UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2018

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: 000-51476

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

Indicate by check mark if the registrant is a well-known seasoned issuer as defined in Rule 405 of the Securities Act. Yes [ ] No [X]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes [ ] No [X]

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No [ ]

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	[ ]	Accelerated filer	[ ]
Non-accelerated filer	[ ]	Smaller reporting company	[X]
(Do not check if a smaller reporting company)		Emerging growth company	[X]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act):
Yes [ ] No [X]

The aggregate market value of the common stock held by non-affiliates of the registrant as of June 30, 2018 was approximately $3,376,000.

The Company had 67,045,814 shares of common stock, $0.0001 par value, issued and outstanding as of March 1, 2019.

Documents incorporated by reference: None.

TABLE OF CONTENTS

Introductory Comment

Throughout this Annual Report on Form 10-K, the terms "we," "us," "our," "our company," "Lixte," the "Company" and the "Registrant" refer to Lixte Biotechnology Holdings, Inc., a Delaware corporation, and Lixte Biotechnology, Inc., our wholly-owned subsidiary.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (the "Report") contains certain forward-looking statements. For example, statements regarding our financial position, business strategy and other plans and objectives for future operations, and assumptions and predictions about future product demand, supply, manufacturing, costs, marketing and pricing factors are all forward-looking statements. These statements are generally accompanied by words such as "intend," "anticipate," "believe," "estimate," "potential(ly)," "continue," "forecast," "predict," "plan," "may," "will," "could," "would," "should," "expect" or the negative of such terms or other comparable terminology. We believe that the assumptions and expectations reflected in such forward-looking statements are reasonable, based on information available to us on the date hereof, but we cannot assure you that these assumptions and expectations will prove to have been correct or that we will take any action that we may presently be planning. However, these forward-looking statements are inherently subject to known and unknown risks and uncertainties. Actual results or experience may differ materially from those expected or anticipated in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, regulatory policies, competition from other similar businesses, and market and general policies, competition from other similar businesses, and market and general economic factors. This discussion should be read in conjunction with the consolidated financial statements and notes thereto included in this Report.

If one or more of these or other risks or uncertainties materialize, or if our underlying assumptions prove to be incorrect, actual results may vary materially from what we project. Any forward-looking statement you read in this Report reflects our current views with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our operations, results of operations, growth strategy, and liquidity. All subsequent forward-looking statements attributable to us or individuals acting on our behalf are expressly qualified in their entirety by this paragraph. You should specifically consider the factors identified in this Report, which would cause actual results to differ before making an investment decision. We are under no duty to update any of these forward-looking statements after the date of this Report or to conform these statements to actual results.

PART I

ITEM 1. BUSINESS

Company Overview

Lixte Biotechnology Holdings, Inc., a Delaware corporation, including its wholly-owned Delaware subsidiary, Lixte Biotechnology, Inc. (collectively, the "Company"), is a drug discovery company that uses biomarker technology to identify enzyme targets associated with serious common diseases and then designs novel compounds to attack those targets. The Company's product pipeline encompasses two major categories of compounds at various stages of pre-clinical and clinical development that the Company believes have broad therapeutic potential not only for cancer but also for other debilitating and life-threatening diseases.

The Company's activities are subject to significant risks and uncertainties, including the need for additional capital, as described below. The Company has not yet commenced any revenue-generating operations, does not have positive cash flows from operations, and is dependent on periodic infusions of equity capital to fund its operating requirements.

Description of Business

The Company's primary focus is developing new treatments for human cancers for which better therapies are urgently needed. The scope of potential applications of the Company's products has expanded to other common non-malignant diseases, including vascular diseases (heart attacks and stroke, diabetes, genetic diseases, such as Gaucher's disease), and recently to depression and potentially post-traumatic stress syndrome. This has occurred because the targets selected by the Company have multiple functions in the cell, which, when altered, result in different disorders that may benefit by treatment from the Company's products.

The Company's drug discovery process is based on discerning clues to potential new targets for disease treatments reported in the increasingly large body of literature identifying the molecular variants which characterize human cancers and other non-cancer disorders. The Company designs drugs for which there are existing data suggesting that they may affect the altered pathways of the cancer cell and may be given safely to humans. The Company seeks to rapidly arrive at patentable structures through analysis of the literature rather than screening of thousands of structures for activity against a particular biochemical pathway.

This approach has led to the development of two classes of drugs for the treatment of cancer, consisting of protein phosphatase inhibitors (PTase-i), designated by the Company as the LB-100 series of compounds, and histone deacetylase inhibitors (HDACi), designated by the Company as the LB-200 series of compounds.

The LB-100 series consists of novel structures which have the potential to be first in their class and may be useful in the treatment of not only several types of cancer but also vascular and metabolic diseases. The LB-200 series contains compounds which have the potential to be the most effective in its class and may be useful for the treatment of chronic hereditary diseases, such as Gaucher's disease, in addition to cancer and neurodegenerative diseases.

The Company has demonstrated that lead compounds of both the LB-100 series and the LB-200 are active against a broad spectrum of human cancers in cell culture and against several types of human cancers in animal models. The research on these compounds was initiated in 2006 under a Cooperative Research and Development Agreement ("CRADA") with the National Institute of Neurologic Disorders and Stroke ("NINDS") of the National Institutes of Health ("NIH") dated March 22, 2006 that was subsequently extended through a series of amendments until it terminated on April 1, 2013.

Effective treatment of brain tumors depends upon the ability of compounds to penetrate a physiological barrier known as the "blood-brain barrier" which protects the brain from exposure to potentially toxic substances in the blood. Because there is no certainty that the Company's compounds will be active against tumors confined to the brain, the LB-100 compounds have been studied against a variety of common and rare cancer types and have been shown to potentiate the activity of standard anti-cancer drugs in animal models of breast and pancreatic cancer, melanoma, pheochromcytomas and sarcomas. Because the LB-100 compounds appear to exert their ability to improve the effectiveness of different forms of chemotherapy and radiation therapy by inhibiting a process upon which most, if not all, cancer cell types depend on to survive treatment, the Company believes the LB-100 series of compounds may be useful against most, if not all, cancer types.

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

The Company's primary objective has been to bring one lead compound of the LB-100 series to clinical trial. In 2012, the Company completed the pre-clinical studies needed to prepare an Investigation New Drug ("IND") application to the United States Food and Drug Administration ("FDA") to conduct a Phase 1 clinical trial of LB-100, and engaged Theradex Systems, Inc. ("Theradex"), an international contract research organization ("CRO") that provides professional services for the clinical research and development of pharmaceutical compounds, to be responsible for the clinical development of the Company's lead compound LB-100 and to prepare an IND application for filing with the FDA.

The Company filed an IND application with the FDA on April 30, 2012, and on July 24, 2012, the FDA notified the Company that it would allow initiation of a Phase 1 clinical trial of LB-100. The purpose of this clinical trial was to demonstrate that LB-100 can be administered safely to human beings at a dose and at a frequency that achieves the desired pharmacologic effect; in this case, inhibition of a specific enzyme, without being associated with toxicities considered unacceptable.

The Phase 1 clinical trial of LB-100 began in April 2013 with the entry of patients into the clinical trial initiated at the City of Hope National Medical Center in Duarte, California, and was extended in December 2013 to include the Mayo Clinic in Rochester, Minnesota, both of which are Comprehensive Cancer Centers designated by the National Cancer Institute. As the accrual of patients was slower than anticipated, in October 2014, the Company entered into a Clinical Research Agreement ("CRA") with US Oncology Research, LLC, a large community-based research network based in Texas, to increase the rate of entry of patients into the clinical trial by adding four more active clinical oncologic research sites.

Patient entry into the Phase 1 clinical trial was completed in May 2016. The cost of the clinical trial was higher than originally estimated, in part because patients were able to tolerate higher doses of LB-100 than originally expected, thus requiring more dose escalation steps to determine the maximum tolerable dose ("MTD") of LB-100 given alone. In addition, patients achieved stabilization without any dose-limiting toxicity ("DLT"), remaining on treatment with LB-100 for longer periods of time than is usual in a Phase 1 clinical trial of a new drug in patients failing all previous treatments. The Company's interpretation of the clinical trial results to date is that LB-100 as a single agent has activity against several types of cancer, as evidenced by stabilization of progressive disease in the absence of DLT.

The costs of the Phase 1 clinical trial of LB-100 were paid to or through Theradex, the CRO responsible for the clinical development of LB-100. Total costs charged to operations from 2013 through December 31, 2017 for services paid to or through Theradex pursuant to this arrangement aggregated $2,233,248, of which $105,698 was incurred during the year ended December 31, 2017, or approximately 24% of research and development costs for the year ended December 31, 2017.

In early November 2018, the Company received approval from the FDA for its Investigational New Drug (IND) Application to conduct a Phase 1b/2 clinical trial to evaluate the safety and therapeutic benefit of the Company's lead clinical compound LB-100 in patients with low and intermediate-1 risk myelodysplastic syndrome (MDS) who have failed or are intolerant of standard treatment.

The clinical trial will be managed and conducted at Moffitt Cancer Center in Tampa, Florida. This clinical trial is currently expected to begin during the quarter ending June 30, 2019, to complete patient accrual over a period of two years, and to take approximately three years to complete.

Presented below are proposed clinical trials that the Company would like to conduct over the next few years. The Company expects that these potential clinical trials, and the details thereof, will change over time as the Company obtains more clinical information on LB-100. The Company's ability to conduct these clinical trials is subject to the availability of sufficient financial resources.

(1) A Phase 1b/2 randomized clinical trial in previously untreated patients with small cell lung cancer (SCLC) comparing the standard regimen, carboplatin/etoposide, with and without LB-100. The malignant cells of this uniformly rapidly fatal lung cancer are genetically sensitive to PP2A inhibition (by a process termed synthetic lethality).

(2) A Phase 1b/2 randomized clinical trial in patients adding LB-100 to PD-1 inhibitors against one of several cancers in which PD-1 inhibitors alone have definite but modest activity.

The Phase 1b/2 clinical trials in SCLC and in LB-100 plus a PD-1 inhibitor in yet to be specified solid tumors will require additional financing in excess of that currently budgeted to fund a Phase 1b/2 clinical trial in myelodysplastic syndrome that is scheduled to begin during the quarter ending June 30, 2019 as described above, and/or partnering relationships with other pharmaceutical companies, in order for the Company to undertake and complete such clinical studies. The Company is in discussions with various parties with respect to the financing of these clinical studies, although there can be no assurances that the Company will be able to obtain such financing and/or partnering relationships on acceptable terms or at all. The Company's longer-term objective is to secure one or more strategic partnerships with pharmaceutical companies with major programs in cancer research and drug development.

As a compound moves through the FDA-approval process, it becomes an increasingly valuable property, but at a cost of additional investment at each stage. As the potential effectiveness of LB-100 has been documented at the clinical trial level, the Company has allocated resources to expand the breadth and depth of its patent portfolio. The Company's approach has been to operate with a minimum of overhead, moving compounds forward as efficiently and inexpensively as possible, and to raise funds to support each of these stages as certain milestones are reached.

Publications

The following publications have included articles discussing the Company's compounds:

An article in the December 12, 2011 edition of the Proceedings of the National Academy of Sciences in the United States reported that the Company's investigational drug, LB-205 was shown to have therapeutic potential in a laboratory model of the genetic illness Gaucher's disease.

On June 18, 2013, an article was published in Clinical Cancer Research showing that LB-100 is a radiotherapy sensitizing agent that increases the effectiveness of x-ray treatment against human pancreatic cancer cells in an animal model, as the Company has shown for two other types of human cancers. These results are in keeping with the ability of LB-100 to enhance the effectiveness of existing cytotoxic treatments, both chemotherapy and radiotherapy, against different types of cancers. Because LB-100 itself does not readily enter the brain in animal models, the Company has developed new related compounds which have been shown to penetrate the blood brain barrier (entering the brain after systemic injection) in mice and is evaluating the effectiveness of these compounds in the treatment of brain tumors in animal models.

The June 25, 2013 issue of the Proceedings of the National Academy of Sciences reported that scientists at the National Institutes of Health had determined that one of the Company's 200 series compounds significantly reduced the extent of structural damage in the brain and lessened neurological functional impairment in a rat model of traumatic brain injury (TBI). Given the need for methods to reduce injury to the brain after acute injuries caused by explosive devices, sports injuries and accidental falls, the Company is seeking partners in the private and governmental sectors to assist in developing these compounds for clinical evaluation.

In May 2014 an article was published in Molecular Cancer Therapeutics reporting that LB-100 enhanced the therapeutic effectiveness of chemotherapeutic drugs (doxorubicin and cisplatin) without significantly enhancing toxicity against HCC in animal models. HCC is the most common cancer in Asia and one of the leading causes of death from cancer worldwide.

In October 2014, investigators reported in Cancer Letters that LB-100 enhanced the therapeutic effectiveness of chemotherapy in animal models of pancreatic cancer can without significantly enhancing toxicity.

In November 2014, investigators from the National Institutes of Health reported in Molecular Cancer Therapeutics that LB-100 overcomes the resistance of cisplatin-resistant human ovarian cancer cells in the peritoneal cavity of animals. This finding is of particular interest as platinum-based chemotherapy drugs are the first-line treatment for women with unresectable ovarian cancer and patients so treated eventually relapse because of development of platinum-resistant disease.

In December 2014, scientists from the Terry Fox Cancer Center, Vancouver, British Columbia, reported at the Annual Society of Hematology Meeting that LB-100 is active alone and potentiates the activity of Imatinib (Gleevec) against human cell lines of chronic myelogenous leukemia (CML), both imatinib-naïve CML cells and Imatinib-resistant CML cells. Although virtually all patients with CML worldwide receive Imatinib as initial therapy and most patients have an excellent response, almost every patient relapses because of development of Imatinib–resistance.

On November 6, 2015, it was reported at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, Boston, Massachusetts, that in an ongoing Phase 1 clinical trial, LB-100 was associated with stabilization of a variety of advanced cancers that had been progressing despite extensive prior treatment without dose-limiting toxicity. The authors reporting this development were Vincent Chung, City of Hope, Duarte, California; Donald Richard, Texas Oncology, Tyler, Texas; Fadi Braiteh, Comprehensive Cancer Centers of Nevada, Las Vegas, Nevada; John S. Kovach, Lixte Biotechnology Holdings, Inc. East Setauket, New York; and Aaron Scott Mansfield, May Clinic, Rochester, Minnesota

On January 25, 2016, in the journal Nature Medicine, neuroscientists at the French Institute of Health and Medical Research (Inserm) using a mouse model of depression identified protein phosphatase 2A (PP2A) as a potential pharmacological target for therapy. Administration of LB-100, the Company's proprietary inhibitor of PP2A, rapidly reduced depressive-like symptoms in these conditioned animals.

On January 4, 2017, the Company issued a news release to announce the publication online of Phase 1 results of the Company's novel anti-cancer compound in Clinical Cancer Research, entitled "Safety, tolerability, and preliminary activity of LB-100, an inhibitor of protein phosphatase 2A, in patients with relapsed solid tumors". Ten (46.7%) of twenty-one patients receiving at least 2 cycles of LB-100, a small molecule inhibitor of protein phosphatase (PP2A), achieved stable disease without limiting toxicity for up to 15 cycles of therapy, including one patient with pancreatic cancer who had a partial regression. PP2A has long been recognized as a potentially important cancer treatment target, but its inhibition was thought to be too toxic for clinical use. This Phase 1 clinical trial demonstrated the safety and tolerability of PP2A inhibition in patients with refractory solid tumors. In numerous animal models of cancer, inhibition of PP2A by LB-100 enhanced the anti-tumor activity of standard chemotherapy drugs and radiation without significantly enhancing their toxicity by altering cell cycle regulation and the DNA-damage repair response pathways. The mechanism by which LB-100 used alone apparently inhibited the growth of a variety of cancers in patients in the recently completed Phase 1 clinical trial is not clear, but PP2A activity is reduced by mutation directly or indirectly in many cancer types, rendering them vulnerable to pharmacologic inhibition of PP2A. The Company believes that the results reported in Clinical Cancer Research support further development of LB-100 alone and in combination with standard cytotoxic regimens for a broad spectrum of tumors.

On April 17, 2017, the Company issued a news release to announce the presentation of a late-breaking abstract entitled "Protein phosphatase 2A inhibition with a novel small molecule inhibitor, LB-100, achieves durable immune-mediated antitumor activity when combined with PD-1 blockage in a preclinical model" as a poster (abstract number LB-193) at the American Association for Cancer Research (AACR) Annual Meeting 2017 in Washington, D.C. on April 4, 2017. This research was done in collaboration with scientists at the National Institute of Neurological Disorders and Stroke (NINDS) of the National Institutes of Health (NIH).The study showed that in an animal model, the Company lead clinical compound, LB-100, has a synergistic potential in conjunction with immune checkpoint blockade supporting investigation of its ability to enhance immunotherapy in the clinic. Based on a number of published pre-clinical studies, the Company had expected that LB-100 would be therapeutically useful primarily as a potentiator of cytotoxic anti-cancer drugs and x-ray. However, this study raises the possibility that LB-100 may also have a role in enhancing the efficacy of so-called 'immune checkpoint blockers' –agents that allow the patients' own immune system to attack their own cancers.

On February 9, 2018, the Company issued a news release to announce that investigators at the Terry Fox Laboratory, British Columbia Cancer Agency, Vancouver, British Columbia, Canada, reported on February 7,2018 (Lai et al., Sci. Transl. Med. 10, eaan8735 (2018)) that in animal models the Company's protein phosphatase 2A (PP2A) inhibitors overcome resistance of chronic myelogenous leukemia (CML) cells to standard treatment. The vast majority of CML cells are killed by drugs called tyrosine kinase inhibitors (TKI), the prototype of which is imatinib (Gleevec), considered the first truly targeted form of chemotherapy. Imatinib and subsequent variants were a great advance in turning CML from a fatal to a controllable illness. However, almost without exception, from the onset of the disease some CML cells are resistant to TKI treatment so that continuous therapy is required and in some patients the number of TKI resistant cells accelerates out of control. The persistence and progression of CML despite TKI treatment is believed to arise from a niche of intrinsically resistant leukemia stem cells. The Terry Fox Laboratory investigators found inhibition of PP2A with LB-100 or LB-102 preferentially sensitizes these resistant CML cells to killing by TKI compared to normal bone marrow stem cells. If these results can be replicated in the clinic, LB-100 and analogs may further improve the effectiveness of CML therapy.

On March 29, 2018, it was reported in Nature Communications that LB-100 enhances the antitumor activity of an immune checkpoint inhibitor (an anti-PD-1 drug) in two different mouse cancers. This discovery raises the possibility that LB-100 may be a means for improving the effectiveness of the rapidly expanding field of immune driven anti-cancer therapy. Thus, the Company is developing clinical protocols to test the hypothesis that the addition of LB-100 to an anti-PD-1 drug will improve the significant but low rates of objective remission to anti-PD-1 treatment alone.

Key pre-clinical studies supporting the hypothesis that LB-100 may be an effective addition to standard regimens including immunotherapy for the treatment of many human cancers was recently reviewed in the journal BBA-Molecular Cell Research (Mazhar et al 2019).

Intellectual Property

The Company's products will ultimately derive directly from its intellectual property and are expected to include the property covered by its patents. These patents now cover sole rights to the composition and synthesis of the LB-100 and LB-200 series of drugs. Joint patent applications with the NIH have been filed for the treatment of glioblastoma multiforme, medulloblastoma, and neuroblastoma. The Company has also filed claims for the use of certain homologs of both series of drugs for the potential treatment of neurodegenerative diseases such as Alzheimer's Disease and Parkinson's Disease, Amyotrophic Lateral Sclerosis (ALS, or Lou Gehrig's Disease), stroke, and traumatic brain injury, and of homologs of the LB-200 series for treatment of serious systemic fungal infections and for the treatment of common fungal infections of the skin and nails.

Patents for the LB-100 series (oxabicycloheptanes and heptenes) and the LB-200 series (histone deacetylase inhibitors; HDACi) have been filed in the United States and internationally under the Patent Cooperation Treaty. Patents for composition of matter and for several uses of both the LB-100 series and the LB-200 series have been issued in the United States, Mexico, Australia, Japan, China, Hong Kong, Canada, Germany, France, the United Kingdom, the European Patent Office and the Eurasian Patent Office.

The Company's portfolio of 42 domestic and international patents issued is summarized below, of which 14 patents were issued during the year ended December 31, 2018. The Company has additional domestic and international patents pending.

LB-100 Series of Compounds - Phosphatase Inhibitors – Composition and Use in Cancer Treatment
Oxabicycloheptanes and Oxabicycloheptenes, Their Preparation and Use

Patent	Priority Date or International Filing Date (non-U.S. applications)	Issue/Grant Date	Expiration Date
AM 023804	2/6/2008	7/29/2016	2/6/2028
AU 2008214299	2/6/2008	4/24/2014	2/6/2028
AZ 023804	2/6/2008	7/29/2016	2/6/2028
BY 023804	2/6/2008	7/29/2016	2/6/2028
CA 2,676,422	2/6/2008	10/16/2018	2/6/2028
CN 101662939	2/6/2008	11/25/2015	2/6/2028
CN 103788108	2/6/2008	4/12/2017	2/6/2028
EP 2124550	2/6/2008	4/19/2017	2/6/2028
EA 023804	2/6/2008	7/29/2016	2/6/2028
HK 1140375	2/6/2008	3/9/2018	2/6/2028
JP 5693850	2/6/2008	2/13/2015	2/6/2028
KG 023804	2/6/2008	7/29/2016	2/6/2028
KZ 023804	2/6/2008	7/29/2016	2/6/2028
MD 023804	2/6/2008	7/29/2016	2/6/2028
MX 309985	2/6/2008	5/28/2013	2/6/2028
RU 023804	2/6/2008	7/29/2016	2/6/2028
TJ 023804	2/6/2008	7/29/2016	2/6/2028
TM 023804	2/6/2008	7/29/2016	2/6/2028
US 7,998,957	2/6/2007	8/16/2011	2/20/2030
US 8,426,444	2/6/2007	4/23/2013	2/6/2028
US 8,227,473	8/1/2008	7/24/2012	3/11/2030
US 8,541,458	8/1/2008	9/24/2013	7/17/2029
US 8,822,461	2/6/2007	9/2/2014	6/30/2031
US 9,079,917	2/6/2007	7/14/2015	4/19/2033
US 10,023,587	2/6/2007	7/17/2018	9/26/2036

LB-100 Series of Compounds – LB-100 in Combination with Anti-Cancer Agents
Methods for Regulating Cell Mitosis by Inhibiting Serine/Threonine Phosphatase

Patent	Priority Date or International Filing Date (non-U.S. applications)	Issue/Grant Date	Expiration Date
US 9,526,915	8/1/2008	12/27/2016	3/31/2032

LB-100 and LB-200 Series of Compounds – Use in Treatment of Multiple CNS Diseases
Neuroprotective Agents for the Prevention and Treatment of Neurodegenerative Diseases

Patent	Priority Date or International Filing Date (non-U.S. applications)	Issue/Grant Date	Expiration Date
EP 2318005	7/29/2009	11/1/2017	7/29/2029
US 8,058,268	8/1/2008	11/15/2011	12/31/2029
US 8,329,719	8/1/2008	12/11/2012	7/29/2029

Oxabicycloheptanes and Oxabicycloheptenes for the Treatment of Reperfusion Injury

Patent	Priority Date or International Filing Date (non-U.S. applications)	Issue/Grant Date	Expiration Date
CN ZL 201380035527.1	6/28/2013	9/22/2017	6/28/2033
EP 2870161	6/28/2013	8/8/2018	6/28/2033
DE 2870161	6/28/2013	8/8/2018	6/28/2033
FR 2870161	6/28/2013	8/8/2018	6/28/2033
GB 2870161	6/28/2013	8/8/2018	6/28/2033

Oxabicycloheptanes and Oxabicycloheptenes for the Treatment of Depressive and Stress Disorders

Patent	Priority Date or International Filing Date (non-U.S. applications)	Issue/Grant Date	Expiration Date
US 9,833,450	2/19/2015	12/5/2017	2/19/2036

HDAC Inhibitors

Patent	Priority Date or International Filing Date (non-U.S. applications)	Issue/Grant Date	Expiration Date
HK 1145420	10/1/2008	1/26/2018	10/1/2028

Oxabicycloheptanes and Oxabicycloheptenes for the Treatment of Diabetes

Patent	Priority Date or International Filing Date (non-U.S. applications)	Issue/Grant Date	Expiration Date
US 10,149,847	12/16/2014	12/11/2018	12/7/2033

Formulations of Oxabicycloheptanes and Oxabicycloheptenes

Patent	Priority Date or International Filing Date (non-U.S. applications)	Issue/Grant Date	Expiration Date
CN ZL 201480027138.9	4/8/2014	10/26/2018	4/8/2034

Process of Synthesizing 3-(4-Methylpiperazine-1-Carbonyl)-7-Oxabicyclo[2.2.1]Heptane-2-Carboxylic Acid

Patent	Priority Date or International Filing Date (non-U.S. applications)	Issue/Grant Date	Expiration Date
US 9,994,584	10/15/2014	6/12/2018	10/14/2035

Protein Phosphatase 2A Inhibitors for Treating Myelodysplastic Syndromes

Patent	Priority Date or International Filing Date (non-U.S. applications)	Issue/Grant Date	Expiration Date
US 10,071,094	1/23/2017	9/11/2018	7/23/2035
JP 6453441	7/23/2015	12/21/2018	7/23/2035

Oxabicycloheptane Prodrugs

Patent	Priority Date or International Filing Date (non-U.S. applications)	Issue/Grant Date	Expiration Date
US 9,988,394	5/13/2016	6/5/2018	5/13/2036

The Market

Anti-Cancer Drugs

The Company has developed two series of pharmacologically active drugs, the LB-100 series and the LB-200 series. The Company believes that the mechanism by which compounds of the LB-100 series affect cancer cell growth is different from cancer agents currently approved for clinical use. Lead compounds from each series have activity against a broad spectrum of common and rarer human cancers in cell culture systems. In addition, compounds from both series have anti-cancer activity in animal models of glioblastoma multiforme, neuroblastoma, and medulloblastoma, all cancers of neural tissue. Lead compounds of the LB-100 series also have activity against melanoma, breast cancer and sarcoma in animal models and enhance the effectiveness of commonly used anti-cancer drugs in these model systems. The enhancement of anti-cancer activity of these anti-cancer drugs occurs at doses of LB-100 that do not significantly increase toxicity in animals. It is therefore hoped that when combined with standard anti-cancer regimens against many tumor types, the Company’s compounds will improve therapeutic benefit without enhancing toxicity in humans.

Marketing Plan

The primary goal of the Company to date has been to take LB-100 through Phase 1 clinical trials. Because of the novelty and spectrum of activity of LB-100, the Company believes it is reasonably likely it will find a partner in the pharmaceutical industry with interest in this compound at some stage of its clinical development. However, the Company would prefer to delay the partnering/licensing decision until the potential value of its products is augmented by demonstrating there is no impediment to clinical evaluation and a therapeutic dose level is determined in clinical trials. Demonstration of clinical usefulness would be expected to substantially increase the value of the Company's product.

Research and Development

Further development of lead compounds in addition to LB-100 will require pharmacokinetic/pharmacodynamic characterization (i.e., how long a drug persists in the blood and how long the drug is active at the intended target) and large animal toxicologic evaluation under conditions meeting FDA requirements. Most anti-cancer drugs fail in development because of unacceptable toxicity. However, by analogy with mechanistically related compounds, there is good reason to believe that lead compounds in addition to LB-100 will be able to be given to humans safely by routes and at doses resulting in concentration of drug producing anti-cancer activity in animal model systems.

One of the Company's most valuable resources is its scientific team, a coalition of various experts brought together through contracts and other collaborative arrangements. The team has expertise in cancer biology, proteomics (cancer biomarkers), medicinal and synthetic chemistry, pharmacology, clinical oncology and drug evaluation. In a relatively short period of time and at low cost, this group has developed lead compounds of two different classes of drugs that are positioned for development as new treatments for several types of cancer.

Product Development

The Company is subject to FDA regulations as it conducts clinical trials. Additionally, any product for which the Company obtains marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continual review and periodic inspections by the FDA and other regulatory bodies. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with the Company's products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturer or manufacturing processes, or failure to comply with regulatory requirements, may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recall, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

Competition

The life sciences industry is highly competitive and subject to rapid and profound technological change. The Company's present and potential competitors include major pharmaceutical companies, as well as specialized biotechnology and life sciences firms in the United States and in other countries. Most of these companies have considerably greater financial, technical and marketing resources than the Company does. Additionally, mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated in the Company's competitors. The Company's existing or prospective competitors may develop processes or products that are more effective than the Company's or be more effective at implementing their technologies to develop commercial products faster. The Company's competitors may succeed in obtaining patent protection and/or receiving regulatory approval for commercializing products before the Company does. Developments by the Company's competitors may render the Company's product candidates obsolete or non-competitive.

The Company also experiences competition from universities and other research institutions, and the Company is likely to compete with others in acquiring technology from those sources. There can be no assurance that other organizations will not develop technologies with significant advantages over those that the Company is seeking to develop. Any such development could harm the Company's business.

The Company competes with universities and other research institutions engaged in research in these areas. Many of the Company's competitors have greater technical and financial resources than the Company does.

The Company's ability to compete successfully is based on numerous factors, including:

- the cost-effectiveness of any product that the Company ultimately commercializes relative to competing products;
- the ease of use and ready availability of any product that the Company brings to market; and
- the relative speed with which the Company is able to bring any product resulting from its research to market in its target markets.

If the Company is unable to distinguish its products from competing products, or if competing products reach the market first, the Company may be unable to compete successfully with current or future competitors.

Employees

As of December 31, 2018, the Company had no full-time employees, other than Dr. Kovach. Effective February 23, 2017, Dr. Kovach retired from his part-time (50%) academic position at SUNY – Stony Brook, as a result of which he has been devoting 100% of his time to the Company's business activities since that date.

Prior to February 23, 2017, Dr. Kovach was a Professor (part-time) in the Department of Preventive Medicine at the State University of New York at Stony Brook ("SUNY – Stony Brook") in Stony Brook, New York. Dr. Kovach devoted approximately 50% of his efforts to the Company, including research planning and management functions. Dr. Kovach's contributions to the Company were made outside of his academic responsibilities at SUNY – Stony Brook.

Dr. Kovach directs, coordinates and manages the scientific and business development of the Company with the advice of the Company's Board of Directors, input from the Scientific Advisory Committee, and, from time to time, various consultants with specific expertise.

Government Regulation

Studies done under the CRADA were carried out in compliance with applicable Statutes, Executive Capital Orders, HHS regulations and all FDA, CDC, and NIH policies as specified in Article 13, 13.1 and 13.2, of the PHS CRADA.

The Company's business is subject to the regulations of the FDA as it conducts clinical trials. Clinical trials are research studies to answer specific questions about new therapies or new ways of using known treatments. Clinical trials determine whether new drugs or treatments are both safe and effective and the FDA has determined that carefully conducted clinical trials are the fastest and safest way to find treatments that work in people.

The FDA also requires that an independent review body consider the benefits and risks of a clinical trial and grant approval for the proposed study including selecting of initial doses, plans for escalation of dose, plans for modification of dose if toxicity is encountered, plans for monitoring the wellbeing of individuals participating in the study, and for defining and measuring, to the extent possible, any untoward effects related to drug administration. Serious adverse effects, such as life-threatening toxicities and death, are immediately reportable to the review body and to the FDA. To minimize risk when studying a new drug, the initial dose is well below that expected to cause any toxicity. No more than three patients are entered at a given dose. In general, a dose is not escalated within an individual patient. Once safety is established by the absence of toxicity or low toxicity in a group of three patients, a planned higher dose is then evaluated in a subsequent group of three individuals and so on until dose-limiting toxicity is encountered. The dose level producing definite but acceptable toxicity is then selected as the dose level to be evaluated in Phase 2 trials. Thus, the goal of Phase 1 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 which no beneficial treatment is established.

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

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

ITEM 1A. RISK FACTORS

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

Risks Related to Business

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

A key element of our strategy is to discover, develop and commercialize a portfolio of new drugs. 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 the following reasons:

- the research methodology used may not be successful in identifying potential product candidates; however, the Company has identified two promising lead candidate compounds which have activity in animal models, one of which, LB-100, has completed a Phase 1 clinical trial; 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.

If we are unable to discover suitable potential product candidates, develop additional delivery technologies through internal research programs or in-license suitable products or delivery technologies on acceptable business terms, our business prospects will suffer.

Our auditors have included a going concern modification in their opinion; we do not expect to obtain any significant revenues for several years and there is no assurance that we will ever generate any revenues or be profitable.

The Company's consolidated financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has not generated any revenues from operations to date and does not expect to do so in the foreseeable future. The Company has experienced recurring losses and negative operating cash flows since inception and has financed its working capital requirements during this period primarily through the recurring sale of its equity securities and the exercise of outstanding common stock options and purchase warrants.

As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern within one year of the date that the consolidated financial statements were issued. In addition, the Company's independent registered public accounting firm, in their report on the Company's consolidated financial statements for the year ended December 31, 2018, has also expressed substantial doubt about the Company's ability to continue as a going concern.

Because the Company is currently engaged in clinical research at a relatively early stage, it will likely take a significant amount of time to develop any product or intellectual property capable of generating sustainable revenues. Accordingly, the Company's business is unlikely to generate any sustainable operating revenues in the next several years and may never do so. In addition, to the extent that the Company is able to generate revenues through licensing its technologies or through product sales, there can be no assurance that the Company will be able to achieve positive earnings and operating cash flows.

The amount and timing of future cash requirements will depend on the pace and design of the Company's clinical trial program. As market conditions present uncertainty as to the Company's ability to secure additional funds, there can be no assurances that the Company will be able to secure additional financing on acceptable terms, or at all, as and when necessary to continue to conduct operations. If cash resources are insufficient to satisfy the Company's ongoing cash requirements, the Company would be required to scale back or discontinue its technology and product development programs and/or clinical trials, or obtain funds, if available (although there can be no certainty), through strategic alliances that may require the Company to relinquish rights to certain of its compounds, or to discontinue its operations entirely.

If we were to materially breach any existing or 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 intend to enter into intellectual property licenses and agreements, all of which we expect would be integral to our business. These licenses and agreements would 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 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; 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 could affect our ability to achieve revenues and 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 founder and Chief Executive Officer, Dr. John S. Kovach. Dr. Kovach is 82 years old. The loss of services of Dr. Kovach could delay or reduce our product development and commercialization efforts and would require that we hire a qualified replacement to fill the position of the Chief Executive Officer. 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 significantly weaken our management, harm our ability to compete effectively and harm our business.

During September 2015, we entered into a Collaboration Agreement with BioPharmaWorks, pursuant to which we engaged BioPharmaWorks to perform certain services for us. Those services include, among other things: (a) assisting us to (i) commercialize our products and strengthen our patent portfolio, (ii) identify large pharmaceutical companies with potential interest in our product pipeline, and (iii) prepare and deliver presentations concerning our products; (b) at the request of the Board of Directors, serving as backup management for up to three months should our Chief Executive Officer and scientific leader be temporarily unable to carry out his duties; (c) being available for consultation in drug discovery and development; and (d) identifying providers and overseeing tasks relating to clinical use and commercialization of new compounds. BioPharmaWorks was founded in 2015 by former Pfizer scientists with extensive multi-disciplinary research and development and drug development experience. Services under this Collaboration Agreement has been periodically suspended and resumed; effective March 1, 2019, the Company and BioPharmaWorks agreed to resume services under this Collaboration Agreement. We believe that this Collaboration Agreement mitigates, to a certain extent, our reliance on the services of Dr. Kovach, and would allow us the time to replace Dr. Kovach in the event that such a need arose.

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 1 clinical trial contract for ten years at the Mayo Clinic, Rochester, Minnesota. However, the Company has no experience in conducting clinical trials and expects to rely heavily on collaborative partners and contract research organizations for their performance and management of clinical trials of our product candidates.

Our products under development may not be effective in treating any of our targeted disorders or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may prevent or limit their commercial use. Institutional review boards or regulators, including the FDA, may hold, suspend or terminate our clinical research or the clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements or if, in their opinion, the participating subjects are being exposed to unacceptable health risks. Additionally, the failure of third parties conducting or overseeing the operation of the clinical trials to perform their contractual or regulatory obligations in a timely fashion could delay the clinical trials. Failure of clinical trials can occur at any stage of testing. Any of these events would adversely affect our ability to market a product candidate.

The development process necessary to obtain regulatory approval is lengthy, complex and costly. If we and our collaborative partners do not obtain necessary regulatory approvals at each stage of development, then our business would not be successful, and the market price of our common stock could decline substantially.

To the extent that we, or our collaborative partners, are able to successfully advance a product candidate through the clinic, we, or such partner, will be required to obtain regulatory approval prior to marketing and selling such product. The process of obtaining FDA and other required regulatory approvals is costly and lengthy. The time required for FDA and other approvals is uncertain and can typically take a number of years, depending on the complexity and novelty of the product.

Any regulatory approval to market a product may be subject to limitations on the indicated uses for which we, or our collaborative partners, may market the product. These limitations may restrict the size of the market for the product and affect reimbursement by third-party payors. In addition, regulatory agencies may not grant approvals on a timely basis or may revoke or significantly modify previously granted approvals.

We, or our collaborative partners, also are subject to numerous foreign regulatory requirements governing the manufacturing and marketing of our potential future products outside of the United States. The approval procedure varies among countries, additional testing may be required in some jurisdictions, and the time required to obtain foreign approvals often differs from that required to obtain FDA approvals. Moreover, approval by the FDA does not ensure approval by regulatory authorities in other countries, and vice versa.

As a result of these factors, we, or our collaborative partners, may not successfully complete clinical trials in the time periods estimated, if at all. Moreover, if we, or our collaborative partners, incur unanticipated costs and/or delays in development programs or if we fail to successfully develop and commercialize products based upon our technologies, we may not be able to generate significant operating revenues and sustainable profitability, as a result of which our stock price could decline substantially.

Even if our products are approved by regulatory authorities, if we fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continual review and periodic inspections by the FDA and other regulatory bodies. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturer or manufacturing processes, or failure to comply with regulatory requirements, may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recall, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products abroad.

We intend to market our products in international markets. In order to market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

We are subject to uncertainty relating to health care reform measures and reimbursement policies which, if not favorable to our product candidates, could hinder or prevent commercial success of our product candidates.

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 United States Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict the effects of the implementation of any new legislation or whether any current legislative or regulatory proposals affecting our business will be adopted, the implementation of new legislation or the announcement or adoption of current proposals could have a material and adverse effect on our business, financial condition and results of operations.

Our ability to commercialize our product candidates successfully will depend in part on the extent to which governmental authorities, private health insurers and other organizations establish appropriate reimbursement levels for the cost of our products and related treatments. Third-party payors are increasingly challenging the prices charged for medical products and services. Also, the trend toward managed health care in the United States, which could significantly influence the purchase of health care services and products, as well as legislative efforts to implement health care reforms such as the Patient Protection and Affordable Care Act (the "ACA"), which became law in 2010, and other measures, 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 the ACA and other health care reform, could materially and adversely affect our results of operations.

The product candidates that we may develop may not gain market acceptance among physicians, healthcare payors, patients and the medical community. 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. 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;
- cost effectiveness;
- effectiveness of our marketing strategy and the pricing of any product that we may develop;
- publicity concerning our products or competitive products; and
- our ability to obtain third-party coverage or insurance 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. 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 at that time. If we are unable to obtain insurance at acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may harm our business. These liabilities could prevent or interfere with our product commercialization efforts. Defending a suit, regardless of merit, could be costly, could divert management attention, and might result in adverse publicity or reduced acceptance of our products in the market.

We cannot be certain we will be able to obtain patent protection to protect our product candidates and technology.

We cannot be certain that all patents applied for will be issued. If a third party has also filed a patent application relating to an invention claimed by us or our licensors, we may be required to participate in an interference proceeding declared by the United States Patent and Trademark Office to determine priority of invention, which could result in substantial uncertainties and cost for us, even if the eventual outcome is favorable to us. The degree of future protection for our proprietary rights is uncertain. For example:

- we or our licensors might not have been the first to make the inventions covered by our pending or future patent applications;
- we or our licensors might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our patent applications will not result in an issued patent or patents, or that the scope of protection granted by any patents arising from our patent applications will be significantly narrower than expected;
- any patents under which we hold ultimate rights may not provide us with a basis for commercially-viable products, may not provide us with any competitive advantages or may be challenged by third parties as not infringed, invalid, or unenforceable under United States or foreign laws;
- any patent issued to us in the future or under which we hold rights may not be valid or enforceable; or
- we may develop additional proprietary technologies that are not patentable and which may not be adequately protected through trade secrets; for example if a competitor independently develops duplicative, similar, or alternative technologies.

If we are not able to protect and control our unpatented trade secrets, know-how and other technological innovation, we may suffer competitive harm.

We also rely on proprietary trade secrets and unpatented know-how to protect our research and development activities, particularly when we do not believe that patent protection is appropriate or available. However, trade secrets are difficult to protect. We will attempt to protect our trade secrets and unpatented know-how by requiring our employees, consultants and advisors to execute a confidentiality and non-use agreement. We cannot guarantee that these agreements will provide meaningful protection, that these agreements will not be breached, that we will have an adequate remedy for any such breach, or that our trade secrets will not otherwise become known or independently developed by a third party. Our trade secrets, and those of our present or future collaborators that we utilize by agreement, may become known or may be independently discovered by others, which could adversely affect the competitive position of our product candidates.

We may incur substantial costs enforcing our patents, defending against third-party patents, invalidating third-party patents or licensing third-party intellectual property, as a result of litigation or other proceedings relating to patent and other intellectual property rights.

We may not have rights under some patents or patent applications that may cover technologies that we use in our research, drug targets that we select, or product candidates that we seek to develop and commercialize. Third parties may own or control these patents and patent applications in the United States and elsewhere. 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 legal 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, it is possible that we may become so in the future. We are not currently aware of any actual or potential third-party infringement claim involving our products. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. The outcome of patent litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of the adverse party, especially in biotechnology related patent cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. If a patent or other proceeding is resolved against us, we may be enjoined from researching, developing, manufacturing or commercializing our products without a license from the other party and we may be held liable for significant damages. We may not be able to obtain any required license on commercially acceptable terms or at all.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could harm our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

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

The following factors are important to our success:

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

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

Because issues of patentability involve complex legal and factual questions, the issuance, scope and enforceability of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. United States patents and patent applications may also be subject to interference proceedings, and United States patents may be subject to reexamination proceedings in the United States 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 or otherwise promote 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 would require FDA approval. This revalidation may be costly and time consuming. If we are unable to arrange for third-party manufacturing of our products, or to do so on commercially reasonable terms, we may not be able to complete development or marketing of our products.

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

The availability and levels of reimbursement by governmental and other third-party payors affect the market for our products. The efficacy, safety and cost-effectiveness of our products, as well as the efficacy, safety and cost-effectiveness of any competing products, will determine the availability and level of reimbursement. These third-party payors continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services. In certain countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to twelve months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct clinical trials that compare the cost-effectiveness of our products to other available therapies. If reimbursement for our products is unavailable, limited in scope or amount, or if pricing is set at unsatisfactory levels, our potential revenues would be reduced, and our results of operations would be negatively impacted.

Another development that may affect the pricing of drugs is regulatory action regarding drug re-importation 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 United States Department of Health and Human Services to promulgate regulations allowing drug re-importation 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 re-importation may also attempt to pass legislation that would remove the requirement for the Secretary's certification or allow re-importation under circumstances beyond those anticipated under current law. If legislation is enacted, or regulations issued, allowing the re-importation 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 that an established public trading market for our common stock will ultimately develop, and if it does develop, that it is sustainable, which would adversely affect the ability of our investors to sell their shares of common stock in the public market.

Although our common stock is registered under the Exchange Act and our stock is traded on the OTCQB operated by the OTC Markets, an active trading market for the securities does not yet exist and may not exist or be sustained in the future. The OTCQB is an over-the-counter market that provides significantly less liquidity than the NASDAQ Stock Market. Quotes for stocks included on the OTCQB are not listed in the financial sections of newspapers as are those for the NASDAQ Stock Market. Therefore, prices for securities traded solely on the OTCQB may be difficult to obtain and holders of common stock may be unable to resell their securities at or near their original offering price or at any price. Market prices for our common stock could 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 pharmaceutical 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 founder and Chief Executive Officer, is currently eligible to sell his shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144 promulgated under the Securities Act ("Rule 144"), subject to certain limitations. Rule 144 also permits the sale of securities, without any limitations, by a non-affiliate that has satisfied a six-month holding period. Any substantial sale of common stock pursuant to Rule 144 may have an adverse effect on the market price of our common stock by creating an excessive supply.

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 Securities and Exchange Commission 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.

Dr. John Kovach, our principal stockholder and our Chief Executive Officer, beneficially owns 13.6% of our outstanding common stock (the Company's only voting security currently issued and outstanding). As a result of the combination of these factors, Dr. Kovach possesses significant influence on the operations and corporate governance of the Company, giving him substantial influence over the election of the members of the Board of Directors and the approval of significant corporate transactions. Such influence may also have the effect of delaying or preventing a future change in control transaction, 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

The Company conducts clinical research required to bring a compound through the clinical trial process at medical centers and contract research organizations. The Company maintains a single office in a designated area of Dr. Kovach's residence as the Company's administrative offices. The Company receives corporate mail at the post office depot, 248 Route 25A, No. 2, East Setauket, New York 11733. The Company also conducts certain corporate office functions at the Eric Foreman Law Office, 401 Park Avenue, New York, New York 10016. Management does not believe that any additional facilities are needed at this time.

ITEM 3. LEGAL PROCEEDINGS

The Company is not a party to any threatened or pending legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

The Company's common stock trades on the OTCQB under the symbol "LIXT". There is limited trading in the Company's common stock. The stock market in general has experienced extreme stock price fluctuations in the past few years. In some cases, these fluctuations have been unrelated to the operating performance of the affected companies. Many companies have experienced dramatic volatility in the market prices of their common stock. The Company believes that a number of factors, both within and outside its control, could cause the price of the Company's common stock to fluctuate, perhaps substantially.

The following table sets forth the range of reported closing prices of the Company's common stock during the periods presented. Such quotations reflect prices between dealers in securities and do not include any retail mark-up, markdown or commissions, and may not necessarily represent actual transactions.

	High	Low
Year Ended December 31, 2017		
First Quarter	$ 0.45	$ 0.12
Second Quarter	$ 0.23	$ 0.11
Third Quarter	$ 0.40	$ 0.20
Fourth Quarter	$ 0.20	$ 0.12

	High	Low
Year Ended December 31, 2018		
First Quarter	$ 0.13	$ 0.17
Second Quarter	$ 0.13	$ 0.28
Third Quarter	$ 0.25	$ 1.00
Fourth Quarter	$ 0.70	$ 1.30

Holders

As of March 1, 2019, the Company had 80 stockholders of record holding 67,045,814 shares of the Company's common stock outstanding, including 6,240,208 shares of common stock held by an indeterminate number of beneficial owners of securities whose shares are held in the names of various brokerage firms and clearing agencies.

Dividends

The Company's dividend policy is determined by its Board of Directors and will depend upon a number of factors, including the Company's financial condition and performance, its cash needs and expansion plans, income tax consequences, and the restrictions that applicable laws and any credit or other contractual arrangements may then impose. The Company has not paid any cash dividends on its common stock to date and at the current time the Company does not anticipate paying a cash dividend on its common stock in the foreseeable future.

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, 2018, 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 compensation plans (excluding securities reflected in column 2)
	(1)	(2)	(3)
Equity Compensation Plans Approved by Security Holders	N/A	$ N/A	N/A
Equity Compensation Plans Not Approved by Security Holders	7,750,000	$ 0.41	N/A(1)

(1) The Company's 2007 Stock Option Plan terminated on June 19, 2017.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

Overview

The Company is a drug discovery company that uses biomarker technology to identify enzyme targets associated with serious common diseases and then designs novel compounds to attack those targets. The Company's product pipeline encompasses two major categories of compounds at various stages of pre-clinical and clinical development that the Company believes have broad therapeutic potential not only for cancer but also for other debilitating and life-threatening diseases.

The Company's activities are subject to significant risks and uncertainties, including the need for additional capital, as described below. The Company has not yet commenced any revenue-generating operations, does not have positive cash flows from operations, and is dependent on periodic infusions of equity capital to fund its operating requirements.

The Company's common stock is traded on the OTCQB operated by the OTC Markets under the symbol "LIXT".

Recent Development

In early November 2018, the Company received approval from the FDA for its Investigational New Drug (IND) Application to conduct a Phase 1b/2 clinical trial to evaluate the safety and therapeutic benefit of the Company's lead clinical compound LB-100 in patients with low and intermediate-1 risk myelodysplastic syndrome (MDS) who have failed or are intolerant of standard treatment.

The clinical trial will be managed and conducted at Moffitt Cancer Center in Tampa, Florida. This clinical trial is currently expected to begin during the quarter ending June 30, 2019, to complete patient accrual over a period of two years, and to take approximately three years to complete.

Going Concern

The Company's consolidated financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has not generated any revenues from operations to date and does not expect to do so in the foreseeable future. Furthermore, the Company has experienced recurring operating losses and negative operating cash flows since inception and has financed its working capital requirements during this period primarily through the recurring sale of its equity securities and the exercise of outstanding common stock options and purchase warrants.

As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern within one year of the date that the consolidated financial statements are being issued. In addition, the Company's independent registered public accounting firm, in their report on the Company's consolidated financial statements for the year ended December 31, 2018, has also expressed substantial doubt about the Company's ability to continue as a going concern.

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

Because the Company is currently engaged in clinical research at a relatively early stage, it will likely take a significant amount of time to develop any product or intellectual property capable of generating sustainable revenues. Accordingly, the Company's business is unlikely to generate any sustainable operating revenues in the next several years and may never do so. In addition, to the extent that the Company is able to generate revenues through licensing its technologies or through product sales, there can be no assurance that the Company will be able to achieve positive earnings and operating cash flows.

At December 31, 2018, the Company had cash of $4,273,012 available to fund its operations. The next step in the development of the Company's lead anti-cancer clinical compound LB-100 is to evaluate its safety and therapeutic benefit in a Phase 1b/2 clinical trial. This clinical trial is currently expected to begin during the quarter ending June 30, 2019, to complete patient accrual over a period of two years, and to take approximately three years to complete. The Company's longer-term objective is to secure one or more strategic partnerships with pharmaceutical companies with major programs in cancer.

The amount and timing of future cash requirements will depend on the pace and design of the Company's clinical trial program. As market conditions present uncertainty as to the Company's ability to secure additional funds, there can be no assurances that the Company will be able to secure additional financing on acceptable terms, or at all, as and when necessary to continue to conduct operations. If cash resources are insufficient to satisfy the Company's ongoing cash requirements, the Company would be required to scale back or discontinue its technology and product development programs and/or any clinical trials, or obtain funds, if available (although there can be no certainty), through strategic alliances that may require the Company to relinquish rights to certain of its compounds, or to discontinue its operations entirely.

Recent Accounting Pronouncements

Recently Adopted Accounting Standards

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASU 2014-09"). ASU 2014-09 eliminates transaction- and industry-specific revenue recognition guidance under current GAAP and replaces it with a principles-based approach for determining revenue recognition. ASU 2014-09 requires that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. The FASB has recently issued ASU 2016-08, ASU 2016-10, ASU 2016-11, ASU 2016-12, and ASU 2016-20, all of which clarify certain implementation guidance within ASU 2014-09. ASU 2014-09 is effective for reporting periods beginning after December 15, 2017. The Company adopted the provisions of ASU 2014-09 in the quarter beginning January 1, 2018. The adoption of ASU 2014-09 did not have any impact on the Company's financial statement presentation or disclosures.

In July 2017, the FASB issued Accounting Standards Update No. 2017-11, Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features; (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception ("ASU 2017-11"). ASU 2017-11 allows companies to exclude a down round feature when determining whether a financial instrument (or embedded conversion feature) is considered indexed to the entity's own stock. As a result, financial instruments (or embedded conversion features) with down round features are no longer required to be accounted for as derivative liabilities. A company will recognize the value of a down round feature only when it is triggered and the strike price has been adjusted downward. For equity-classified freestanding financial instruments, an entity will treat the value of the effect of the down round as a dividend and a reduction of income available to common shareholders in computing basic earnings per share. For convertible instruments with embedded conversion features containing down round provisions, entities will recognize the value of the down round as a beneficial conversion discount to be amortized to earnings. ASU 2017-11 is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. The Company early adopted the provisions of ASU 2017-11 in the quarter beginning January 1, 2018. The adoption of ASU 2017-11 did not have any impact on the Company's financial statement presentation or disclosures.

Recently Issued Accounting Standards

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, Leases (Topic 842) ("ASU 2016-02"). ASU 2016-02 requires a lessee to record a right-of-use asset and a corresponding lease liability, initially measured at the present value of the lease payments, on the balance sheet for all leases with terms longer than 12 months, as well as the disclosure of key information about leasing arrangements. ASU 2016-02 requires recognition in the statement of operations of a single lease cost, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. ASU 2016-02 requires classification of all cash payments within operating activities in the statement of cash flows. Disclosures are required to provide the amount, timing and uncertainty of cash flows arising from leases. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. ASU 2016-02 has subsequently been amended and modified by ASU 2018-10, 2018-11 and 2018-20. ASU 2016-02 (including the subsequent amendments and modifications) is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company will adopt the provisions of ASU 2016-02 in the quarter beginning January 1, 2019. The adoption of ASU 2016-02 is not expected to have any impact on the Company's financial statement presentation or disclosures.

In June 2018, the FASB issued Accounting Standards Update 2018-07, Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting ("ASU 2018-07"). ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. ASU 2018-07 also clarifies that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Revenue from Contracts with Customers (Topic 606). ASU 2018-07 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company will adopt the provisions of ASU 2018-07 in the quarter beginning January 1, 2019. The adoption of ASU 2018-07 is not expected to have any impact on the Company's financial statement presentation or disclosures.

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

Concentration of Risk

The Company periodically contracts with directors, including companies controlled by or associated with directors, to provide consulting services related to the Company's research and development and clinical trial activities. Agreements for these services can be for a specific time period (typically one year) or for a specific project or task and can include both cash and non-cash compensation. The only such contracts that represent 10% or more of general and administrative or research and development costs are described below.

The Company has retained Theradex to provide technical and advisory services to the Company with respect to clinical trial matters involving the FDA. Total costs charged to operations from 2013 through December 31, 2017 for services paid to or through Theradex for the Phase 1 clinical trial of LB-100 aggregated $2,233,248, with approximately 60% of such costs allocated for services provided by Theradex and approximately 40% for pass-through costs for clinical center laboratory costs and investigator costs over the life of the clinical trial. During the year ended December 31, 2018, the Company did not incur any such clinical trial costs with Theradex. During the year ended December 31, 2017, the Company incurred $105,698 of such clinical trial costs with Theradex, representing approximately 24% of research and development costs for the year ended December 31, 2017. Costs incurred pursuant to this agreement are included in research and development costs in the Company's consolidated statements of operations.

Critical Accounting Policies and Estimates

The preparation of the Company's consolidated financial statements in conformity with generally accepted accounting principles in the United States ("GAAP") requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and the notes to the consolidated financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions.

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

Research and Development

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

Research and development costs are expensed ratably over the life of the underlying contracts, unless the achievement of milestones, the completion of contracted work, or other information indicates that a different expensing schedule is more appropriate.

Obligations incurred with respect to mandatory scheduled payments under research agreements without milestone provisions are recognized ratably over the appropriate period, as specified in the agreement, and are recorded as liabilities in the Company's consolidated balance sheet, with a corresponding charge to research and development costs in the Company's consolidated statement of operations.

The Company retained Theradex, an international contract research organization ("CRO") that provides professional services for the clinical research and development of pharmaceutical compounds, to be responsible for managing and administering the Company's Phase 1 clinical trial of LB-100. The costs of the Phase 1 clinical trial of LB-100 that were paid through Theradex were recorded and expensed based upon the documentation provided by the CRO.

Payments made pursuant to research and development contracts are initially recorded as advances on research and development contract services in the Company's balance sheet and then charged to research and development costs in the Company's statement of operations as those contract services are performed. Expenses incurred under research and development contracts in excess of amounts advanced are recorded as research and development contract liabilities in the Company's balance sheet, with a corresponding charge to research and development costs in the Company's statement of operations. The Company reviews the status of its research and development contracts on a quarterly basis.

Patent and Licensing Costs

Due to the significant uncertainty associated with the successful development of one or more commercially viable products based on the Company's research efforts and related patent applications, all patent-related legal and filing fees and licensing-related legal fees are expensed as incurred. Patent and licensing costs are included in general and administrative costs in the Company's consolidated statements of operations.

Stock-Based Compensation

The Company periodically issues common stock and stock options to officers, directors, Scientific Advisory Committee members and consultants for services rendered. Options vest and expire according to terms established at the issuance date of each grant.

The Company accounts for stock-based payments to officers and directors by measuring the cost of services received in exchange for equity awards based on the grant date fair value of the awards, with the cost recognized as compensation expense on the straight-line basis in the Company's financial statements over the vesting period of the awards. The Company accounts for stock-based payments to Scientific Advisory Committee members and consultants by determining the value of the stock compensation based upon the measurement date at either (a) the date at which a performance commitment is reached or (b) at the date at which the necessary performance to earn the equity instruments is complete.

Stock grants, which are generally time vested, are measured at the grant date fair value and charged to operations ratably over the vesting period.

Stock options granted to members of the Company's Scientific Advisory Committee and to outside consultants are revalued each reporting period to determine the amount to be recorded as an expense in the respective period. As the stock options vest, they are valued on each vesting date and an adjustment is recorded for the difference between the value already recorded and the value on the date of vesting.

The fair value of common stock issued as stock-based compensation is determined by reference to the closing price of the Company's common stock on the date of issuance. The fair value of stock options granted as stock-based compensation is determined utilizing the Black-Scholes option-pricing model, and is affected by several variables, the most significant of which are the life of the equity award, the exercise price of the stock option as compared to the fair market value of the common stock on the grant date, and the estimated volatility of the common stock over the term of the equity award. Estimated volatility is based on the historical volatility of the Company's common stock. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. The fair market value of common stock is determined by reference to the quoted market price of the Company's common stock.

The Company recognizes the fair value of stock-based compensation awards in general and administrative costs and in research and development costs, as appropriate, in the Company's consolidated statement of operations. The Company issues new shares of common stock to satisfy stock option exercises.

Plan of Operation

Overview of Plans

The Company has two classes of drugs under development for the treatment of cancer, consisting of protein phosphatase inhibitors (PTase-i), designated by the Company as the LB-100 series of compounds, and histone deacetylase inhibitors (HDACi), designated by the Company as the LB-200 series of compounds. Compounds of both types also have potential use in the prevention and treatment of neurodegenerative diseases. The LB-100 series consists of novel structures, which have the potential to be first in their class and may be useful in the treatment of not only several types of cancer, but also vascular and metabolic diseases. The LB-200 series contains compounds which have the potential to be the most effective in its class and may be useful for the treatment of chronic hereditary diseases, such as Gaucher's disease, in addition to cancer and neurodegenerative diseases.

The Company completed a Phase 1 clinical of its lead anti-cancer compound LB-100 that showed it is associated with anti-tumor activity in humans at doses that are readily tolerable. Responses included objective regression (tumor shrinkage) lasting for 11 months of a pancreatic cancer and cessation of growth (stabilization of disease) for 4 months or more of 9 other progressive solid tumors out of 20 patients who had measurable disease. As Phase 1 clinical trials are fundamentally designed to determine safety of a new compound in humans, the Company was encouraged by these results. The next step is to demonstrate in Phase 2 clinical trials the efficacy of LB-100 in one or more specific tumor types, against which the compound has well documented activity in pre-clinical models.

Collaborations with leading academic research centers in the United States, Europe and Asia have established the breadth of activity of LB-100 in pre-clinical models of several major cancers. There is considerable scientific interest in LB-100 because it exerts its activity by a novel mechanism and is the first of its type to be evaluated so broadly in multiple animal models of cancer and now in human beings. LB-100 is one a series of serine/threonine phosphatase (s/t ptase) inhibitors designed by the Company. The s/t ptases are ubiquitous enzymes that regulate many cell signaling networks important to cell growth, division and death. The s/t ptases have long been appreciated as potentially important targets for anti-cancer drugs. However, because of the multi- functionality of these enzymes, it had been widely held that pharmacologic inhibitors of s/t ptases would be too toxic to allow their development as anti-cancer treatments, but the Company has shown that this is not the case. LB-100 was well tolerated at doses associated with objective regression (significant tumor shrinkage) and/or the arresting of tumor progression in patients with progressive cancers.

Pre-clinical studies showed that LB-100 itself inhibits a spectrum of human cancers and that combined with standard cytotoxic drugs and/or radiation, LB-100 potentiates their effectiveness against hematologic and solid tumor cancers without enhancing toxicity. Recently, given at very low doses in animal models of cancer, LB-100 markedly increased the effectiveness of a PD-1 blocker, one of the widely used new immunotherapy drugs. This finding raises the possibility that LB-100 may further expand the value of the expanding field of cancer immunotherapy.

Although the Company's focus has been on developing drugs for cancer treatment, several academic centers studying LB-100 under material transfer agreements with the Company have generated pre-clinical data indicating that LB-100 may be therapeutically effective in important non-neoplastic diseases. This development stems from the fact that dysregulation of the PP2A function is not only a feature of many cancers but is also a component of the basic inflammatory response elicited by diverse types of injury in animal models. These include lipid buildup in the blood vessels (type 2 diabetes), acute oxygen deprivation (myocardial infarction and stroke (MI/S)), and aversive physical and/or psychological trauma (depression and post traumatic shock-like syndromes.). The Company's patent portfolio covers composition of matter for structurally distinct but comparably effective PP2A inhibitors and their use in the therapy of a broad spectrum of human diseases. However, the focus of the Company at this time is on demonstrating the value of LB-100 against specific cancers in humans.

At this time, the Company is not aware of any compound in clinical study that is a potent inhibitor of PP2A. Revlimid (Celgene) has recently been recognized to have weak PP2A activity, which presumably underlies its effects in myelodysplastic syndrome (MDS). Over 30 articles have been published reporting the anti-cancer activity of LB-100 against many different types of human cancers in model systems. As a result, the Company believes that some pharmaceutical companies are either evaluating LB-100 and/or designing their own inhibitors of PP2A. The Company's patent portfolio includes composition of matter and multiple uses of LB-100 and analogs and PP2A inhibition in general for multiple cancers and non-neoplastic diseases.

The LB-200 series consists of histone deacetylase inhibitors (HDACi). Many pharmaceutical companies are also developing drugs of this type, and at least two companies have HDACi approved for clinical use, in both cases for the treatment of a type of lymphoma. Despite this significant competition, the Company has demonstrated that its HDACi have broad activity against many cancer types, has neuroprotective activity, and has anti-fungal activity. In addition, these compounds have low toxicity, making them attractive candidates for development. It appears that one type of molecule has diverse effects, affecting biochemical processes that are fundamental to the life of the cell, whether they are cancer cells, nerve cells, or even fungal cells. The neuroprotective activity of the Company's HDACi has been demonstrated in the test tube in model systems that mimic injury to brain cells, such as occurs in stroke and Alzheimer's disease. This type of protective activity may have potential application to a broad spectrum of other chronic neurodegenerative diseases, including Parkinson's disease and Amytrophic Lateral Sclerosis (ALS, or Lou Gehrig's disease). LB-200 has not yet advanced to the clinical stage and would require additional capital to fund further development. Accordingly, because of the Company's focus on the clinical development of LB-100 and analogs for cancer therapy as described below in more detail, the Company has decided not to actively pursue the pre-clinical development of its LB-200 series of compounds at this time. At this time, the Company intends to only maintain its composition of matter patents for LB-200.

Operating Plans

LB-100 Anti-Cancer Targets and Recent Developments

LB-100 used alone has modest inhibitory activity against many cancers in model systems, but certain human cancers possessing unique genetic changes, in addition to those reducing DNA damage repair, are particularly susceptible to inhibition of PP2A by LB-100.

Among these cancers is MDS, an increasingly common neoplastic disease, especially in persons aged 65 and older, characterized by failure of the bone marrow. In particular, a variant of MDS termed del(5q)MDS is missing 50% of its PP2A activity, rendering this tumor potentially more sensitive to further pharmacologic inhibition of PP2A. There is only one drug, Revlimid (Celgene), that is currently approved for the treatment of del(5q)MDS and there is no drug for MDS in general.

Other cancers, in particular small cell lung cancer (SCLC) and hepatocellular cancer occurring in the liver (HCC), have acquired genetic abnormalities, which render them sensitive to inhibition of PP2A by a process termed synthetic lethality. Pre-clinical studies have shown that both SCLC and HCC are sensitive to PP2A inhibition by LB-100 alone and especially so when LB-100 is combined with drugs used as standard treatment for these diseases. SCLC is the lung cancer variant associated with cigarette smoke and comprises about 15% of all lung cancers. HCC is the 5th most common cancer in the world and the 3rd leading cause of death from cancer, with the majority of cases being in Asia. There is no satisfactory treatment available for either of these devastating tumors.

Scientists at the National Institute of Neurological Disorders and Stroke (NINDS) have conducted pre-clinical studies of LB-100 that showed anti-cancer activity in models of a variety of human brain tumors, including glioblastomamultiforme (GBM), medulloblastoma and malignant meningioma. Studies of LB-100 and analogs in models of human brain tumors of adults and children are continuing under a Material-Cooperative Research and Development Agreement (M-CRADA) with the National Cancer Institute (NCI). The NCI has an FDA-approved clinical pharmacokinetic (non-therapeutic) study of LB-100 (Phase 0 Trial, NCT03027388) in patients with recurrent GBM to assess penetration of the compound into these highly malignant tumors. The rationale for this clinical study is that LB-100 potentiates the anti-tumor activity of both x-ray and the drug temozolomide, which are the mainstays of treatment for GBM.

Recent extensive pre-clinical studies of the Company's lead PP2A inhibitor, LB-100, raise the possibility that LB-100 has the potential to enhance the effectiveness of the now widely used PD-1 inhibitors that attack a variety of cancers by activating the patient's own immune system to reject their own tumors (Ho et al. (2018) Pharmacologic inhibition of protein phosphatase-2A achieves durable immune-mediated antitumor activity when combined with PD-1 blockade. Nature Communications (2018), 9:2126; Maggio et al. (2017) PD-1 Antagonism With Concurrent Competitive Inhibition Of PP2A Promotes Enhanced Regression Of Intracranial Glioblastoma. Neuro-Oncology, (2017) 19(6): vi75. DOI: 10.1093/neuonc/nox168.306). If these findings were confirmed in clinical studies, there could potentially be multiple clinical applications of combination therapy with a PD-1 inhibitor plus LB-100. In the animal models, there was no evidence that LB-100 potentiation of PD-100 immunological repression of cancers is accompanied by autoimmune toxicity to normal tissue targets.

In addition, an entirely new application of LB-100 to a specific class of hematologic cancers called B cell leukemias and lymphomas was reported by a group of hematological cancer experts from several national cancer centers in the journal Cell (Xiao et al. (2018) B-Cell-Specific Diversion of Glucose Carbon Utilization Reveals a Unique Vulnerability in B Cell Malignancies. Cell (2018) 173:1-15). The seminal finding was that B cell cancers in general require overexpression of PP2A for survival, and that in multiple pre-clinical models and in isolated human B cell cancers, LB-100 is highly inhibitory. The journal *Cell* is a peer-reviewed scientific journal publishing research papers across a broad range of disciplines within the life sciences. Although B cell cancer therapy is a crowded field with many treatments available, the discovery that these cancers are apparently dependent for survival on abnormally high levels of PP2A activity, the enzyme target of LB-100, merits further exploration of new regimens incorporating LB-100 for therapy of these diseases.

Near-Term Objectives

The Company's immediate goals are to demonstrate significant therapeutic benefit of LB-100, the Company's lead anti-cancer clinical compound, against one or more specific human cancers in Phase 2 clinical trials. The Company has several attractive targets for new therapies incorporating LB-100. The potentiation of cancer immunotherapy by adding LB-100 to regimens of PD-1 blockers, as reported by Ho et al (2018), and the unexpected findings of Muschen et al (2018) that a metabolic imbalance involving over activity of the enzyme PP2A in B cell cancers, which is the target of LB-100, may provide a selective advantage in the therapy of B cell cancers. These findings have also led the Company to reexamine the most attractive cancer targets for demonstrating the clinical effectiveness LB-100 and to enter into discussions with cancer centers that focus on the inhibition of PP2A as an important cancer target.

Effective August 20, 2018, the Company and the Moffitt Cancer Center and Research Institute Hospital Inc., Tampa, Florida ("Moffitt") entered into a Clinical Trial Research Agreement (the "Clinical Trial Research Agreement") effective for a term of five years, unless terminated earlier by the Company pursuant to 30 days written notice. Pursuant to the Clinical Trial Research Agreement, Moffitt will conduct and manage a Phase 1b/2 clinical trial to evaluate the safety and therapeutic benefit of the Company's lead anti-cancer clinical compound LB-100 to be administered intravenously in patients with low or intermediate-1 risk MDS. This clinical trial is currently expected to begin during the quarter ending June 30, 2019, to complete patient accrual over a period of two years, and to take approximately three years to complete. This Phase 1b/2 clinical trial will utilize LB-100 as a single agent in the treatment of patients with del(5q) myelodysplastic syndrome (del5qMDS) failing first line therapy. The bone marrow cells of these patients are deficient in PP2A and are especially vulnerable to further inhibition of PP2A by LB-100.

Presented below are proposed clinical trials that the Company would like to conduct over the next few years. The Company expects that these potential clinical trials, and the details thereof, will change over time as the Company obtains more clinical information on LB-100. The Company's ability to conduct these clinical trials is subject to the availability of sufficient financial resources.

(1) A Phase 1b/2 randomized clinical trial in previously untreated patients with small cell lung cancer (SCLC) comparing the standard regimen, carboplatin/etoposide, with and without LB-100. The malignant cells of this uniformly rapidly fatal lung cancer are genetically sensitive to PP2A inhibition (by a process termed synthetic lethality).

(2) A Phase 1b/2 randomized clinical trial in patients adding LB-100 to PD-1 inhibitors against one of several cancers in which PD-1 inhibitors alone have definite but modest activity.

The Phase 1b/2 clinical trials in SCLC and in LB-100 plus a PD-1 inhibitor in yet to be specified solid tumors will require additional financing in excess of that currently budgeted to fund a Phase 1b/2 clinical trial in myelodysplastic syndrome that is scheduled to begin during the quarter ending June 30, 2019 as described above, and/or partnering relationships with other pharmaceutical companies, in order for the Company to undertake and complete such clinical studies. The Company is in discussions with various parties with respect to the financing of these clinical studies, although there can be no assurances that the Company will be able to obtain such financing and/or partnering relationships on acceptable terms or at all. The Company's longer-term objective is to secure one or more strategic partnerships with pharmaceutical companies with major programs in cancer research and drug development.

As a compound moves through the FDA-approval process, it becomes an increasingly valuable property, but at a cost of additional investment at each stage. As the potential effectiveness of LB-100 has been documented at the clinical trial level, the Company has allocated resources to expand the breadth and depth of its patent portfolio. The Company's approach has been to operate with a minimum of overhead, moving compounds forward as efficiently and inexpensively as possible, and to raise funds to support each of these stages as certain milestones are reached.

Results of Operations

At December 31, 2018, the Company had not yet commenced any revenue-generating operations, does not have any positive cash flows from operations, and is dependent on its ability to raise equity capital to fund its operating requirements.

The Company's consolidated statements of operations as discussed herein are presented below.

	Years Ended December 31,	
	2018	**2017**
Revenues	$ —	$ —
Costs and expenses:		
General and administrative costs	2,097,348	1,342,531
Research and development costs	40,703	467,258
Total costs and expenses	2,138,051	1,809,789
Loss from operations	(2,138,051)	(1,809,789)
Interest income	4,923	1,375
Net loss	$ (2,133,128)	$ (1,808,414)
Net loss per common share – basic and diluted	$ (0.04)	$ (0.03)
Weighted average common shares outstanding – basic and diluted	58,796,115	55,817,458

Years Ended December 31, 2018 and 2017

Revenues. The Company did not have any revenues for the years ended December 31, 2018 and 2017.

General and Administrative Costs. For the year ended December 31, 2018, general and administrative costs were $2,097,348, which consisted of the fair value of vested stock options issued to directors and consultants of $785,612 (including the cost of extending certain stock options previously granted to a consultant of $711,738), patent and licensing legal fees and costs of $842,325, other consulting and professional fees of $300,649, insurance expense of $52,060, officer's salary and related costs of $67,656, stock transfer fees of $12,822, travel and entertainment costs of $1,789, listing fees of $12,000, filing fees of $7,490, and other operating costs of $14,945.

For the year ended December 31, 2017, general and administrative costs were $1,342,531, which consisted of the fair value of vested stock options issued to directors and consultants of $38,675, patent and licensing legal fees and costs of $846,169, other consulting and professional fees of $273,260, insurance expense of $53,045, officer's salary and related costs of $67,489, stock transfer fees of $9,944, filing fees of $6,593, travel and entertainment costs of $14,840, listing fees of $10,000, conference fees of $9,946, and other operating costs of $12,570.

General and administrative costs increased by $754,817 or 56.2% in 2018 as compared to 2017, primarily as a result of an increase in the fair value of stock options issued to directors and consultants of $746,937.

Research and Development Costs. For the year ended December 31, 2018, research and development costs were $40,703, which consisted entirely of contractor costs, primarily in connection with the Company's pre-clinical research focused on the development of additional novel anti-cancer compounds to add to its clinical pipeline, and is stated net of a credit of $25,000 for a reversal of an obligation to the National Cancer Institute in connection with Amendment No. 3 to the M-CRADA, which updated collaboration plans between the National Cancer Institute and the Company.

For the year ended December 31, 2017, research and development costs were $467,258, which consisted of the fair value of vested common stock options and warrants of $32,020, and contractor costs of $435,238, incurred primarily in connection with the Company's pre-clinical research focused on the development of additional novel anti-cancer compounds to add to the Company's clinical pipeline, including $105,698 to Theradex in connection with the Phase 1 clinical trial of LB-100, $60,000 to BioPharma Works, and $75,000 to the National Cancer Institute in connection with Amendment No. 1 to the M-CRADA.

Research and development costs decreased by $426,555 or 91.3% in 2018 as compared to 2017, primarily as a result of a decrease of $394,535 in contractor costs and a decrease of $32,020 for the fair value of vested stock options.

Interest Income. For the year ended December 31, 2018, the Company had interest income of $4,923, as compared to interest income of $1,375 for the year ended December 31, 2017.

Net Loss. For the year ended December 31, 2018, the Company incurred a net loss of $2,133,128, as compared to a net loss of $1,808,414 for the year ended December 31, 2017.

Liquidity and Capital Resources – December 31, 2018

The Company's consolidated financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has not generated any revenues from operations to date and does not expect to do so in the foreseeable future. Furthermore, the Company has experienced recurring operating losses and negative operating cash flows since inception and has financed its working capital requirements during this period primarily through the recurring sale of its equity securities and the exercise of outstanding common stock options and purchase warrants. As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern within one year of the date that the condensed consolidated financial statements are being issued. In addition, the Company's independent registered public accounting firm, in their report on the Company's consolidated financial statements for the year ended December 31, 2018, has also expressed substantial doubt about the Company's ability to continue as a going concern (see "Going Concern" above).

At December 31, 2018, the Company had working capital of $4,123,530, as compared to working capital of $995,041 at December 31, 2017, reflecting an increase in working capital of $3,128,489 for the year ended December 31, 2018. The increase in working capital during the year ended December 31, 2018 was the result primarily of net proceeds from the sale of common stock units on November 30, 2018, in the amount of $4,475,298, offset by working capital being utilized to fund the Company's research and development activities and ongoing operating expenses, including maintaining and developing the Company's patent portfolio.

At December 31, 2018, the Company had cash of $4,273,012 available to fund its operations. The next step in the development of the Company's lead anti-cancer clinical compound LB-100 is to evaluate its safety and therapeutic benefit in a Phase 1b/2 clinical trial. This clinical trial is currently expected to begin during the quarter ending June 30, 2019, to complete patient accrual over a period of two years, and to take approximately three years to complete. The Company's longer-term objective is to secure one or more strategic partnerships with pharmaceutical companies with major programs in cancer.

The amount and timing of future cash requirements will depend on the pace and design of the Company's clinical trial program. As market conditions present uncertainty as to the Company's ability to secure additional funds, there can be no assurances that the Company will be able to secure additional financing on acceptable terms, or at all, as and when necessary to continue to conduct operations. If cash resources are insufficient to satisfy the Company's ongoing cash requirements, the Company would be required to scale back or discontinue its technology and product development programs and/or any clinical trials, or obtain funds, if available (although there can be no certainty), through strategic alliances that may require the Company to relinquish rights to certain of its compounds, or to discontinue its operations entirely.

Operating Activities. For the year ended December 31, 2018, operating activities utilized cash of $1,511,034, as compared to utilizing cash of $1,412,181 for the year ended December 31, 2017, to fund the Company's ongoing research and development activities and to fund its other ongoing operating expenses, including maintaining and developing its patent portfolio.

Investing Activities. For the years ended December 31, 2018 and 2017, the Company had no investing activities.

Financing Activities. For the year ended December 31, 2018, financing activities consisted of net proceeds from the sale of 9,000,000 common stock units on November 30, 2018, in the amount of $4,475,298 and $3,000 received from the exercise of stock options to acquire 20,000 shares of the Company's common stock at an exercise price of $0.15 per share. For the year ended December 31, 2017, financing activities consisted of the receipt of $1,000,000 and $1,500,000 of proceeds from the sale of 4,000,000 shares and 6,000,000 shares of the Company's common stock at $0.25 per share in closings occurring in January 2017 and April 2017, respectively. In addition, on July 6, 2017, the Company received $18,000 from a former director for the exercise of stock options to acquire 150,000 shares of the Company's common stock at an exercise price of $0.12 per share.

Principal Commitments

Effective October 18, 2013, the Company entered into a Materials Cooperative Research and Development Agreement (M-CRADA) with the National Institute of Neurological Disorders and Stroke (NINDS) of the National Institutes of Health (NIH) for a term of four years. The Surgical Neurology Branch of NINDS is conducting research characterizing a variety of compounds proprietary to the Company and is examining the potential of the compounds for anti-cancer activity, reducing neurological deficit due to ischemia and brain injury, and stabilizing catalytic function of misfolded proteins for inborn brain diseases. Under an M-CRADA, a party provides research material, in this case proprietary compounds from the Company's pipeline, for study by scientists at NIH. The exchange of material is for research only and does not imply any endorsement of the material on the part of either party. Under the M-CRADA, the NIH grants a collaborator an exclusive option to elect an exclusive or non-exclusive commercialization license.

On June 14, 2017, the Company executed Amendment No. 1 to the M-CRADA, pursuant to which the Company agreed to provide funding in the amount of $100,000 to the National Cancer Institute for use in acquiring technical, statistical and administrative support for research activities. The $100,000 amount was scheduled to be paid in two equal installments of $50,000, the first installment of which was paid, as scheduled, on July 9, 2017, and was charged to research and development costs in the consolidated statement of operations on such date. The second installment of $50,000 was scheduled to be paid on the June 14, 2018 anniversary date of the amendment and was accreted ratably through such date and included in research and development contract liabilities in the Company's consolidated balance sheet. Pursuant to revised and updated collaboration plans, on November 3, 2018, the NINDS and the Company agreed to a cancellation of the second installment payment of $50,000. Accordingly, the previously accreted charge of $50,000, of which $25,000 was recorded during the six months ended June 30, 2018, was reversed during the fourth quarter of the year ended December 31, 2018. During the years ended December 31, 2018 and 2017, $0 and $75,000, respectively, was included in research and development costs in the consolidated statement of operations.

On December 24, 2013, the Company entered into an agreement with NDA Consulting Corp. ("NDA") for consultation and advice in the field of oncology research and drug development. As part of the agreement, NDA also agreed to cause its president, Dr. Daniel D. Von Hoff, M.D., to become a member of the Company's Scientific Advisory Committee. The term of the agreement was for one year and provided for a quarterly cash fee of $4,000. In 2014, 2015, 2016, 2017 and 2018, the agreement had been automatically renewed on its anniversary date for an additional one-year term. Consulting and advisory fees charged to operations pursuant to this agreement were $16,000 during the years ended December 31, 2018 and 2017.

Effective September 14, 2015, the Company entered into a Collaboration Agreement with BioPharmaWorks, pursuant to which the Company engaged BioPharmaWorks to perform certain services for the Company. Those services include, among other things: (a) assisting the Company to (i) commercialize its products and strengthen its patent portfolio, (ii) identify large pharmaceutical companies with potential interest in the Company's product pipeline, and (iii) prepare and deliver presentations concerning the Company's products; (b) at the request of the Board of Directors, serving as backup management for up to three months should the Company's Chief Executive Officer and scientific leader be temporarily unable to carry out his duties; (c) being available for consultation in drug discovery and development; and (d) identifying providers and overseeing tasks relating to clinical use and commercialization of new compounds.

BioPharmaWorks was founded in 2015 by former Pfizer scientists with extensive multi-disciplinary research and development and drug development experience. The Collaboration Agreement was for an initial term of two years and automatically renews for subsequent annual periods unless terminated by a party not less than 60 days prior to the expiration of the applicable period. In connection with the Collaboration Agreement, the Company agreed to pay BioPharmaWorks a monthly fee of $10,000, subject to the right of the Company to pay a negotiated hourly rate in lieu of the monthly payment and agreed to issue to BioPharmaWorks certain equity-based compensation as described at Note 5. In November 2016, it was mutually agreed to suspend services and payments under the Collaboration Agreement, without extending its term, for the period from November 1, 2016 through March 31, 2017. The Collaboration Agreement resumed as scheduled on April 1, 2017 and was automatically renewed for additional one-year periods on September 13, 2017 and 2018, respectively. In April 2018, it was again mutually agreed to suspend services and payments under the Collaboration Agreement, without extending its term, for the period from February 1, 2018 through the September 13, 2019 anniversary date. In February 2019, the Company and BioPharmaWorks subsequently agreed to resume the Collaboration Agreement effective March 1, 2019. The Company recorded charges to operations pursuant to this Collaboration Agreement of $10,000 and $60,000, which were included in research and development costs in the consolidated statement of operations, during the years ended December 31, 2018 and 2017, respectively.

On March 22, 2018, the Company entered into a Patent Assignment and Exploitation Agreement (the "Agreement") with INSERM TRANSFERT SA, acting as delegatee of the French National Institute of Health and Medical Research ("INSERM"), for the assignment to the Company of INSERM'S interest in United States Patent No. 9,833,450 entitled "Oxabicyloheptanes and Oxabicycloheptenes for the Treatment of Depressive and Stress Disorders", which was filed with the United States Patent and Trademark Office in the name of INSERM and the Company as co-owners on February 19, 2015 and granted on May 12, 2017, and related patent applications and filings. INSERM is a French public institution dedicated to research in the field of health and medicine that had previously entered into a Material Transfer Agreement ("MTA") with the Company to allow INSERM to conduct research on the Company's proprietary compound LB-100 and/or its analogs for the treatment of depressive or stress disorders in humans. Pursuant to the Agreement, the Company has agreed to make certain milestone payments to INSERM aggregating up to $1,750,000 upon achievement of development milestones and up to $6,500,000 upon achievement of commercial milestones. The Company also agreed to pay INSERM certain commercial royalties on net sales of products attributed to the Agreement. The Company's current plan is to complete the validation process to evaluate LB-100 for the treatment of depressive or stress disorders in humans within three years; however, the exploitation of this patent for the treatment of depressive and stress disorders in humans will require substantial additional capital and/or a joint venture or other type of business arrangement with a pharmaceutical company with substantially greater capital and business resources than the Company. As there can be no assurances that the Company will be able to obtain the capital or business resources necessary to focus on the exploitation of this patent, it is uncertain when the Company may reach any of the development or commercialization milestones under the Agreement, if at all.

Effective April 2, 2018, the Company entered into a consulting agreement for a term of two years with Liberi Life Sciences Consultancy BV, located in The Netherlands, for consulting and advisory services with respect to sales and licensing, as well as the procurement of investors in China, Japan and South Korea (the "Consulting Agreement"). The Consulting Agreement provided for the payment of a fixed, one-time retainer of EURO 15,000 (US $18,348), which was paid on April 5, 2018, and 2.5% of the net payments received by the Company from sales of products or licensing activities arising directly and exclusively from leads generated by the advisor during the term of the Consulting Agreement, and any investors introduced to the Company by the advisor that results in an investment in the Company during the term of the Consulting Agreement. The Company recorded the payment of the retainer as a prepaid expense in the Company's consolidated balance sheet. The Company is amortizing the retainer payment over the two-year life of the Consulting Agreement, as a result of which the Company recorded a charge to operations of $6,881 during the year ended December 31, 2018. At December 31, 2018, the unamortized balance of the retainer payment was $11,468, of which $9,174 was classified as a current asset and $3,294 was classified as a non-current asset in the Company's consolidated balance sheet at such date.

Effective August 20, 2018 (the "Effective Date"), the Company and the Moffitt Cancer Center and Research Institute Hospital Inc., Tampa, Florida ("Moffitt") entered into an Exclusive License Agreement (the "License Agreement"). Pursuant to the License Agreement, Moffitt granted the Company an exclusive license under certain patents owned by Moffitt (the "Licensed Patents") relating to the treatment of MDS and a non-exclusive license under inventions, concepts, processes, information, data, know-how, research results, clinical data, and the like (other than the Licensed Patents) necessary or useful for the practice of any claim under the Licensed Patents or the use, development, manufacture or sale of any product for the treatment of MDS which would otherwise infringe a valid claim under the Licensed Patents. The Company is obligated to pay Moffitt a non-refundable license issue fee of $25,000 on the date on which the first patient is entered into a Phase 1b/2 clinical trial to be managed and conducted by Moffitt that is scheduled to begin during the quarter ending June 30, 2019. The Company is also obligated to pay Moffitt an annual license maintenance fee of $25,000 commencing on the first anniversary of the Effective Date and every anniversary thereafter until the Company commences payment of minimum royalty payments. The Company has also agreed to pay non-refundable milestone payments to Moffitt, which cannot be credited against earned royalties payable by the Company, based on reaching various clinical and commercial milestones aggregating $1,897,000, subject to reduction by 40% under certain circumstances relating to the status of Valid Claims, as such term is defined in the License Agreement.

The Company will be obligated to pay Moffitt earned royalties of 4% on worldwide cumulative net sales of royalty-bearing products, subject to reduction to 2% under certain circumstances, on a quarterly basis, with a minimum royalty payment of $50,000 in the first four years after sales commence, and $100,000 in year five and each year thereafter, subject to reduction by 40% under certain circumstances relating to the status of Valid Claims, as such term is defined in the License Agreement. The Company's obligation to pay earned royalties under the License Agreement commences on the date of the first sale of a royalty-bearing product, and shall automatically expire on a country-by-country basis on the date on which the last valid claim of the Licensed Patents expires, lapses or is declared invalid, and the obligation to pay any earned royalties under the License Agreement shall terminate on the date on which the last valid claim of the Licensed Patents expires, lapses, or is declared to be invalid in all countries.

Effective August 20, 2018, the Company and Moffitt also entered into a Clinical Trial Research Agreement (the "Clinical Trial Research Agreement") effective for a term of five years, unless terminated earlier by the Company pursuant to 30 days written notice. Pursuant to the Clinical Trial Research Agreement, Moffitt will conduct and manage a Phase 1b/2 clinical trial to evaluate the safety and therapeutic benefit of the Company's lead anti-cancer clinical compound LB-100 to be administered intravenously in patients with low or intermediate-1 risk MDS.

In early November 2018, the Company received approval from the FDA for its Investigational New Drug (IND) Application to conduct a Phase 1b/2 clinical trial to evaluate the safety and therapeutic benefit of the Company's lead clinical compound, LB-100, in patients with low and intermediate-1 risk myelodysplastic syndrome (MDS) who have failed or are intolerant of standard treatment. The clinical trial will be managed and conducted by Moffitt Cancer Center in Tampa, Florida. This clinical trial is currently expected to begin during the quarter ending June 30, 2019, to complete patient accrual over a period of two years, and to take approximately three years to complete.

On September 12, 2018, the Company entered into a work order agreement with Theradex to monitor the Phase 1b/2 clinical trial scheduled to begin at Moffitt during the quarter ending June 30, 2019. The clinical trial will be managed and conducted by Moffitt to evaluate the safety and therapeutic benefit of the Company's lead anti-cancer clinical compound LB-100 administered intravenously in patients with low or intermediate-1 risk MDS. This work order agreement became effective in August 2018 and is estimated to be completed by December 2021. Costs under this work order agreement are estimated to be approximately $954,000. As of December 31, 2018, costs of $11,906 have been incurred pursuant to this work order agreement.

Off-Balance Sheet Arrangements

At December 31, 2018, the Company did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The Company's consolidated financial statements and notes thereto and the related report of its independent registered public accounting firm are attached to this Annual Report beginning on page F-1.

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

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

Management's Annual Report on Internal Controls Over Financial Reporting

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

The Company's management, consisting of its chief executive officer and chief financial officer, has evaluated the Company's internal control over financial reporting as of December 31, 2016 based on the 2013 Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations (COSO) of the Treadway Commission. Based on this assessment, the Company's management has concluded that its internal control over financial reporting was effective as of December 31, 2018.

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

Changes In Internal Controls Over Financial Reporting

There were no changes in our internal controls over financial reporting during or subsequent to the fourth quarter of the year ended December 31, 2018 that materially affected or are reasonably likely to materially affect the Company's internal controls over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table and text set forth the names of all directors and executive officer of the Company as of December 31, 2018. 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 officer or persons nominated or charged by the 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.

The Company's directors and executive officer are as follows:

Name	Age	Position(s) Held with the Registrant
Dr. John S. Kovach	82	President, Chief Executive Officer, Chief Financial Officer and Director
Dr. Philip F. Palmedo	84	Director
Dr. Stephen J. Forman	70	Director
Dr. Winson Sze Chun Ho	34	Director
Dr. Yun Yen	64	Director

Biographies of Directors and Executive Officer

Dr. John S. Kovach

Dr. John S. Kovach founded the Company in August 2005 and is its President, Chief Executive Officer, Chief Financial Officer and a member of its Board of Directors. He received a B.A. (cum laude) from Princeton University and an M.D. (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 at the National Institute of Arthritis and Metabolic diseases studying control of gene expression in bacterial systems.

Dr. Kovach was recruited to the State University of New York at Stony Brook ("SUNY – Stony Brook") in Stony Brook, New York in 2000 to found the Long Island Cancer Center (now named the Stony Brook University Cancer Center). From 1994 to 2000, Dr. Kovach was Executive Vice President for Medical and Scientific Affairs at the 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, Dr. Kovach 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, M.D., Ph.D., 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.

Effective February 23, 2017, Dr. Kovach retired from his part-time (50%) academic position at SUNY – Stony Brook, as a result of which he has been devoting 100% of his time to the Company's business activities since that date.

Dr. Philip F. Palmedo

Philip F. Palmedo, Ph.D., is a physicist, entrepreneur and corporate manager. Dr. Palmedo joined the Company's Board of Directors on June 30, 2006. He founded and served as Chairman of the International Resources Group (IRG), an international consultancy in energy, natural resources and economic development. IRG was bought by L3 Communications in 2008. Dr. Palmedo designed and was the first President of the Long Island Research Institute formed by Brookhaven National Laboratory, Cold Spring Harbor Laboratory, and SUNY – Stony Brook to facilitate the commercialization of technologies. In 1988, Dr. Palmedo joined in the formation of Kepler Financial Management, Ltd., a quantitative financial research and trading company. He was President and Managing Director until 1991, when Renaissance Technologies Corporation acquired the company.

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

Dr. Stephen J. Forman

Stephen J. Forman, M.D., is an internationally recognized expert in hematologic malignancies and bone marrow transplantation and is a leader in preclinical and clinical cancer research. He is co-editor of Thomas' Hematopoietic Cell Transplantation, a definitive textbook for clinicians, scientists and health care professionals. Dr. Forman is the Francis and Kathleen McNamara Distinguished Chair in Hematology and Hematopoietic Cell Transplantation at the City of Hope Comprehensive Cancer Center, a position he has held since 1987.

In nearly 40 years at City of Hope, Dr. Forman has been instrumental in advancing the survival rates for patients suffering from cancers of the blood and immune system such as leukemia, lymphoma and myeloma.

As Director of the T Cell Immunotherapy Research Laboratory, his current research is focused on cancer immunotherapy, using the body's own immune system to attack cancer. Pharmacological enhancement of patients' immune responses to their cancers is of special interest to the Company as the enzyme target of its lead clinical compound, LB-100, has been reported recently to be critical to immune function. Much of Dr. Forman's current work centers on T cells and their cancer-fighting potential.

Dr. Winson Sze Chun Ho

Winson Sze Chun Ho, M.D., is presently a pediatric neurosurgery fellow at the University of Utah School of Medicine. After receiving his M.D. from Yale University School of Medicine in 2011, Dr. Ho had four years of training in Neurosurgery at the University of Virginia, Charlottesville, Virginia. Prior to his final year as chief resident at the University of Virginia, Dr. Ho spent three years doing molecular pharmacologic research on methods to enhance the efficacy of cancer therapy as a Clinical and Research Fellow in the Surgical Neurology Branch, National Institute of Neurological Disorders and Stroke, National Institutes of Health. His research included several studies of the Company's lead clinical compound, the protein phosphatase 2A inhibitor LB-100, including the demonstration that LB-100 potentiates the effectiveness of the immune checkpoint blocker PD-1 in several preclinical models. These results were recently published in the scientific journal *Nature Communications*.

Dr. Yun Yen

Yun Yen, M.D., Ph.D., F.A.C.P. is a physician, scientist, innovator, and philanthropist. He is widely regarded as an expert in ribonucleotide reductase, a critical target in cancer therapy and diagnostics. He is President Emeritus of Taipei Medical University (TMU) and Chair Professor of the Ph.D. Program for Cancer Biology and Drug Discovery. Prior to TMU, Dr. Yen was the Allen and Lee Chao Endowed Chair in Developmental Cancer Therapeutics, Chair of Molecular Pharmacology Department, Associate Director for Translational Research, and Co-Director of the Developmental Cancer Therapeutics Program at the City of Hope NCI-designated Comprehensive Cancer Center, Duarte California. He has published more than 300 peer-reviewed articles, holds over 60 patents, and has commercialized multiple methodologies involving nanoparticles, small and large molecule drugs, biomarkers, stem cells, and medical devices. Dr. Yen also founded philanthropic organizations aimed at serving the global cancer community and holds membership in numerous professional societies. He serves on the boards of Fulgent Genetics and Tanvex BioPharma Inc.

SCIENTIFIC ADVISORY COMMITTEE

The Scientific Advisory Committee (the "Committee") was established to advise management of the Company in three areas: human molecular pathology; the clinical management of human brain tumors; and medicinal chemistry. The Company's objective is to meet with the Committee as a group annually, with some members participating via telephone conference. The Committee members have been apprised of the Company's general objectives and several of the specific challenges and leads for developing improved therapies for human brain tumors. The Committee members do not serve in any management capacity with the Company. The members of the Company's Committee currently are:

Iwao Ojima, B.S., M.S., Ph.D.

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

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

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

Daniel D. Von Hoff, M.D.

Dr. Von Hoff is currently Physician in Chief, Distinguished Professor and Director of the Clinical Translational Research Division at the Translational Genomics Research Institute in Phoenix, Arizona. He is also Chief Scientific Officer for US Oncology and for Scottsdale Healthcare's Clinical Research Institute. He holds an appointment as Professor of Medicine, Mayo Clinic, Scottsdale, Arizona. Dr. Von Hoff is a Fellow of the American College of Physicians.

Dr. Von Hoff's major interest is in the development of new anticancer agents, both in the clinic and in the laboratory. He and his colleagues were involved in the beginning of the development of many of the agents that are now used routinely, including mitoxantrone, fludarabine, paclitaxel, docetaxel, gemcitabine, irinotecan, nelarabine, capecitabine and lapatinib. At present, he and his colleagues are concentrating on the development of molecularly targeted therapies, particularly for patients with advanced pancreatic cancer.

Dr. Von Hoff has published more than 620 papers, 137 book chapters and over 1,050 abstracts. Dr. Von Hoff received the 2010 David A. Karnofsky Memorial Award from the American Society of Clinical Oncology for his outstanding contributions to cancer research leading to significant improvement in patient care.

Dr. Von Hoff was appointed to President Bush's National Cancer Advisory Board from 2004 to 2010. Dr. Von Hoff is the past President of the American Association for Cancer Research (the world's largest cancer research organization), a Fellow of the American College of Physicians, and a member and past board member of the American Society of Clinical Oncology. He is a founder of ILEX™ Oncology, Inc. (acquired by Genzyme in 2004 after Ilex had two agents, alemtuzumab and clofarabine, approved by the FDA for patients with leukemia). Dr. Von Hoff is founder and the Editor Emeritus of Investigational New Drugs – The Journal of New Anticancer Agents; and, Editor-in-Chief of Molecular Cancer Therapeutics. He is a co-founder of the AACR/ASCO Methods in Clinical Cancer Research Workshop.

Audit Committee

The Company does not presently have an audit committee. The Board of Directors acts in that capacity and has determined that it does not currently have a person qualifying as an audit committee financial expert serving on the Company's Board of Directors.

Code of Ethics

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

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

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

To the Company's knowledge, based solely on its review of the copies of the Section 16(a) reports furnished to the Company and any 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 2018.

ITEM 11. EXECUTIVE COMPENSATION

Option Grants in 2017 and 2018 - Named Executive Officer

None.

Aggregated Option Exercises in 2017 and 2018 – Named Executive Officer

None.

Option Values at December 31, 2017 and at 2018 - Named Executive Officer

None.

Employment Agreements; Compensation

The Company has not entered into any employment agreements with management. Any future compensation arrangements are subject to the approval of the Board of Directors.

During the years ended December 31, 2017 and 2018, the Company paid Dr. John S. Kovach, the Company's Chief Executive Officer and Chief Financial Officer, an annual salary of $60,000. Prior to February 23, 2017, Dr. Kovach devoted approximately 50% of his time to his academic commitments at SUNY – Stony Brook and approximately 50% of his time to the Company's business activities. Effective February 23, 2017, Dr. Kovach retired from his part-time (50%) academic position at SUNY – Stony Brook, as a result of which he has been devoting 100% of his time to the Company's business activities since that date.

Dr. Kovach is not compensated separately for his service on the Company's Board of Directors. Dr. Kovach is reimbursed for out-of-pocket expenses.

Consulting Agreements

See "ITEM 16. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS, AND DIRECTOR INDEPENDENCE – Related Party Transactions" for disclosures with respect to consulting agreements involving directors and related parties.

Board of Director Compensation

Effective May 13, 2016, in conjunction with his appointment as a director of the Company, the Company granted to Dr. Stephen J. Forman stock options to purchase an aggregate of 200,000 shares of common stock under the 2007 Plan, exercisable for a period of five years from vesting date at $0.16 per share, which was the fair market value of the Company's common stock on such date. One-half of such stock option (100,000 shares) vested on May 13, 2016 and the remaining one-half of such stock option (100,000 shares) vested on May 13, 2017. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $31,180 ($0.1559 per share), of which $15,590 was attributable to the stock options fully-vested on May 13, 2016 and was therefore was charged to operations on that date. The remaining unvested portion of the fair value of the stock options was charged to operations ratably from May 13, 2016 through May 13, 2017. During the year ended December 31, 2017, the Company recorded a charge to operations of $5,681 with respect to these stock options.

Effective October 16, 2017, in connection with his continuing role as a member of the Company's Board of Directors, Dr. Philip F. Palmedo was granted fully-vested stock options to purchase 50,000 shares of the Company's common stock. The stock options are exercisable for a period of five years from the date of grant at $0.15 per share, which was the fair market value of the Company's common stock on such date. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $7,499 ($0.1500 per share), which was charged to operations on the date of grant.

Effective October 16, 2017, in connection with his continuing role as a member of the Company's Board of Directors, Dr. Stephen J. Forman was granted fully-vested stock options to purchase 50,000 shares of the Company's common stock. The stock options are exercisable for a period of five years from the date of grant at $0.15 per share, which was the fair market value of the Company's common stock on such date. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $7,499 ($0.1500 per share), which was charged to operations on the date of grant.

Effective August 4, 2018, in conjunction with their appointments as directors of the Company, the Company granted to Dr. Winson Sze Chun Ho and Dr. Yun Yen stock options for each to purchase an aggregate of 200,000 shares of common stock, exercisable for a period of five years from the vesting date at $0.28 per share, which was the approximate fair market value of the Company's common stock on such date. One-half of such stock options (100,000 shares each) vested on August 4, 2018 and the remaining one-half of such stock options (100,000 shares each) will vest on August 4, 2019. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $104,920 ($0.2623 per share), of which $52,460 was attributable to the stock options fully-vested on August 4, 2018 and was therefore was charged to operations on that date. The remaining unvested portion of the fair value of the stock options will be charged to operations ratably from August 4, 2018 through August 4, 2019. During the year ended December 31, 2018, the Company recorded a charge to operations of $73,874 with respect to these stock options.

DIRECTOR COMPENSATION TABLE

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($) (1)	Non-Equity Incentive Plan Compensation ($)	Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)(2)	Total ($)
John S. Kovach	2018	$ 60,000	0	0	0	0	0	0	0
Director (3)	2017	$ 60,000	0	0	0	0	0	0	0
	2016	$ 60,000	0	0	0	0	0	0	0
Philip F. Palmedo	2018	0	0	0	$ 0	0	0	0	0
Director	2017	0	0	0	$ 7,499	0	0	0	0
	2016	0	0	0	$ 52,604	0	0	0	0
Kathleen P. Mullinix	2018	0	0	0	0	0	0	0	0
Director (4)	2017	0	0	0	0	0	0	0	0
	2016	0	0	0	$ 17,535	0	0	0	0
Stephen J. Forman	2018	0	0	0	$ 0	0	0	0	0
Director	2017	0	0	0	$ 7,499	0	0	0	0
	2016	0	0	0	$ 31,180	0	0	0	0
Winson Sze Chun Ho Director	2018	0	0	0	$ 52,460	0	0	0	0
Yun Yen Director	2018	0	0	0	$ 52,460	0	0	0	0

(1) Consists of grant date fair value of option award calculated pursuant to the Black-Scholes option-pricing model.

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

(3) Dr. Kovach is also the Company's President, Chief Executive officer and Chief Financial Officer.

(4) Dr. Mullinix resigned from the Company's Board of Directors on November 22, 2016.

Scientific Advisory Committee Compensation

On December 24, 2013, the Company entered into an agreement with NDA Consulting Corp. ("NDA") for consultation and advice in the field of oncology research and drug development. As part of the agreement, NDA also agreed to cause its president, Dr. Daniel D. Von Hoff, M.D., to become a member of the Company's Scientific Advisory Committee. In connection with this agreement, NDA was granted stock options to purchase 100,000 shares of the Company's common stock, which vested 25,000 shares on June 24, 2014, 2015, 2016 and 2017, exercisable for a period of five years from the date of grant at $0.13 per share, which was the fair market value of the Company's common stock on the grant date. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be $12,960 ($0.13 per share). The Company re-measures the non-vested options to fair value at the end of each reporting period. During the year ended December 31, 2017, the Company recorded a charge to operations of $2,492 with respect to these stock options.

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

The following table sets forth, as of March 1, 2019, certain information regarding beneficial ownership of the Company's common stock (the only class of the Company's voting equity securities issued and outstanding) by (i) each person or entity who is known by the Company to own beneficially more than 5% of the Company's outstanding shares of common stock, (ii) each of the Company's directors, and (iii) all directors and executive officers of the Company as a group. As of March 1, 2019, there were 67,045,814 shares of the Company's common stock issued and outstanding. In computing the number and percentage of shares beneficially owned by a person, shares of common stock that a person has a right to acquire within sixty (60) days of March 1, 2019 pursuant to stock options, warrants, convertible preferred stock or other rights are counted as outstanding, while these shares are not counted as outstanding for computing the percentage ownership of any other person. Unless otherwise indicated, the address for each stockholder listed in the following table is c/o Lixte Biotechnology Holdings, Inc., 248 Route 25A, No. 2, East Setauket, New York 11733. This table is based upon information supplied by the Company's directors, officers and principal stockholders and reports filed with the Securities and Exchange Commission.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percent of Class
Officers, Directors and 5% stockholders		
Dr. John S. Kovach 248 Route 25A, No. 2 East Setauket, New York 11733	9,114,503	13.6%
Dr. Philip F. Palmedo 248 Route 25A, No. 2 East Setauket, New York 11733	1,766,020(1)	2.6%
Dr. Stephen J. Forman 248 Route 25A, No. 2 East Setauket, New York 11733	472,500(2)	0.7%
Dr. Yun Yen 248 Route 25A, No. 2 East Setauket, New York 11733	200,000	0.3%
Dr. Winson Sze Chun Ho 248 Route 25A, No. 2 East Setauket, New York 11733	200,000(11)	0.3%
All officers and directors as a group (three persons)	11,753,023	17.2%
John and Barbara Kovach 2015 Trust Eric J. Forman, Trustee 401 Park Avenue South, 10th Floor New York, New York 10016	8,000,000(3)	11.9%
Eric J. Forman 401 Park Avenue South, 10th Floor New York, New York 10016	8,320,000(4)	12.4%
Gil Schwartzberg 5500 Military Trail, Suite 22, Box 356 Jupiter, Florida 33458	11,618,739(5)	16.1%
Dr. Debbie Schwartzberg 5500 Military Trail, Suite 22, Box 356 Jupiter, Florida 33458	9,874,845(6)	13.86%
Dr. Arthur and Jane Riggs 4852 Saint Andres Avenue La Verne, California 91750	11,745,000(7)	16.2%
Robert and Susan Greenberg 228 Manhattan Beach Boulevard Manhattan Beach, California 90266	7,650,000(8)	11.1%
Lalit R. Bahl and Kavit K. Kinra 3 Pheasant Run Setauket, New York 11733	6,000,000	8.8%
Lawrence J. Goldstein 1865 Palmer Avenue Larchmont, NY 10538	4.000,000(9)	5.8%
Hung Tak Ho Mayfair by the Sea II Tower T8, 1/F, Unit A 21 Fo Chun Road Pak ShekKok Taipo NT, Hong Kong SAR	6,000,000(10)	8.9%

(1) Includes of 1,100,000 shares of common stock and stock warrants to purchase 100,000 shares of common stock owned by the Philip Palmedo Partnership, and 66,020 shares of common stock and stock options to purchase 500,000 shares of common stock owned by Dr. Philip Palmedo. Dr. Palmedo, as the general partner of the Philip Palmedo Partnership, has voting, dispositive and investment control with respect to the common stock and common stock warrants owned by the partnership. All stock options and common stock warrants are immediately exercisable or within 60 days.

(2) Includes of 22.500 shares of common stock owned by Dr. Stephen Forman and stock options to purchase 250,000 shares of common stock which are immediately exercisable or within 60 days. Also includes 100,000 shares of common stock and stock warrants to purchase 100,000 shares of common stock owned by the Stephen Forman Living Trust dated 12/16/98. Stephen Forman is trustee of the trust and holds voting and dispositive power over the common stock and common stock warrants owned by the trust.

(3) Includes 8,000,000 shares of common stock transferred by John Kovach and his wife, Barbara C.H. Kovach, as grantors, to the John and Barbara Kovach 2015 Trust, an irrevocable trust dated July 6, 2015. The primary beneficiaries of the trust are the two adult daughters of John and Barbara Kovach. Eric J. Forman is the trustee of the John and Barbara Kovach 2015 Trust.

(4) Includes 100,000 shares of common stock owned by Eric J. Forman, stock options to purchase 200,000 shares of common stock and stock warrants to purchase 20,000 shares of common stock. Eric Forman is the husband of Julie (Schwartzberg) Forman, the son-in-law of Gil and Debbie Schwartzberg, and the trustee of the John and Barbara Kovach 2015 Trust. Also includes 8,000,000 shares of common stock owned by the John and Barbara Kovach 2015 Trust, as to which Eric Forman, as trustee, has voting, dispositive and investment control. Excludes 1,120,000 shares of common stock, stock options to purchase 1,750,000 shares of common stock and common stock warrants to purchase 500,000 of common stock owned by the Julie Schwartzberg Trust, as to which Julie (Schwartzberg) Forman is the beneficiary, and as to which Eric Forman disclaims beneficial ownership or control. Also excludes 30,000 shares of common stock owned by the Julie Forman 2015 Trust, the beneficiary of which is Cole Forman, the son of Eric and Julie Forman, as to which David Sterling, as trustee, has voting, dispositive and investment control. Also excludes 100,000 shares of common stock owned by each of the Savannah Sterling Trust, Amanda Sterling Trust, Daniel Sterling Trust and Charles Sterling Trust, as to which Julie Forman is the trustee. All stock options and stock warrants are immediately exercisable or within 60 days.

(5) Includes 2,255,556 shares of common stock owned by the Gil & Debbie Schwartzberg Family Trust dated November 19, 2003, Gil Schwartzberg Separate Property, as to which Gil Schwartzberg, as trustee, has voting, dispositive and investment control, and stock options to purchase 500,000 shares of common stock owned by Gil Schwartzberg. All stock options and common stock warrants are immediately exercisable or within 60 days.

Also includes the following:

- 855,068 shares of common stock owned by the Gil Schwartzberg IRA;
- 638,115 shares of common stock owned by Continuum Capital Partners, LP, as to which Gil Schwartzberg has sole voting, dispositive and investment control;
- 1,120,000 shares of common stock, stock options to purchase 1,750,000 shares of common stock and common stock warrants to purchase 500,000 shares of common stock owned by the Julie Schwartzberg Trust, as to which Gil Schwartzberg is the co-trustee;
- 1,150,000 shares of common stock, stock options to purchase 1,750,000 shares of common stock and common stock warrants to purchase 500,000 shares of common stock owned by the David N. Sterling Trust, as to which Gil Schwartzberg is the co-trustee;
- 100,000 shares of common stock owned by each of the Savannah Sterling Trust, Amanda Sterling Trust, Daniel Sterling Trust and Charles Sterling Trust, as to which Julie Forman is the trustee;
- 200,000 shares of common stock owned by the Julie Forman 2015 Trust, David Sterling trustee.

Excludes the following:

- 2,504,845 shares of common stock owned by the Gil & Debbie Schwartzberg Family Trust dated November 19, 2003, Debbie Schwartzberg Separate Property, the wife of Gil Schwartzberg, as to which Gil Schwartzberg disclaims beneficial ownership or control.

(6) Includes 2,504,845 shares of common stock owned by the Gil & Debbie Schwartzberg Family Trust dated November 19, 2003, Debbie Schwartzberg Separate Property, as to which Debbie Schwartzberg, as trustee, has voting, dispositive and investment control. All stock options and common stock warrants are immediately exercisable or within 60 days.

Also includes the following:

- 1,120,000 shares of common stock, stock options to purchase 1,750,000 shares of common stock and common stock warrants to purchase 500,000 shares of common stock owned by the Julie Schwartzberg Trust, as to which Debbie Schwartzberg is the co-trustee;
- 1,150,000 shares of common stock, stock options to purchase 1,750,000 shares of common stock and common stock warrants to purchase 500,000 shares of common stock owned by the David N. Sterling Trust, as to which Debbie Schwartzberg is the co-trustee;
- 100,000 shares of common stock owned by each of the Savannah Sterling Trust, Amanda Sterling Trust, Daniel Sterling Trust and Charles Sterling Trust, as to which Julie Forman is the trustee;
- 200,000 shares of common stock owned by the Julie Forman 2015 Trust, David Sterling trustee.

Excludes the following:

- 2,255,556 shares of common stock and stock options to purchase 500,000 shares of common stock owned by the Gil & Debbie Schwartzberg Family Trust dated November 19, 2003, Gil Schwartzberg Separate Property, as to which Debbie Schwartzberg, the wife of Gil Schwartzberg, disclaims beneficial ownership or control;
- 855,068 shares of common stock owned by the Gil Schwartzberg IRA;
- 638,115 shares of common stock owned by Continuum Capital Partners, LP, as to which Gil Schwartzberg has sole voting, dispositive and investment control.

(7) Includes 6,110,000 shares of common stock and 4,375,000 shares of common stock issuable upon conversion of 350,000 shares of Series A Convertible Preferred Stock owned by the Arthur and Jane Riggs 1990 Revocable Trust. Arthur Riggs and his wife, Jane Riggs, are co-trustees of the trust and share voting and dispositive power over the shares of preferred stock. The shares of Series A Convertible Preferred Stock were acquired on March 17, 2015 and January 15, 2016, are non-voting, and are immediately convertible into common stock.

(8) Consists of 5,650,000 shares of common stock owned by the Greenberg Family Trust dated May 3, 1988 and stock warrants to purchase 2,000,000 shares of common stock. The trust is a revocable trust, and Arthur Greenberg and his wife, Susan Greenberg, are co-trustees of the trust and share voting and dispositive power over the shares of common stock.

(9) Includes 1,000,000 shares of common stock owned by Lawrence J. Goldstein and common stock warrants to purchase 1,000,000 shares of common stock owned by Lawrence J. Goldstein. Also includes 1,000,000 shares of common stock owned by Santa Monica Partners, L.P. and common stock warrants to purchase 1,000,000 shares of common stock owned by the Santa Monica Partners, L.P. Lawrence J. Goldstein is the sole managing member of the general partner, SMP Asset Management LLC.

(10) Excludes stock options to purchase 200,000 shares of common stock owned by Dr. Winson Sze Chun Ho, a director of the Company and the son of Hung Tak Ho, as to which Hung Tak Ho disclaims beneficial ownership or control.

(11) Excludes 6,000,000 shares of common stock owned by Hung Tak Ho, the father of Dr. Winson Sze Chun Ho, a director of the Company, as to which Dr. Winson Sze Chun Ho disclaims beneficial ownership or control.

Information with respect to securities authorized for issuance under equity compensation plans is provided at “ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS”.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS, AND DIRECTOR INDEPENDENCE

(a) Related Party Transactions

The Company’s principal office facilities are being provided without charge by Dr. John S. Kovach, the Company’s President, Chief Executive Officer and Chief Financial Officer. Such costs were not material to the Company’s consolidated financial statements and accordingly, have not been reflected therein.

On September 12, 2007, the Company entered into a consulting agreement with Gil Schwartzberg for Mr. Schwartzberg to provide financial advisory and consulting services to the Company with respect to financing matters, capital structure and strategic development, and to assist management in communications with investors and shareholders. Mr. Schwartzberg is currently a significant stockholder of the Company and continues to be a consultant to the Company. Consideration under this consulting agreement, including subsequent extensions, has been paid exclusively in the form of stock options. On January 28, 2014, the Company entered into a second amendment to its consulting agreement with Mr. Schwartzberg to extend it to January 28, 2019.

On August 2, 2018, with the approval of the Board of Directors, the Company entered into a third amendment to its consulting agreement with Mr. Schwartzberg to extend it to January 28, 2024. In conjunction with such amendment, the Company extended the expiration date of the fully-vested stock options for 4,000,000 shares of common stock previously granted to Mr. Schwartzberg, from January 28, 2019 to January 28, 2024. The fair value of the extension of these vested stock options, as calculated pursuant to the Black-Scholes option-pricing model, was measured for accounting purposes as the difference in the fair value of the stock options immediately before and immediately after the extension date, and was determined to be $711,738 ($0.1779 per share), which was charged to general and administrative costs in the consolidated statement of operations on the extension date.

Legal and consulting fees charged to operations for services rendered by the Eric Forman Law Office were $48,000 for the years ended December 31, 2018 and 2017. In addition, effective October 16, 2017, in connection with his continuing role as a consultant to the Company, Eric Forman was granted fully-vested stock options to purchase 100,000 shares of the Company's common stock. The stock options are exercisable for a period of five years from the date of grant at $0.15 per share, which was the fair market value of the Company's common stock on such date. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $14,997 ($0.1500 per share), which was charged to operations on the date of grant

Eric J. Forman is the son-in-law of Gil Schwartzberg, a significant stockholder of and consultant to the Company, and is the son of Dr. Stephen J. Forman, who was elected to the Company's Board of Directors on May 13, 2016. Julie Forman, the wife of Eric Forman and the daughter of Gil Schwartzberg, is Vice President of Morgan Stanley Wealth Management, where the Company maintains a banking relationship.

See "ITEM 11. EXECUTIVE COMPENSATION - Directors Compensation" for disclosures with respect to compensation (both cash and equity-based) to certain of the Company's directors for services.

(b) Director Independence

The Company considers Dr. Palmedo, Dr. Forman, Dr. Yen and Dr. Ho to be "independent directors", as such term is defined by the NASDAQ Rules or Rule 10A-3 of the Exchange Act.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Weinberg & Company, P.C. acted as the Company's independent registered public accounting firm for the years ended December 31, 2017 and 2018 and for the interim periods in such fiscal years. The following table shows the fees that were incurred by the Company for audit and other services provided by Weinberg & Company, P.C. for the years ended December 31, 2017 and 2018.

	Years Ended December 31,	
	2017	**2018**
Audit Fees[1]	$ 61,960	$ 65,980
Audit-Related Fees[2]	—	—
Tax Fees[3]	14,352	12,264
All Other Fees[4]	—	—
Total	$ 76,312	$ 78,244

(1) Audit fees represent fees for professional services provided in connection with the audit of the Company's annual financial statements and the review of its financial statements included in the Company's Quarterly Reports on Form 10-Q and services that are normally provided in connection with statutory or regulatory filings.

(2) Audit-related fees represent fees for assurance and related services that are reasonably related to the performance of the audit or review of the Company's financial statements and not reported above under "Audit Fees".

(3) Tax fees represent fees for professional services related to tax compliance, tax advice and tax planning.

(4) All other fees represent fees related to Sarbanes-Oxley compliance work.

All audit related services, tax services and other services rendered by Weinberg & Company, P.C. were pre-approved by the Company's Board of Directors. The Board of Directors has adopted a pre-approval policy that provides for the pre-approval of all services performed for the Company by its independent registered public accounting firm.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) List of documents filed as part of this report:

(1) Financial Statements

Reference is made to the Index to Financial Statements on page F-1, where these documents are listed.

(2) Financial Statement Schedules

The financial statement schedules have been omitted because the required information is not applicable, or not present in amounts sufficient to require submission of the schedules, or because the information is included in the financial statements or notes thereto.

(3) Exhibits

See (b) below.

(b) Exhibits:

A list of exhibits required to be filed as part of this Annual Report on Form 10-K is set forth in the Index to Exhibits, which is presented elsewhere in this document, and is incorporated herein by reference.

ITEM 16. FORM 10-K SUMMARY

None

SIGNATURES

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

Date: March 25, 2019

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
(Registrant)

By: */s/ JOHN S. KOVACH*
Name: John S. Kovach
Title: President, Chief Executive Officer and Chief Financial 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	President, Chief Executive Officer and Chief Financial Officer Principal Financial and Accounting Officer and Director	March 25, 2019
/s/ PHILIP F. PALMEDO Philip F. Palmedo	Director	March 25, 2019
/s/ STEPHEN J. FORMAN Stephen J. Forman	Director	March 25, 2019
/s/ WINSON SZE CHUN HO Winson Sze Chun Ho	Director	March 25, 2019
/s/ YUN YEN Yun Yen	Director	March 25, 2019

INDEX TO EXHIBITS

Exhibit Number	Description of Document
2.1	Share Exchange Agreement dated as of June 8, 2006 among the Company, John S. Kovach and Lixte Biotechnology, Inc.[1]
3.1	Certificate of Incorporation, as filed with the Delaware Secretary of State on May 24, 2005.[2]
3.2	Certificate of Amendment of Certificate of Incorporation.[3]
3.3	Certificate of Designations for the Company's Series A Convertible Preferred Stock.[6]
3.4	Certificate of Amendment of Certificate of Designations of the Series A Convertible Preferred Stock[8]
3.6	Bylaws.[2]
10.1	Master Agreement between Lixte Biotechnology Holdings, Inc. and Theradex Systems, Inc. dated January 12, 2010.[4]
10.2	Materials Cooperative Research and Development Agreement between Lixte Biotechnology Holdings, Inc. and the National Institute of Neurological Disorders and Stroke dated October 18, 2013.[5]
10.3	Scientific Advisory Board Agreement between Lixte Biotechnology Holdings, Inc. and NDA Consulting Corp. dated December 24, 2013.[5]
10.4	Collaboration Agreement between Lixte Biotechnology Holdings, Inc. and BioPharmaWorks LLC effective September 14, 2015.[7]
10.5	Form of First Warrant to purchase common stock issued to BioPharmaWorks LLC dated September 14, 2015.[7]
10.6	Form of Second Warrant to purchase common stock issued to BioPharmaWorks LLC dated September 14, 2015.[7]
10.7	Form of Securities Purchase Agreement dated as of February 24, 2017 between the Company and Lalit Bahl.[9]
10.8	Form of Securities Purchase Agreement dated as of April 3, 2017 between the Company and Hung Tak Ho.[10]
10.9**	Consulting Agreement between Liberi Life Sciences Consultancy BV and Lixte Biotechnology Holdings, Inc. dated and effective as of April 2, 2018.[11]
10.10	Clinical Trial Research Agreement between H. Lee Moffitt Cancer Center and Research Institute Hospital, Inc. and Lixte Biotechnology Holdings, Inc. dated and effective as of August 20, 2018.[12]
10.11	Exclusive License Agreement between H. Lee Moffitt Cancer Center and Research Institute Hospital, Inc. and Lixte Biotechnology Holdings, Inc. dated and effective as of August 20, 2018 (certain portions of this exhibit have been omitted based on a request for confidential treatment filed by the Company with the Securities and Exchange Commission that was granted on September 17, 2018).[12]
10.12	Form of Warrant to Purchase Common Stock of Llxte Biotechnology Holdings, Inc. (issued in connection with common stock unit rights offering that closed on November 30, 2018).[13]
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.
101.INS***	XBRL Instance Document
101.SCH***	XBRL Taxonomy Extension Schema Document
101.CAL***	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB***	XBRL Taxonomy Extension Label Linkbase Document
101.PRE***	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF***	XBRL Taxonomy Extension Definition Linkbase Document

1 Filed as an Exhibit to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on July 7, 2006 and incorporated herein by reference.

2 Filed as an Exhibit to the Company's Registration Statement on Form 10-SB, as filed with the Securities and Exchange Commission on August 3, 2005 and incorporated herein by reference.

3 Filed as Appendix A to the Company's Information Statement, as filed with the Securities and Exchange Commission on September 20, 2006 and incorporated herein by reference.

4 Filed as an Exhibit to the Company's Annual Report on Form 10-K, as filed with the Securities and Exchange Commission on March 15, 2013 and incorporated herein by reference.

5 Filed as an Exhibit to the Company's Annual Report on Form 10-K, as filed with the Securities and Exchange Commission on March 21, 2014 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 March 18, 2015 and incorporated herein by reference.

7 Filed as an Exhibit to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on September 18, 2015 and incorporated herein by reference.

8 Filed as an Exhibit to the Company's Annual Report on Form 10-K, as filed with the Securities and Exchange Commission on March 28, 2016 and incorporated herein by reference.

9 Filed as an Exhibit to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on February 28, 2017 and incorporated herein by reference.

10 Filed as an Exhibit to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on April 10, 2017 and incorporated herein by reference.

11 Filed as an Exhibit to the Company's Quarterly Report on Form 10-Q, as filed with the Securities and Exchange Commission on August 2, 2018 and incorporated herein by reference.

12 Filed as an Exhibit to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on August 23, 2018 and incorporated herein by reference.

13 Filed as an Exhibit to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on December 5, 2018 and incorporated herein by reference.

* Filed herewith.

** Each of these Exhibits constitutes a management contract, compensatory plan or other arrangement.

*** In accordance with Regulation S-T, the XBRL related information on Exhibit No. 101 to the Annual Report on Form 10-K shall be deemed "furnished" but not "filed".

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
(INCLUDING REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM)

Years Ended December 31, 2018 and 2017

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Lixte Biotechnology Holdings, Inc. and subsidiary (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations, stockholders' equity and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2018 and 2017, and the results of its consolidated operations and its consolidated cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1, the Company has no recurring source of revenue and has experienced negative operating cash flows since inception. The Company has financed its working capital requirements during this period primarily through the recurring sale of its equity securities and the exercise of outstanding common stock options and purchase warrants. These matters raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1 to the consolidated financial statements. These consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission (the "SEC") and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, and audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

We have served as the Company's auditor since 2008.

/s/ Weinberg & Company, P.A.

Los Angeles, California
March 25, 2019

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2018	**2017**
ASSETS		
Current assets:		
Cash	$ 4,273,012	$ 1,305,748
Prepaid expenses and other current assets	61,433	62,317
Total current assets	4,334,445	1,368,065
Prepaid expense, less current portion	2,293	—
Total assets	$ 4,336,738	$ 1,368,065
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 195,211	$ 312,034
Research and development contract liabilities	15,704	60,990
Total current liabilities	210,915	373,024
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, $0.0001 par value; authorized – 10,000,000 shares; issued and outstanding – 350,000 shares of Series A Convertible Preferred Stock, $10.00 per share stated value, $50.00 per share cash redemption value; aggregate cash redemption value – $17,500,000; liquidation preference based on assumed conversion into common shares – 4,375,000 shares	3,500,000	3,500,000
Common stock, $0.0001 par value; authorized – 100,000,000 shares; issued and outstanding – 67,045,814 shares and 58,025,814 shares at December 31, 2018 and 2017, respectively	6,704	5,802
Additional paid-in capital	25,267,662	20,004,654
Accumulated deficit	(24,648,543)	(22,515,415)
Total stockholders' equity	4,125,823	995,041
Total liabilities and stockholders' equity	$ 4,336,738	$ 1,368,065

See accompanying notes to consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,	
	2018	**2017**
Revenues	$ —	$ —
Costs and expenses:		
General and administrative costs, including $759,738 and $83,686 to related parties for the years ended December 31, 2018 and 2017, respectively	2,097,348	1,342,531
Research and development costs, including $22,198 and $105,698 to Theradex for the years ended December 31, 2018 and 2017, respectively	40,703	467,258
Total costs and expenses	2,138,051	1,809,789
Loss from operations	(2,138,051)	(1,809,789)
Interest income	4,923	1,375
Net loss	$ (2,133,128)	$ (1,808,414)
Net loss per common share – basic and diluted	$ (0.04)	$ (0.03)
Weighted average common shares outstanding – basic and diluted	58,796,115	55,817,458

See accompanying notes to consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

Years Ended December 31, 2018 and 2017

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Par Value			
Balance, December 31, 2016	350,000	$ 3,500,000	47,875,814	$ 4,787	$ 17,416,974	$ (20,707,001)	$ 214,760
Sale of common stock	—	—	10,000,000	1,000	2,499,000	—	2,500,000
Exercise of common stock options	—	—	150,000	15	17,985	—	18,000
Stock-based compensation expense	—	—	—	—	70,695	—	70,695
Net loss	—	—	—	—	—	(1,808,414)	(1,808,414)
Balance, December 31, 2017	350,000	3,500,000	58,025,814	5,802	20,004,654	(22,515,415)	995,041
Sale of common stock units	—	—	9,000,000	900	4,499,100	—	4,500,000
Costs incurred in connection with the sale of common stock units	—	—	—	—	(24,702)	—	(24,702)
Exercise of common stock options	—	—	20,000	2	2,998	—	3,000
Stock-based compensation expense, including $711,738 for extension of stock options to related party	—	—	—	—	785,612	—	785,612
Net loss	—	—	—	—	—	(2,133,128)	(2,133,128)
Balance, December 31, 2018	350,000	$ 3,500,000	67,045,814	$ 6,704	$ 25,267,662	$ (24,648,543)	$ 4,125,823

See accompanying notes to consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (2,133,128)	$ (1,808,414)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense included in -		
General and administrative costs	785,612	38,675
Research and development costs	—	32,020
Changes in operating assets and liabilities:		
(Increase) decrease in -		
Advances on research and development contract services	—	183,490
Prepaid expenses and other current assets	(1,409)	(12,325)
Increase (decrease) in -		
Accounts payable and accrued expenses	(116,823)	152,439
Research and development contract liabilities	(45,286)	1,934
Net cash used in operating activities	(1,511,034)	(1,412,181)
Cash flows from financing activities:		
Exercise of common stock options	3,000	18,000
Proceeds from sale of common stock and common stock units	4,500,000	2,500,000
Costs incurred in connection with the sale of common stock units	(24,702)	—
Net cash provided by financing activities	4,478,298	2,518,000
Cash:		
Net increase (decrease)	2,967,264	1,105,819
Balance at beginning of period	1,305,748	199,929
Balance at end of period	$ 4,273,012	$ 1,305,748
Supplemental disclosures of cash flow information:		
Cash paid for -		
Interest	$ —	$ —
Income taxes	$ —	$ —

See accompanying notes to consolidated financial statements.

1. Organization and Basis of Presentation

Lixte Biotechnology Holdings, Inc., a Delaware corporation ("Holdings"), including its wholly-owned Delaware subsidiary, Lixte Biotechnology, Inc. ("Lixte") (collectively, the "Company"), is a drug discovery company that uses biomarker technology to identify enzyme targets associated with serious common diseases and then designs novel compounds to attack those targets. The Company's product pipeline encompasses two major categories of compounds at various stages of pre-clinical and clinical development that the Company believes have broad therapeutic potential not only for cancer but also for other debilitating and life-threatening diseases.

The Company's activities are subject to significant risks and uncertainties, including the need for additional capital, as described below. The Company has not yet commenced any revenue-generating operations, does not have positive cash flows from operations, and is dependent on periodic infusions of equity capital to fund its operating requirements.

The Company's common stock is traded on the OTCQB operated by the OTC Markets under the symbol "LIXT".

Going Concern

The Company's consolidated financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has not generated any revenues from operations to date and does not expect to do so in the foreseeable future. Furthermore, the Company has experienced recurring operating losses and negative operating cash flows since inception and has financed its working capital requirements during this period primarily through the recurring sale of its equity securities and the exercise of outstanding common stock options and purchase warrants.

As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern within one year of the date that the consolidated financial statements are being issued. In addition, the Company's independent registered public accounting firm, in their report on the Company's consolidated financial statements for the year ended December 31, 2018, has also expressed substantial doubt about the Company's ability to continue as a going concern.

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

Because the Company is currently engaged in clinical research at a relatively early stage, it will likely take a significant amount of time to develop any product or intellectual property capable of generating sustainable revenues. Accordingly, the Company's business is unlikely to generate any sustainable operating revenues in the next several years and may never do so. In addition, to the extent that the Company is able to generate revenues through licensing its technologies or through product sales, there can be no assurance that the Company will be able to achieve positive earnings and operating cash flows.

At December 31, 2018, the Company had cash of $4,273,012 available to fund its operations. The next step in the development of the Company's lead anti-cancer clinical compound LB-100 is to evaluate its safety and therapeutic benefit in a Phase 1b/2 clinical trial. This clinical trial is currently expected to begin during the quarter ending June 30, 2019, to complete patient accrual over a period of two years, and to take approximately three years to complete. The Company's longer-term objective is to secure one or more strategic partnerships with pharmaceutical companies with major programs in cancer.

The amount and timing of future cash requirements will depend on the pace and design of the Company's clinical trial program. As market conditions present uncertainty as to the Company's ability to secure additional funds, there can be no assurances that the Company will be able to secure additional financing on acceptable terms, or at all, as and when necessary to continue to conduct operations. If cash resources are insufficient to satisfy the Company's ongoing cash requirements, the Company would be required to scale back or discontinue its technology and product development programs and/or any clinical trials, or obtain funds, if available (although there can be no certainty), through strategic alliances that may require the Company to relinquish rights to certain of its compounds, or to discontinue its operations entirely.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements of the Company have been prepared in accordance with United States generally accepted accounting principles ("GAAP") and include the financial statements of Holdings and its wholly-owned subsidiary, Lixte. Intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP 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. Management bases its estimates on historical experience and on various assumptions that are believed to be reasonable in relation to the financial statements taken as a whole under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Management regularly evaluates the key factors and assumptions used to develop the estimates utilizing currently available information, changes in facts and circumstances, historical experience and reasonable assumptions. After such evaluations, if deemed appropriate, those estimates are adjusted accordingly. Actual results could differ from those estimates. Significant estimates include those related to assumptions used in accruals for potential liabilities, valuing equity instruments issued for services, and the realization of deferred tax assets.

Cash Concentrations

The Company maintains its cash balances with financial institutions in federally-insured accounts. The Company may periodically have cash balances in banks in excess of FDIC insurance limits. The Company maintains its accounts with financial institutions with high credit ratings. The Company has not experienced any losses to date resulting from this practice. Beginning in 2019, the Company intends to invest the majority of its cash resources in short-term federally insured certificates of deposit.

Research and Development

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

Research and development costs are charged to operations ratably over the life of the underlying contracts, unless the achievement of milestones, the completion of contracted work, or other information indicates that a different expensing schedule is more appropriate.

Obligations incurred with respect to mandatory scheduled payments under research agreements without milestone provisions are recognized ratably over the appropriate period, as specified in the agreement, and are recorded as liabilities in the Company's consolidated balance sheet, with a corresponding charge to research and development costs in the Company's consolidated statement of operations.

On January 10, 2010, the Company retained Theradex Systems, Inc. ("Theradex") under a Master Agreement to provide technical and advisory services to the Company with respect to clinical trial matters involving the U.S. Food and Drug Administration ("FDA"). Theradex is an international contract research organization ("CRO") that provides technical and advisory services with respect to clinical research and development of pharmaceutical compounds under the rules and regulations of the FDA. On September 21, 2012, the Company entered into a work order agreement with Theradex to manage and administer the Company's Phase 1 clinical trial of LB-100. This Phase 1 clinical trial had been substantially completed at December 31, 2017. The costs of the Phase 1 clinical trial of LB-100 paid to or through Theradex were recorded and charged to operations based upon the periodic documentation provided by the CRO. During the year ended December 31, 2018, the Company has paid Theradex $10,292 to update FDA documents relative to the completed Phase 1 clinical trial of LB-100.

On September 12, 2018, the Company finalized a work order agreement with Theradex to monitor a Phase 1b/2 clinical trial that was approved by the FDA in early November 2018. This clinical trial is currently expected to begin during the quarter ending June 30, 2019, to complete patient accrual over a period of two years, and to take approximately three years to complete. The clinical trial will be managed and conducted by the Moffitt Cancer Center and Research Institute Hospital Inc., Tampa, Florida, to evaluate the safety and therapeutic benefit of the Company's lead anti-cancer clinical compound LB-100 administered intravenously in patients with low or intermediate-1 risk myelodysplastic syndrome (MDS). This work order agreement became operational in August 2018 and is estimated to be completed by December 2021. Costs under this work order agreement are estimated to be approximately $954,000, with such payments expected to be divided approximately 94% to Theradex for services and approximately 5% for payments for pass-through costs. The costs of the upcoming Phase 1b/2 clinical trial to be paid to or through Theradex will be recorded and charged to operations based on the periodic documentation provided by the CRO. As of December 31, 2018, costs of $11,906 have been incurred pursuant to this work order agreement.

In addition to the costs associated with the previously described work order agreements with Theradex with respect to the Company's clinical trials, the Company has also from time to time engaged Theradex to provide other technical and advisory services.

Payments made pursuant to research and development contracts are initially recorded as advances on research and development contract services in the Company's consolidated balance sheet and then charged to research and development costs in the Company's consolidated statement of operations as those contract services are performed. Expenses incurred under research and development contracts in excess of amounts advanced are recorded as research and development contract liabilities in the Company's consolidated balance sheet, with a corresponding charge to research and development costs in the Company's consolidated statement of operations. The Company reviews the status of its research and development contracts on a quarterly basis.

Patent and Licensing Costs

Due to the significant uncertainty associated with the successful development of one or more commercially viable products based on the Company's research efforts and related patent applications, all patent-related legal and filing fees and licensing-related legal fees are charged to operations as incurred. Patent and licensing costs were $842,325 and $846,169 for the years ended December 31, 2018 and 2017, respectively. Patent and licensing costs are included in general and administrative costs in the Company's consolidated statements of operations.

Accounting for Preferred Stock

The Company accounts for preferred stock as either equity or debt, depending on the specific characteristics of the security issued. The Series A Convertible Preferred Stock issued by the Company in January 2016 and March 2015 has been classified as a component of stockholders' equity (see Note 3).

Concentration of Risk

The Company periodically contracts with directors, including companies controlled by or associated with directors, to provide consulting services related to the Company's research and development and clinical trial activities. Agreements for these services can be for a specific time period (typically one year) or for a specific project or task and can include both cash and non-cash compensation. The only such contracts that represent 10% or more of general and administrative or research and development costs are described below.

As discussed above at "Research and Development", the Company has retained Theradex to provide technical and advisory services to the Company with respect to clinical trial matters involving the FDA. Total costs charged to operations from 2013 through December 31, 2017 for services paid to or through Theradex for the Phase 1 clinical trial of LB-100 aggregated $2,233,248, with approximately 60% of such costs allocated for services provided by Theradex and approximately 40% for pass-through costs for clinical center laboratory costs and investigator costs over the life of the clinical trial. During the year ended December 31, 2018, the Company did not incur any such clinical trial costs with Theradex. During the year ended December 31, 2017, the Company incurred $105,698 of such clinical trial costs with Theradex, representing approximately 24% of research and development costs for the year ended December 31, 2017. Costs incurred pursuant to this agreement are included in research and development costs in the Company's consolidated statements of operations.

Income Taxes

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

The Company has elected to deduct research and development costs on a current basis for federal income tax purposes. For federal tax purposes, start-up and organization costs were deferred until January 1, 2008 at which time the Company began to amortize such costs over a 180-month period.

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

The Company is subject to U.S. federal income taxes and income taxes of various state tax jurisdictions. As the Company's net operating losses have yet to be utilized, all previous tax years remain open to examination by Federal authorities and other jurisdictions in which the Company currently operates or has operated in the past. The Company had no unrecognized tax benefits as of December 31, 2018 and 2017 and does not anticipate any material amount of unrecognized tax benefits within the next 12 months.

The Company accounts for uncertainties in income tax law under a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns as prescribed by GAAP. The tax effects of a position are recognized only if it is "more-likely-than-not" to be sustained by the taxing authority as of the reporting date. If the tax position is not considered "more-likely-than-not" to be sustained, then no benefits of the position are recognized. As of December 31, 2018, the Company had not recorded any liability for uncertain tax positions. In subsequent periods, any interest and penalties related to uncertain tax positions will be recognized as a component of income tax expense.

On December 22, 2017, the Tax Reform Act was signed into law. The Tax Reform Act is effective for tax years beginning on or after January 1, 2018, except for certain provisions, and resulted in significant changes to existing United States tax law, including various provisions that are expected to impact the Company. Among other provisions, the Tax Reform Act reduced the federal corporate tax rate from 35% to 21% effective January 1, 2018.

Stock-Based Compensation

The Company periodically issues common stock and stock options to officers, directors, Scientific Advisory Committee members and consultants for services rendered. Options vest and expire according to terms established at the issuance date of each grant.

The Company accounts for stock-based payments to officers and directors by measuring the cost of services received in exchange for equity awards utilizing the grant date fair value of the awards, with the cost recognized as compensation expense on the straight-line basis in the Company's financial statements over the vesting period of the awards. The Company accounts for stock-based payments to Scientific Advisory Committee members and consultants by determining the value of the stock compensation based upon the measurement date at either (a) the date at which a performance commitment is reached or (b) at the date at which the necessary performance to earn the equity instruments is complete.

Stock grants, which are generally time vested, are measured at the grant date fair value and charged to operations ratably over the vesting period.

Stock options granted to members of the Company's Scientific Advisory Committee and to outside consultants are revalued each reporting period to determine the amount to be recorded as an expense in the respective period. As the stock options vest, they are valued on each vesting date and an adjustment is recorded for the difference between the value already recorded and the value on the date of vesting.

The fair value of common stock issued as stock-based compensation is determined by reference to the closing price of the Company's common stock on the date of issuance. The fair value of stock options granted as stock-based compensation is determined utilizing the Black-Scholes option-pricing model, and is affected by several variables, the most significant of which are the life of the equity award, the exercise price of the stock option as compared to the fair market value of the common stock on the grant date, and the estimated volatility of the common stock over the term of the equity award. Estimated volatility is based on the historical volatility of the Company's common stock. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. The fair market value of common stock is determined by reference to the quoted market price of the Company's common stock.

The Company recognizes the fair value of stock-based compensation awards in general and administrative costs and in research and development costs, as appropriate, in the Company's consolidated statements of operations. The Company issues new shares of common stock to satisfy stock option exercises.

Earnings (Loss) Per Share

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

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

At December 31, 2018 and 2017, the Company excluded the outstanding securities summarized below, which entitle the holders thereof to acquire shares of common stock, from its calculation of earnings per share, as their effect would have been anti-dilutive.

	December 31,	
	2018	**2017**
Series A Convertible Preferred Stock	4,375,000	4,375,000
Common stock warrants	9,000,000	—
Common stock options, including options issued in the form of warrants	7,750,000	7,470,000
Total	21,125,000	11,845,000

Fair Value of Financial Instruments

The authoritative guidance with respect to fair value established a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three levels and requires that assets and liabilities carried at fair value be classified and disclosed in one of three categories, as presented below. Disclosure as to transfers in and out of Levels 1 and 2, and activity in Level 3 fair value measurements, is also required.

Level 1. Observable inputs such as quoted prices in active markets for an identical asset or liability that the Company has the ability to access as of the measurement date. Financial assets and liabilities utilizing Level 1 inputs include active-exchange traded securities and exchange-based derivatives.

Level 2. Inputs, other than quoted prices included within Level 1, which are directly observable for the asset or liability or indirectly observable through corroboration with observable market data. Financial assets and liabilities utilizing Level 2 inputs include fixed income securities, non-exchange-based derivatives, mutual funds, and fair-value hedges.

Level 3. Unobservable inputs in which there is little or no market data for the asset or liability which requires the reporting entity to develop its own assumptions. Financial assets and liabilities utilizing Level 3 inputs include infrequently-traded non-exchange-based derivatives and commingled investment funds and are measured using present value pricing models.

The Company determines the level in the fair value hierarchy within which each fair value measurement falls in its entirety, based on the lowest level input that is significant to the fair value measurement in its entirety. In determining the appropriate levels, the Company performs an analysis of the assets and liabilities at each reporting period end.

The carrying value of financial instruments (consisting of cash and accounts payable and accrued expenses) is considered to be representative of their respective fair values due to the short-term nature of those instruments.

Recent Accounting Pronouncements

Recently Adopted Accounting Standards

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASU 2014-09"). ASU 2014-09 eliminates transaction- and industry-specific revenue recognition guidance under current GAAP and replaces it with a principles-based approach for determining revenue recognition. ASU 2014-09 requires that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. The FASB has recently issued ASU 2016-08, ASU 2016-10, ASU 2016-11, ASU 2016-12, and ASU 2016-20, all of which clarify certain implementation guidance within ASU 2014-09. ASU 2014-09 is effective for reporting periods beginning after December 15, 2017. The Company adopted the provisions of ASU 2014-09 in the quarter beginning January 1, 2018. The adoption of ASU 2014-09 did not have any impact on the Company's financial statement presentation or disclosures.

In July 2017, the FASB issued Accounting Standards Update No. 2017-11, Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features; (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception ("ASU 2017-11"). ASU 2017-11 allows companies to exclude a down round feature when determining whether a financial instrument (or embedded conversion feature) is considered indexed to the entity's own stock. As a result, financial instruments (or embedded conversion features) with down round features are no longer required to be accounted for as derivative liabilities. A company will recognize the value of a down round feature only when it is triggered and the strike price has been adjusted downward. For equity-classified freestanding financial instruments, an entity will treat the value of the effect of the down round as a dividend and a reduction of income available to common shareholders in computing basic earnings per share. For convertible instruments with embedded conversion features containing down round provisions, entities will recognize the value of the down round as a beneficial conversion discount to be amortized to earnings. ASU 2017-11 is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. The Company early adopted the provisions of ASU 2017-11 in the quarter beginning January 1, 2018. The adoption of ASU 2017-11 did not have any impact on the Company's financial statement presentation or disclosures.

Recently Issued Accounting Standards

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, Leases (Topic 842) ("ASU 2016-02"). ASU 2016-02 requires a lessee to record a right-of-use asset and a corresponding lease liability, initially measured at the present value of the lease payments, on the balance sheet for all leases with terms longer than 12 months, as well as the disclosure of key information about leasing arrangements. ASU 2016-02 requires recognition in the statement of operations of a single lease cost, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. ASU 2016-02 requires classification of all cash payments within operating activities in the statement of cash flows. Disclosures are required to provide the amount, timing and uncertainty of cash flows arising from leases. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. ASU 2016-02 has subsequently been amended and modified by ASU 2018-10, 2018-11 and 2018-20. ASU 2016-02 (including the subsequent amendments and modifications) is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company will adopt the provisions of ASU 2016-02 in the quarter beginning January 1, 2019. The adoption of ASU 2016-02 is not expected to have any impact on the Company's financial statement presentation or disclosures.

In June 2018, the FASB issued Accounting Standards Update 2018-07, Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting ("ASU 2018-07"). ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. ASU 2018-07 also clarifies that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Revenue from Contracts with Customers (Topic 606). ASU 2018-07 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company will adopt the provisions of ASU 2018-07 in the quarter beginning January 1, 2019. The adoption of ASU 2018-07 is not expected to have any impact on the Company's financial statement presentation or disclosures.

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

3. Stockholders' Equity

Preferred Stock

The Company has authorized a total of 10,000,000 shares of preferred stock, par value $0.0001 per share. On March 17, 2015, the Company filed a Certificate of Designations, Preferences, Rights and Limitations (the "Certificate of Designations") of its Series A Convertible Preferred Stock with the Delaware Secretary of State to amend the Company's certificate of incorporation. The Company designated 175,000 shares as Series A Convertible Preferred Stock, which are non-voting and are not subject to increase without the written consent of a majority of the holders of the Series A Convertible Preferred Stock or as otherwise set forth in the Certificate of Designations. The holders of each tranche of 175,000 shares of the Series A Convertible Preferred Stock are entitled to receive a per share dividend equal to 1% of the annual net revenue of the Company divided by 175,000, until converted or redeemed.

Effective January 28, 2016, the Series A Convertible Preferred Stock Certificate of Designations was amended to increase the authorized shares of Series A Convertible Preferred Stock from 175,000 shares to 350,000 shares. Accordingly, as of December 31, 2017, 9,650,000 shares of preferred stock were undesignated and may be issued with such rights and powers as the Board of Directors may designate.

Each share of Series A Convertible Preferred Stock may be converted, at the option of the holder, into 12.5 shares of common stock (subject to customary anti-dilution provisions) and the Series A Convertible Preferred Stock is subject to mandatory conversion at the conversion rate in the event of a merger or sale transaction resulting in gross proceeds to the Company of at least $21,875,000. The Series A Convertible Preferred Stock has a liquidation preference based on its assumed conversion into shares of common stock. The Series A Convertible Preferred Stock does not have a cash liquidation preference.

If fully converted, the 350,000 outstanding shares of Series A Convertible Preferred Stock would convert into 4,375,000 shares of common stock at December 31, 2018. The Company has the right to redeem the Series A Convertible Preferred Stock up to the fifth anniversary of the respective closing dates at a price per share equal to $50.00. The Series A Convertible Preferred Stock has no right to cash, except for the payment of the aforementioned dividend based on the generation of revenues by the Company and does not have any registration rights.

Based on the attributes of the Series A Convertible Preferred Stock described above, the Company determined to account for the Series A Convertible Preferred Stock as a permanent component of stockholders' equity.

Common Stock

The Company is authorized to issue up to 100,000,000 shares of common stock (par value $0.0001). As of December 31, 2018 and 2017, the Company had 67,045,814 shares and 58,025,814 shares of common stock issued and outstanding, respectively.

Effective February 24, 2017, the Company entered into a Securities Purchase Agreement with an accredited investor pursuant to which the purchaser purchased 4,000,000 shares of the Company's common stock at a price of $0.25 per share for an aggregate purchase price of $1,000,000.

Effective April 3, 2017, the Company entered into a Securities Purchase Agreement with an accredited investor pursuant to which the purchaser purchased 6,000,000 shares of the Company's common stock at a price of $0.25 per share for an aggregate purchase price of $1,500,000.

Effective November 30, 2018, the Company raised $4,500,000 through the sale to sixteen accredited investors of 9,000,000 units at a purchase price of $0.50 per unit. Each unit consisted of one share of common stock and one four-year warrant to purchase one share of common stock at an exercise price of $1.00 per share. Accordingly, a total of 9,000,000 shares of common stock and warrants to purchase 9,000,000 shares of common stock were issued by the Company. The warrants do not have any reset provisions. Legal costs of the private placement were $24,702. There were no commissions paid with respect to the private placement. The units sold were not registered under the Securities Act of 1933, as amended (the "Act"), in reliance upon the exemption from registration contained in Section 4(2) of the Act and Regulation D promulgated thereunder. The Company accounted for the issuance of the units as a capital transaction.

Common Stock Warrants

A summary of common stock warrant activity, including warrants to purchase common stock that were issued in conjunction with the Company's private placements, is presented below.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Warrants outstanding at December 31, 2017	—	$ —	
Issued	9,000,000	1.000	
Exercised	—	—	
Expired	—	—	
Warrants outstanding at December 31, 2018	9,000,000	$ 1.000	3.92

At December 31, 2018, all outstanding warrants are exercisable at $1.000 per common share.

Based on a fair market value of $0.93 per share on December 31, 2018, there were no exercisable but unexercised in-the-money common stock warrants on that date. Accordingly, there was no intrinsic value attributed to exercisable but unexercised common stock warrants at December 31, 2018.

Information with respect to the issuance of common stock in connection with various stock-based compensation arrangements is provided at Note 5.

4. Related Party Transactions

The Company's Chairman and major stockholder, Dr. John Kovach, was paid a salary of $60,000 for the years ended December 31, 2018 and 2017, which amounts are included in general and administrative costs in the Company's consolidated statements of operations. Beginning in late February 2017, Dr. Kovach began devoting 100% of his time to the Company's business activities.

The Company's principal office facilities are being provided without charge by Dr. Kovach. Such costs were not material to the Company's consolidated financial statements and, accordingly, have not been reflected therein.

On September 12, 2007, the Company entered into a consulting agreement with Gil Schwartzberg for Mr. Schwartzberg to provide financial advisory and consulting services to the Company with respect to financing matters, capital structure and strategic development, and to assist management in communications with investors and shareholders. Mr. Schwartzberg is currently a significant stockholder of the Company and continues to be a consultant to the Company. Consideration under this consulting agreement, including subsequent extensions, has been paid exclusively in the form of stock options. On January 28, 2014, the Company entered into a second amendment to its consulting agreement with Mr. Schwartzberg to extend it to January 28, 2019. In conjunction with such amendment, the Company granted Mr. Schwartzberg stock options to purchase an additional 4,000,000 shares of common stock, exercisable at $0.50 per share for a period of the earlier of five years from the grant date or the termination of the consulting agreement, with one-half of the stock options (2,000,000 shares) vested immediately and one-half of the stock options (2,000,000 shares) vested on January 28, 2015. Stock-based compensation expense with respect to the grant of the stock options to purchase the 4,000,000 shares of common stock was previously charged to general and administrative costs in the consolidated statement of operations over the vesting period. On August 2, 2018, with the approval of the Board of Directors, the Company entered into a third amendment to its consulting agreement with Mr. Schwartzberg to extend it to January 28, 2024. In conjunction with such amendment, the Company extended the expiration date of the fully-vested stock options for 4,000,000 shares of common stock previously granted to Mr. Schwartzberg, from January 28, 2019 to January 28, 2024. The fair value of the extension of these vested stock options, as calculated pursuant to the Black-Scholes option-pricing model, was measured for accounting purposes as the difference in the fair value of the stock options immediately before and immediately after the extension date, and was determined to be $711,738 ($0.1779 per share), which was charged to general and administrative costs in the consolidated statement of operations on the extension date.

Legal and consulting fees charged to operations for services rendered by the Eric Forman Law Office were $48,000 for the years ended December 31, 2018 and 2017, respectively. In addition, effective October 16, 2017, in connection with his continuing role as a consultant to the Company, Eric Forman was granted fully-vested stock options to purchase 100,000 shares of the Company's common stock. The stock options are exercisable for a period of five years from the date of grant at $0.15 per share, which was the fair market value of the Company's common stock on such date. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $14,997 ($0.1500 per share), which was charged to operations on the date of grant. Eric J. Forman is the son-in-law of Gil Schwartzberg, a significant stockholder of and consultant to the Company, and is the son of Dr. Stephen J. Forman, who was elected to the Company's Board of Directors on May 13, 2016. Julie Forman, the wife of Eric Forman and the daughter of Gil Schwartzberg, is Vice President of Morgan Stanley Wealth Management, where the Company maintains a banking relationship.

Stock-based compensation arrangements involving members of the Company's Board of Directors and affiliates are described at Note 5. Total stock-based compensation expense relating to directors, officers, affiliates and related parties was $785,612 and $35,676 for the years ended December 31, 2018 and 2017, respectively.

5. Stock-Based Compensation

The Company issues common stock and stock options as incentive compensation to directors and as compensation for the services of independent contractors and consultants of the Company.

On June 20, 2007, the Board of Directors of the Company approved the 2007 Stock Compensation Plan (the "2007 Plan"), which provides for the granting of awards, consisting of stock options, stock appreciation rights, performance shares, or restricted shares of common stock, to employees and independent contractors, for up to 2,500,000 shares of the Company's common stock, under terms and conditions as determined by the Company's Board of Directors. The 2007 Plan terminated on June 19, 2017. As of December 31, 2018, unexpired stock options for 1,250,000 shares were issued and outstanding under the 2007 Plan.

The fair value of each stock option awarded is calculated on the date of grant and subsequent measurement dates using the Black-Scholes option-pricing model. The expected dividend yield assumption is based on the Company's expectation of dividend payouts. The expected volatilities are based on historical volatility of the Company's stock. The risk-free interest rate is based on the U.S. treasury yield curve in effect as of the grant date. The expected life of the stock options is the average of the vesting term and the full contractual term of the stock options.

For stock options requiring an assessment of value during the year ended December 31, 2018, the fair value of each stock option award was calculated using the Black-Scholes option-pricing model utilizing the following assumptions:

Risk-free interest rate	2.44% to 3.01%
Expected dividend yield	0%
Expected volatility	170.32%
Expected life	0.5 to 5.5 years

For stock options requiring an assessment of value during the year ended December 31, 2017, the fair value of each stock option award was calculated using the Black-Scholes option-pricing model utilizing the following assumptions:

Risk-free interest rate	1.18% to 2.47%
Expected dividend yield	0%
Expected volatility	308.51% to 332.63%
Expected life	1.5 to 5.0 years

On December 24, 2013, the Company entered into an agreement with NDA Consulting Corp. ("NDA") for consultation and advice in the field of oncology research and drug development. As part of the agreement, NDA also agreed to cause its president, Dr. Daniel D. Von Hoff, M.D., to become a member of the Company's Scientific Advisory Committee. In connection with this agreement, NDA was granted stock options to purchase 100,000 shares of the Company's common stock, vesting 25,000 shares on June 24, 2014, and thereafter 25,000 shares annually on June 24, 2015, 2016 and 2017, exercisable for a period of five years from the date of grant at $0.13 per share, which was the fair market value of the Company's common stock on the grant date. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be $12,960 ($0.13 per share). The Company re-measured the non-vested options to fair value at the end of each reporting period. The unvested portion of the fair value of the stock options was charged to operations ratably from December 24, 2013 through June 24, 2017. During the year ended December 31, 2017, the Company recorded a charge to operations of $2,492 with respect to these stock options.

Effective September 14, 2015, the Company entered into a Collaboration Agreement with BioPharmaWorks LLC ("BioPharmaWorks"), pursuant to which the Company engaged BioPharmaWorks to perform certain services for the Company as described at Note 7. In connection with the Collaboration Agreement, the Company agreed to issue to BioPharmaWorks 1,000,000 fully-vested shares of the Company's common stock, valued at $260,000, based upon the closing price of the Company's common stock of $0.26 per share, on September 14, 2015. Additionally, the Company issued to BioPharmaWorks two options in the form of warrants to purchase 1,000,000 shares (500,000 shares per warrant) of the Company's common stock. The first warrant vested on September 14, 2016 and is exercisable for a period of five years from the date of grant at $1.00 per share. The second warrant vested on September 14, 2017 and is exercisable for a period of five years from the date of grant at $2.00 per share. The fair value of the first and second warrants, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $128,400 ($0.2568 per share) and $127,850 ($0.2557 per share), respectively. The Company re-measured the non-vested stock options to fair value at the end of each reporting period through September 30, 2017. During the year ended December 31, 2017, the Company recorded a charge to operations of $29,528 with respect to these warrants.

Effective May 13, 2016, in conjunction with his appointment as a director of the Company, the Company granted to Dr. Stephen J. Forman stock options to purchase an aggregate of 200,000 shares of the Company's common stock under the 2007 Plan, exercisable for a period of five years from vesting date at $0.16 per share, which was the fair market value of the Company's common stock on such date. One-half of such stock options (100,000 shares) vested on May 13, 2016 and the remaining one-half of such stock options (100,000 shares) vested on May 13, 2017. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $31,180 ($0.1559 per share), of which $15,590 was attributable to the stock options fully-vested on May 13, 2016 and was therefore was charged to operations on that date. The remaining unvested portion of the fair value of the stock options was charged to operations ratably from May 13, 2016 through May 13, 2017. During the year ended December 31, 2017, the Company recorded a charge to operations of $5,681 with respect to these stock options.

Effective October 16, 2017, in connection with his continuing role as a member of the Company's Board of Directors, Dr. Philip F. Palmedo was granted fully-vested stock options to purchase 50,000 shares of the Company's common stock. The stock options are exercisable for a period of five years from the date of grant at $0.15 per share, which was the fair market value of the Company's common stock on such date. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $7,499 ($0.1500 per share), which was charged to operations on the date of grant.

Effective October 16, 2017, in connection with his continuing role as a member of the Company's Board of Directors, Dr. Stephen J. Forman was granted fully-vested stock options to purchase 50,000 shares of the Company's common stock. The stock options are exercisable for a period of five years from the date of grant at $0.15 per share, which was the fair market value of the Company's common stock on such date. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $7,499 ($0.1500 per share), which was charged to operations on the date of grant.

Effective August 4, 2018, in conjunction with their appointments as directors of the Company, the Company granted to Dr. Winson Sze Chun Ho and Dr. Yun Yen stock options for each person to purchase an aggregate of 200,000 shares of the Company's common stock, exercisable for a period of five years from the vesting date at $0.28 per share, which was the approximate fair market value of the Company's common stock on such date. One-half of such stock options (100,000 shares each) vested on August 4, 2018 and the remaining one-half of such stock options (100,000 shares each) will vest on August 4, 2019. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $104,920 ($0.2623 per share), of which $52,460 was attributable to the stock options fully-vested on August 4, 2018 and was therefore was charged to operations on that date. The remaining unvested portion of the fair value of the stock options will be charged to operations ratably from August 4, 2018 through August 4, 2019. During the year ended December 31, 2018, the Company recorded a charge to operations of $73,874 with respect to these stock options.

Total stock-based compensation expense was $785,612 and $70,695 for the years ended December 31, 2018 and 2017, respectively. The total stock-based compensation expense for the year ended December 31, 2018 of $785,612 includes $711,738 of costs associated with the extension of stock options previously granted to Gil Schwartzberg, as described at Note 4.

A summary of stock option activity, including options issued in the form of warrants, during the years ended December 31, 2018 and 2017 is presented below.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Stock options outstanding at December 31, 2016	8,600,000	$ 0.583	
Granted	220,000	0.150	
Exercised	(150,000)	0.120	
Expired	(1,200,000)	0.796	
Stock options outstanding at December 31, 2017	7,470,000	0.545	
Granted	400,000	0.280	
Exercised	(20,000)	0.150	
Expired	(100,000)	0.130	
Stock options outstanding at December 31, 2018	7,750,000	$ 0.538	3.68
Stock options exercisable at December 31, 2017	7,470,000	$ 0.545	
Stock options exercisable at December 31, 2018	7,550,000	$ 0.545	3.65

Total deferred compensation expense for the outstanding value of unvested stock options was approximately $31,000 at December 31, 2018, which will be recognized subsequent to December 31, 2018 over a weighted-average period of approximately seven months.

The exercise prices of common stock options outstanding and exercisable, including options issued in the form of warrants, are as follows at December 31, 2018:

Exercise Prices	Options Outstanding (Shares)	Options Exercisable (Shares)
$ 0.120	450,000	450,000
$ 0.150	300,000	300,000
$ 0.160	200,000	200,000
$ 0.200	500,000	500,000
$ 0.250	500,000	500,000
$ 0.280	400,000	200,000
$ 0.500	4,400,000	4,400,000
$ 1.000	500,000	500,000
$ 2.000	500,000	500,000
	7,750,000	7,550,000

The intrinsic value of exercisable but unexercised in-the-money stock options at December 31, 2018 was approximately $3,482,800, based on a fair market value of $0.93 per share on December 31, 2018.

Outstanding options to acquire 200,000 shares of the Company's common stock had not vested at December 31, 2018.

The Company expects to satisfy such stock obligations through the issuance of authorized but unissued shares of common stock.

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, 2018 and 2017 are summarized below. The calculations presented below at December 31, 2018 and 2017 reflect the new U.S. federal statutory corporate tax rate of 21% effective January 1, 2018 (see Note 2).

	December 31,	
	2018	2017
Start-up and organization costs	$ 14,000	$ 19,000
Research credits	351,000	316,000
Stock-based compensation	626,000	407,000
Net operating loss carryforwards	4,395,000	4,020,000
Total deferred tax assets	5,386,000	4,762,000
Valuation allowance	(5,386,000)	(4,762,000)
Net deferred tax assets	$ —	$ —

In assessing the potential realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the Company attaining future taxable income during the periods in which those temporary differences become deductible. As of December 31, 2018 and 2017, management was unable to determine if it is more likely than not that the Company's deferred tax assets will be realized and has therefore recorded an appropriate valuation allowance against deferred tax assets at such dates.

No federal tax provision has been provided for the years ended December 31, 2018 and 2017 due to the losses incurred during such periods. The reconciliation below presents the difference between the income tax rate computed by applying the U.S. federal statutory rate and the effective tax rate for the years ended December 31, 2018 and 2017.

	Years Ended December 31,	
	2018	2017
U. S. federal statutory tax rate	(21.0)%	(35.0)%
State income taxes, net of federal tax benefit	(6.0)%	(6.0)%
Expirations related to stock-based compensation	0.2%	13.4%
Adjustment to deferred tax asset	(1.3)%	(1.0)%
Change in valuation allowance	28.1%	28.6%
Effective tax rate	0.0%	0.0%

At December 31, 2018, the Company has available net operating loss carryforwards for federal and state income tax purposes of approximately $15,389,000 and $16,288,000, respectively. Federal net operating losses, if not utilized earlier, expire through 2038. The state net operating loss carryovers were incurred solely in New York. New York tax law requires New York net operating loss carryovers from years prior to 2015 to be converted, by applying a formula, into a Prior Net Operating Loss Conversion (PNOLC) subtraction pool. The Company may utilize up to 1/10 of the PNOLC subtraction pool, or $928,367 each year. Unutilized PNOLC amounts carry forward to succeeding years until they expire in 2035. In addition, the full New York net operating loss incurred in post-2015 tax years may be utilized in future tax years. Post-2015 New York net operating losses expire through 2038.

7. Commitments and Contingencies

Legal claims

The Company may be subject to legal claims and actions from time to time as part of its business activities. As of December 31, 2018, the Company was not subject to any pending or threatened legal claims or actions.

Significant agreements and contracts

Effective October 18, 2013, the Company entered into a Materials Cooperative Research and Development Agreement (M-CRADA) with the National Institute of Neurological Disorders and Stroke (NINDS) of the National Institutes of Health (NIH) for a term of four years. The Surgical Neurology Branch of NINDS is conducting research characterizing a variety of compounds proprietary to the Company and is examining the potential of the compounds for anti-cancer activity, reducing neurological deficit due to ischemia and brain injury, and stabilizing catalytic function of misfolded proteins for inborn brain diseases. Under an M-CRADA, a party provides research material, in this case proprietary compounds from the Company's pipeline, for study by scientists at NIH. The exchange of material is for research only and does not imply any endorsement of the material on the part of either party. Under the M-CRADA, the NIH grants a collaborator an exclusive option to elect an exclusive or non-exclusive commercialization license.

On June 14, 2017, the Company executed Amendment No. 1 to the M-CRADA, pursuant to which the Company agreed to provide funding in the amount of $100,000 to the National Cancer Institute for use in acquiring technical, statistical and administrative support for research activities. The $100,000 amount was scheduled to be paid in two equal installments of $50,000, the first installment of which was paid, as scheduled, on July 9, 2017, and was charged to research and development costs in the consolidated statement of operations on such date. The second installment of $50,000 was scheduled to be paid on the June 14, 2018 anniversary date of the amendment and was accreted ratably through such date and included in research and development contract liabilities in the Company's consolidated balance sheet. Pursuant to revised and updated collaboration plans, on November 3, 2018, the NINDS and the Company agreed to a cancellation of the second installment payment of $50,000. Accordingly, the previously accreted charge of $50,000, of which $25,000 was recorded during the six months ended June 30, 2018, was reversed during the fourth quarter of the year ended December 31, 2018. During the years ended December 31, 2018 and 2017, $0 and $75,000, respectively, was included in research and development costs in the consolidated statement of operations.

On December 24, 2013, the Company entered into an agreement with NDA Consulting Corp. ("NDA") for consultation and advice in the field of oncology research and drug development. As part of the agreement, NDA also agreed to cause its president, Dr. Daniel D. Von Hoff, M.D., to become a member of the Company's Scientific Advisory Committee. The term of the agreement was for one year and provided for a quarterly cash fee of $4,000. In 2014, 2015, 2016, 2017 and 2018, the agreement was automatically renewed on its anniversary date for an additional one-year term. Consulting and advisory fees charged to operations pursuant to this agreement were $16,000 during the years ended December 31, 2018 and 2017.

Effective September 14, 2015, the Company entered into a Collaboration Agreement with BioPharmaWorks, pursuant to which the Company engaged BioPharmaWorks to perform certain services for the Company. Those services include, among other things: (a) assisting the Company to (i) commercialize its products and strengthen its patent portfolio, (ii) identify large pharmaceutical companies with potential interest in the Company's product pipeline, and (iii) prepare and deliver presentations concerning the Company's products; (b) at the request of the Board of Directors, serving as backup management for up to three months should the Company's Chief Executive Officer and scientific leader be temporarily unable to carry out his duties; (c) being available for consultation in drug discovery and development; and (d) identifying providers and overseeing tasks relating to clinical use and commercialization of new compounds.

BioPharmaWorks was founded in 2015 by former Pfizer scientists with extensive multi-disciplinary research and development and drug development experience. The Collaboration Agreement was for an initial term of two years and automatically renews for subsequent annual periods unless terminated by a party not less than 60 days prior to the expiration of the applicable period. In connection with the Collaboration Agreement, the Company agreed to pay BioPharmaWorks a monthly fee of $10,000, subject to the right of the Company to pay a negotiated hourly rate in lieu of the monthly payment and agreed to issue to BioPharmaWorks certain equity-based compensation as described at Note 5. In November 2016, it was mutually agreed to suspend services and payments under the Collaboration Agreement, without extending its term, for the period from November 1, 2016 through March 31, 2017. The Collaboration Agreement resumed as scheduled on April 1, 2017 and was automatically renewed for additional one-year periods on September 13, 2017 and 2018, respectively. In April 2018, it was again mutually agreed to suspend services and payments under the Collaboration Agreement, without extending its term, for the period from February 1, 2018 through the September 13, 2019 anniversary date. In February 2019, the Company and BioPharmaWorks subsequently agreed to resume the Collaboration Agreement effective March 1, 2019. The Company recorded charges to operations pursuant to this Collaboration Agreement of $10,000 and $60,000, which were included in research and development costs in the consolidated statement of operations, during the years ended December 31, 2018 and 2017, respectively.

On March 22, 2018, the Company entered into a Patent Assignment and Exploitation Agreement (the "Agreement") with INSERM TRANSFERT SA, acting as delegatee of the French National Institute of Health and Medical Research ("INSERM"), for the assignment to the Company of INSERM'S interest in United States Patent No. 9,833,450 entitled "Oxabicyloheptanes and Oxabicycloheptenes for the Treatment of Depressive and Stress Disorders", which was filed with the United States Patent and Trademark Office in the name of INSERM and the Company as co-owners on February 19, 2015 and granted on May 12, 2017, and related patent applications and filings. INSERM is a French public institution dedicated to research in the field of health and medicine that had previously entered into a Material Transfer Agreement ("MTA") with the Company to allow INSERM to conduct research on the Company's proprietary compound LB-100 and/or its analogs for the treatment of depressive or stress disorders in humans. Pursuant to the Agreement, the Company has agreed to make certain milestone payments to INSERM aggregating up to $1,750,000 upon achievement of development milestones and up to $6,500,000 upon achievement of commercial milestones. The Company also agreed to pay INSERM certain commercial royalties on net sales of products attributed to the Agreement. The Company's current plan is to complete the validation process to evaluate LB-100 for the treatment of depressive or stress disorders in humans within three years; however, the exploitation of this patent for the treatment of depressive and stress disorders in humans will require substantial additional capital and/or a joint venture or other type of business arrangement with a pharmaceutical company with substantially greater capital and business resources than those available to the Company. As there can be no assurances that the Company will be able to obtain the capital or business resources necessary to focus on the exploitation of this patent, it is uncertain when the Company may reach any of the development or commercialization milestones under the Agreement, if at all.

Effective April 2, 2018, the Company entered into a consulting agreement for a term of two years with Liberi Life Sciences Consultancy BV, located in The Netherlands, for consulting and advisory services with respect to sales and licensing, as well as the procurement of investors in China, Japan and South Korea (the "Consulting Agreement"). The Consulting Agreement provided for the payment of a fixed, one-time retainer of EURO 15,000 (US $18,348), which was paid on April 5, 2018, and 2.5% of the net payments received by the Company from sales of products or licensing activities arising directly and exclusively from leads generated by the advisor during the term of the Consulting Agreement, and any investors introduced to the Company by the advisor that results in an investment in the Company during the term of the Consulting Agreement. The Company recorded the payment of the retainer as a prepaid expense in the Company's consolidated balance sheet. The Company is amortizing the retainer payment over the two-year life of the Consulting Agreement, as a result of which the Company recorded a charge to operations of $6,881 during the year ended December 31, 2018. At December 31, 2018, the unamortized balance of the retainer payment was $11,468, of which $9,175 was classified as a current asset and $2,293 was classified as a non-current asset in the Company's consolidated balance sheet at such date.

Effective August 20, 2018 (the "Effective Date"), the Company and the Moffitt Cancer Center and Research Institute Hospital Inc., Tampa, Florida ("Moffitt") entered into an Exclusive License Agreement (the "License Agreement"). Pursuant to the License Agreement, Moffitt granted the Company an exclusive license under certain patents owned by Moffitt (the "Licensed Patents") relating to the treatment of MDS and a non-exclusive license under inventions, concepts, processes, information, data, know-how, research results, clinical data, and the like (other than the Licensed Patents) necessary or useful for the practice of any claim under the Licensed Patents or the use, development, manufacture or sale of any product for the treatment of MDS which would otherwise infringe a valid claim under the Licensed Patents. The Company is obligated to pay Moffitt a non-refundable license issue fee of $25,000 on the date on which the first patient is entered into a Phase 1b/2 clinical trial to be managed and conducted by Moffitt that is scheduled to begin during the quarter ending June 30, 2019. The Company is also obligated to pay Moffitt an annual license maintenance fee of $25,000 commencing on the first anniversary of the Effective Date and every anniversary thereafter until the Company commences payment of minimum royalty payments. The Company has also agreed to pay non-refundable milestone payments to Moffitt, which cannot be credited against earned royalties payable by the Company, based on reaching various clinical and commercial milestones aggregating $1,897,000, subject to reduction by 40% under certain circumstances relating to the status of Valid Claims, as such term is defined in the License Agreement.

The Company will be obligated to pay Moffitt earned royalties of 4% on worldwide cumulative net sales of royalty-bearing products, subject to reduction to 2% under certain circumstances, on a quarterly basis, with a minimum royalty payment of $50,000 in the first four years after sales commence, and $100,000 in year five and each year thereafter, subject to reduction by 40% under certain circumstances relating to the status of Valid Claims, as such term is defined in the License Agreement. The Company's obligation to pay earned royalties under the License Agreement commences on the date of the first sale of a royalty-bearing product, and shall automatically expire on a country-by-country basis on the date on which the last valid claim of the Licensed Patents expires, lapses or is declared invalid, and the obligation to pay any earned royalties under the License Agreement shall terminate on the date on which the last valid claim of the Licensed Patents expires, lapses, or is declared to be invalid in all countries.

Effective August 20, 2018, the Company and Moffitt also entered into a Clinical Trial Research Agreement (the "Clinical Trial Research Agreement") effective for a term of five years, unless terminated earlier by the Company pursuant to 30 days written notice. Pursuant to the Clinical Trial Research Agreement, Moffitt will conduct and manage a Phase 1b/2 clinical trial to evaluate the safety and therapeutic benefit of the Company's lead anti-cancer clinical compound LB-100 to be administered intravenously in patients with low or intermediate-1 risk MDS.

In early November 2018, the Company received approval from the FDA for its Investigational New Drug (IND) Application to conduct a Phase 1b/2 clinical trial to evaluate the safety and therapeutic benefit of the Company's lead clinical compound LB-100 in patients with low and intermediate-1 risk myelodysplastic syndrome (MDS) who have failed or are intolerant of standard treatment. This clinical trial is currently expected to begin during the quarter ending June 30, 2019, to complete patient accrual over a period of two years, and to take approximately three years to complete.

On September 12, 2018, the Company finalized a work order agreement with Theradex to monitor the Phase 1b/2 clinical trial that is scheduled to begin during the quarter ending June 30, 2019. The clinical trial will be managed and conducted by Moffitt to evaluate the safety and therapeutic benefit of the Company's lead anti-cancer clinical compound LB-100 administered intravenously in patients with low or intermediate-1 risk MDS. This work order agreement became operational in August 2018 and is estimated to be completed by December 2021. Costs under this work order agreement are estimated to be approximately $954,000. As of December 31, 2018, costs of $11,906 have been incurred pursuant to this work order agreement.

8. Subsequent Events

The Company performed an evaluation of subsequent events through the date of filing of these consolidated financial statements with the SEC. There were no material subsequent events which affected, or could affect, the amounts or disclosures in the consolidated financial statements**.**

CERTIFICATIONS OF THE CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John S. Kovach, Chief Executive Officer and Chief Financial Officer of Lixte Biotechnology Holdings, Inc. (the "Registrant"), certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2018 of Lixte Biotechnology Holdings, Inc. (the "Annual Report");

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

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

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and I have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this Annual Report is being prepared;

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

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

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

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

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

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

Date: March 25, 2019

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

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

In connection with the filing by Lixte Biotechnology Holdings, Inc. (the "Registrant") of its Annual Report on Form 10-K for the fiscal year ended December 31, 2018 (the "Annual Report") with the Securities and Exchange Commission, I, John S. Kovach, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

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

Date: March 25, 2019

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