## 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, 2006

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 Setauhet, New York (Address of principal executive offices) **20-2903526** (I.R.S. Employer Identification Number)

> 11733 (Zip Code)

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

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

Securities registered under Section 12(g) of the Act: Common Stock, \$0.000 par value per share.

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  $\square$ 

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, 2006: \$0

Aggregate market value of the common stock held by non-affiliates of the Issuer as of March 15, 2007 was approximately \$0.

There were 26,582,183 shares of the Company's common stock outstanding on March 15, 2007.

Documents incorporated by reference: None.

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 10KSB (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.

Lixte 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.

Lixte's initial focus is on developing new treatments for the most common and most aggressive type of primary brain cancer, gliobastoma multiforme (which we refer to as GBM). On March 22, 2006, Lixte entered into a Cooperative Research and Development Agreement (which we refer to as the CRADA) with the National Institute of Neurological Diseases and Stroke (which we refer to as NINDS) of the National Institutes of Health (which we refer to as NIH) to identify and evaluate drugs that target a specific biochemical pathway for GBM cell differentiation. The CRADA also covers research to determine whether expression of a component of this pathway correlates with prognosis in glioma patients.

The lead scientist at NINDS collaborating with Lixte under the CRADA is Dr. Zhengping Zhuang. Dr. Zhuang is internationally recognized for his research in molecular pathology. Dr. Zhuang has four issued and two pending patents related to molecular pathology of human cancers. He has recently discovered a biomarker of relevance to the growth of GBMs that Lixte believes can be used as a tool for identifying drugs that affect the growth of GBM cells. Under the CRADA, Lixte will support two persons at NIH to work under the direction of Dr. Zhuang. The goal is to identify drugs that inhibit GBM cell growth and to determine if the identified biomarker may be useful for estimation of prognosis. Lixte's annual contribution to the collaborative research done by Lixte and NIH is \$200,000 for each of two years for two research assistants expected to be at the post-doctoral level and supplies.

Lixte sponsored the development and submission of a provisional patent application filed February 6, 2006 naming as co-inventors Dr. Zhuang, several other NIH investigators, and Dr. Kovach. When the final patent application is filed in early 2007, the named inventors will assign their rights in the inventions to their employers, meaning that any patent (or patents) arising out of the application will be jointly owned by the U.S. Government and Lixte. Lixte is currently in negotiations with the NIH to obtain the exclusive commercial rights to the inventions covered by the Provisional Patent Application. As its research progresses, Lixte expects to file further patent applications relating to the categories of products described below. Patent applications arising out of research pursuant to the CRADA are likely to be jointly owned by Lixte and the U.S. Government. In such cases of joint ownership, Lixte will likely seek to obtain the exclusive commercial rights to those inventions, the terms of which are presently unknown.

Lixte's products will derive directly from its intellectual property consisting of its Provisional Patent Application and other patents it anticipates will arise out of its research activities. Those patents are expected to cover biomarkers uniquely associated with specific types of cancer, patents on methods to identify drugs that inhibit growth of specific tumor types and combinations of drugs and potential therapeutic agents for the treatment of specific cancers.

We face several potential challenges in our drive for commercial success, including raising sufficient capital to fund our business plan, achieving commercially applicable results of our research program, continued access to tissue and blood samples from cancer patients, competition from 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 us.

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 memorandum, "**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 Biotechnology, Inc.

#### Metastasis

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

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

#### Mutation

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

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

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

Research on <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 cells arising from its uncontrolled cell growth. If the products of the altered genes in these cancer cells are detectable in the body, they may reveal the presence of the cancer at a stage when it is curable by surgery.

#### Prognosis

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

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

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

### Proteins

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

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

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

## **Research Objectives**

In the first year of operation, we will concentrate on exploiting the biomarker pathway associated with the growth of GBMs to identify drugs with potential selective activity against this type of tumor. In the first year, we will also collect the clinical samples needed for the identification of biomarkers for ovarian and stomach cancer. Subsequently, we will include cancers of the breast, prostate, colon, bladder, and kidney. For each of these diseases, a biomarker that would enable identification of the presence of cancer at a stage curable by surgery would save thousands of lives annually. Biomarkers specific to these diseases may also provide clues as to processes (biological pathways) that may be important to the growth of the cancer and therefore be vulnerable to drug treatments targeted to the biomarker pathway.

We will seek to identify new treatments for the most common and most aggressive type of primary brain cancer, glioblastoma multiforme ("GBM") under a Cooperative Research and Development Agreement ("CRADA") with the National Institute of Neurological Diseases and Stroke ("NINDS") of the National Institutes of Health ("NIH"). A second goal of the CRADA is to determine whether expression of a component of the biomarker pathway correlates with prognosis in glioma patients.

The collaborating NIH laboratory is directed by Dr. Zhengping Zhuang, who is an internationally recognized molecular pathologist. He has four issued and two pending patents related to molecular pathology of human cancers. Dr. Zhuang and colleagues at NIH recently discovered a biomarker that we believe can be used as a tool for identifying drugs that affect the growth of GBM cells. Under the CRADA, we will support studies in Dr. Zhuang's laboratory with \$200,000 annually for two years for two research assistants expected to be at the post-doctoral level and supplies. Dr. Zhuang will make the selection of the research personnel.

#### **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 USA 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 USA. 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, NIH. As such, we are entitled to obtain an exclusive license to such claims as specified in the standard NIH CRADA agreement. 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) will be subject to negotiations between us and NINDS, NIH in the future.

In February 2007, a new US provisional application was filed on behalf of Lixte Biotechnology Holdings, Inc. This provisional patent application identifies a new lead compound that has activity against glioblastoma multiform cell lines in vitro. This provisional patent application also describes a series of homologs of the lead compound.

#### Access to Clinical Materials

To detect and to assess the clinical relevance of biomarkers, we need access to human tissue, blood and perhaps other body fluids of patients with and without the specific types of cancer under study. On January 5, 2007 we entered into a two-year agreement with the Institute of Pathology at the University of Regensburg in Germany to receive a supply of high quality, accurately annotated tissue and blood samples for cancers other than brain cancers. This arrangement provides us with appropriate clinical samples for which permission has been obtained to study any molecular feature of the tissue for commercial purposes. This is an absolute requirement for success of a for-profit company in this field. Pursuant to the Agreement, the University will provide us with certain samples of primary cancer tissue and related biological fluids to be obtained from patients affiliated with specified types of cancer. The University will also provide certain information relating to such patients. We will pay the University 72,000 Euros (approximately \$99,702) in two installments of 36,000 Euros, the first installment was paid in March 2007 and the second installment to be paid within 60 days of the earlier of (i) January, 2008 or (ii) the University's fulfillment of certain obligations relating to the delivery of materials.

Clinical samples will be obtained from patients who have given their signed informed consent by persons identified by the University of Regensburg, Germany. These are employees of the University who have approval by the University to seek such permission under a consent form approved by the University. The scope of use has been narrowed to the study of human cancers for the purposes of developing improved methods of diagnosis, estimation of prognosis, treatment and understanding causation of human cancers.

The collection, selection, histological characterization, and processing of tissue samples and collection of blood samples will be managed by Arndt Hartmann, M.D., a Professor in the Institute of Pathology at the University of Regensburg. Dr. Hartmann is an expert clinical and molecular pathologist and is keenly interested in the project. His research is focused on the molecular genetics of breast, bladder, prostate and kidney cancer. He was a research fellow for three years in Dr. Kovach's laboratory at the Mayo Clinic, Rochester, Minnesota, before completing his residency in pathology and joining the faculty at Regensburg University. Dr. Hartmann is a member of the Scientific Advisory Committee of Lixte.

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 are confident that the molecular approaches that led to the discovery of the biomarker for GBMs (and the subject of the Provisional Patent Application) could 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 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 we should have access to the clinical samples needed for our program from the Institute of Pathology at University of Regensburg in Germany. We expect that the samples we will obtain will be or have been 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 agreement, 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 focus for the first two years, in addition to GBMs, will be 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 our resources increase as anticipated, 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, 2006, we had no full-time employees. Dr. Kovach is Chair of the Department of Preventive Medicine at SUNY, in Stony Brook. 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 will work under the supervision of Dr. Zhuang on the aims of the CRADA. Dr. Kovach will devote 20% of his efforts per year to research planning and design and will monitor the research progress under the CRADA. Dr. Kovach's contributions will be made outside of his academic responsibilities.

#### Properties

At present, we conduct all laboratory activities at NIH under the CRADA agreement. We will also collect and store samples of human tumors other than brain cancers under a service agreement with the University of Regensburg, Germany. The Company maintains a single office in a designated area of Dr. Kovach's residence and receives mail at the post office depot, 248 Route 25A, No. 2, East Setauket, New York 11733. No additional facilities are needed until the Company develops its independent laboratory.

#### **Government Regulation**

At its present stage of development, our business is not subject to any specific government regulation with respect to its ongoing research and plan service agreement. Our only collaborator at present is National Institute of Neurological Diseases and Stroke (NINDS), National Institutes of Health. This collaboration is defined in CRADA 2165 under which NINDS evaluates compounds for their ability to inhibit the growth of brain tumor cells. The NINDS laboratory that is carrying out this activity is a research laboratory that operates in compliance with various federal and state's statutes and regulations including the OSHA. All activities of this laboratory are monitored by the compliance of NINDS.

We have 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 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.

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 agreement 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 agreement .

Our business will become subject to the regulations of the FDA when we begin to pursue development of clinical trials. Clinical trials are research studies to answer specific questions about new therapies or new ways of using known treatments. Clinical trials 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 a pharmaceutical company in association with NIH under the existing CRADA or under a new CRADA or with a pharmaceutical company without association with NIH. In either case, we would be primarily responsible for filing and obtaining approval from the FDA of an Investigational New Drug Application (IND). In the event that we seek to raise sufficient capital to conduct a phase I clinical trial without a partner in the pharmaceutical industry in collaboration with NIH or independently, we would become subject to FDA regulation as we sought to obtain an IND for clinical evaluation of a therapeutic regimen with the long-range goal of receiving FDA approval of the drug for commercial use. 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. FDA's role in the development of a new drug 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 spe



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 can 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 placement 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. Most immediately, in addition to the \$1.118 million from the Private Placement, we expect to require up to \$2.3 million in the near term to enable us to obtain a wet lab to further advance our research projects. 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 either one or a combination of additional financings, mergers or acquisitions, or via the sale or license of certain of our assets. 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 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.

Our auditors opinion regarding our financial statements include 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 commenced operations. All activity through December 31, 2006 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 and unrelated 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 \$522,939. On July 27, 2006, we completed a second closing of a private placement, selling 1,581,351 shares of common stock at a price of \$0.333 per share and receiving net proceeds of \$411,302.

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 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. Accordingly, we will need to raise additional funds in order to satisfy our future working capital requirements. In the short-term, in addition to the net proceeds from the private placement, we estimate that it will approximately require additional funding of approximately \$2,300,000. 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 either one or a combination of additional financings, mergers or acquisitions, or via the sale or license of certain of our assets.

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 will negotiate 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 70 years old, and, because of his arrangement with the State University of New York, does not devote his full time to us although Dr. Kovach generally devotes a minimum of twenty hours a week to our business. The loss of services of any of these persons could delay or reduce our product development and commercialization efforts. Furthermore, recruiting and retaining qualified scientific personnel to perform future research and development work will be critical to our success. The loss of members of our scientific personnel, or our inability to attract or retain other qualified personnel or advisors, could significant weaken our management, harm our ability to compete effectively and harm our business.

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

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

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

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

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

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

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;
  - 21

- · 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;
- $\cdot$  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. Although we believe that all necessary consents will be obtained from any patient who donates samples for our research purposes, there is a risk that, without our knowledge and through inadvertence or neglect, proper consents will not be obtained from all patients. The responsibility for obtaining the consents is vested in the physicians at the University. If a patient does not give a proper consent and we develop a product using a sample obtained from him or her, we could be forced to pay royalties or to cease selling that product. All tissue samples are de-identified when they are sent to us. We have no way to link any of our studies to an individual patient. Therefore, the risk of an individual patient objecting to development of any product is extremely remote.

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

The following factors are important to our success:

- receiving patent protection for our product candidates;
- · preventing others from infringing our intellectual property rights; and
- · maintaining our patent rights and trade secrets.

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

To date, we have sought to protect our proprietary position by filing for a Patent Cooperation Treaty patent and a non-provisional patent in the U.S. related to inventions that form the basis of our research arrangements with the NIH and potential pipeline of future products. We also filed a new provisional application in the U.S. in February 2007 relating to a lead compound that has activity against glioblastoma multiform cell lines in vitro. We anticipate that we will apply for further patents based on our ongoing research. Because issues of patentability involve complex legal and factual questions, the issuance, scope and enforceability of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. U.S. patents and patent applications may also be subject to interference proceedings, and U.S. patents may be subject to reexamination proceedings in the U.S. Patent and Trademark Office and foreign patents may be subject to opposition or comparable proceedings in corresponding foreign patent offices, which proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, reexamination and opposition proceedings may be costly. Thus, any patents that we own or license from others may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third-party receiving the patent rights sought by us, which in turn could affect our ability to market a potential product to which that patent filing was directed. Our pending patent applications, those that we may file in the future, or those that we may license from third parties may not result in patents being issued. If issued, they may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, others may independently develop similar technologies or duplicate any technology that we have developed. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. For example, compulsory licenses may be required in cases where the patent owner has failed to "work" the invention in that country, or the third-party has patented improvements. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patent and other intellectual property protection, which makes it difficult to stop infringement.



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

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

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

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

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

The availability and levels of reimbursement by governmental and other third-party payors affect the market for our products. The efficacy, safety and 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 is not and has never been publicly traded. As such, a regular trading market for the securities does not yet exist and may not exist or be sustained in the future. We intend to seek a listing on the OTC Bulletin Board. No assurance can be given that such listing will be obtained or the timing of the listing. Even if such listing is obtained, the NASD has enacted recent changes that limit quotations on the OTC Bulletin Board to securities of issuers that are current in their reports filed with the Securities and Exchange Commission. The effect on the OTC Bulletin Board of these rule changes and other proposed changes cannot be determined at this time. 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 may be difficult to obtain and holders of common stock may be unable to resell their securities at or near their original offering price or at any price. Market prices for our common stock will be influenced by a number of factors, including:

- the issuance of new equity securities pursuant to a future offering or acquisition;
- changes in interest rates;
- competitive developments, including announcements by competitors of new products or services or significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;
- · variations in quarterly operating results;
- · changes in financial estimates by securities analysts;
- the depth and liquidity of the market for our common stock;
- · investor perceptions of our company and the medical device industry generally; and
- · general economic and other national conditions.

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

Dr. John Kovach, our current Chief Executive Officer, was the former stockholder of Lixte, our operating subsidiary, and received shares of our stock in the Reverse Merger. He will be eligible to sell all or 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"), commencing one year after the Reverse Merger, subject to certain limitations. In general, pursuant to Rule 144, a stockholder (or stockholders whose shares are aggregated) who has satisfied a one-year holding period may, under certain circumstances, sell within any three-month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale if the shares are listed on a national exchange or on NASDAQ. Rule 144 also permits, under certain circumstances, the sale of securities, without any limitations, by a non-affiliate that has satisfied a two-year holding period. Additionally, this prospectus covers the resale of shares issued in the private placement and the shares owed by certain of our stockholders immediately prior to the Reverse Merger. Any substantial sale of common stock pursuant to this prospectus or Rule 144 may have an adverse effect on the market price of our common stock by creating an excessive supply.

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

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

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

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

#### Our principal stockholder has significant influence over our company.

As a result of the Reverse Merger, Dr. John Kovach, our principal stockholder and our Chief Executive Officer, beneficially owns approximately 64% of our outstanding voting stock after giving effect to the private placement. 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.



## Standards for compliance with Section 404 of the Sarbanes-Oxley Act of 2002 are uncertain, and if we fail to comply in a timely manner, our business could be harmed and our stock price could decline.

Rules adopted by the SEC pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 require annual assessment of our internal control over financial reporting, and attestation of our assessment by our independent registered public accountants. On September 22, 2005, the SEC extended the compliance dates for non-accelerated filers, as defined by the SEC, by one year. Accordingly, we believe that this requirement will first apply to our annual report for fiscal 2007. The SEC has recently proposed new rules on compliance with Section 404. In any event, the standards that must be met for management to assess the internal control over financial reporting as effective are new and complex, and require significant documentation, testing and possible remediation to meet the detailed standards. We may encounter problems or delays in completing activities necessary to make an assessment of our internal control over financial reporting. In addition, the attestation process by our independent registered public accountants is new and we may encounter problems or delays in completing the implementation of any requested improvements and receiving an attestation of our assessment by our independent registered public accountants are unable to provide an unqualified attestation report on such assessment, investor confidence and share value may be negatively impacted.

## 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 agreement. We will also collect and store samples of human tumors other than brain cancers under a service agreement with the University of Regensburg, Germany. The Company maintains a single office in a designated area of Dr. Kovach's residence and receives mail at the post office depot, 248 Route 25A, No. 2, East Setauket, New York 11733. No additional facilities are needed until the Company develops its independent laboratory.

## **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, 2006.

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

There is no trading of our capital stock on any publicly traded market. Even if such stock becomes publicly tradable, the price of our common stock will likely fluctuate in the future. The stock market in general has experienced extreme stock price fluctuations in the past few years. In some cases, these fluctuations have been unrelated to the operating performance of the affected companies. Many companies have experienced dramatic volatility in the market prices of their common stock. We believe that a number of factors, both within and outside our control, could cause the price of our common stock to fluctuate, perhaps substantially. Factors such as the following could have a significant adverse impact on the market price of our common stock:

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

## Holders

As of December 31, 2006, we currently have 26,582,183 shares of our common stock outstanding. As of December 31, 2006, 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.

### Sales of Unregistered Securities

On May 26, 2005, we sold 2,700,000 shares of common stock to five accredited investors (two of whom were officers and directors) for aggregate cost consideration of \$25,000. Such shares were issued after we issued a stock dividend of 11% to stockholders or record on May 8, 2006. The securities were issued pursuant to Section 4(2) of the Securities Act of 1933, as amended. The issuees also represented that they were acquiring the securities for their own account and a legend was placed on the stock certificates.

On May 17, 2006, we issued 905,000 shares of our common stock to TMC Ulster Holdings, Inc. for \$100,000. The shares were issued pursuant to Section 4(2) of the Securities Act of 1933, as amended. The purchaser represented that it was acquiring the securities for its own account, and a legend was placed on the securities.

On June 30, 2006, we issued 19,021,786 shares of common stock in connection with the acquisition of Lixte Biotechnology, Inc., and sold an aggregate of 1,973,871 shares of common stock to 26 accredited investors in a private placement at a per share price of \$0.333. On July 27, 2006, we sold an aggregate of 1,581,351 shares of common stock to 57 accredited investors in a private placement at a per share price of \$0.333. 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 426,626 shares of common stock in connection with the private placements. All of the issuees 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 issuees also represented that they were acquiring the securities for their own account and a legend was placed on the stock certificates.

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 5-year option to purchase 100,000 shares at the same exercise price subject to certain conditions. The options will be issued pursuant to Section4(2) of the Securities Act of 1933, as amended.

## 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, 2006, the most recently completed fiscal year.

Plan Category	Number of Securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column 2)
Equity Compensation Plans Approved by Security Holders	N/A	N/A	N/A
Equity Compensation Plans Not Approved by Security			
Holders	490,000 \$	3.33	N/A
	30		

## ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION

## AND RESULTS OF OPERATIONS

#### **Recent Events**

On June 30, 2006, Lixte Biotechnology, Inc., a privately-held Delaware corporation, completed a reverse merger transaction with our company, a public "shell" company, whereby Lixte became our wholly-owned subsidiary. 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 our historical financial results. All costs associated with the reverse merger transaction were expensed as incurred. On December 7, 2006, we changed our name to Lixte Biotechnology Holdings, Inc. Lixte Biotechnology, Inc., is a holding company for Lixte Biotechnology, Inc., the company acquired in the reverse merger and our operating company. When we refer to "Lixte," we are referring to Lixte Biotechnology, Inc., our operating subsidiary.

#### Overview

Lixte Biotechnology, Inc. 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.

As a result of the reverse merger, we are now 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.

## **Critical Accounting Policies and Estimates**

We prepared the 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 our consolidated financial statements.

#### **Research and Development**

Research and development costs are expensed as incurred. Amounts due 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.

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

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 123R, "Share-Based Payment" ("SFAS 123R"). SFAS 123R requires all share-based payments, including grants of employee stock options to employees, to be recognized in the financial statements based on their grant date fair values. Effective January 1, 2006, SFAS 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.

## Income Taxes

We account for income taxes under Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes", which requires the recognition of 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 must be deferred until we commence business operations and then they may be written off over a 60-month period. These expenses will not be deducted for tax purposes and will represent a deferred tax asset. We will provide a valuation allowance for the full amount of the deferred tax asset since there is no assurance of future taxable income. Tax deductible losses can be carried forward for 20 years until utilized.

#### **Plan of Operation**

Our initial focus is on developing new treatments for the most common and most aggressive type of primary brain cancer, glioblastoma multiforme ("GBM"). We entered into a Cooperative Research and Development Agreement with the National Institute of Neurological Diseases and Stroke of the National Institutes of Health to identify and evaluate drugs that target a specific biochemical pathway for GBM cell differentiation. The CRADA also covers research to determine whether expression of a component of this pathway correlates with prognosis in glioma patients.

The lead scientist at NINDS collaborating with us under the CRADA is Dr. Zhengping Zhuang. Dr. Zhuang is internationally recognized for his research in molecular pathology. Dr. Zhuang has four issued and two pending patents related to molecular pathology of human cancers. Dr. Zhuang recently discovered a biomarker of relevance to the growth of GBMs that we believe can be used as a tool for identifying drugs that affect the growth of GBM cells. Under the CRADA, we will support two persons at NIH to work under the direction of Dr. Zhuang. The goal is to identify drugs that inhibit GBM cell growth and to determine if the identified biomarker may be useful for estimation of prognosis. Our contribution to the collaborative research done by us and NIH is \$200,000 annually for two years to fund two research assistants expected to be at the post-doctoral level, as well as supplies and travel expenses.

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 USA 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 USA. 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 2007 patent filings fall under the CRADA agreement with NINDS, NIH. As such, we are entitled to obtain an exclusive license to such claims as specified in the standard NIH CRADA agreement. 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) will be subject to negotiations between us and NINDS, NIH in the future.

In February 2007, a new US provisional application was filed on behalf of Lixte Biotechnology Holdings, Inc. This provisional patent application identifies a lead compound that has activity against glioblastoma multiform cell lines in vitro. This provisional patent application also describes a series of homologs of the lead compound.

As our research progresses, we expect to file further patent applications relating to the categories of products described below. Patent applications arising out of research pursuant to the CRADA are likely to be jointly owned by us and the U.S. Government. In such cases of joint ownership, we will likely seek to obtain the exclusive commercial rights to those inventions.

We expect that the products will derive directly from our intellectual property, which will consist of patents that we anticipate will arise out of our 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 potential drugs and potential therapeutic agents for the treatment of specific cancers.

We face several potential challenges in our efforts to achieve commercial success, including raising sufficient capital to fund our business plan, achieving commercially applicable results of our research program, continued access to tissue and blood samples from cancer patients, 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 us.

There is substantial uncertainty as to our ability to fund our operations and continue as a going concern (see "Liquidity and Capital Resources - Going Concern" below).

We have two major goals to achieve over the next 12 months. The prime objective, in collaboration with the National Institute of Neurological Diseases and Stroke (NINDS) under CRADA # 02165, is to extend the characterization of potentially more effective drugs and drug combinations (identified by us and jointly with NINDS) for the treatment of the incurable human brain tumor, glioblastoma multiforme (GBM). The second goal is to obtain well characterized samples of common human cancers other than GBM under conditions needed to identify new biomarkers for the earlier detection and identification of biochemical pathways as potential targets for new treatments.

#### Goal I: Development of more effective regimens for the treatment of GBM

Over the next 12 months, we will continue to develop preclinical data supporting the potential effectiveness of several drugs for the treatment of GBM when used alone or in combination. The drugs that have been identified as active in vitro have never been used for the treatment of GBM in humans. Some of these compounds were included in claims of a provisional patent filed jointly by the company and NINDS in February 2006. Over the past 6 months, the activity of these drugs has been documented and several new lead compounds were identified. This work was done under the CRADA. The combinations of several pairs of lead drugs appear to have some specificity for GBM in that at equimolar doses these drugs are more active against GBMs than against other human cancer cell types tested. Some of the drug combinations are synergistic in their ability to inhibit the growth of GBMs, e.g., the combination of two drugs inhibits GBMs to a greater extent than would be expected from the sum of their inhibitory effects when used alone. For several of the lead compounds, toxicity in mice was determined previously by others and for two lead compounds, doses that are tolerable in man and the specific toxicities induced by those doses are known. None of the lead compounds, however, have been evaluated as potential treatments for GBM.

We have converted the provisional patent filed by us and scientists at NINDS in February 2006 to a Patent Treaty Cooperation international patent (PCT). The PCT presents evidence supporting claims made in the provisional patent regarding the identification of new regimens for the treatment of GBM and add new claims. The new claims include new lead compounds used alone and in combinations, which are effective in inhibiting GBMs in vitro. The data demonstrates that some of the single agents are active at doses expected to be compatible with administration to humans based on their use in humans in the past for other purposes. The PCT was filed in February 2007 jointly by us and NINDS as work done collaboratively under the CRADA.

We also filed a second provisional patent which specifies claims for regimens active against GBMs that were not stated in either the PCT or the non-provisional U.S. patent.

Over the next 6-12 months, we will evaluate two or more lead compounds alone and in combination for activity against human GBMs in an animal (mouse) model. These evaluations will be done at NIH under protocols developed by NINDS and us. The protocols will be approved by NIH committees responsible for approving the conduct of animal research at NIH and will be carried out by NIH personnel as a joint activity under the CRADA. The CRADA agreement specifies evaluation of drug regimens in animal models as one of the activities to be pursued by the company and NINDS. It is anticipated that the animal studies will include 3 regimens identified under the CRADA that have never been investigated as treatment for human GBMs. We expect these animal studies to be completed in September 2007.

As the effectiveness of lead regimens against GBMs in the animal model is determined, a decision will be made as to which regimens are most promising for development for human studies. This decision will be made jointly by the company with the advice of its scientific advisory board and its CRADA partner, NINDS. At this point, NINDS and the company will consider whether development of specific regimens for evaluation in humans should proceed via an extension of the existing CRADA, under a new CRADA with NINDS, or possibly with another institute at NIH and/or with a partner in the pharmaceutical industry interested in and capable of taking the drug though the IND process and conducting clinical evaluations.

#### **Goal II: Collection of Human Tumor Samples**

Over the next 12 months, samples of human tumors and associated blood and urine samples will be collected by the University of Regensburg under our January 5, 2007 agreement with the Free State of Bavaria, Germany. Technology comparable to that used to detect the biomarker for GBM will be applied to these tumors to identify new biomarkers for cancers of the breast, colon, stomach, kidney, bladder, prostate, and ovary. The present CRADA with NINDS is limited to the study of GBM.

#### Plans Beyond the Next 12 Months

In early 2008, we expect to be in a position to begin analyses of tumor types other than GBM. The company plans to establish a laboratory to proceed with biomarker discovery independent of NIH. To do this we will need approximately \$2.3 million to establish and operate the laboratory for 2 years i.e., to January 2010. The creation and operation of the laboratory for two years until December, 2009, will cost about \$1.7 million. During 2007 and 2008 patent costs, accounting and legal fees and office management expenses are estimated to be approximately \$500,000. Thus, the Company will need to raise about \$2.3 million at the end of 2007 and beginning of 2008 to take the next step to biomarker discovery in cancers other than GBM. Funds will come either from payments as part of licensing rights to developing for clinical applications the regimens active against GBM or though the sale of new stock.



The laboratory (rented space) is expected to be located in a biotechnology incubator of the State of Maryland in close proximity to NIH or comparable incubator near an academic biomedical research center. This incubator offers low-cost, high-quality space and shared resources necessary for a molecular biology research. Because of proximity to NIH or other academic biomedical research center, we will have access to many highly trained scientists and technical personnel to staff the laboratory.

Projected major expenses for the wet laboratory are:

Year 1:

\$48,000	for rental of 800 sq. ft. wet lab in MD incubator (\$4000/month plus utilities/phone/internet)
\$300,000	for staff salaries plus fringe (1 scientist and 2 technicians)
\$100,000	for disposable equipment and reagents (\$33K/lab person)
\$300,000	for equipment (one time expense)
\$100,000	for outsourced technical services (LC/MS/MS, immunoassay development)
Total Year 1:	\$848,000

Year 2:

\$50,400	for rental of wet lab
\$315,000	for staff salaries
\$105,000	for supplies
\$300,000	for outsource technology services (LC/MS/MS, immunoassay development)
Total Year 2:	\$770,400

Total Costs for Laboratory Start Up and 2 Years of Operation = \$1,618,400.

## **Results of Operations - Year Ended December 31, 2006**

Comparative financial statements for the period ended December 31, 2005 reflect the results of operations of Lixte, our operating subsidiary, for the period August 9, 2005 (inception) to December 31, 2005 as Lixte, the accounting acquirer in the reverse merger transaction, was not formed until August 9, 2005. As such, the operations of the Company during this period were nominal.

We are a development stage company and have not yet commenced revenue-generating operations.

General and Administrative. For the year ended December 31, 2006, general and administrative expenses were \$299,420, which included \$97,400 for the vested portion of the fair value of stock options issued to a director and certain members of the Company's Scientific Advisory Committee on June 30, 2006. Significant components of general and administrative expenses to date consist of board compensation and legal and accounting fees.

Depreciation. For the year ended December 31, 2006, depreciation expense was \$462.

Research and Development Costs. Effective March 22, 2006, Lixte entered into a Cooperative Research and Development Agreement (the "CRADA") with the U.S. Department of Health and Human Services, as represented by National Institute of Neurological Disorders and Stroke ("NINDS") of the National Institutes of Health. The CRADA is for a term of two years from the effective date and may be unilaterally terminated by either party by providing written notice within sixty days. Pursuant to the CRADA, Lixte agreed to provide total payments of \$400,000 over the term of the CRADA.

The current amount due pursuant to the CRADA was recorded as a liability (and was subsequently reduced by any applicable payments), with the related amount of such contract 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. For the year ended December 31, 2006, research and development costs aggregating \$150,100 were charged to operations.

Reverse Merger Costs. On June 30, 2006, pursuant to a Share Exchange Agreement dated as of June 8, 2006 by and among us, Dr. John S. Kovach and Lixte, we issued 19,021,786 shares of our common stock in exchange for all of the issued and outstanding shares of Lixte, and Lixte became a wholly owned subsidiary of SRKP. In connection with this transaction, we paid WestPark Capital, Inc. a cash fee of \$50,000, which was charged to operations during the year ended December 31, 2006.

Net Loss. For the year ended December 31, 2006, we incurred a net loss of \$488,084.

## Liquidity and Capital Resources - December 31, 2006

## **Going Concern**

At December 31, 2006, we had not yet commenced any revenue-generating operations and were therefore considered a "development stage company". All activity through December 31, 2006 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 is essentially dependent on debt and equity funding from both related and unrelated parties to finance its operations. Prior to June 30 2006, Lixte's cash requirements were funded by advances from Lixte's founder, Dr. John Kovach, our Chief Executive Officer. On June 30, 2006, we completed an initial closing of our 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, we completed a second closing of our private placement, selling 1,581,351 shares of common stock at a price of \$0.333 per share and receiving net proceeds of \$411,302.

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 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.

Based on the proceeds received from the private placement, we may not have sufficient resources to completely fund its 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, we will need to raise additional funds in order to satisfy its future working capital requirements. In the short-term, in addition to the net proceeds from the private placement, we estimate that it will require additional funding of approximately \$2,300,000. 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 its products. We will need to fund these cash requirements from either one or a combination of additional financings, mergers or acquisitions, or via the sale or license of certain of its assets.

Current market conditions present uncertainty as to our ability to secure additional funds, as well as its 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 its 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 its operating plan and the Company may have to reduce the scope of its planned operations. If cash and cash equivalents are insufficient to satisfy the Company's liquidity requirements, we would be required to scale back or discontinue its product development program, or obtain funds if available through strategic alliances that may require the Company to relinquish rights to certain of its technologies or discontinue its operations.

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Operating Activities. For the year ended December 31, 2006, operating activities utilized cash of \$443,451.

The Company had working capital of \$625,502 at December 31, 2006, primarily as a result of the Company's private placement closings on June 30, 2006 and July 27, 2006, which generated net proceeds of \$522,939 and \$411,302, respectively.

Investing Activities. For the year ended December 31, 2006, investing activities utilized net cash of \$498 for the purchase of office equipment.

<u>Financing Activities</u>. 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, 2006, we did not have any material commitments for capital expenditures. Our principal commitments at December 31, 2006 consisted of the contractual obligations as summarized below.

Effective March 22, 2006, Lixte entered into a Cooperative Research and Development Agreement (the "CRADA") with the U.S. Department of Health and Human Services, as represented by National Institute of Neurological Disorders and Stroke ("NINDS") of the National Institutes of Health. The CRADA is for a term of two years from the effective date and may be unilaterally terminated by either party by providing written notice within sixty days. Pursuant to the CRADA, Lixte agreed to provide total payments of \$400,000 over the term of the CRADA, of which \$200,000 had been paid at December 31, 2006 and \$200,000 is due and payable in April 2007.

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 will also provide certain information relating to such patients. Lixte will pay the University 72,000 Euros (approximately \$99,700) in two installments of 36,000 Euros (approximately \$49,850), the first installment to be paid within sixty days of January 5, 2007 and the second installment to be paid within sixty days of the earlier of (i) January 5, 2008 or (ii) the University's fulfillment of certain obligations relating to the delivery of materials.

On February 5, 2007, we entered into an agreement (the "Agreement") with Chem-Master International, Inc. ("Chem-Master") pursuant to which the Company engaged Chem-Master to synthesize a compound designated as "LB-1", and any other compound synthesized by Chem-Master pursuant to the Company's request, which have potential use in treating a disease, including, without limitation, cancers such as glioblastomas. Pursuant to the Agreement, we agreed to reimburse Chem-Master for the cost of materials, labor and expenses for other items used in synthesis process, and to grant to Chem-Master a five-year option to purchase 100,000 shares of our common stock with an exercise price of \$0.333 per share. Additionally, provided that the Agreement is not terminated by us without cause or by any party for cause prior to the second anniversary of the Agreement, we agreed to grant to Chem-Master a five-year option to purchase an additional 100,000 shares of the Company's common stock at \$0.333 per share.

#### **Off-Balance Sheet Arrangements**

At December 31, 2006, the Company did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

#### **Recent Accounting Pronouncements**

In September 2006, the Financial Accounting Standards Board ("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. 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 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 consolidated 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 that can create artificial volatility in earnings. SFAS No. 159 helps to mitigate this type of accounting-induced volatility by enabling companies to report related assets and liabilities at fair value, which would likely reduce the need for companies to comply with detailed rules for hedge accounting. SFAS No. 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS No. 159 requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of the company's choice to use fair value on its earnings. SFAS No. 159 also requires companies to display the fair value of those assets and liabilities for which the company has chosen to use fair value on the face of the balance sheet. SFAS No. 159 does not eliminate disclosure requirements included in other accounting standards, including requirements for disclosures about fair value measurements included in SFAS No. 157 and SFAS No. 159 and SFAS No. 159 and SFAS No. 159 and SFAS No. 157 and SFAS No. 159 and SFAS No. 159 assets and liabilities 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 that the company makes that choice in t

Management does not believe that any other recently issued, but not yet effective, accounting standards, if currently adopted, would have a material effect on the Company's financial statements.

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

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

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

Not Applicable.

#### **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.

### **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, 2006. The Board of Directors is comprised of only one class. All of the directors will serve until the next annual meeting of stockholders and until their successors are elected and qualified, or until their earlier death, retirement, resignation or removal. There are no family relationships between or among the directors, executive officers or persons nominated or charged by our Company to become directors or executive officers. The executive officer serves at the discretion of the Board of Directors, and is appointed to serve until the first Board of Directors meeting following the annual meeting of stockholders. The brief descriptions of the business experience of each director and executive officer and an indication of directorships held by each director in other companies subject to the reporting requirements under the Federal securities laws are provided herein below. Also provided are the biographies of the members of the Scientific Advisory Committee.

Our directors and executive officer are as follows:

Name	Age	Position Held with the Registrant
Dr. John S. Kovach	70	Chief Executive Officer, Director
Dr. Philip F. Palmedo	72	Director

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

#### Dr. John S. Kovach

Dr. John S. Kovach, age 70, founded Lixte in August 2005 and was its President and a member of the Board of Directors. He received a BA (cum laude) from Princeton University and an MD (AOA) from the College of Physicians & Surgeons, Columbia University. Dr. Kovach trained in Internal Medicine and Hematology at Presbyterian Hospital, Columbia University and spent six years in the laboratory of Chemical Biology, National Institute of Arthritis and Metabolic diseases studying control of gene expression in bacterial systems.

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

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

#### Chief Executive Officer

Initially, leadership and management of our company will be provided by Dr. Kovach with the advice of the board of Directors and the Scientific Advisory Committee. The activities for the first year at least will be 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, will pursue development of lead compounds for the treatment of malignant brain tumors. During the initial year, Dr. Kovach will also oversee the collection of the clinical samples needed to validate the biomarker observations regarding GBMs and to be in a position to extend the discovery process to ovarian and stomach cancers. At this point, we will consider seeking another CRADA to extend the scope of our research or establishing an independent laboratory. The timing of this expansion will depend on raising additional capital of approximately \$2.3 million by sale of additional shares of stock. A chief executive officer would then be recruited to manage our business affairs. It is anticipated that this may require less than full time effort for the second year with a need developing for a full time CEO and at least a part time financial officer in the third year of operation.

#### 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 remains as Chairman of the company. In 1985 the company was recognized by Inc. Magazine as one of the 500 fastest growing private companies in the U.S.

In 1988, Dr. Palmedo joined in the formation of Kepler Financial Management, Ltd., a quantitative financial research and trading company. Dr. Palmedo held the position of President and Managing Director until the end of 1991 when Renaissance Technologies Corporation acquired the company. In 2005 he started a new hedge fund, Kepler Asset Management, and is a Managing Director of the firm.

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

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

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

### SCIENTIFIC ADVISORY COMMITTEE

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

#### Arndt Hartmann, MD

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

#### Ferdinand Hofstadter, MD

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

#### 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 anticancer agents and enzyme inhibitors, development of efficient synthetic methods for organic synthesis by means of organometallic reagents, homogeneous catalysis and organometallic chemistry, peptide and peptide mimetics, beta-lactam chemistry, and organoflourine chemistry at the biomedical interface.

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

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

#### Audit Committee

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

### **Code of Ethics**

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

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

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

To the Company's knowledge based solely on its review of the copies of the Section 16(a) reports furnished to the Company and written representations to the Company that no other reports were required, the Company believes that all individual filing requirements applicable to the Company's directors and executive officers were complied with under Section 16(a) during 2006.

### **ITEM 10. EXECUTIVE COMPENSATION**

For the fiscal years ended December 31, 2006 and 2005, no individual, including Richard Rappaport, who served as our President in 2005 through the date of the reverse merger, and Dr. John Kovach, our current Chief Executive Officer, received any compensation. Dr. Kovach will be reimbursed for any out-of-pocket expenses. Any future compensation arrangements will be subject to the approval of the board of directors.

#### Option Grants in 2005 and 2006

None.

#### Aggregated Option Exercises in 2005 and 2006 Option Values at December 31, 2005 and at 2006

None.

### **Employment Agreements; Compensation**

We have not entered into any employment agreements. As of December 31, 2006, 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. Dr. Phillip Palmedo, our sole outside director, has received options to purchase 200,000 shares of common stock at the initial private placement price of \$0.333 per share with one third of the options (66,666 shares) vesting immediately upon joining the board and one third vesting annually for two years on the anniversary of that date. Dr. Palmedo has also received options to purchase 190,000 shares of common stock at \$0.333 per share for services rendered in developing the business plan for Lixte.

### **Director Compensation**

### Members of the Board of Directors

On June 30, 2006, Dr. Palmedo was granted options to purchase 200,000 shares of common stock at the initial private placement price of \$0.333 per share with one third of the options (66,666 shares) vesting on such date and one third vesting annually for two years on the anniversary of that date. Any additional outside member of the Board will 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. On June 30, 2006, Dr. Palmedo also was granted options to purchase 190,000 shares of common stock exercisable for a period of five years at \$0.333 per share for services rendered in developing our business plan, all of which were fully vested upon issuance.



### DIRECTOR COMPENSATION TABLE

						Non-Equity			
						Incentive	Non-Qualified		
				Stock	Option	Plan	Deferred	All Other	
		Salary	Bonus	Awards	Awards	Compensation	Compensation	Compensation	Total
Name and Principal Position	Year	(\$)	(\$)	(\$)	(\$)	(\$)	Earnings (\$)	(\$)(1)	(\$)
Philip F. Palmedo Director	2006	0	0	0	120,900	0	0		120,900

#### Members of the Scientific Advisory Committee

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

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

#### AND MANAGEMENT

The following table sets forth, as of January 15, 2007, 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 January 15, 2007, there were 26,582,183 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 January 15, 2007, 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 SRKP 7, 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.

	Amount and	
	Nature of	
	Beneficial	
Name and Address of Beneficial Owner	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	64.03%
Dr. Philip F. Palmedo 248 Route 25A, No. 2		
East Setauket, New York 11733	256,666 <sup>(1)</sup>	0.96%
Richard Rappaport <sup>(2)</sup> 1900 Avenue of the Stars	1 591 471	5 950/
Los Angeles, California 90067	1,581,471	5.85%
All Officers and directors as a group (two persons)	17,278,452 <sup>(1)</sup>	64.37%

(1) Includes options to purchase an aggregate of 256,666 shares of common stock, which are immediately exercisable.

(2) Mr. Rappaport served as the Company's President from May 2005 until June 30, 2006. Mr. Rappaport is the Chief Executive Officer of WestPark Capital Inc. The number in the table includes 426,626 shares of our common stock issuable upon the exercise of warrants issued to WestPark Capital, Inc. with respect to which Mr. Rappaport disclaims beneficial ownership.

### 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, 2006.

On May 26, 2005, we sold 1,155,000 shares and 270,000 shares of our common stock to Richard Rappaport and Anthony Pintsopoulos at a per share price of \$0.009. Messrs Rappaport and Pintsopoulos were our officers and directors prior to the Reverse Merger.

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

In connection with the private placement of our securities in June and July 2006, we paid WestPark Capital, Inc. fees of \$165,744 representing a commission of 10% and a nonaccountable expense fee of 4% on the gross proceeds. We also issued five year warrants to purchase an aggregate of 426,626 shares of common stock equal to 12% of the number of shares sold in the private placement at an exercise price of \$0.333 per share. We also paid WestPark Capital, Inc. a \$50,000 fee in connection with the Reverse Merger. Richard Rappaport, the Chief Executive Officer of WestPark Capital, Inc., was our President from our formation through the date of the Reverse Merger.

Also, Dr. Kovach, our President, has advanced to us an aggregate of \$92,717 through December 31, 2006 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, 2007.6
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
<sup>1</sup> Filed as an Exhibit t	
<sup>2</sup> Filed as an Exhibit t	o 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.

<sup>3</sup> 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.

<sup>4</sup> 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.

<sup>5</sup> 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.

### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND EXPENSES

The Company has appointed AJ. Robbins, P.C. as our independent registered public accounting firm for the fiscal year ended December 31, 2006. The following table shows the fees that were billed by us for audit and other services provided by AJ. Robbins, P.C. for the 2005 and 2006 fiscal years.

	 2006	 2005
Audit Fees (1)	\$ 40,000	\$ 4,750
Audit-Related Fees (2)	-	-
Tax Fees (3)	5,000	1,000
All Other Fees	-	-
Total	\$ 45,000	\$ 5,750

(1) Audit fees represent fees for professional services provided in connection with the audit of our annual financial statements and the review of our financial statements included in our Form 10-QSB quarterly reports and services that are normally provided in connection with statutory or regulatory filings for the 2005 and 2006 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 Committee has adopted a pre-approval policy that provides for the pre-approval of all services performed for us by AJ. Robbins, 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.

Date: March 28, 2007

# LIXTE BIOTECHNOLOGY HOLDINGS, INC.

By: /s/ John S. Kovach

Name: John S. Kovach Title: Chief Executive Officer

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

Signature	Title	Date
/s/ John S. Kovach John S. Kovach	Chief Executive Officer, Principal Financial Officer, Principal Accounting Officer and Director	March 28, 2007
/s/ Philip F. Palmedo Philip F. Palmedo	Director	March 28, 2007

### LIXTE BIOTECHNOLOGY HOLDINGS, INC. (FORMERLY SRKP 7, INC.) AND SUBSIDIARY (a development stage company)

# CONSOLIDATED FINANCIAL STATEMENTS

# December 31, 2006

Report of Independent Registered Public Accounting Firm	F-2
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### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheet of Lixte Biotechnology Holdings, Inc. (formerly SRKP 7, Inc.) and subsidiary (a development stage company) as of December 31, 2006, and the related consolidated statements of operations, changes in stockholders' equity (deficiency) and cash flows for the year then ended and for the periods from August 9, 2005 (inception) to December 31, 2006 and 2005, respectively. 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. An audit includes examining on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Lixte Biotechnology Holdings, Inc. and subsidiary as of December 31, 2006, and the results of their operations and their cash flows for the year then ended and for the periods from August 9, 2005 (inception) to December 31, 2006 and 2005, respectively, 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 2 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, locate and complete a merger with another company 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 February 5, 2007

(a development stage company)

# CONSOLIDATED BALANCE SHEET December 31, 2006

ASSETS	
Current assets:	
Cash and cash equivalents	\$ 679,640
Advances on research and development contract services	50,000
Prepaid insurance	20,365
Total current assets	750,005
Office equipment, net of accumulated depreciation of \$575	1,062
Total assets	\$ 751,067
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current liabilities:	
Accounts payable and accrued expenses	\$ 31,786
Due to stockholder	92,717
Total current liabilities	 124,503
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 - 26,582,183 shares	2,658
Additional paid-in capital	1,128,114
Deficit accumulated during the development stage	(504,208)
Total stockholders' equity	626,564
Total liabilities and stockholders' equity	\$ 751,067
See accompanying notes to consolidated financial statements	

(a development stage company)

# CONSOLIDATED STATEMENTS OF OPERATIONS

	1	Period from August 9, Year 2005 Ended (Inception) to December 31, December 31, 2006 2005		August 9, 2005 (Inception) to December 31,		Period from August 9, 2005 (Inception) to December 31, 2006 (Cumulative)
Revenues	\$	_	\$	_	\$	
Costs and expenses: General and administrative, including \$97,400 of stock-based compensation to director during the year ended December 31, 2006 and the period from August 9, 2005 inception)		200.400				
to December 31, 2006 (cumulative) Depreciation		299,420 462		16,011		315,431 575
Research and development costs Reverse merger costs		150,100 50,000				150,100 50,000
Total costs and expenses		499,982 (499,982)		16,124 (16,124)		516,106
Interest income		11,898		_		11,898
Net loss	\$	(488,084)	\$	(16,124)	\$	(504,208)
Net loss per common share - basic and diluted	\$	(0.02)	\$	(0.00)		
Weighted average number of common shares outstanding - basic and diluted		22,750,033		19,021,786		

See accompanying notes to consolidated financial statements

(a development stage company)

# CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)

	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	_	—	—	(488,084)	(488,084)
Balance, December 31, 2006	26,582,183	\$ 2,658	\$ 1,128,114	\$ (504,208)	\$ 626,564

See accompanying notes to consolidated financial statements  $$\rm F{\text -}5$$ 

(a development stage company)

# CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2006	Period from August 9, 2005 (Inception) to December 31, 2005	Period from August 9, 2005 (Inception) to December 31, 2006 (Cumulative)
Cash flows from operating activities			
Net loss	\$ (488,084)	\$ (16,124)	\$ (504,208)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	462	113	575
Stock-based compensation	97,400	_	97,400
Changes in operating assets and liabilities:			
Decrease in -			
Advances on research and development contract services	(50,000)	—	(50,000)
Prepaid insurance	(20,365)	_	(20,365)
Increase (decrease) in -			
Accounts payable and accrued expenses	17,136	14,650	31,786
Net cash used in operating activities	(443,451)	(1,361)	(444,812)
Cash flows from investing activities			
Purchase of office equipment	(498)	(1,139)	(1,637)
Net cash used in investing activities	(498)	(1,139)	(1,637)
Cash flows from financing activities			
Proceeds from sale of common stock to founder	_	1,500	1,500
Cash acquired in reverse merger transaction	62,500	_	62,500
Gross proceeds from sale of common stock	1,183,889		1,183,889
Payment of private placement offering costs	(214,517)	_	(214,517)
Advances from stockholder	86,771	5,946	92,717
Net cash provided by financing activities	1,118,643	7,446	1,126,089
Net increase in cash	674,694	4,946	679,640
Cash at beginning of period	4,946	_	_
Cash at end of period	\$ 679,640	\$ 4,946	\$ 679,640

(continued)

See accompanying notes to consolidated financial statements

(a development stage company)

# CONSOLIDATED STATEMENTS OF CASH FLOWS (continued)

	En Decen	Year Ended December 31, 2006			Period from August 9, 2005 (Inception) to December 31, 2006 (Cumulative)	
Supplemental disclosures of cash flow information:						
Cash paid for -						
Interest	\$		\$		\$	_
Income taxes	\$		\$	_	\$	

See accompanying notes to consolidated financial statements

(a development stage company)

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### December 31, 2006

#### 1. Organization and Basis of Presentation

On June 30, 2006, Lixte Biotechnology, Inc., a privately-held Delaware corporation ("Lixte"), completed a reverse merger transaction with SRKP 7, Inc. ("SRKP"), a 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. Comparative financial statements for the period ended December 31, 2005 reflect the results of operations of Lixte for the period August 9, 2005 (inception) to December 31, 2005 as Lixte, the accounting acquirer in the reverse merger transaction, was not formed until August 9, 2005. As such, the operations of the Company during this period, was nominal. 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").

#### 2. Business Operations and Summary of Significant Accounting Policies

#### Nature of Operations

Lixte was incorporated in Delaware on August 9, 2005 to capitalize on opportunities to develop low cost, specific and sensitive tests for the early detection of cancers to better estimate prognosis, to monitor treatment response, and to reveal targets for development of more effective treatments.

The Company's initial focus is on developing new treatments for the most common and most aggressive type of primary brain cancer, glioblastoma multiforme ("GBM"). Lixte entered into a Cooperative Research and Development Agreement ("CRADA") with the National Institute of Neurological Diseases and Stroke ("NINDS") of the National Institutes of Health ("NIH") to identify and evaluate drugs that target a specific biochemical pathway for GBM cell differentiation. The CRADA also covers research to determine whether expression of a component of this pathway correlates with prognosis in glioma patients.

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 potential drugs and potential therapeutic agents for the treatment of specific cancers.

At December 31, 2006, the Company was considered a "development stage company" as defined in Statement of Financial Accounting Standards No. 7, "Accounting and Reporting by Development Stage Enterprises", as it had not yet commenced any revenue-generating operations, did not have any cash flows from operations, and was dependent on debt and equity funding to finance its operations. The Company has selected December 31 as its fiscal year-end.

#### Going Concern and Plan of Operations

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 earned any revenues from operations to date, which raises substantial doubt about its ability to continue as a going concern.

The Company's ability to continue as a going concern is dependent upon its ability to develop additional sources of capital, and 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, 2006, the Company had not yet commenced any revenue-generating operations. All activity through December 31, 2006 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 its 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 \$522,939. On July 27, 2006, the Company completed a second closing of its 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.

Because the Company is 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, 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.

Based on the proceeds received from the private placement (see Note 3), the Company may not have sufficient resources to completely fund its 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. In the short-term, in addition to the net proceeds from the private placement, the Company estimates that it will require additional funding of approximately \$2,300,000. Additionally, the amount and timing of future cash requirements will depend on market acceptance of the Company's products, if any, and the resources that the Company devotes to developing and supporting its products. The Company will need to fund these cash requirements from either one or a combination of additional financings, mergers or acquisitions, or via the sale or license of certain of its assets.

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 and the Company may have to reduce the scope of its planned operations. If cash and cash equivalents are insufficient to satisfy the Company's liquidity requirements, the Company would be required to scale back or discontinue its product development program, or obtain funds if available through strategic alliances that may require the Company to relinquish rights to certain of its technologies or discontinue its operations.

#### 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.

### Income Taxes

The Company accounts for income taxes under Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes", which requires the recognition of 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

In December 2004, the Financial Accounting Standards Board ("FASB") issued 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 superseded APB No. 25. Effective January 1, 2006, 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 adopted SFAS No. 123R effective January 1, 2006, and is using the modified prospective method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS No. 123R for all share-based payments granted after the effective date and (b) based on the requirements of SFAS No. 123R for all awards granted to employees prior to the effective date of SFAS No. 123R that remain unvested on the effective date.

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 during the year ended December 31, 2006.

In addition, commencing January 1, 2006, the Company is 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.

Pro forma information regarding net income (loss) per share is required by SFAS No. 123 as if the Company had accounted for its employee stock options and warrants under the fair value method of such statement. However, during the period from August 9, 2005 (Inception) to December 31, 2005, Lixte had no stock options or warrants outstanding. Accordingly, no pro forma financial disclosure has been presented for the period from August 9, 2005 (Inception) to December 31, 2005.

Information with respect to stock options and warrants issued during 2006 is presented at Note 3. A summary of stock option and warrant activity for the year ended December 31, 2006 is shown below.

	Number of Shares	Weighted Average Exercise Price		Weighted Average Remaining Contractual Life (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	
Options and warrants exercisable at December 31, 2006	683,292	\$	0.333	4.52	

#### **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. 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 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 consolidated 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 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 and 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 that the company makes that choice in the first 120 days of that fiscal year and also elects to apply the provisions of SFAS No. 157. The Company is currently assessing the potential effect of SFAS No. 159 on its consolidated financial statements.

Management does not believe that any other recently issued, but not yet effective, accounting standards, if currently adopted, would have a material effect on the Company's financial statements.

#### Loss per Common Share

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.

#### **Research and Development**

Research and development costs are expensed as incurred. 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 funds paid to The U.S. Department of Health and Human Services (as represented by the National Institute of Neurological Disorders and Stroke, or the "ICD"), pursuant to the CRADA effective March 22, 2006, represent an advance on research and development costs and therefore have future economic benefit. As such, the costs should be 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 will be 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 payments under the CRADA during May, June and July 2006 aggregating \$200,000 are intended to fund ongoing research and development activities through March 2007.

### 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.

#### 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.

### 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. a 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 26 accredited investors in an initial closing of its 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 31 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.

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%.

### Stock Options

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

will be charged to operations ratably from July 1, 2006 through June 30, 2008. During the year ended December 31, 2006, the Company recorded a charge to operations of \$31,000 with respect to these options.

On June 30, 2006, effective with the closing of the Exchange, the Company also granted to Dr. Palmedo additional stock options to purchase 190,000 shares of common stock exercisable for a period of five years at \$0.333 per share for services rendered in developing the business plan for Lixte, all of which were fully vested upon issuance. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$58,900 (\$0.31 per share), and was charged to operations at June 30, 2006.

On June 30, 2006, effective with the closing of the Exchange, the Company granted to certain members of its Scientific Advisory Committee stock options to purchase an aggregate of 100,000 shares of common stock exercisable for a period of five years at \$0.333 per share, with one-half of the options vesting annually on each of June 30, 2007 and June 30, 2008. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be \$31,000 (\$0.31 per share). The fair value of such options will be charged to operations ratably from July 1, 2006 through June 30, 2008. In accordance with EITF 96-18, options granted to committee members are valued each reporting period to determine the amount to be recorded as an expense in the respective period. On December 31, 2006, the fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$30,000 (\$0.30 per share) which resulted in a charge to operations of \$7,500 during the year ended December 31, 2006. As the options vest, they will be valued one final time on each vesting date and an adjustment will be recorded for the difference between the value already recorded and the then current value on the date of vesting.

On June 30, 2006, the fair value of the aforementioned stock options was initially calculated 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%. 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.

### 4. Related Party Transactions

Since inception, Dr. John Kovach, Lixte's founding stockholder, 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, 2006 stockholder advances totaled \$92,717.

Through December 31, 2006, the Company's office facilities have been provided without charge by the Company's founding stockholder and President. Such costs were not material to the financial statements and accordingly, have not been reflected therein.

Through December 31, 2006, Dr. John Kovach, the Company's President, did not receive any compensation from the Company in view of the Company's early stage status and limited activities. Any future compensation arrangements will be subject to the approval of the Board of Directors.

Dr. John Kovach, the Company's President, is involved in other business activities and may, in the future, become involved in other business opportunities that become available. Accordingly, the President 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. 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, 2006 are as follows:

Start-up and organization costs	\$ 129,000
Net operating loss carryforwards	58,000
Total deferred tax assets	187,000
Valuation allowance	(187,000)
Net deferred tax assets	\$ _

No federal tax provision has been provided for the periods ended December 31, 2006 and 2005 due to the losses incurred to date.

The reconciliation between the income tax rate computed by applying the U.S. federal statutory rate and the effective rate for the periods ended December 31, 2006 and 2005 is as follows:

		Periods Ended December 31,			
	2006	2005			
U. S. federal statutory tax rate	(34.0%)	(34.0%)			
Pre-merger loss of accounting acquiree	(4.3%)	(69.3%)			
State income taxes	(6.2%)	(22.8%)			
Non-deductible merger costs	3.5%				
Non-deductible stock-based compensation	6.8%				
Change in valuation allowance	34.2%	126.1%			
Effective tax rate	0.0%	0.0%			

At December 31, 2006, the Company has available net operating loss carryforwards for federal income tax purposes of approximately \$139,000 which, if not utilized earlier, expire in 2025.

#### 7. Commitments and Contingencies

Effective March 22, 2006, Lixte entered into a Cooperative Research and Development Agreement (the "CRADA") with the U.S. Department of Health and Human Services, as represented by National Institute of Neurological Disorders and Stroke ("NINDS") of the National Institutes of Health. The CRADA is for a term of two years from the effective date and may be unilaterally terminated by either party by providing written notice within sixty days. Pursuant to the CRADA, Lixte agreed to provide total payments of \$400,000 over the term of the CRADA. 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 is due within thirty days of the first anniversary of the effective 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 will also provide certain information relating to such patients. Lixte will pay the University 72,000 Euros (approximately \$99,700) in two installments of 36,000 Euros

(approximately \$49,850), the first installment to be paid within sixty days of January 5, 2007 and the second installment to be paid within sixty days of the earlier of (i) January 5, 2008 or (ii) the University's fulfillment of certain obligations relating to the delivery of materials.

On February 5, 2007, the Company entered into an agreement (the "Agreement") with Chem-Master International, Inc. ("Chem-Master") pursuant to which the Company engaged Chem-Master to synthesize a compound designated as "LB-1", and any other compound synthesized by Chem-Master pursuant to the Company's request, which have potential use in treating a disease, including, without limitation, cancers such as glioblastomas. Pursuant to the Agreement, the Company agreed to reimburse Chem-Master for the cost of materials, labor and expenses for other items used in synthesis process, and to grant to Chem-Master a five-year option to purchase 100,000 shares of the Company's common stock with an exercise price of \$0.333 per share. Additionally, provided that the Agreement is not terminated by the Company without cause or by any party for cause prior to the second anniversary of the Agreement, the Company agreed to grant to Chem-Master a five-year option to purchase an additional 100,000 shares of the Company's common stock at \$0.333 per share.

### 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 28, 2007

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, 2006 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: March 28, 2007

By: /s/ John S. Kovach

John S. Kovach Chief Executive Officer and Chief Financial Officer

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.