to meet operating expenses. Such advances are non-interest bearing and are due on demand.

## **ITEM 13. EXHIBITS**

Exhibit No.	Description
2.1	Share Exchange Agreement dated as of June 8, 2006 among the Company, John S. Kovach and Lixte Biotechnology, Inc. <sup>1</sup>
2.2	Securities Purchase Agreement <sup>3</sup>
2.3	Registration Rights Agreement <sup>3</sup>
3.1	Certificate of Incorporation, as filed with the Delaware Secretary of State on May 24, 2005. <sup>2</sup>
3.2	Certificate of Amendment of Certificate of Incorporation
3.2	Bylaws <sup>2</sup>
10.1	Cooperative Research and Development Agreement (CRADA) between the U.S. Department of Health and Human Services, as represented by National Institute of Neurological Disorders and Stroke of the National Institutes of Health and Lixte Inc., as amended. <sup>4</sup>
10.2	Services Agreement between Lixte and the Free State of Bavaria represented by the University of Regensburg dated as of January 5, 2007. <sup>7</sup>
10.3	Agreement between Lixte Biotechnology Holdings, Inc. and Chem-Master International, Inc. dated as of February 5, 2007. <sup>6</sup>
10.4	Stock Option Agreement between Lixte Biotechnology Holdings, Inc. and Stephen K. Carter dated September 12, 2007. <sup>7</sup>
10.5	Stock Option Agreement between Lixte Biotechnology Holdings, Inc. and Francis Johnson dated September 12, 2007. <sup>7</sup>
10.6	Stock Option Agreement between Lixte Biotechnology Holdings, Inc. and Gil Schwartzberg dated September 12, 2007. <sup>7</sup>
10.7	Consulting Agreement between Lixte Biotechnology Holdings, Inc. and Gil Schwartzberg dated September 12, 2007. <sup>7</sup>
10.8	Consulting Agreement between Lixte Biotechnology Holdings, Inc. and Mirador Consulting, Inc. dated September 20, 2007. <sup>7</sup>
10.9	Consulting Agreement between Lixte Biotechnology Holdings, Inc. and Francis Johnson dated September 12, 2007. <sup>7</sup>
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, and incorporated herein by reference.

### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND EXPENSES

The Company has appointed AJ. Robbins, P.C. as our independent registered public accounting firm for the years ended December 31, 2006 and 2007. 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 years ended December 31, 2006 and 2007.

	 Years Ended December 31,			
	 2006		2007	
Audit Fees (1)	\$ 40,000	\$	60,853	
Audit-Related Fees (2)	-		-	
Tax Fees (3)	5,000		7,500	
All Other Fees	-		-	
Total	\$ 45,000	\$	68,353	

(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 during the 2006 and 2007 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 were pre-approved by our Board of Directors. The Board of Directors has adopted a pre-approval policy that provides for the pre-approval of all services performed for us by AJ. Robbin, P.C.



## SIGNATURES

In accordance with Section 13 and 15(d) of the Securities Exchange Act of 1934, the Registrant caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

## LIXTE BIOTECHNOLOGY HOLDINGS, INC.

Date: March 31, 2008

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 31, 2008
/s/ Philip F. Palmedo Philip F. Palmedo	Director	March 31, 2008
/s/ Stephen K. Carter Stephen K. Carter	Director	March 31, 2008
	53	

AND SUBSIDIARY

## (a development stage company)

## CONSOLIDATED FINANCIAL STATEMENTS

And

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

## December 31, 2007 and 2006

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

We have audited the accompanying consolidated balance sheets of Lixte Biotechnology Holdings, Inc. and subsidiary (a development stage company) as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity (deficiency) and cash flows for the years then ended and for the period from August 9, 2005 (Inception) to December 31, 2007. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that we considered appropriate under the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. 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 audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Lixte Biotechnology Holdings, Inc. and subsidiary as of December 31, 2007 and 2006, and the results of their operations and their cash flows for the years then ended and for the period from August 9, 2005 (Inception) to December 31, 2007, 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

## CONSOLIDATED BALANCE SHEETS

	December 31,			
		2007		2006
ASSETS				
Current assets:				
Cash and cash equivalents	\$	508,070	\$	679,640
Advances on research and development contract services		88,180		50,000
Prepaid expenses and other current assets		32,117		20,365
Total current assets		628,367		750,005
Office equipment, net of accumulated depreciation of \$1,167 and \$575 at December 31, 2007 and 2006, respectively		742		1,062
Total assets	\$	629,109	\$	751,067
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable and accrued expenses	\$	73,741	\$	31.786
Liquidated damages payable under registration rights agreement	Ģ	74.000	Ģ	74,000
Research and development contract liabilities		11,725		
Due to stockholder		92,717		92,717
Total current liabilities		252,183		198,503
Commitments and contingencies				
Stockholders' equity:				
Preferred stock, \$0.0001 par value; authorized - 10,000,000 shares; issued - none		_		_
Common stock, \$0.0001 par value; authorized - 100,000,000 shares;				
issued and outstanding - 27,832,178 shares and 26,582,183 shares at December 31, 2007 and 2006, respectively		2,783		2,658
Additional paid-in capital		2,600,839		1,128,114
Deficit accumulated during the development stage		(2,226,696)		(578,208)
Total stockholders' equity		376,926		552,564
Total liabilities and stockholders' equity	\$	629,109	\$	751,067

See accompanying notes to consolidated financial statements.

## CONSOLIDATED STATEMENTS OF OPERATIONS

	 Years Ended December 31,				
	2007 2006			Period from August 9, 2005 (Inception) to December 31, 2007 (Cumulative)	
Revenues	\$ _	\$	_	\$	_
Costs and expenses:					
General and administrative costs, including \$890,444, \$97,400 and \$987,844 of stock-based compensation during the years ended December 31, 2007 and 2006, and					
the period from August 9, 2005 (inception) to December 31, 2007 (cumulative), respectively	1,234,616		268,951		1,504,928
Depreciation	592		462		1,167
Research and development costs, including \$50,836, \$0 and \$50,836 of stock-based compensation during the years ended December 31, 2007 and 2006, and the period from August 9, 2005 (inception) to December 31, 2007					
(cumulative), respectively	423,829		180,569		619,048
Reverse merger costs	 _		50,000		50,000
Total costs and expenses	1,659,037		499,982		2,175,143
	(1,659,037)		(499,982)		(2,175,143)
Interest income	10,549		11,898		22,447
Liquidated damages under registration rights agreement	 		(74,000)		(74,000)
Net loss	\$ (1,648,488)	\$	(562,084)	\$	(2,226,696)
Net loss per common share - basic and diluted	\$ (0.06)	\$	(0.02)		
Weighted average common shares outstanding - basic and diluted	26,707,525		22,750,033		

See accompanying notes to consolidated financial statements.

## CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIENCY)

## Period from August 9, 2005 (Inception) to December 31, 2007

	Commo	n Stock	Additional Paid-in	Deficit Accumulated During the Development	Total Stockholders' Equity
	Shares	Amount	Capital	Stage	(Deficiency)
Balance, August 9, 2005 (inception)	—	\$	\$ —	\$	\$
Shares issued to founding stockholder	19,021,786	1,902	(402)	_	1,500
Net loss	—	—	_	(16,124)	(16,124)
Balance, December 31, 2005	19,021,786	1,902	(402)	(16,124)	(14,624)
Shares issued in connection with reverse					
merger transaction	4,005,177	401	62,099	—	62,500
Shares issued in private placement, net of offering costs 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

See accompanying notes to consolidated financial statements.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

		Years Ended I		
Cook flows from an anti-itize		2007	Period from August 9, 2005 (Inception) to December 31, 2007 (Cumulative)	
Cash flows from operating activities:	•	(1. 6 10. 100)	<b>•</b> ( <b>• • • • • • • • • •</b>	
Net loss Adjustments to reconcile net loss to net cash used in operating activities:	\$	(1,648,488)	\$ (562,084)	\$ (2,226,696)
Depreciation		592	462	1,167
Stock-based compensation		890,444	97,400	987,844
Stock-based research and development		50,836	_	50,836
Changes in operating assets and liabilities:				
(Increase) decrease in -				
Advances on research and development contract services		(38,180)	(50,000)	(88,180)
Prepaid expenses and other current assets		(11,752)	(20,365)	(32,117)
Increase (decrease) in -				
Accounts payable and accrued expenses		41,955	17,136	73,741
Liquidated damages payable under registration rights agreement		_	74,000	74,000
Research and development contract liabilities		11,725	_	11,725
Net cash used in operating activities		(702,868)	(443,451)	(1,147,680)
		(702,000)	(++3,+31)	(1,147,000)
Cash flows from investing activities:				
Purchase of office equipment		(272)	(498)	(1,909)
Net cash used in investing activities				<u>_</u>
- -		(272)	(498)	(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
Cash acquired in reverse merger transaction			62,500	62,500
Gross proceeds from sale of common stock		650,000	1,183,889	1,833,889
Payment of private placement offering costs		(118,680)	(214,517)	(333,197)
Advances from stockholder		_	86,771	92,717
Net cash provided by financing activities		531,570	1,118,643	1,657,659
Net increase (decrease) in cash		(171,570)	674,694	508,070
Cash at beginning of period		679,640	4,946	
Cash at end of period	\$	508,070	\$ 679,640	\$ 508,070

(continued)

## CONSOLIDATED STATEMENTS OF CASH FLOWS (continued)

	 Years Ended Dec	ember 31,	Period from August 9, 2005 (Inception) to December 31, 2007
	 2007	2006	2007 (Cumulative)
Supplemental disclosures of cash flow information:			
Cash paid for -			
Interest	\$ \$		<u>\$                                    </u>
Income taxes	\$ \$		<u> </u>

See accompanying notes to consolidated financial statements.

## LIXTE BIOTECHNOLOGY HOLDINGS, INC. AND SUBSIDIARY

(a development stage company)

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

### December 31, 2007 and 2006

### 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. 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.

Unless the context indicates otherwise, SRKP and Lixte are hereinafter referred to as the "Company". On December 7, 2006, the Company amended its Certificate of Incorporation to change its name from SRKP 7, Inc. to Lixte Biotechnology Holdings, Inc. ("Holdings").

### Operations

The Company is concentrating on discovering biomarkers for common cancers for which better diagnostic and therapeutic measures are needed. For each of these diseases, a biomarker that would enable identification of the presence of cancer at a stage curable by surgery could possibly save thousands of lives annually. In addition, biomarkers specific to these diseases may also provide clues as to processes (biological pathways) that characterize specific cancer types and that may be vulnerable to drug treatment targeted to the activity of the biomarker.

The Company is currently focusing on developing new treatments for the most common and most aggressive type of brain cancer of adults, glioblastoma multiforme ("GBM"). 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.

AND SUBSIDIARY (a development stage company)

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### December 31, 2007 and 2006

The Company is conducting its anti-cancer activities primarily through a collaborative program governed by a Cooperative Research and Development Agreement ("CRADA") with the National Institute of Neurological Disorders and Stroke ("NINDS") of the National Institutes of Health ("NIH").

The Company expects that its products will derive directly from its intellectual property, which will consist of patents that it anticipates will arise out of its research activities. These patents are expected to cover biomarkers uniquely associated with the specific types of cancer, patents on methods to identify drugs that inhibit growth of specific tumor types, and combinations of drugs and other potential therapeutic agents for the treatment of specific cancers. 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.

The Company is considered a "development stage company" as defined in 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 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.

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 accompanying financial statements do not include any adjustments that might result from the outcome of these uncertainties.

The Company is currently devoting its efforts to research and development related to specific cancer biomarkers for early detection, estimation of prognosis, monitoring response to treatment, and development of targeted therapeutic agents. The Company is seeking to exploit this opportunity through execution of its business plan and the development of related patents.

At December 31, 2007, the Company had not yet commenced any revenue-generating operations. All activity through December 31, 2007 related to the Company's formation, capital raising efforts and initial research and development activities. As such, the Company has yet to generate any cash flows from operations, and is essentially 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 Lixte's founder. On June 30, 2006, the Company completed an initial closing of a private placement (see Note 3), selling 1,973,869 shares of common stock at a price of \$0.333 per share and receiving net proceeds of \$426,433. On December 12, 2007, the Company completed a second private placement, selling 999,995 shares of common stock at a price of \$0.65 per share and receiving net proceeds of \$531,320.

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 such revenues will exceed its expenses.

The Company current resources may not be sufficient to fully fund all of the Company's planned operations for the next twelve months. The Company does not have sufficient resources to fully develop and commercialize any products that may arise from its research. Accordingly, the Company will need to raise additional funds in order to satisfy its future working capital requirements. The Company expects that the net proceeds from the second private placement which closed in December 2007 of approximately \$531,000 will be adequate to fund the Company's updated and revised 2008 operating budget. Thereafter, the Company currently estimates that it will require approximately \$3,000,000 of additional funding to finance future operations by late 2008, including the costs of the pre-clinical evaluation and submission to the FDA of two lead compounds in 2009, and the possible establishment of a laboratory (depending on the availability of capital and various other operating developments). The amount and timing of future cash requirements will depend on the market's evaluation of the Company's technology and products, and the resources that the Company devotes to developing and supporting its activities. The Company anticipates funding these cash requirements from a combination of debt or equity financings and the sale, licensing or joint venturing of its intellectual properties.



AND SUBSIDIARY (a development stage company)

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### December 31, 2007 and 2006

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 its ability to achieve positive cash flow 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.

#### 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.

The funds paid to NINDS of the NIH, pursuant to the CRADA effective March 22, 2006, as amended, represent an advance on research and development costs and therefore have future economic benefit. As such, such costs are being charged to expense when they are actually expended by the provider, which is, effectively, as they perform the research activities that they are contractually committed to provide. Absent information that would indicate that a different expensing schedule is more appropriate (such as, for example, from the achievement of performance milestones or the completion of contract work), such advances are being expensed over the contractual service term on a straight-line basis, which reflects a reasonable estimate of when the underlying research and development costs are being incurred. The Company's \$200,000 financial obligation due under the CRADA as of March 22, 2007, was paid on June 29, 2007, and is intended to fund ongoing research and development activities through June 30, 2008.



AND SUBSIDIARY (a development stage company)

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### December 31, 2007 and 2006

#### 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 \$94,232 and \$30,469 for the years ended December 31, 2007 and 2006, respectively, and \$139,351 for the period from August 9, 2005 (inception) to December 31, 2007 (cumulative). Patent costs are included in research and development costs in the Company's statement of operations.

### Income Taxes

The Company accounts for income taxes pursuant to Statement of Financial Accounting Standards 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 60-month period. The Company has elected to deduct research and development costs currently.

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.

#### Stock-Based Compensation

Effective January 1, 2006, the Company adopted 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. Accordingly, the Company recognizes compensation cost for equity-based compensation for all new or modified grants issued after December 31, 2005. The Company did not have any modified grants subsequent to December 31, 2005.

In December 2007, the Securities and Exchange Commission ("SEC") 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 is not expected to have a significant impact on the Company's consolidated financial statements.



AND SUBSIDIARY (a development stage company)

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### December 31, 2007 and 2006

In addition, commencing January 1, 2006, the Company was required to recognize the unvested portion of the grant date fair value of awards issued prior to the adoption of SFAS No. 123R based on the fair values previously calculated for disclosure purposes over the remaining vesting period of the outstanding stock options and warrants. The Company did not have any unvested outstanding stock options or warrants at December 31, 2005.

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.

### Earnings Per Share

The Company computes earnings per share 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, 2007 and 2006, the Company had securities outstanding entitling the holder thereof to acquire shares of common stock as follows:

	Decem	December 31,	
	2007	2006	
Warrants	546,626	426,626	
Stock options	2,090,000	490,000	
Total	2,636,626	916,626	

### 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 and/or the current interest rates payable in relation to current market conditions.

#### 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.

AND SUBSIDIARY (a development stage company)

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### December 31, 2007 and 2006

#### Reclassification

Certain reclassifications have been made to the December 31, 2006 balances to conform to the December 31, 2007 presentation. Such reclassifications did not have any effect on results of operations.

#### Adoption of New Accounting Policies

In December 2006, the FASB issued FSP EITF 00-19-2, "Accounting for Registration Payment Arrangements" ("EITF 00-19-2"), which addresses an issuer's accounting for registration payment arrangements. EITF 00-19-2 specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with FASB No. 5, "Accounting for Contingencies". EITF 00-19-2 further clarifies that a financial instrument subject to a registration payment arrangement should be accounted for in accordance with other applicable generally accepted accounting principles without regard to the contingent obligation to transfer consideration pursuant to the registration payment arrangement. EITF 00-19-2 is effective immediately for registration payment arrangements and the financial instruments subject to those arrangements that are entered into or modified subsequent to the date of issuance of EITF 00-19-2. For registration payment arrangements and financial instruments subject to those arrangements that were entered into prior to the issuance of EITF 00-19-2, EITF 00-19-2 is effective for financial statements issued for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. Early adoption of EITF 00-19-2 for interim or annual periods for which financial statements or interim reports have not been issued is permitted. The Company chose to early adopt EITF 00-19-2 effective December 31, 2006 (see Note 3).

Effective 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 should be 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, 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, 2007, no liability for unrecognized tax benefits was required to be recorded.

The Company files income tax returns in the U.S. federal jurisdiction and various states. The Company is subject to U.S. federal or state income tax examinations by tax authorities for years after 2004.

The Company's policy is to record interest and penalties on uncertain tax provisions as income tax expense. As of December 31, 2007, the Company has no accrued interest or penalties related to uncertain tax positions.

#### Recent Accounting Pronouncements

In September 2006, the FASB issued Statement of Financial Accounting Standards 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. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company is currently assessing the potential effect of SFAS No. 157 on its financial statements.



AND SUBSIDIARY (a development stage company)

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### December 31, 2007 and 2006

In February 2007, the FASB issued Statement of Financial Accounting Standards 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. SFAS No. 159's objective 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 also requires company for disclosure requirements included in other accounting standards, including requirements for disclosures about fair value measurements included in SFAS No. 157 and SFAS No. 107. SFAS No. 159 is effective as of the beginning of a company's first fiscal year beginning after November 15, 2007. Early adoption is permitted as of the beginning of the previous fiscal year provided the company makes that choice in the first 120 days of that fiscal year and also elects to apply the provision

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 Company has not yet determined the effect on its consolidated financial statements, if any, upon adoption of SFAS No. 141(R).

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 so 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 di



AND SUBSIDIARY (a development stage company)

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### December 31, 2007 and 2006

#### 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 Company is now controlled by the former stockholder of Lixte.

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 Placement

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 have been accounted for as equity.

AND SUBSIDIARY (a development stage company)

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### December 31, 2007 and 2006

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 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 - 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 SEC. 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 agregating approximately \$74,000, which has been presented as a current liability at December 31, 2007 and 2006. No further registration penalty accrual was required at December 31, 2007, as the Company's registration statement on Form SB-2 was declared effective by the Securities and Exchange Commission on May 14, 2007. The Company will continue to review the status of the registration statement at each quarter end in the future and record further liquidated damages under the registration rights agreement as necessary. At December 31, 2007, the registration penalty to the investors was still due and payable.

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 have been accounted for as equity.

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 share) 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%.

AND SUBSIDIARY (a development stage company)

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### December 31, 2007 and 2006

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.

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

#### 4. Related Party Transactions

Since inception, Lixte's founding stockholder and Chief Executive Officer, Dr. John Kovach, has periodically made advances to the Company to meet operating expenses. Such advances are non-interest-bearing and are due on demand. At December 31, 2007 and 2006, 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, 2007 and 2006, and for the period from August 9, 2005 (Inception) through December 31, 2005, 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. 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 are common stock with a par value of \$0.0001 per share and 10,000,000 shares are 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.

#### 6. 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 is being charged to operations ratably from July 1, 2006 through June 30, 2008. During the years ended December 31, 2007 and 2006, the Company recorded a charge to operations of \$20,668 and \$31,000, 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.



AND SUBSIDIARY (a development stage company)

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### December 31, 2007 and 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 initially determined to be \$31,000 (\$0.31 per share), and is being charged to operations ratably from July 1, 2006 through June 30, 2008. On December 31, 2007 and 2006, the fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$63,000 (\$0.63 per share) and \$30,000 (\$0.30 per share), respectively, which resulted in a charge to operations of \$23,212 and \$7,500 during the years ended December 31, 2007 and 2006, respectively.

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 years; expected volatility - 150%; expected dividend yield - 0%; risk-free interest rate - 5%. On December 31, 2006, the Black-Scholes input variables utilized to determine the fair value of the aforementioned stock options were deemed to be the same as at June 30, 2006, except for an expected life of 4.5 years. On December 31, 2007, the fair value of the aforementioned stock options was calculated using the following Black-Scholes input variables: stock price - \$0.75; exercise price - \$0.333 to \$1.00; expected life - 3.5 to 6.7 years; expected volatility - 118.6%; expected dividend yield - 0%; risk-free interest rate - 4%.

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, which resulted in a charge to operations of \$30,655 during the year ended December 31, 2007.

On September 12, 2007, the Company entered into a consulting agreement with Gil Schwartzberg and granted to Mr. Schwartzberg stock options to purchase an aggregate of 1,000,000 shares of common stock, exercisable for a period of four years from vesting date at \$1.00 per share, with one-half of the options (500,000 shares) vesting immediately and one-half (500,000 shares) vesting on September 12, 2008. 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 these options ratably from September 12, 2007 through September 12, 2008. During the year ended December 31, 2007, the Company recorded a charge to operations of \$553,662 with respect to these options.

On September 12, 2007, the Company entered into a consulting agreement with Francis Johnson and granted to Professor Johnson stock options to purchase an aggregate of 300,000 shares of common stock, exercisable for a period of four years from 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 December 31, 2007, the fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$198,000 (\$0.66 per share), which resulted in a charge to operations of \$19,836 during the year ended December 31, 2007.

AND SUBSIDIARY (a development stage company)

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### December 31, 2007 and 2006

In accordance with EITF 96-18, options granted to 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.

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 December 31, 2007, 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 - \$0.75; exercise price - \$0.333 to \$1.00; expected life - 4.7 years; expected volatility - 118.6%; expected dividend yield - 0%; risk-free interest rate - 4%. The Company used a revised volatility factor at December 31, 2007 as it had trading data commencing September 24, 2007.

Information with respect to common stock warrants issued during the years ended December 31, 2006 and 2007 is provided at Notes 3 and 8.

A summary of stock option and warrant activity for the years ended December 31, 2007 and 2006 is as follows:

	Number of Shares	Av Exc	ighted erage ercise rice	Weighted Average Remaining Contractual Life (in Years)
Options and warrants outstanding at December 31, 2005	—	\$	—	—
Granted	916,626		0.333	5.00
Exercised	_		—	—
Cancelled				—
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
Options and warrants exercisable at December 31, 2007	1,519,958	\$	0.577	3.73

The intrinsic value of exercisable but unexercised in-the-money stock options and warrants at December 31, 2007 was \$262,953, based on a fair market value of \$0.75 per share on December 31, 2007.

AND SUBSIDIARY (a development stage company)

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### December 31, 2007 and 2006

Information regarding stock options and warrants outstanding and exercisable at December 31, 2007 is summarized as follows:

	Warrants and Options Outstanding	Warrants and Options Exercisable
Exercise Prices	(Shares)	(Shares)
\$0.333	1,516,626	899,958
\$0.65	120,000	120,000
\$1.00	1,000,000	500,000
	2,636,626	1,519,958

Information regarding the Company's non-vested stock options and warrants as of December 31, 2006 and 2007, and the changes during such years, is summarized as follows:

	Number of Shares
Options and warrants outstanding but unvested at December 31, 2005	—
Granted	916,626
Vested	(683,292)
Forfeited	—
Expired	
Options and warrants outstanding but unvested at December 31, 2006	233,334
Granted	1,720,000
Vested	(836,666)
Forfeited	—
Expired	
Options and warrants outstanding but unvested at December 31, 2007	1,116,668

## 7. Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets as of December 31, 2007 and 2006 are summarized as follows:

	D		
	2007	_	2006
Start-up and organization costs	\$ 310,000	\$	129,000
Contingent liability	31,000		31,000
Net operating loss carryforwards	170,000		58,000
Total deferred tax assets	511,000		218,000
Valuation allowance	(511,000)		(218,000)
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, 2007 and 2006, 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.



AND SUBSIDIARY (a development stage company)

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### December 31, 2007 and 2006

No federal tax provision has been provided for the years ended December 31, 2007 and 2006 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 rate for the years ended December 31, 2007 and 2006 is as follows:

	Years Ended Decem	Years Ended December 31,		
	2007	2006		
U. S. federal statutory tax rate	(34.0%)	(34.0%)		
Pre-merger loss of accounting acquiree	_	(3.7%)		
Non-deductible merger costs	_	3.0%		
Non-deductible stock-based compensation	19.4%	5.9%		
Change in valuation allowance	14.6%	28.8%		
Effective tax rate	0.0%	0.0%		

At December 31, 2007, the Company has available net operating loss carryforwards for federal income tax purposes of approximately \$408,000 which, if not utilized earlier, expire in 2026.

#### 8. Commitments and Contingencies

Effective March 22, 2006, Lixte entered into a CRADA, as amended, with the NINDS of the NIH. The CRADA is for a term of 27 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 installment of \$200,000 was due within 180 days of the effective date and was paid in full on July 6, 2006. The second installment of \$200,000 was paid in full on June 29, 2007. The CRADA was extended to June 30, 2008 from March 2008 at no additional cost as the funds provided by the Company are expected to support the collaboration at least until that date.

On January 5, 2007, Lixte entered into a Services Agreement with The Free State of Bavaria (Germany) represented by the University of Regensburg (the "University") pursuant to which Lixte 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. Lixte 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, Lixte 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, Lixte entered into a two-year agreement (the "Chem-Master Agreement") with Chem-Master International, Inc. ("Chem-Master") 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. 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. 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 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.

AND SUBSIDIARY (a development stage company)

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### December 31, 2007 and 2006

On September 12, 2007, the Company entered into two consulting agreements for financial and scientific services. Compensation related to these agreements is primarily in the form of stock options (see Note 6).

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, Lixte 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 such that Mirador forgave 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.

### Certification of the Principal Executive Officer and Chief Financial Officer Under Section 302 of the Sarbanes-Oxley Act

I, John 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-KSB 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 issuer 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)) for the issuer and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the issuer's disclosure controls and procedures and presented in this report our 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
  - (c) Disclosed in this report any change in the issuer's internal control over financial reporting that occurred during the issuer's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the issuer'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 issuer's auditors and the audit committee of issuer'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 issuer'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 issuer's internal control over financial reporting.

Date: March 31, 2008

By: /s/ John S. Kovach

Name: John Kovach Title: Chief Executive Officer and Chief Financial Officer

## CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER

## AND PRINCIPAL FINANCIAL OFFICER

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Lixte Biotechnology Holdings, Inc. (the "Company") hereby certifies that, to his knowledge:

(i) The Annual Report on Form 10-KSB of the Company for the fiscal year ended December 31, 2007 (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

Company.

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

Date: March 31, 2008

By: /s/ John S. Kovach

John Kovach Chief Executive Officer and Chief Financial Officer