The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion, dated November 2, 2020

PRELIMINARY PROSPECTUS

1,500,000 Shares

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

Common Stock

We are offering shares of our common stock. Our application for listing of our common stock on The Nasdaq Capital Market has been approved subject to notice of issuance.

Our common stock is currently quoted on the OTCQB Marketplace. under the symbol "LIXT". On October 30, 2020, the last reported sale price of our common stock on the OTCQB was $1.12 per share, which giving effect to a one-for-six reverse split of our common stock to be effected prior to or upon the effective date of our registration statement, equates to $6.72 per share. However, in this prospectus, we assume that the price per share in this offering, on a post-split basis, will be in the range of $5.75 to $6.75, and we have used the midpoint of such range ($6.25 per share) for the assumptions set forth herein. Following the stock split, our common stock may not trade at a price consistent with such reverse split. The actual public offering price per share will be determined between us and the underwriters at the time of pricing and may be at a discount to the current market price. Therefore, the assumed public offering price used throughout this prospectus may not be indicative of the final offering price.

Investing in our common stock involves risks. See "Risk Factors" beginning on page 11.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Total
Price to the public	$ 6.25	$ 9,375,000
Underwriting discounts and commissions	$ 0.46875	$ 703,125
Proceeds to us (before expenses)(1)	$ 5.78125	$ 8,671,875

(1) Does not include a non-accountable expense allowance equal to 1.7% of the gross proceeds of this offering payable to the underwriters, or the reimbursement of certain expenses of the underwriters. We refer you to "Underwriting" beginning on page 101 of this prospectus for additional information regarding underwriting compensation.

We have granted the underwriters the option for a period of 45 days to purchase up to an additional 225,000 shares of common stock at the public offering price, less underwriting discounts and commissions, solely to cover over-allotments, if any.

The underwriters expect to deliver the shares on or about _____, 2020.

WestPark Capital, Inc. **WallachBeth Capital, LLC**

Prospectus dated _____, 2020

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We have not, and the underwriters have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give to you.

You should rely only on the information contained in this prospectus. No dealer, salesperson or other person is authorized to give information that is not contained in this prospectus. This prospectus is not an offer to sell nor is it seeking an offer to buy these securities in any jurisdiction where the offer or sale is not permitted. The selling stockholders are offering to sell and seeking offers to buy our common stock only in jurisdictions where offers and sales are permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of these securities.

All trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the ® and ^{TM} symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

PROSPECTUS SUMMARY

The following summary highlights selected information contained elsewhere in this prospectus and is qualified in its entirety by the more detailed information and financial statements included elsewhere in this prospectus. It does not contain all the information that may be important to you and your investment decision. You should carefully read this entire prospectus, including the matters set forth under "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our financial statements and related notes included elsewhere in this prospectus. In this prospectus, unless context requires otherwise, references to "we," "us," "our," "LIXT" "Lixte Biotechnology," or "the Company" refer to Lixte Biotechnology Holdings, Inc.

Company Overview

We are 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. Our product pipeline is primarily focused on inhibitors of protein phosphatases, used alone and in combination with cytotoxic agents and/or x-ray and immune checkpoint blockers, and encompasses two major categories of compounds at various stages of pre-clinical and clinical development that we believe have broad therapeutic potential not only for cancer but also for other debilitating and life-threatening diseases.

We have developed two series of pharmacologically active drugs, the LB-100 series and the LB-200 series. We believe 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, our compounds will improve therapeutic benefit without enhancing toxicity in humans.

Our activities are subject to significant risks and uncertainties, including the need for additional capital, as described below. We have not yet commenced any revenue-generating operations, do not have positive cash flows from operations, and are dependent on periodic infusions of equity capital to fund our operating requirements.

Product Candidates

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.

We have 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, or CRADA, with the National Institute of Neurologic Disorders and Stroke, or NINDS, of the National Institutes of Health, or NIH, dated March 22, 2006 that was subsequently extended through a series of amendments until it terminated on April 1, 2013. As discussed below, our primary focus is on the clinical development of LB-100.

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, we have demonstrated that our HDACi have broad activity against many cancer types, have neuroprotective activity, and have anti-fungal activity. In addition, these compounds have low toxicity. LB-200 has not yet advanced to the clinical stage and would require additional capital to fund further development. Accordingly, because of our focus on the clinical development of LB-100 and analogs for cancer therapy as described below in more detail, we have decided not to actively pursue the pre-clinical development of our LB-200 series of compounds at this time. At this time, we intend to only maintain composition of matter patents for LB-200.

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 of a series of serine/threonine phosphatase (s/t ptase) inhibitors designed by us. 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 we have 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. 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.

We completed a Phase 1 clinical trial of LB-100 to evaluate its safety that showed it is associated with antitumor 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, we were 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.

Current Studies

Moffitt. Effective August 20, 2018, we entered into a Clinical Trial Research Agreement with the Moffitt Cancer Center and Research Institute Hospital Inc., Tampa, Florida, effective for a term of five years, unless terminated earlier by us pursuant to 30 days written notice. Pursuant to the Clinical Trial Research Agreement, Moffitt agreed to conduct and manage a Phase 1b/2 clinical trial to evaluate the therapeutic benefit of our lead anti-cancer clinical compound LB-100 to be administered intravenously in patients with low or intermediate-1 risk myelodysplastic syndrome (MDS).

In November 2018, we received approval from the U.S. Food and Drug Administration or “FDA” for our Investigational New Drug or “IND” Application to conduct a Phase 1b/2 clinical trial to evaluate the therapeutic benefit of LB-100 in patients with low and intermediate-1 risk MDS who have failed or are intolerant of standard treatment. Patients with MDS, although usually older, are generally well except for severe anemia requiring frequent blood transfusions. This Phase 1b/2 clinical trial utilizes LB-100 as a single agent in the treatment of patients with low and intermediate-1 risk MDS, including patients with del(5q) myelodysplastic syndrome (del5qMDS) failing first line therapy. The bone marrow cells of patients with del5qMDS are deficient in PP2A by virtue of an acquired mutation and are especially vulnerable to further inhibition of PP2A by LB-100. The clinical trial began at a single site in April 2019 and the first patient was entered into the clinical trial in July 2019. A total enrollment of 41 patients is planned. An interim analysis will be done after the first 21 patients are entered. If there are 3 or more responders but fewer than 7, an additional 20 patients will be entered. If at any point there are 7 or more responders, this will be sufficient evidence to support continued development of LB-100 for the treatment of low and intermediate-1 risk MDS. Recruitment has been slow and the Covid-19 pandemic has further reduced recruitment of patients into the protocol. At the current rate of accrual, the trial would be completed over a period of four years from its initiation, with the final analysis and reporting expected by July 2023. However, with additional funds, our objective would be to add two additional MDS centers to the Phase 2 portion of the study to accelerate patient accrual, with the goal of an earlier reporting date.

GEIS. As of July 31, 2019, we entered into a Collaboration Agreement for an Investigator-Initiated Clinical Trial with the Spanish Sarcoma Group (Grupo Español de Investigación en Sarcomas or "GEIS"), Madrid, Spain, to carry out a clinical trial to obtain information about the efficacy and safety of LB-100 combined with doxorubicin in soft tissue sarcomas. Doxorubicin is the global standard for initial treatment of advanced soft tissue sarcomas ("ASTS"). Doxorubicin alone has been the mainstay of first line treatment of ASTS for over 40 years, with little therapeutic gain from adding cytotoxic compounds to or substituting other cytotoxic compounds for doxorubicin. In animal models, LB-100 consistently enhances the anti-tumor activity of doxorubicin without apparent increases in toxicity.

GEIS has a network of referral centers in Spain and across Europe that have an impressive track record of efficiently conducting innovative studies in ASTS. We agreed to provide GEIS with a supply of LB-100 to be utilized in the conduct of this clinical trial, as well as to provide funding for the clinical trial. The goal was to enter the first patient during the quarter ending December 31, 2020, with approximately 150 patients to be enrolled over two years. Advanced sarcoma is a very aggressive disease.

We had previously expected that this clinical trial would commence during the quarter ended June 30, 2020. However, during July 2020, a Spanish regulatory body advised us that although it had approved the scientific and ethical basis of the protocol, it required that we manufacture a new inventory of LB-100 under current Spanish pharmaceutical manufacturing standards. These regulations were adopted subsequent to the production of our existing LB-100 inventory. We are in the process of determining how soon new inventory of LB-100 meeting Spanish specifications can be produced. Accordingly, the clinical trial is now estimated to begin during the quarter ending September 30, 2021 and to be completed by the quarter ending September 30, 2024. The interim analysis expected in June 2023 could indicate either inferiority or superiority of the LB-100 plus doxorubicin arm compared to doxorubicin alone. A positive study would have the potential to change the standard therapy for this disease after four decades of failure to improve the marginal benefit of doxorubicin alone.

NCI. During the fourth quarter of 2019, the National Cancer Institute, or NCI, enrolled the first two patients of a planned eight patient pharmacologic study of the ability of LB-100 to enter the brain and penetrate recurrent brain tumors in patients where surgical removal of the cancers is indicated (clinical trials registry NCT03027388). This study is being conducted and funded by the NCI under a CRADA with us; additional information will be reported by us as it is provided by the NCI.

Primary malignant brain tumors (gliomas) are very challenging to treat. Radiation combined with the chemotherapeutic drug temozolomide has been the mainstay of therapy of the most aggressive gliomas (glioblastoma multiforme or GBM) for decades, with some further benefit gained by the addition of one or more anti-cancer drugs, but without major advances in overall survival for the majority of patients. In animal models of GBM, LB-100 enhances the effectiveness of radiation, temozolomide chemotherapy treatments and immunotherapy, raising the possibility that LB-100 may improve outcomes of standard GBM treatment in the clinic. Although LB-100 has proven safe in patients at doses associated with apparent anti-tumor activity against several human cancers arising outside the brain, the ability of LB-100 to penetrate tumor tissue arising in the brain is not known. Unfortunately, many drugs potentially useful for GBM treatment do not enter the brain in amounts necessary for anti-cancer action.

The NCI study is designed to determine the extent to which LB-100 enters recurrent malignant gliomas. Patients having surgery to remove one or more tumors will receive one dose of LB-100 prior to surgery and have blood and tumor tissue analyzed to determine the amount of LB-100 present and to determine whether the cells in the tumors show the biochemical changes expected to be present if LB-100 reaches its molecular target. The goal is to obtain data in up to eight patients. As a result of the innovative design of the NCI study, data from so few patients should be sufficient to provide a sound rationale for conducting a larger clinical trial to determine the effectiveness of adding LB-100 to the standard treatment regimen for GBMs.

Future Clinical Trials:

Presented below are clinical trials that we would currently consider conducting over the next few years. We expect that these potential clinical trials, and the details thereof, will change over time as we obtain more clinical information on LB-100. Our ability to conduct these clinical trials is subject to the availability of sufficient additional 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/atezolizumab, 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 began in April 2019, and/or partnering relationships with other pharmaceutical companies, in order for us to undertake and complete such clinical studies. We are in discussions with various parties with respect to the financing of these clinical studies, although there can be no assurances that we will be able to obtain such financing and/or partnering relationships on acceptable terms or at all. Our longer-term objective is to secure one or more strategic partnerships with pharmaceutical companies with major programs in cancer research and drug development.

Marketing Plan

Our primary goal to date has been to take LB-100 through Phase 2 clinical trials. Because of the novelty and spectrum of activity of LB-100, we believe 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, we would prefer to delay the partnering/licensing decision until the potential value of our 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 our product.

Risks Associated with Our Business

Our business is subject to a number of risks of which you should be aware of before making an investment decision. These risks are discussed more fully in the "*Risk Factors*" section of this prospectus immediately following this prospectus summary. Some of these risks include the following:

- We have incurred substantial losses since our inception and anticipate that we will continue to incur substantial and increasing losses for the foreseeable future.
- We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.
- We currently have no source of revenues. We may never generate revenues or achieve profitability.
- We expect to continue to incur significant operating and non-operating expenses, which may make it difficult for us to secure sufficient financing and may lead to uncertainty about our ability to continue as a going concern.
- We are dependent in part on technologies we license, and if we lose the right to license such technologies or we fail to license new technologies in the future, our ability to develop new products would be harmed, and if we fail to meet our obligations under our current or future license agreements, we may lose the ability to develop our product candidate.
- We expect to face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- We are currently a clinical-stage biopharmaceutical company with a product candidate in clinical development. If we are unable to successfully develop and commercialize our product candidate or experience significant delays in doing so, our business may be materially harmed.

- Our success relies on third-party suppliers and manufacturers. Any failure by such third parties, including, but not limited to, failure to successfully perform and comply with regulatory requirements, could negatively impact our business and our ability to develop and market our product candidate, and our business could be substantially harmed.

- Our future success is dependent on the regulatory approval of our product candidate.

- Our business may be adversely affected by the ongoing coronavirus pandemic.

- Business interruptions could adversely affect future operations, revenues, and financial conditions, and may increase our cost of expenses.

- Our failure to find third party collaborators to assist or share in the costs of product development could materially harm our business, financial condition, and results of operations.

- If we fail to comply with our obligations under our license agreement with licensors, we could lose rights that are important to our business.

- We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts.

- Our intellectual property may not be sufficient to protect our products from competition.

Proposed Changes to Our Capital Structure

Reverse Stock Split

We will effect a reverse split of our shares of common stock of 1-for-6 prior to, or upon, effectiveness of the registration statement of which this prospectus forms a part. No fractional shares will be issued in connection with the reverse stock split and all such fractional interests will be rounded up to the nearest whole number of shares of common stock. The conversion and/or exercise prices of our issued and outstanding convertible securities, including shares of our series A convertible preferred stock, stock options and warrants, will be adjusted accordingly. All information presented in this prospectus assumes a 1-for-6 reverse split of our outstanding shares of common stock, and unless otherwise indicated, all such amounts and corresponding conversion price and/or exercise price data set forth in this prospectus have been adjusted to give effect to the assumed reverse stock split.

Corporate Information

We were incorporated as a Delaware corporation on May 24, 2005 under the name SRKP 7, Inc. On June 30, 2006, pursuant to a share exchange agreement dated as of June 8, 2006, among us, Dr. John Kovach, and Lixte Biotechnology, Inc., we acquired all of the issued and outstanding shares of Lixte Biotechnology, Inc., which then became our wholly owned subsidiary. On December 7, 2006, we changed our name to Lixte Biotechnology Holdings, Inc. Our principal executive offices are located at 248 Route 25A, No. 2, East Setauket, New York 11733 and our telephone number is (631) 880-2907. Our website address is www.lixte.com. The information contained on our website is not incorporated by reference into this prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus or in deciding whether to invest in our common stock.

THE OFFERING

Common stock offered by us	1,500,000 shares
Common stock outstanding prior to this offering	11,174,302 shares
Common stock to be outstanding immediately after this offering	12,674,302 shares (12,899,302 shares if the underwriters exercise their over-allotment option in full)
Option to purchase additional shares	The underwriters have an option for a period of 45 days to purchase up to an additional 225,000 shares of our common stock.
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $8,137,500, or approximately $9,414,375 if the underwriters exercise their over-allotment option in full, at an assumed public offering price of $6.25 per share, the midpoint of the range set forth on the cover page of this prospectus, after deducting the underwriting discounts and commissions, the non-accountable expense allowance payable to the underwriters, and estimated offering expenses payable by us. We intend to use the net proceeds from this offering to fund our planned clinical trials, manufacturing our product candidate, maintain and extend our patent portfolio, retention of contract research organizations, development of a form of our primary compound, LB-100 for oral administration, and for working capital and other general corporate purposes. See “Use of Proceeds” for a more complete description of the intended use of proceeds from this offering.
Lock-up agreements	Our executive officers, directors and principal shareholders have agreed with the underwriters not to sell, transfer or dispose of any shares or similar securities for a period of 180 days after the date of this prospectus. For additional information regarding our arrangement with the underwriters, please see “Underwriting.”
Risk factors	See “Risk Factors” on page 11 and other information included in this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Current trading symbol	LIXT
Proposed market symbol	“LIXT”

The number of shares of our common stock to be outstanding after this offering is based on 11,174,302 shares of our common stock outstanding as of October 30, 2020, assumes no exercise by the underwriters of their over-allotment option, and excludes the following

- 729,167 shares of common stock issuable upon conversion of 350,000 shares of our Series A Preferred Stock outstanding at a conversion rate of 2.083 common shares per preferred share, reflecting an effective conversion price of $4.800 per common share.
- 1,508,333 shares of common stock issuable upon exercise of outstanding common stock options issued to members of management, consultants, and directors at a weighted average exercise price of $4.11 per common share.
- 1,500,000 shares of common stock issuable upon exercise of outstanding common stock warrants at an average exercise price of $6.00 per common share.
- 2,133,333 shares of common stock reserved for future grants pursuant to our 2020 Stock Incentive Plan.
- 150,000 shares of common stock issuable upon exercise of warrants to be issued to the underwriters as part of this offering at an exercise price of $7.50 per common share (120% of the assumed public offering price of $6.25 per share (the midpoint of the price range set forth on the cover page of this prospectus)).

Except as otherwise indicated herein, all information in this prospectus assumes or gives effect to:

- a 1-for-6 reverse stock split to be effected immediately prior to the effectiveness of the registration statement of which

this prospectus is a part. No fractional shares will be issued as a result of the reverse split. Any fractional shares resulting from the reverse split will be rounded up to the nearest whole share.

- no exercise by the underwriters of their option to purchase an additional 225,000 shares of common stock.

Summary Financial Data

The following tables set forth our summary financial data as of the dates and for the periods indicated. We have derived the summary statement of operations data for the years ended December 31, 2019 and 2018 from our audited financial statements included elsewhere in this prospectus. The summary statements of operations data for the six months ended June 30, 2020 and 2019 and the summary balance sheet data as of June 30, 2020 have been derived from our unaudited financial statements included elsewhere in this prospectus. The following summary financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes and other information included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected in the future and the results for the six months ended June 30, 2020 are not necessarily indicative of the results that may be expected for the full fiscal year ending December 31, 2020. All share and per share amounts presented herein have been restated to reflect the implementation of the proposed 1-for-6 reverse stock split as if it had occurred at the beginning of the earliest period presented.

Statement of Operations Data:

	Years Ended December 31,		Six Months Ended June 30, (unaudited)	
	2019	**2018**	**2020**	**2019**
Revenues	$ —	$ —	$ —	$ —
Operating costs and expenses				
Research and development	820,906	40,703	212,618	128,437
General and administrative	1,669,160	2,097,348	547,928	938,191
Total operating expenses	2,490,066	2,138,051	760,546	1,066,628
Net loss	$ (2,440,343)	$ (2,133,128)	$ (756,300)	$ (1,039,200)
Net loss per common share – basic and diluted[(1)]	$ (0.22)	$ (0.22)	$ (0.07)	$ (0.09)
Weighted average common shares outstanding – basic and diluted[(1)]	11,174,302	9,799,352	11,174,302	11,174,302

(1) See Note 2 to our financial statements for an explanation of the method used to compute basic and diluted net loss per share.

Balance Sheet Data

	As of June 30, 2020 (unaudited)	
	Actual	**Pro Forma[(1)]**
Cash	$ 1,774,332	$ 9,967,682
Total assets	$ 1,891,800	$ 9,998,300
Total liabilities	$ 213,965	$ 182,965
Accumulated deficit	$ (27,845,186)	$ (27,845,186)
Total stockholders' equity	$ 1,677,835	$ 9,998,300

(1) On a pro forma basis to give further effect to the issuance and sale of shares of common stock in this offering at an assumed public offering price of $6.25 per share, the midpoint of the price range listed on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions, the non-accountable expense allowance payable to the underwriters, and estimated offering costs payable by us.

(2) Each $1.00 increase (decrease) in the assumed public offering price of $6.25 per share, the midpoint of the price range listed on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, working capital, total assets and total stockholders' equity (deficiency) by approximately $1,362,000, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and the non-accountable expense allowance payable to the underwriters. Each increase (decrease) of 500,000 shares in the number of shares offered by us at the assumed public offering price per share, the midpoint of the price range listed on the cover page of this prospectus, would increase (decrease) the pro forma amount of each of cash, working capital, total assets and total stockholders' equity (deficiency) by approximately $2,837,500.

RISK FACTORS

An investment in our common stock involves a high degree of risk. Before making an investment decision, you should give careful consideration to the following risk factors, in addition to the other information included in this prospectus, including our financial statements and related notes, before deciding whether to invest in shares of our common stock. The occurrence of any of the adverse developments described in the following risk factors could materially and adversely harm our business, financial condition, results of operations or prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Relating to Our Financial Position and Capital Needs

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, we have 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.

We have incurred substantial losses since our inception and anticipate that we will continue to incur substantial and increasing losses for the foreseeable future.

We are a clinical stage biopharmaceutical company that uses biomarker technology to identify enzyme targets associated with serious common diseases and then designs novel compounds to attack those threats. We do not have any products approved by regulatory authorities and have not generated any revenues from collaboration and licensing agreements or product sales to date, and have incurred significant research, development and other expenses related to our ongoing operations and expect to continue to incur such expenses. As a result, we have not been profitable and have incurred significant operating losses since our inception. For the six months ended June 30, 2020 and 2019, we reported a net loss of $756,300 and $1,039,200, respectively. For the years ended December 31, 2019 and 2018, we reported a net loss of $2,440,343 and $2,133,128, respectively. As of June 30, 2020 and December 31, 2019, we had an accumulated deficit of $27,845,186 and $27,088,886, respectively.

We do not expect to generate revenues for many years, if at all. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate these losses to increase as we continue to research, develop and seek regulatory approvals for our product candidate and any additional product candidates we may acquire, and potentially begin to commercialize product candidates that may achieve regulatory approval. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. Our expenses will further increase as we:

- conduct clinical trials of our lead product candidate, LB-100;
- in-license or acquire the rights to, and pursue development of, other products, product candidates or technologies;
- hire additional clinical, manufacturing, quality control, quality assurance and scientific personnel;
- seek marketing approval for any product candidates that successfully complete clinical trials;
- develop our outsourced manufacturing and commercial activities and establish sales, marketing and distribution capabilities, if we receive, or expect to receive, marketing approval for any product candidates;
- maintain, expand and protect our intellectual property portfolio; and
- add operational, financial and management information systems and personnel.

We need significant additional financing to fund our operations and complete the development and, if approved, the commercialization of our product candidate. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect our existing cash as of June 30, 2020 together with proceeds from this offering will enable us to fund our operating expenses through and capital expenditure requirements for [12] months from the date of this prospectus; however, our existing cash will not be sufficient to complete development and obtain regulatory approval for our product candidate, and we will need to raise significant additional capital to help us do so. In addition, our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned.

We expect to expend substantial resources for the foreseeable future to continue the clinical development and manufacturing of our product candidate and the advancement and expansion of our preclinical research pipeline. These expenditures will include costs associated with research and development, potentially acquiring new product candidates or technologies, conducting preclinical studies and clinical trials and potentially obtaining regulatory approvals and manufacturing products, as well as marketing and selling products approved for sale, if any.

Budgets and future capital requirements depend on many factors, including:

- the scope, progress, results and costs of our ongoing and planned development programs for our product candidate, as well as any additional clinical trials we undertake to obtain data sufficient to seek marketing approval for our product candidate;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidate if our clinical trials are successful;
- the cost of commercialization activities for our product candidate, if our product candidate is approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our product candidate for clinical trials in preparation for regulatory approval, including the cost and timing of process development, manufacturing scale-up and validation activities;

- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the costs to in-license future product candidates or technologies;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the costs in defending and resolving future derivative and securities class action litigation;
- our operating expenses; and
- the emergence of competing technologies or other adverse market developments.

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. We have no committed source of additional capital. If adequate funds are not available to us on a timely basis, we may not be able to continue as a going concern or we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for our product candidate or target indications, or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidate.

We currently have no source of revenues. We may never generate revenues or achieve profitability.

Currently, we do not generate any revenues from product sales or otherwise. Even if we are able to successfully achieve regulatory approval for our product candidate, we do not know when we will generate revenues or become profitable, if at all. Our ability to generate revenues from product sales and achieve profitability will depend on our ability to successfully commercialize products, including our primary product candidate, LB-100, and any other product candidates that we may develop, in-license or acquire in the future. Our ability to generate revenues and achieve profitability also depends on a number of additional factors, including our ability to:

- successfully complete development activities, including the necessary clinical trials;
- complete and submit New Drug Applications, or NDAs, to the FDA and obtain U.S. regulatory approval for indications for which there is a commercial market;
- complete and submit applications to foreign regulatory authorities;
- obtain regulatory approval in territories with viable market sizes;
- obtain coverage and adequate reimbursement from third parties, including government and private payors;
- set commercially viable prices for our product, if any;
- establish and maintain supply and manufacturing relationships with reliable third parties and/or build our own manufacturing facility and ensure adequate, legally globally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- develop distribution processes for our product candidate;
- develop commercial quantities of our product candidate, once approved, at acceptable cost levels; obtain additional funding, if required to develop and commercialize our product candidate;
- develop a commercial organization capable of sales, marketing and distribution for any products we intend to sell ourselves, in the markets in which we choose to commercialize on our own;
- achieve market acceptance of our product;
- attract, hire and retain qualified personnel; and
- protect our rights in our intellectual property portfolio.

Our revenues for any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which it gains regulatory approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable disease patients is not as significant as our estimates, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenues from sales of such products, even if approved. In addition, we anticipate incurring significant costs associated with commercializing any approved product candidate. As a result, even if we generate revenues, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce our operations.

The Tax Cuts and Jobs Act could adversely affect our business and financial condition.

H.R. 1, "An Act to provide for reconciliation pursuant to title II and V of the concurrent resolution on the budget for fiscal year 2018," informally entitled the Tax Cuts and Jobs Act ("Tax Act") enacted on December 22, 2017, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a single rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted taxable income (except for certain small businesses), limitation of the deduction for net operating losses carried forward from taxable years beginning after December 31, 2017 to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), providing immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits (including reduction of tax credits under the Orphan Drug Act). Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the Tax Act.

Our ability to use net operating losses to offset future taxable income may be subject to limitations.

As of December 31, 2019, we had federal net operating loss, or NOLs, carryforwards of approximately $17,088,000. Our NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 years under applicable U.S. tax laws, and will begin to expire, if not utilized, beginning in 2027. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Act, federal NOLs incurred in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs is limited. It is uncertain if and to what extent various states will conform to the Tax Act, or whether any further regulatory changes may be adopted in the future that could minimize its applicability. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and certain corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in the ownership of its equity over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited.

Risks Related to the Development and Regulatory Approval of Our Product Candidate

Clinical-stage biopharmaceutical companies with product candidates in clinical development face a wide range of challenging activities which may entail substantial risk.

We are a clinical-stage biopharmaceutical company with a product candidate in clinical development. The success of our product candidate will depend on several factors, including the following:

- designing, conducting and successfully completing preclinical development activities, including preclinical efficacy and IND-enabling studies, for our product candidate or product candidates we may, in the future, in-license or acquire;
- designing, conducting and completing clinical trials for our product candidate with positive results;
- receipt of regulatory approvals from applicable authorities;

- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidate;
- making arrangements with third-party manufacturers, receiving regulatory approval of our manufacturing processes and our third-party manufacturers' facilities from applicable regulatory authorities and ensuring adequate supply of drug product;
- manufacturing our product candidate at an acceptable cost;
- effectively launching commercial sales of our product candidate, if approved, whether alone or in collaboration with others;
- achieving acceptance of our product candidate, if approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- if our product candidate is approved, obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for our product candidate;
- complying with all applicable regulatory requirements, including FDA current Good Clinical Practices ("GCP"), current Good Manufacturing Practices ("cGMP"), and standards, rules and regulations governing promotional and other marketing activities;
- maintaining a continued acceptable safety profile of the product during development and following approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully develop and commercialize our product candidate, which could materially harm our business.

We may find it difficult to enroll patients in our clinical trials which could delay or prevent the start of clinical trials for our product candidate.

Identifying and qualifying patients to participate in clinical trials of our product candidate is essential to our success. The timing of our clinical trials depends in part on the rate at which we can recruit patients to participate in clinical trials of our product candidate, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. If we experience delays in our clinical trials, the timeline for obtaining regulatory approval of our product candidate will most likely be delayed.

Many factors may affect our ability to identify, enroll and maintain qualified patients, including the following:

- eligibility criteria of our ongoing and planned clinical trials with specific characteristics appropriate for inclusion in our clinical trials;
- design of the clinical trial;
- size and nature of the patient population;
- patients' perceptions as to risks and benefits of the product candidate under study and the participation in a clinical trial generally in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- the availability and efficacy of competing therapies and clinical trials;
- pendency of other trials underway in the same patient population;
- willingness of physicians to participate in our planned clinical trials;
- severity of the disease under investigation;

- proximity of patients to clinical sites;
- patients who do not complete the trials for personal reasons; and
- issues with CROs and/or with other vendors that handle our clinical trials.

We may not be able to initiate or continue to support clinical trials of LB-100, our product candidate, for one or more indications, or any future product candidates if we are unable to locate and enroll a sufficient number of eligible participants in these trials as required by the FDA or other regulatory authorities. Even if we are able to enroll a sufficient number of patients in our clinical trials, if the pace of enrollment is slower than we expect, the development costs for our product candidate may increase and the completion of our trials may be delayed or our trials could become too expensive to complete.

If we experience delays in the completion of, or termination of, any clinical trials of our product candidate, the commercial prospects of our product candidate could be harmed, and our ability to generate product revenue from any of our product candidate could be delayed or prevented. In addition, any delays in completing our clinical trials would likely increase our overall costs, impair product candidate development and jeopardize our ability to obtain regulatory approval relative to our current plans. Any of these occurrences may harm our business, financial condition, and prospects significantly.

The results of preclinical studies or earlier clinical trials are not necessarily predictive of future results. Our existing product candidate in clinical trials, and any other product candidates that may advance into clinical trials, may not have favorable results in later clinical trials or receive regulatory approval.

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of an investigational drug. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier preclinical studies or clinical trials.

Despite the results reported in earlier preclinical studies or clinical trials for our product candidate, we do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidate for a particular indication, in any particular jurisdiction. Efficacy data from prospectively designed trials may differ significantly from those obtained from retrospective subgroup analyses. If later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for our product candidate may be adversely impacted. Even if we believe that we have adequate data to support an application for regulatory approval to market our current product candidate or any future product candidates, the FDA or other regulatory authorities may not agree and may require that we conduct additional clinical trials.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome.

Clinical testing is expensive and can take many years to complete, with the outcome inherently uncertain. Failure can occur at any time during the clinical trial process. Before obtaining approval from regulatory authorities for the sale of our product candidate, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidate in humans. Prior to initiating clinical trials, a sponsor must complete extensive preclinical testing of a product candidate, including, in most cases, preclinical efficacy experiments as well as IND-enabling toxicology studies. These experiments and studies may be time-consuming and expensive to complete. The necessary preclinical testing may not be completed successfully for a preclinical product candidate and a potentially promising product candidate may therefore never be tested in humans. Once it commences, clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. We may experience numerous unforeseen events during drug development that could delay or prevent our ability to receive marketing approval or commercialize our product candidate. In particular, clinical trials of our product candidate may produce inconclusive or negative results. We have limited data regarding the safety, tolerability and efficacy of our product candidate. Clinical trials also require the review and oversight of an institutional review board (“IRB”). An inability or delay in obtaining IRB approval could prevent or delay the initiation and completion of clinical trials, and the FDA may decide not to consider any data or information derived from a clinical investigation not subject to initial and continuing IRB review and approval.

We may experience delays in our ongoing or future clinical trials, and we do not know whether planned clinical trials will begin or enroll subjects on time, will need to be redesigned or will be completed on schedule, if at all. There can be no assurance that the FDA will not put clinical trials of our product candidate on hold in the future. Clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, such as:

- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a clinical trial design that we are able to execute;
- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a trial;
- delay or failure in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delay or failure in obtaining IRB approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct a clinical trial at each site;
- withdrawal of clinical trial sites from our clinical trials or the ineligibility of a site to participate in our clinical trials;
- delay or failure in recruiting and enrolling suitable subjects to participate in a trial;
- delay or failure in subjects completing a trial or returning for post-treatment follow-up;
- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication;
- failure of our third-party clinical trial managers, CROs, clinical trial sites, contracted laboratories or other third-party vendors to satisfy their contractual duties, meet expected deadlines or return trustworthy data;
- delay or failure in adding new trial sites;
- interim results or data that are ambiguous or negative or are inconsistent with earlier results or data;
- alteration of trial design necessitated by re-evaluation of design assumptions based upon observed data;
- feedback from the FDA, the IRB or a comparable foreign regulatory authority, or results from earlier stage or concurrent preclinical studies and clinical trials, that might require modification to the protocol for a trial;
- a decision by the FDA, the IRB, a comparable foreign regulatory authority, or us to suspend or terminate clinical trials at any time for safety issues or for any other reason;
- unacceptable risk-benefit profile, unforeseen safety issues or adverse side effects;
- failure to demonstrate a benefit from using a product candidate;
- difficulties in manufacturing or obtaining from third parties sufficient quantities of a product candidate to start or to use in clinical trials;

- lack of adequate funding to continue a trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional studies or increased expenses associated with the services of our CROs and other third parties; or

- changes in governmental regulations or administrative actions or lack of adequate funding to continue a clinical trial.

If we experience delays in the completion or termination of any clinical trial of our product candidate, the approval and commercial prospects of our product candidate will be harmed, delaying our ability to generate product revenues from such product candidate and our costs will most likely increase. The required regulatory approvals may also be delayed, thereby jeopardizing our ability to commence product sales and generate revenues and the period of commercial exclusivity for our product may be decreased. Regulatory approval of our product candidate may be denied for the same reasons that caused the delay.

Risks associated with operating in foreign countries could materially adversely affect our product development.

We may conduct future studies in countries outside of the U.S. Consequently, we may be subject to risks related to operating in foreign countries. Risks associated with conducting operations in foreign countries include:

- differing regulatory requirements for drug approvals and regulation of approved drugs in foreign countries; more stringent privacy requirements for data to be supplied to our operations in the U.S., *e.g.*, General Data Protection Regulation in the European Union;

- unexpected changes in tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign taxes, including withholding of payroll taxes;

- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;

- foreign currency fluctuations, which could result in increased operating expenses or reduced revenues, and other obligations incident to doing business or operating in another country;

- workforce uncertainty in countries where labor unrest is more common than in the U.S.;

- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

- business interruptions resulting from geopolitical actions, including war and terrorism.

Our current and future product candidates, the methods used to deliver them or their dosage levels may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any regulatory approval.

Undesirable side effects caused by our current or future product candidates, their delivery methods or dosage levels could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval or termination of clinical trials by the FDA or other comparable foreign regulatory authorities; or an IRB, that approves and, monitors biomedical research to protect the rights and welfare of human subjects. As a result of safety or toxicity issues that we may experience in our clinical trials, or negative or inconclusive results from the clinical trials of others for drug candidates similar to our own, we may not receive approval to market our current product candidate or any product candidates we may pursue, which could prevent us from ever generating revenues or achieving profitability. Results of our trials could reveal an unacceptably high severity and incidence of side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our current or any future product candidates for any or all targeted indications. The drug-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may have a material adverse effect on our business, results of operations, financial condition, cash flows and future prospects.

Additionally, if our product candidate receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including that:

- we may be forced to suspend marketing of such product;
- regulatory authorities may withdraw their approvals of such product;
- regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of such product;
- we may be required to conduct post-marketing studies;
- we may be required to change the way the product is administered;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our product candidate, if approved.

Our product development program may not uncover all possible adverse events that patients who take our product candidate may experience. The number of subjects exposed to our product candidate and the average exposure time in the clinical development program may be inadequate to detect rare adverse events or chance findings that may only be detected once the product is administered to more patients and for greater periods of time.

Clinical trials by their nature utilize a sample of the potential patient population. However, with a limited number of subjects and limited duration of exposure, we cannot be fully assured that rare and severe side effects of our product candidate will be uncovered. Such rare and severe side effects may only be uncovered with a significantly larger number of patients exposed to our product candidate. If such safety problems occur or are identified after our product candidate reaches the market, the FDA may require that we amend the labeling of the product or recall the product, or may even withdraw approval for the product.

Our future success is dependent on the regulatory approval of our product candidate.

Our business is dependent on our ability to obtain regulatory approval for our product candidate in a timely manner. We cannot commercialize our product candidate in the U.S. without first obtaining regulatory approval for the product from the FDA. Similarly, we cannot commercialize our product candidate outside of the U.S. without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of our product candidate for a target indication, we must demonstrate with substantial evidence gathered in preclinical studies and clinical trials, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate with respect to such product candidate.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate’s clinical development and may vary among jurisdictions.

Even if a product candidate were to successfully obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. Also, any regulatory approval of our current product candidate or any future product candidates we may pursue, once obtained, may be withdrawn.

Our current product candidate and future product candidates could fail to receive regulatory approval from the FDA.

We have not obtained regulatory approval for our product candidate and it is possible that our existing product candidate or any future product candidates will not obtain regulatory approval, for many reasons, including:

- disagreement with the regulatory authorities regarding the scope, design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for our proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our product candidate to support the submission and filing of an NDA or other submission or to obtain regulatory approval;
- failure to obtain approval of our manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies or our own manufacturing facility; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval or additional studies, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve our current product candidate and any future product candidates we may pursue for fewer or more limited indications than we request (including failing to approve the most commercially promising indications), may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

If we are unable to obtain regulatory approval for our product candidate in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding to continue the development of that product or generate revenues attributable to that product candidate.

Failure to obtain regulatory approval in international jurisdictions would prevent our product candidate from being marketed abroad.

In addition to regulations in the U.S., to market and sell our product candidate in the European Union, United Kingdom, many Asian countries and other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the U.S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. The regulatory approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. We may not be able to obtain approvals from regulatory authorities outside the U.S. on a timely basis, if at all. Clinical trials accepted in one country may not be accepted by regulatory authorities in other countries. In addition, many countries outside the U.S. require that a product be approved for reimbursement before it can be approved for sale in that country. A product candidate that has been approved for sale in a particular country may not receive reimbursement approval in that country.

We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our product in any market. If we are unable to obtain approval of any of our current product candidate or any future product candidates we may pursue by regulatory authorities in the European Union, United Kingdom, Asia or elsewhere, the commercial prospects of that product candidate may be significantly diminished, our business prospects could decline and this could materially adversely affect our business, results of operations and financial condition.

Even if our current primary product candidate received regulatory approval, it may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for our primary product candidate, LB-100, that approval would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, adverse event reporting, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-marketing information. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance by us and/or our CMOs and CROs for any post-approval clinical trials that we may conduct. The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of our product candidate, they may require labeling changes or establishment of a risk evaluation and mitigation strategy, impose significant restrictions on such product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP, GCP, and other regulations. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidate or the manufacturing facilities for our product candidate fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to successfully commercialize our product and generate revenues.

Advertising and promotion of any product candidate that obtains approval in the U.S. is heavily scrutinized by the FDA, the Department of Justice, the Office of Inspector General of Health and Human Services, state attorneys general, members of Congress and the public. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. Additionally, advertising and promotion of any product candidate that obtains approval outside of the U.S. is heavily scrutinized by comparable foreign regulatory authorities. Violations, including actual or alleged promotion of our product for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA, as well as prosecution under the federal False Claims Act. Any actual or alleged failure to comply with labeling and promotion requirements may have a negative impact on our business.

Risks Related to Our Dependence on Third Parties

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 83 years old and is being treated for recurrent asymptomatic prostate cancer. 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. The competition for qualified personnel in the pharmaceutical field is intense and, as a result, we may be unable to attract and retain qualified personnel necessary for the development of 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. The Collaboration Agreement automatically renews annually unless either party elects to terminate it. Services under this Collaboration Agreement have been periodically suspended and resumed; effective March 1, 2019, we and BioPharmaWorks agreed to resume services under this Collaboration Agreement, and the Collaboration Agreement is currently in effect.

Additionally, we have recently hired Dr. James S. Miser as Chief Medical Officer. For the foreseeable future, Dr. Miser will be working with us on a half-time basis. We believe that this Collaboration Agreement with BioPharmaWorks and the hiring of Dr. Miser mitigate, 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, we have 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.

Business interruptions could adversely affect future operations, revenues, and financial conditions, and may increase our costs and expenses.

Our operations, and those of our directors, advisors, contractors, consultants, CROs, and collaborators, could be adversely affected by earthquakes, floods, hurricanes, typhoons, extreme weather conditions, fires, water shortages, power failures, business systems failures, medical epidemics and other natural and man-made disaster or business interruptions. Our phones, electronic devices and computer systems and those of our directors, advisors, contractors, consultants, CROs, and collaborators are vulnerable to damages, theft and accidental loss, negligence, unauthorized access, terrorism, war, electronic and telecommunications failures, and other natural and man-made disasters. Operating as a virtual company, our employees conduct business outside of our headquarters and leased or owned facilities. These locations may be subject to additional security and other risk factors due to the limited control of our employees. If such an event as described above were to occur in the future, it may cause interruptions in our operations, delay research and development programs, clinical trials, regulatory activities, manufacturing and quality assurance activities, sales and marketing activities, hiring, training of employees and persons within associated third parties, and other business activities. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Likewise, we will rely on third parties to manufacture our product candidates and conduct clinical trials, and similar events as those described in the prior paragraph relating to their business systems, equipment and facilities could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidate could be delayed or altogether terminated.

Our failure to find third party collaborators to assist or share in the costs of product development could materially harm our business, financial condition and results of operations.

Our strategy for the development and commercialization of our proprietary product candidates may include the formation of collaborative arrangements with third parties. We have entered into a number of agreements with third parties as described below under "Business," including a clinical trial research agreement with Moffitt Cancer Center, a collaboration agreement with the Spanish Sarcoma Group, a cooperative research and development agreement with the National Cancer Institute, an agreement with Theradex Systems, Inc., a patent assignment and exploitation agreement with Inserm Transfert, SA, a consulting agreement with Liberi Life Sciences Consultancy BV, an exclusive license agreement with Moffitt, a material cooperative research and development agreement with the National Institutes of Health, a collaboration agreement with BioPharmaWorks and a consulting agreement with NDA Consulting Corp. Existing and future collaborators have significant discretion in determining the efforts and resources they apply and may not perform their obligations as expected. Potential third-party collaborators include biopharmaceutical, pharmaceutical and biotechnology companies, academic institutions and other entities. Third-party collaborators may assist us in:

- funding research, preclinical development, clinical trials and manufacturing;
- seeking and obtaining regulatory approvals; and
- successfully commercializing any future product candidates.

If we are not able to establish further collaboration agreements, we may be required to undertake product development and commercialization at our own expense. Such an undertaking may limit the number of product candidates that we will be able to develop, significantly increase our capital requirements and place additional strain on our internal resources. Our failure to enter into additional collaborations could materially harm our business, financial condition and results of operations.

In addition, our dependence on licensing, collaboration and other agreements with third parties may subject us to a number of risks. These agreements may not be on terms that prove favorable to us and may require us to relinquish certain rights in our product candidates. To the extent we agree to work exclusively with one collaborator in a given area, our opportunities to collaborate with other entities could be curtailed. Lengthy negotiations with potential new collaborators may lead to delays in the research, development or commercialization of product candidates. The decision by our collaborators to pursue alternative technologies or the failure of our collaborators to develop or commercialize successfully any product candidate to which they have obtained rights from us could materially harm our business, financial condition and results of operations.

Risks Related to Our Intellectual Property

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 one or more of our licensors, we may be required to participate in an interference or derivation proceeding declared or instituted by the United States Patent and Trademark Office, 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 do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for any product candidates we may develop, our business may be materially harmed.

In the United States, the patent term of a patent that covers an FDA-approved drug may be eligible for limited patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under clinical development and regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent that is applicable to and covers an approved drug may be extended. Similar provisions are available in Europe, such as supplementary protection certificates, and in certain other non-United States jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, if and when our product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those product candidates, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. We may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the length of a patent term extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations and prospects could be materially harmed.

It is possible that we will not obtain patent term extension under the Hatch-Waxman Act for a U.S. patent covering any of our product candidates that we may identify even where that patent is eligible for patent term extension, or if we obtain such an extension, it may be for a shorter period than we had sought.

If we fail to comply with our obligations in the agreements under which we may license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose rights that are important to our business.

We have entered and may be required to enter into intellectual property license agreements that are important to our business. These license agreements may impose various diligence, milestone payment, royalty and other obligations on us. For example, we may enter into exclusive license agreements with various third parties (for example, universities and research institutions), we may be required to use commercially reasonable efforts to engage in various development and commercialization activities with respect to licensed products, and may need to satisfy specified milestone and royalty payment obligations. If we fail to comply with any obligations under our agreements with any of these licensors, we may be subject to termination of the license agreement in whole or in part; increased financial obligations to our licensors or loss of exclusivity in a particular field or territory, in which case our ability to develop or commercialize products covered by the license agreement will be impaired.

In addition, disputes may arise regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our diligence obligations under the license agreement and what activities satisfy those obligations;
- if a third-party expresses interest in an area under a license that we are not pursuing, under the terms of certain of our license agreements, we may be required to sublicense rights in that area to a third party, and that sublicense could harm our business; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our product candidates.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. We cannot guarantee that our products or product candidates, or manufacture or use of our products or product candidates, will not infringe third-party patents. Furthermore, a third party may claim that we are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and scientific personnel. Some of these third parties may be better capitalized and have more resources than us. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In that event, we may not have a viable way around the patent and may need to halt commercialization of the relevant product candidate. In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party's patents. In addition, we may be obligated to indemnify our licensors and collaborators against certain intellectual property infringement claims brought by third parties, which could require us to expend additional resources. The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform.

If we are sued for patent infringement, we would need to demonstrate that our products or products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, and then we will have to defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid or unenforceable, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates.

We cannot be certain that others have not filed patent applications for technology covered by our pending applications, or that we were the first to invent the technology, because:

- some patent applications in the United States may be maintained in secrecy until the patents are issued;
- patent applications in the United States are typically not published until 18 months after the priority date; and
- publications in the scientific literature often lag behind actual discoveries.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed US patent applications on inventions similar to ours that claims priority to any applications filed prior to the priority dates of our applications, we may have to participate in an interference proceeding declared or a derivation proceed instituted by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar inventions prior to our own inventions, resulting in a loss of our U.S. patent position with respect to such inventions. Other countries have similar laws that permit secrecy of patent applications, and thus the third party's patent or patent application may be entitled to priority over our applications in such jurisdictions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed alleged trade secrets.

As is common in the biotechnology and pharmaceutical industries, we employ, and may employ in the future, individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we could lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Our intellectual property may not be sufficient to protect our products from competition, which may negatively affect our business as well as limit our partnership or acquisition appeal.

We may be subject to competition despite the existence of intellectual property we license or own. We can give no assurances that our intellectual property claims will be sufficient to prevent third parties from designing around patents we own or license and developing and commercializing competitive products. The existence of competitive products that avoid our intellectual property could materially adversely affect our operating results and financial condition. Furthermore, limitations, or perceived limitations, in our intellectual property may limit the interest of third parties to partner, collaborate or otherwise transact with us, if third parties perceive a higher than acceptable risk to commercialization of our products or future products.

Our approach involves the filing of patent applications covering new methods of use and/or new formulations of previously known, studied and/or marketed drugs. Although the protection afforded by our patent applications may be significant, when looking at our patents' ability to block competition, the protection offered by our patents may be, to some extent, more limited than the protection provided by patents claiming the composition of matter of entirely new chemical structures previously unknown. If a competitor were able to successfully design around any method of use and formulation patents we may have in the future, our business and competitive advantage could be significantly affected.

We may elect to sue a third party, or otherwise make a claim, alleging infringement or other violation of patents, trademarks, trade dress, copyrights, trade secrets, domain names or other intellectual property rights that we either own or license. If we do not prevail in enforcing our intellectual property rights in this type of litigation, we may be subject to:

- paying monetary damages related to the legal expenses of the third party;
- facing additional competition that may have a significant adverse effect on our product pricing, market share, business operations, financial condition, and the commercial viability of our products; and
- restructuring our company or delaying or terminating select business opportunities, including, but not limited to, research and development, clinical trials, and commercialization activities, due to a potential deterioration of our financial condition or market competitiveness.

A third party may also challenge the validity, enforceability or scope of the intellectual property rights that we license or own; and, the result of these challenges may narrow the scope or claims of or invalidate patents that are integral to our product candidates in the future. There can be no assurance that we will be able to successfully defend patents we own in an action against third parties due to the unpredictability of litigation and the high costs associated with intellectual property litigation, amongst other factors.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and Europe, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products or product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

Changes to patent law, for example the Leahy-Smith America Invests Act, AIA or Leahy-Smith Act, of 2011 and the Patent Reform Act of 2009 and other future article of legislation in the U.S., may substantially change the regulations and procedures surrounding patent applications, issuance of patents, prosecution of patents, challenges to patent validity, and patent enforcement. We can give no assurances that our patents and those of our licensor(s) can be defended or will protect us against future intellectual property challenges, particularly as they pertain to changes in patent law and future patent law interpretations.

In addition, enforcing and maintaining our intellectual property protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by the U.S. Patent and Trademark Office and courts, and foreign government patent agencies and courts, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

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, collaborators, 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 be unaware of or unfamiliar with prior art and/or interpretations of prior art that could potentially impact the validity or scope of our patents or pending patent applications, or patent applications that we will file. We may have elected, or elect now or in the future, not to maintain or pursue intellectual property rights that, at some point in time, may be considered relevant to or enforceable against a competitor.

We take efforts and enter into agreements with employees, consultants, collaborators, and advisors to confirm ownership and chain of title in intellectual property rights. However, an inventorship or ownership dispute could arise that may permit one or more third parties to practice or enforce our intellectual property rights, including possible efforts to enforce rights against us.

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, product candidates and particular uses thereof that we seek to develop and commercialize, as well as synthesis of our product candidates. 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 product candidate, 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 or derivation proceeding declared or instituted before the United States Patent and Trademark Office, regarding intellectual property rights with respect to our products, product candidates 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 product candidates. 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 pharmaceutical and 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 or product candidates 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 may be challenged, invalidated, found unenforceable, or circumvented. United States patents and patent applications may be subject to interference and derivation proceedings, United States patents may also be subject to post grant proceedings, including re-examination, derivation, *Inter Partes* Review and Post Grant Review, 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 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, derivation, post grant 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 or derivation 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 our patents. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patents 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, contractors 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.

Risks Related to Commercialization of Our Current Product Candidate and Future Product Candidates

Our commercial success depends upon attaining significant market acceptance of our current product candidate and future product candidates, if approved, among physicians, patients, healthcare payors and cancer treatment centers.

Even if we obtain regulatory approval for our current product candidate or any future product candidates, the products may not gain market acceptance among physicians, healthcare payors, patients or the medical community, including cancer treatment centers. Market acceptance of any product candidates for which we receive approval depends on a number of factors, including:

- the efficacy and safety of such product candidates as demonstrated in clinical trials;
- the clinical indications and patient populations for which the product candidate is approved;
- acceptance by physicians, major cancer treatment centers and patients of the drug as a safe and effective treatment;
- the adoption of novel immunotherapies by physicians, hospitals and third-party payors;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including our use outside the approved indications;
- any restrictions on use together with other medications;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- the timing of market introduction of our product as well as competitive products;
- the development of manufacturing and distribution processes for commercial scale manufacturing for our current product candidate and any future product candidates;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement from third-party payors and government authorities;
- relative convenience and ease of administration; and
- the effectiveness of our sales and marketing efforts and those of our collaborators.

If our current product and any future product candidates are approved but fail to achieve market acceptance among physicians, patients, healthcare payors or cancer treatment centers, we will not be able to generate significant revenues, which would compromise our ability to become profitable.

Even if we are able to commercialize our current product candidate or any future product candidates, the products may not receive coverage and adequate reimbursement from third-party payors in the U.S. and in other countries in which we seek to commercialize our products, which could harm our business.

Our ability to commercialize any product successfully will depend, in part, on the extent to which coverage and adequate reimbursement for such product and related treatments will be available from third-party payors, including government health administration authorities, private health insurers and other organizations.

Third-party payors determine which medications they will cover and establish reimbursement levels. A primary trend in the healthcare industry is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors may also seek additional clinical evidence, beyond the data required to obtain regulatory approval, demonstrating clinical benefit and value in specific patient populations before covering our product for those patients. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if coverage is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain regulatory approval. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain regulatory approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by third-party payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. No uniform policy for coverage and reimbursement exists in the U.S., and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but also have their own methods and approval process apart from Medicare determinations. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved product that we develop could have a material adverse effect on our operating results, ability to raise capital needed to commercialize our product and overall financial condition.

Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the U.S. and certain international jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our product profitably. In particular, in 2010, the Affordable Care Act (“ACA”) was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government’s comparative effectiveness research. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the current U.S. administration to repeal or repeal and replace certain aspects of the ACA. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as a part of the Tax Act, the remaining provisions of the ACA are invalid as well. While the Texas District Court Judge, as well as the Trump Administration and CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA. Until there is more certainty concerning the future of the ACA, it will be difficult to predict its full impact and influence on our business.

In addition, other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation’s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in 2013, and will remain in effect through 2027 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidate, if we obtain regulatory approval;
- our ability to receive or set a price that we believe is fair for our product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement and new payment methodologies. This could lower the price that we receive for any approved product. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our product candidate, if approved.

Price controls may be imposed in foreign markets, which may adversely affect our future profitability.

In some countries, particularly member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of regulatory approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices.

In some countries, we or our collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidate to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our product is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

Risks Related to Healthcare Compliance Regulations

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. If we or they are unable to comply with these provisions, we may become subject to civil and criminal investigations and proceedings that could have a material adverse effect on our business, financial condition and prospects.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Our current and future arrangements with healthcare providers, healthcare entities, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, develop and will market, sell and distribute our product. As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate include the following:

- the federal healthcare Anti-Kickback Statute which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- federal civil and criminal false claims laws, including the federal False Claims Act that can be enforced through civil whistleblower or qui tam actions, and civil monetary penalty laws, prohibit individuals or entities from knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment or approval that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") which imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information on entities subject to the law, such as certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, and their respective business associates that perform services for them that involve the creation, use, maintenance or disclosure of, individually identifiable health information;

- the federal physician sunshine requirements under the ACA which requires certain manufacturers of drugs, devices, biologics and medical supplies, with certain exceptions, to report annually to HHS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations;

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws which require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or pricing information; and certain state and local laws which require the registration of pharmaceutical sales representatives; and

- state and foreign laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and integrity oversight and reporting obligations.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our current product candidate or future product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our product. If we cannot successfully defend ourselves against claims that our product candidate or product caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trial sites or entire clinical trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any products that we may develop.

Prior to engaging in future clinical trials, we intend to obtain product liability insurance coverage at a level that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks; however, we may be unable to obtain such coverage at a reasonable cost, if at all. If we are able to obtain product liability insurance, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise and such insurance may not be adequate to cover all liabilities that we may incur. Furthermore, we intend to expand our insurance coverage for products to include the sale of commercial products if we obtain regulatory approval for our product candidate in development, but we may be unable to obtain commercially reasonable product liability insurance for any products that receive regulatory approval. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Risks Related to our Business Operations

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

We will face competition from numerous pharmaceutical and biotechnology enterprises, as well as from academic institutions, government agencies and private and public research institutions for our current product candidate. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we may develop. Competition could result in reduced sales and pricing pressure on our current product candidate, if approved, which in turn would reduce our ability to generate meaningful revenues and have a negative impact on our results of operations. In addition, significant delays in the development of our product candidate could allow our competitors to bring products to market before we do and impair our ability to commercialize our product candidate. The biotechnology industry, including the cancer immunotherapy market, is intensely competitive and involves a high degree of risk. We compete with other companies that have far greater experience and financial, research and technical resources than us. Potential competitors in the U.S. and worldwide are numerous and include pharmaceutical and biotechnology companies, educational institutions and research foundations, many of which have substantially greater capital resources, marketing experience, research and development staffs and facilities than ours. Some of our competitors may develop and commercialize products that compete directly with those incorporating our technology or may introduce products to market earlier than our product or on a more cost-effective basis. Our competitors compete with us in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to our technology. We may face competition with respect to product efficacy and safety, ease of use and adaptability to various modes of administration, acceptance by physicians, the timing and scope of regulatory approvals, availability of resources, reimbursement coverage, price and patent position, including the potentially dominant patent positions of others. An inability to successfully complete our product development or commercializing our product candidate could result in our having limited prospects for establishing market share or generating revenue.

Many of our competitors or potential competitors have significantly greater established presence in the market, financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do, and as a result may have a competitive advantage over us. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or potentially advantageous to our business.

As a result of these factors, these competitors may obtain regulatory approval of their products before we are able to obtain patent protection or other intellectual property rights, which will limit our ability to develop or commercialize our current product candidate. Our competitors may also develop drugs that are safer, more effective, more widely used and cheaper than ours, and may also be more successful than us in manufacturing and marketing their products. These appreciable advantages could render our product candidate obsolete or non-competitive before we can recover the expenses of development and commercialization.

Our business may be adversely affected by the ongoing coronavirus pandemic.

The outbreak of the novel coronavirus (COVID-19) has evolved into a global pandemic. The coronavirus has spread to many regions of the world. The extent to which the coronavirus impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

As a result of the continuing spread of the coronavirus, our business operations could be delayed or interrupted. For instance, our clinical trials may be affected by the pandemic. Site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis may be paused or delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. If the coronavirus continues to spread, some participants and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to conduct our clinical trials. Further, if the spread of the coronavirus pandemic continues and our operations are adversely impacted, we risk a delay, default and/or non-performance under existing agreements which may increase our costs. These cost increases may not be fully recoverable or adequately covered by insurance.

Infections and deaths related to the pandemic may disrupt the United States' healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay FDA review and/or approval with respect to, our clinical trials. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates.

We currently utilize third parties to, among other things, manufacture raw materials. If either any third-party parties in the supply chain for materials used in the production of our product candidates are adversely impacted by restrictions resulting from the coronavirus outbreak, our supply chain may be disrupted, limiting our ability to manufacture our product candidates for our clinical trials and research and development operations.

As a result of the shelter-in-place order and other mandated local travel restrictions, our employees conducting research and development or manufacturing activities may not be able to access their laboratory or manufacturing space which may result in our core activities being significantly limited or curtailed, possibly for an extended period of time.

The spread of the coronavirus, which has caused a broad impact globally, including restrictions on travel and quarantine policies put into place by businesses and governments, may have a material economic effect on our business. While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the coronavirus could materially and adversely affect our business and the value of our common stock.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the situation closely.

Significant disruptions of information technology systems, computer system failures or breaches of information security could adversely affect our business.

We rely to a large extent upon sophisticated information technology systems to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, but not limited to, personal information and intellectual property). The size and complexity of our information technology and information security systems, and those of our third-party vendors with whom we may contract, make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees or vendors, or from malicious attacks by third parties. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage and market manipulation) and expertise. While we intend to invest in the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches.

Our internal computer systems, and those of our CROs, our CMOs, and other business vendors on which we may rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. We exercise little or no control over these third parties, which increases our vulnerability to problems with their systems. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. Any interruption or breach in our systems could adversely affect our business operations and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business and reputational harm to us or allow third parties to gain material, inside information that they use to trade in our securities. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we

could incur liability, the further development of our current and future product candidates could be delayed and our business could be otherwise adversely affected.

We will need to grow the size of our organization in the future, and we may experience difficulties in managing this growth.

As of October 31, 2020, we had two full-time employees and two part-time employees. We will need to grow the size of our organization in order to support our continued development and potential commercialization of our product candidate. As our development and commercialization plans and strategies continue to develop, our need for additional managerial, operational, manufacturing, sales, marketing, financial and other resources may increase. Our management, personnel and systems currently in place may not be adequate to support this future growth. Future growth would impose significant added responsibilities on members of management, including:

- managing our clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- improving our managerial, development, operational, information technology, and finance systems; and
- expanding our facilities.

If our operations expand, we will also need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidate and to compete effectively will depend, in part, on our ability to manage any future growth effectively, as well as our ability to develop a sales and marketing force when appropriate for our company. To that end, we must be able to manage our development efforts and preclinical studies and clinical trials effectively and hire, train and integrate additional management, research and development, manufacturing, administrative and sales and marketing personnel. The failure to accomplish any of these tasks could prevent us from successfully growing our company.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, upon completion of this offering and in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to Owning our Common Stock and this Offering

We are a "smaller reporting company" and we have elected to comply with certain reduced reporting and disclosure requirements which could make its common stock less attractive to investors.

We are a "smaller reporting company," as defined in the Regulation S-K of the Securities Act of 1933, as amended, which allows us to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies, including (1) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, and (2) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements in this document. As a result of these reduced reporting and disclosure requirements our financial statements may not be comparable to SEC registrants not classified as emerging growth companies.

We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Our independent registered public accounting firm is not be required to formally attest to the effectiveness of our internal control over financial reporting until we are no longer a "smaller reporting company". We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal controls in the future.

Investors may find our common stock less attractive as a result of our election to utilize these exemptions, which could result in a less active trading market for our common stock and/or the market price of our common stock may be more volatile.

An active trading market for our common stock may not develop, and you may not be able to sell your common stock at or above the public offering price.

Prior to the consummation of this offering, there has been a limited public market for our common stock. An active trading market for shares of our common stock may never develop or be sustained following this offering. If an active trading market does not develop, you may have difficulty selling your shares of common stock at an attractive price, or at all. The price for our common stock in this offering will be determined by negotiations between us and the underwriters, and it may not be indicative of prices that will prevail in the open market following this offering. Consequently, you may not be able to sell your common stock at or above the public offering price or at any other price or at the time that you would like to sell. An inactive market may also impair our ability to raise capital by selling our common stock, and it may impair our ability to attract and motivate our employees through equity incentive awards and our ability to acquire other companies, products or technologies by using our common stock as consideration.

The price of our common stock may fluctuate substantially.

You should consider an investment in our common stock to be risky, and you should invest in our common stock only if you can withstand a significant loss and wide fluctuations in the market value of your investment. Some factors that may cause the market price of our common stock to fluctuate, in addition to the other risks mentioned in this "Risk Factors" section and elsewhere in this prospectus, are:

- sale of our common stock by our stockholders, executives, and directors and our stockholders whose shares are being registered in this offering;
- volatility and limitations in trading volumes of our shares of common stock;
- our ability to obtain financings to conduct and complete research and development activities including, but not limited to, our clinical trials, and other business activities;
- possible delays in the expected recognition of revenue due to lengthy and sometimes unpredictable sales timelines;

- the timing and success of introductions of new products by us or our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors, customers or strategic partners;
- network outages or security breaches;
- our ability to attract new customers;
- our ability to secure resources and the necessary personnel to conduct clinical trials on our desired schedule;
- commencement, enrollment or results of our clinical trials for our product candidate or any future clinical trials we may conduct;
- changes in the development status of our product candidate;
- any delays or adverse developments or perceived adverse developments with respect to the FDA's review of our planned preclinical and clinical trials;
- any delay in our submission for studies or product approvals or adverse regulatory decisions, including failure to receive regulatory approval for our product candidate;
- unanticipated safety concerns related to the use of our product candidate;
- failures to meet external expectations or management guidance;
- changes in our capital structure or dividend policy, future issuances of securities, sales of large blocks of common stock by our stockholders;
- our cash position;
- announcements and events surrounding financing efforts, including debt and equity securities;
- our inability to enter into new markets or develop new products;
- reputational issues;
- competition from existing technologies and products or new technologies and products that may emerge;
- announcements of acquisitions, partnerships, collaborations, joint ventures, new products, capital commitments, or other events by us or our competitors;
- changes in general economic, political and market conditions in or any of the regions in which we conduct our business;
- changes in industry conditions or perceptions;
- changes in valuations of similar companies or groups of companies;
- analyst research reports, recommendation and changes in recommendations, price targets, and withdrawals of coverage;
- departures and additions of key personnel;
- disputes and litigations related to intellectual properties, proprietary rights, and contractual obligations;
- changes in applicable laws, rules, regulations, or accounting practices and other dynamics; and
- other events or factors, many of which may be out of our control.

In addition, if the market for stocks in our industry or industries related to our industry, or the stock market in general, experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, financial condition and results of operations. If any of the foregoing occurs, it could cause our stock price to fall and may expose us to lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management.

A sale or perceived sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

All of our executive officers and directors and certain of our stockholders and warrantholders have agreed not to sell shares of our common stock for a period of 180 days following this offering, subject to extension under specified circumstances. See "Underwriting." Common stock subject to these lock-up agreements will become eligible for sale in the public market upon expiration of these lock-up agreements, subject to limitations imposed by Rule 144 under the Securities Act of 1933, as amended. If our stockholders sell substantial amounts of our common stock in the public market, the market price of our common stock could fall. Moreover, the perceived risk of this potential dilution could cause stockholders to attempt to sell their shares and investors to short our common stock. These sales also may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this public offering, including for any of the currently intended purposes described in the section entitled "Use of Proceeds." Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management may not apply our cash from this offering in ways that ultimately increase the value of any investment in our securities or enhance stockholder value. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply our cash in ways that enhance stockholder value, we may fail to achieve expected financial results, which may result in a decline in the price of our shares of common stock, and, therefore, may negatively impact our ability to raise capital, invest in or expand our business, acquire additional products or licenses, commercialize our product, or continue our operations.

Market and economic conditions may negatively impact our business, financial condition and share price.

Concerns over medical epidemics, energy costs, geopolitical issues, the U.S. mortgage market and a deteriorating real estate market, unstable global credit markets and financial conditions, and volatile oil prices have led to periods of significant economic instability, diminished liquidity and credit availability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth, increased unemployment rates, and increased credit defaults in recent years. Our general business strategy may be adversely affected by any such economic downturns (including the current downturn related to the current COVID-19 pandemic), volatile business environments and continued unstable or unpredictable economic and market conditions. If these conditions continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and share price and could require us to delay or abandon development or commercialization plans.

If securities or industry analysts do not publish research or reports, or publish unfavorable research or reports about our business, our stock price and trading volume may decline.

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us, our business, our markets and our competitors. We do not control these analysts. If securities analysts do not cover our common stock after the closing of this offering, the lack of research coverage may adversely affect the market price of our common stock. Furthermore, if one or more of the analysts who do cover us downgrade our stock or if those analysts issue other unfavorable commentary about us or our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fails to regularly publish reports on us, we could lose visibility in the market and interest in our stock could decrease, which in turn could cause our stock price or trading volume to decline and may also impair our ability to expand our business with existing customers and attract new customers.

Because certain of our stockholders control a significant number of shares of our common stock, they may have effective control over actions requiring stockholder approval.

Following this offering, our directors, executive officers and principal stockholders, and their respective affiliates, will beneficially own approximately 69% of our outstanding shares of common stock. The percentage increases to approximately 71% in the event that the shares of the Company's Series A Preferred Stock are converted into shares of common stock. As a result, these stockholders, acting together, would have the ability to control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, would have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership might harm the market price of our common stock by:

- delaying, deferring or preventing a change in corporate control;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

You will incur immediate dilution as a result of this offering.

If you purchase common stock in this offering, you will pay more for your shares than the net tangible book value of your shares. As a result, you will incur immediate dilution of $5.48 per share, representing the difference between the assumed public offering price of $6.25 per share (the midpoint of the range on the cover of this prospectus) and our estimated pro forma net tangible book value per share as of June 30, 2020 of $0.77 per share. Accordingly, should we be liquidated at our book value, you would not receive the full amount of your investment.

Future sales and issuances of our common stock could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations, including increased marketing, hiring new personnel, commercializing our product, and continuing activities as an operating public company. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

We do not intend to pay cash dividends on our shares of common stock so any returns will be limited to the value of our shares.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the increase, if any, of our share price.

We may be at risk of securities class action litigation.

We may be at risk of securities class action litigation. In the past, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business and results in a decline in the market price of our common stock.

Our Certificate of Incorporation and our Amended and Restated Bylaws, and Delaware law may have anti-takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline.

Our Certificate of Incorporation and our Amended and Restated Bylaws, and Delaware law could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our stockholders. Upon consummation of this offering, we will be authorized to issue up to 10,000,000 shares of preferred stock. This preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our Board of Directors without further action by stockholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. As of October 13, 2020, we have designated 350,000 shares of preferred stock as Series A Convertible Preferred Stock, all of which are issued and outstanding. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third party and thereby preserve control by the present management.

Provisions of our Certificate of Incorporation and our Amended and Restated Bylaws and Delaware law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. Such provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, the certificate of incorporation and bylaws and Delaware law, as applicable, among other things:

- provide the board of directors with the ability to alter the bylaws without stockholder approval;
- place limitations on the removal of directors;
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings; and
- provide that vacancies on the board of directors may be filled by a majority of directors in office, although less than a quorum.

Financial reporting obligations of being a public company in the U.S. are expensive and time-consuming, and our management will be required to devote substantial time to compliance matters.

As a publicly traded company we incur significant additional legal, accounting and other expenses. The obligations of being a public company in the U.S. require significant expenditures and will place significant demands on our management and other personnel, including costs resulting from public company reporting obligations under the Exchange Act and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, and the listing requirements of the stock exchange on which our securities are listed. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. Moreover, despite recent reforms made possible by the JOBS Act, the reporting requirements, rules, and regulations will make some activities more time-consuming and costly, particularly after we are no longer an “emerging growth company.” In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation or being delisted, among other potential problems.

If we fail to comply with the rules under Sarbanes-Oxley related to accounting controls and procedures in the future, or, if we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult.

Section 404 of Sarbanes-Oxley requires annual management assessments of the effectiveness of our internal control over financial reporting. If we fail to comply with the rules under Sarbanes-Oxley related to disclosure controls and procedures in the future, or, if we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult. If material weaknesses or significant deficiencies are discovered or if we otherwise fail to achieve and maintain the adequacy of our internal control, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of Sarbanes-Oxley. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our common stock could drop significantly.

INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve risks and uncertainties. You should not place undue reliance on these forward-looking statements. All statements other than statements of historical facts contained in this prospectus are forward-looking statements. The forward-looking statements in this prospectus are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. In some cases, you can identify these forward-looking statements by terms such as “anticipate,” “believe,” “continue,” “could,” “depends,” “estimate,” “expects,” “intend,” “may,” “ongoing,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative of those terms or other similar expressions, although not all forward-looking statements contain those words. We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements include, but are not limited to, statements concerning the following:

- our projected financial position and estimated cash burn rate;
- our estimates regarding expenses, future revenues and capital requirements;
- our ability to continue as a going concern;
- our need to raise substantial additional capital to fund our operations;
- the success, cost and timing of our clinical trials;
- our dependence on third parties in the conduct of our clinical trials;
- our ability to obtain the necessary regulatory approvals to market and commercialize our product candidate;
- the ultimate impact of the current coronavirus pandemic, or any other health epidemic, on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole;
- the potential that results of preclinical and clinical trials indicate our current product candidate or any future product candidates we may seek to develop are unsafe or ineffective;
- the results of market research conducted by us or others;
- our ability to obtain and maintain intellectual property protection for our current product candidate;
- our ability to protect our intellectual property rights and the potential for us to incur substantial costs from lawsuits to enforce or protect our intellectual property rights;
- the possibility that a third party may claim we or our third-party licensors have infringed, misappropriated or otherwise violated their intellectual property rights and that we may incur substantial costs and be required to devote substantial time defending against claims against us;
- our reliance on third-party suppliers and manufacturers;
- the success of competing therapies and products that are or become available;
- our ability to expand our organization to accommodate potential growth and our ability to retain and attract key personnel;
- the potential for us to incur substantial costs resulting from product liability lawsuits against us and the potential for these product liability lawsuits to cause us to limit our commercialization of our product candidate;

- market acceptance of our product candidate, the size and growth of the potential markets for our current product candidate and any future product candidates we may seek to develop, and our ability to serve those markets; and

- the successful development of our commercialization capabilities, including sales and marketing capabilities.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in "Risk Factors." Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

INDUSTRY AND MARKET DATA

This prospectus contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. We obtained the industry and market data in this prospectus from our own research as well as from industry and general publications, surveys and studies conducted by third parties. This data involves a number of assumptions and limitations and contains projections and estimates of the future performance of the industries in which we operate that are subject to a high degree of uncertainty, including those discussed in "Risk Factors." We caution you not to give undue weight to such projections, assumptions and estimates. Further, industry and general publications, studies and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that these publications, studies and surveys are reliable, we have not independently verified the data contained in them. In addition, while we believe that the results and estimates from our internal research are reliable, such results and estimates have not been verified by any independent source.

EXPLANATORY NOTE REGARDING REVERSE STOCK SPLIT

We will effect a reverse split of our shares of common stock of 1-for-6 prior to or upon effectiveness of the registration statement of which this prospectus forms a part. No fractional shares will be issued in connection with the reverse stock split and all such fractional interests will be rounded up to the nearest whole number of shares of common stock. The conversion and/or exercise prices of our issued and outstanding convertible securities, including shares of our series A convertible preferred stock, stock options and warrants, will be adjusted accordingly. All information presented in this prospectus assumes a 1-for-6 reverse split of our outstanding shares of common stock, and unless otherwise indicated, all such amounts and corresponding conversion price and/or exercise price data set forth in this prospectus have been adjusted to give effect to the assumed reverse stock split.

USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of shares of our common stock in this offering will be approximately $8,137,500, based on an assumed public offering price of $6.25 per share, the midpoint of the price range listed on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their option to purchase additional shares in full, we estimate that the net proceeds from this offering will be approximately $9,414,375.

We intend to use the net proceeds to fund our planned clinical trials, updating our manufacturing protocols, manufacturing our product candidate, maintenance and expansion of our patent portfolio, retention of contract research organizations, development of a form of our primary compound, LB-100, for oral administration, and for general corporate purposes, including working capital.

A $1.00 increase or decrease in the assumed public offering price of $6.25 per share would increase or decrease the net proceeds from this offering by approximately $1,362,000, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and non-accountable expense allowance payable to the underwriters.

This expected use of the net proceeds from this offering and our existing cash represents our intentions based upon our current plans, financial condition and business conditions. Predicting the cost necessary to develop a product candidate can be difficult and the amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development and commercialization efforts, the status of and results from clinical trials, any collaborations that we may enter into with third parties for our product candidate and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering and our existing cash.

In the ordinary course of our business, we expect to from time to time evaluate the acquisition of, investment in or in-license of complementary products, technologies or businesses, and we could use a portion of the net proceeds from this offering for such activities. We currently do not have any agreements, arrangements or commitments with respect to any potential acquisition, investment or license.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and government securities.

DIVIDEND POLICY

We have never paid or declared any cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

CAPITALIZATION

The following table sets forth our capitalization as of June 30, 2020 (unaudited) as described below:

- on an actual basis, as adjusted to give effect to a one-for-six reverse stock split;
- on a pro forma basis to give effect to the issuance and sale of 1,500,000 shares of our common stock at an assumed public offering price of $6.25 per share, which is the midpoint of the price range listed on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions, the non-accounting expense allowance payable to the underwriters, and other estimated offering costs;

	As of June 30, 2020 (unaudited)	
	Actual	Pro Forma
Cash	$ 1,774,332	$ 9,967,682
Stockholders' equity:		
Preferred stock, $0.0001 par value per share, 10,000,000 shares authorized, issued and Outstanding 350,000 shares	3,500,000	3,500,000
Common stock, $0.0001 par value per share; 100,000,000 shares authorized, issued and outstanding 11,174,302 shares actual, and 12,674,302 shares pro forma	1,117	1,267
Additional paid-in capital	26,021,904	34,159,284
Accumulated deficit	(27,845,186)	(27,845,186)
Total stockholders' equity	1,677,835	9,815,335
Total capitalization	$ 1,677,835	$ 9,815,335

A $1.00 increase (decrease) in the assumed public offering price of $6.25 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma amount of each of cash, total stockholders' equity (deficiency) and total capitalization by approximately $1,362,000, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and the non-accountable expense allowance payable to the underwriters. An increase (decrease) of 500,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma amount of each of cash, total stockholders' equity and total capitalization by approximately $2,837,500, assuming no change in the assumed public offering price per share and after deducting estimated underwriting discounts and commissions and the non-accountable expense allowance payable to the underwriters.

The number of shares of our common stock to be outstanding after this offering is based on 11,174,302 shares of common stock outstanding as of June 30, 2020, as adjusted to give effect to a one-for-six reverse stock split, assumes no exercise by the underwriters of their over-allotment option, and excludes the following:

- 729,167 shares of common stock issuable upon conversion of 350,000 shares of our Series A Preferred Stock outstanding at a conversion rate of 2.083 common shares per preferred share, reflecting an effective conversion price of $4.800 per common share;
- 1,308,333 shares of common stock issuable upon exercise of outstanding common stock options issued to members of management, consultants, and directors at a weighted average exercise price of $3.65 per common share;
- 1,500,000 shares of common stock issuable upon exercise of outstanding common stock warrants at an average exercise price of $6.000 per common share;
- 2,333,333 shares of common stock reserved for future grants pursuant to our 2020 Stock Incentive Plan;
- 150,000 shares of common stock issuable upon exercise of warrants to be issued to the underwriters as part of this offering at an exercise price of $7.50 per common share (120% of the assumed public offering price of $6.25 per share (the midpoint of the price range set forth on the cover page of this prospectus)).

DILUTION

If you invest in our common stock, your ownership interest will be diluted to the extent of the difference between the public offering price per share of our common stock and the pro forma net tangible book value per share of our common stock

immediately after this offering.

As of June 30, 2020, we had a historical net tangible book value of $1,677,835, or $0.15 per share of common stock, based on 11,174,302 shares of common stock outstanding at June 30, 2020. Our historical net tangible book value per share is the amount of our total tangible assets less our total liabilities at June 30, 2020, divided by the number of shares of common stock outstanding at June 30, 2020.

Pro forma net tangible book value per share represents pro forma net tangible book value divided by the pro forma total number of shares outstanding as of June 30, 2020.

After giving effect to the issuance and sale of 1,500,000 shares of our common stock in this offering at an assumed public offering price of $6.25 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions, the non-accountable expense allowance payable to the underwriters, and estimated offering costs payable by us, our pro forma net tangible book value as of June 30, 2020 would have been $9,815,335, or $0.77 per share. This represents an immediate increase in pro forma net tangible book value per share of $0.62 to existing stockholders and immediate dilution of $5.48 in pro forma net tangible book value per share to new investors purchasing common stock in this offering. Dilution per share to new investors is determined by subtracting pro forma net tangible book value per share after this offering from the assumed public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Assumed public offering price per share		$ 6.25
Historical net tangible book value per share as of June 30, 2020	$ 0.15	
Increase in pro forma as adjusted net tangible book value per share attributable to new investors purchasing common stock in this offering	0.62	
Pro forma net tangible book value per share after this offering		0.77
Dilution per share to new investors purchasing common stock in this offering		$ 5.48

The dilution information discussed above is illustrative only and will change based on the actual public offering price and other terms of this offering determined at pricing. A $1.00 increase in the assumed public offering price of $6.25 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase our pro forma net tangible book value after this offering by approximately $0.11 per share and the dilution to new investors purchasing common stock in this offering by approximately $0.89 per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discount and commissions and the non-accountable expense allowance payable to the underwriters. A $1.00 decrease in the assumed public offering price of $6.25 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would decrease our pro forma net tangible book value after this offering by approximately $0.10 per share and the dilution to new investors purchasing common stock in this offering by approximately $0.90 per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discount and commissions and the non-accountable expense allowance payable to the underwriters.

An increase of 500,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase our pro forma net tangible book value after this offering by approximately $0.19 per share and decrease the dilution to new investors purchasing common stock in this offering by approximately $0.19 per share, assuming no change in the assumed public offering price per share and after deducting estimated underwriting discounts and commissions and the non-accountable expense allowance payable to the underwriters. A decrease of 500,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease our pro forma net tangible book value after this offering by approximately $0.20 per share and increase the dilution to new investors purchasing common stock in this offering by approximately $0.20 per share, assuming no change in the assumed public offering price per share and after deducting estimated underwriting discounts and commissions and the non-accountable expense allowance payable to the underwriters.

If the underwriters exercise their option to purchase additional shares in full, the pro forma net tangible book value per share after giving effect to the offering would be $0.86 per share. This represents an increase in pro forma net tangible book value of $0.09 per share to existing stockholders and dilution in pro forma net tangible book value of $5.39 per share to new investors.

The number of shares of our common stock to be outstanding after this offering is based on 11,174,302 shares of common stock outstanding as of June 30, 2020, as adjusted to give effect to a one-for-six reverse stock split, assumes no exercise by the underwriters of their over-allotment option and excludes the following:

- 729,167 shares of common stock issuable upon conversion of 350,000 shares of our Series A Preferred Stock outstanding at a conversion rate of 2.083 common shares per preferred share, reflecting an effective conversion price of $4.800 per common share;

- 1,308,333 shares of common stock issuable upon exercise of outstanding common stock options issued to members of management, consultants, and directors at a weighted average exercise price of $3.65 per common share;

- 1,500,000 shares of common stock issuable upon exercise of outstanding common stock warrants at an average exercise price of $6.000 per common share;

- 2,333,333 shares of common stock reserved for future grants pursuant to our 2020 Stock Incentive Plan;

- 150,000 shares of common stock issuable upon exercise of warrants to be issued to the underwriters as part of this offering at an exercise price of $7.50 per common share (120% of the assumed public offering price of $6.25 per share (the midpoint of the price range set forth on the cover page of this prospectus)).

The following table summarizes, on the pro forma basis described above, the total number of shares of common stock purchased from us, the total consideration paid or to be paid, and the average price per share paid or to be paid by existing stockholders and by new investors in this offering at an assumed public offering price of $6.25 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering costs payable by us:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percentage	Amount	Percentage	
Existing stockholders	11,174,302	88.2%	$ 17,291,369	64.8%	$ 1.55
New investors	1,500,000	11.8%	$ 9,375,000	35.2%	$ 6.25
Total	12,674,302	100.0%	$ 26,666,369	100.0%	$ 2.10

A $1.00 increase in the assumed public offering price of $6.25 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase the total consideration paid by new investors by $1,500,000 and would increase the percentage of total consideration paid by new investors by 3.4 percentage points, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same.

A $1.00 decrease in the assumed public offering price of $6.25 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would decrease the total consideration paid by new investors by $1,500,000 and would decrease the percentage of total consideration paid by new investors by 3.9 percentage points, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same.

An increase of 500,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase the total consideration paid by new investors by $3,125,000 and would increase the percentage of total consideration paid by new investors by 6.8 percentage points, assuming no change in the assumed public offering price.

A decrease of 500,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease the total consideration paid by new investors by $3,125,000 and would decrease the percentage of total consideration paid by new investors by 8.7 percentage points, assuming no change in the assumed public offering price.

The table above assumes no exercise of the underwriters' over-allotment option in this offering. If the underwriters' over-allotment option is exercised in full, the number of common shares held by new investors purchasing common stock in this offering would be increased to 13.4% of the total number of shares of common stock outstanding after this offering, and the number of shares held by existing stockholders would be reduced to 86.6% of the total number of shares of common stock outstanding after this offering.

To the extent that stock options or warrants are exercised, we issue new stock options under our 2020 Stock Incentive Plan, or we issue additional common stock in the future, there will be further dilution to investors participating in this offering. In addition, if we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

SELECTED FINANCIAL DATA

The following table sets forth our selected financial data as of the dates and for the periods indicated. We have derived the statement of operations data for the years ended December 31, 2019 and 2018 from our audited financial statements included elsewhere in this prospectus. The statements of operations data for the six months ended June 30, 2020 and 2019 and the balance sheet data as of June 30, 2020 have been derived from our unaudited financial statements included elsewhere in this prospectus. The following summary financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes and other information included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected in the future and the results for the six months ended June 30, 2020 are not necessarily indicative of the results that may be expected for the full fiscal year ending December 31, 2020. All share and per share amounts presented herein have been restated to reflect the implementation of the proposed 1-for-6 reverse stock split as if it had occurred at the beginning of the earliest period presented.

Statement of Operations Data:

	Years Ended December 31,		Six Months Ended June 30, (unaudited)	
	2019	2018	2020	2019
Revenues	$ —	$ —	$ —	$ —
Operating costs and expenses				
Research and development	820,906	40,703	212,618	128,437
General and administrative	1,669,160	2,097,348	547,928	938,191
Total operating expenses	2,490,066	2,138,051	760,546	1,066,628
Net loss	$ (2,440,343)	$ (2,133,128)	$ (756,300)	$ (1,039,200)
Net loss per common share – basic and diluted(1)	$ (0.22)	$ (0.22)	$ (0.07)	$ (0.09)
Weighted average common shares outstanding – basic and diluted(1)	11,174,302	9,799,352	11,174,302	11,174,302

(1) See Note 2 to our financial statements for an explanation of the method used to compute basic and diluted net loss per share.

Balance Sheet Data:

	December 31,		June 30, 2020
	2019	2018	(unaudited)
Cash	$ 2,598,864	$ 4,273,012	$ 1,774,332
Working capital	$ 2,434,135	$ 4,123,530	$ 1,590,985
Total assets	$ 2,672,033	$ 4,336,738	$ 1,891,800
Total liabilities	$ 237,898	$ 210,915	$ 213,965
Accumulated deficit	$ (27,088,886)	$ (24,648,543)	$ (27,845,186)
Total stockholders' equity	$ 2,434,135	$ 4,125,823	$ 1,677,835
Total liabilities and stockholders' equity	$ 2,672,033	$ 4,336,738	$ 1,891,800

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

We are 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. Our product pipeline is primarily focused on inhibitors of protein phosphatases, used alone and in combination with cytotoxic agents and/or x-ray and immune checkpoint blockers, and encompasses two major categories of compounds at various stages of pre-clinical and clinical development that we believe has broad therapeutic potential not only for cancer but also for other debilitating and life-threatening diseases.

Our activities are subject to significant risks and uncertainties, including the need for additional capital, as described below. We have not yet commenced any revenue-generating operations, do not have positive cash flows from operations, and are dependent on periodic infusions of equity capital to fund our operating requirements.

Recent Developments

Extension of Warrants

Effective September 14, 2015, in connection with the Collaboration Agreement with BioPharmaWorks as described at "Principal Commitments – Other Significant Agreements and Contracts," we issued to BioPharmaWorks two stock options, in the form of warrants, to purchase 166,667 shares (83,333 shares per warrant) of our common stock. The first warrant vested on September 14, 2016 and was exercisable for a period of five years from the date of grant at $6.00 per share. The second warrant vested on September 14, 2017 and was exercisable for a period of five years from the date of grant at $12.00 per share. On July 3, 2020, our Board of Directors approved an extension of the term of the outstanding warrants to acquire an aggregate of 166,667 shares of our common stock from September 14, 2020 to September 14, 2025. Our closing stock price on July 2, 2020 was $5.40 per share.

Reverse Stock Split

On July 14, 2020, our Board of Directors approved a 1-for-6 reverse split of our outstanding shares of common stock. Holders of a majority of shares of our common stock have provided their consent for such reverse stock split. We intend to implement such reverse stock split upon receiving regulatory approval for such action, providing appropriate legal notice to stockholders.

Going Concern

Our consolidated financial statements have been presented on the basis that we are a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. We have not generated any revenues from operations to date and does not expect to do so in the foreseeable future. Furthermore, we have experienced recurring operating losses and negative operating cash flows since inception and have financed our 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 our ability to continue as a going concern within one year of the date that the consolidated financial statements are being issued. In addition, our independent registered public accounting firm, in their report on our consolidated financial statements for the year ended December 31, 2019, has also expressed substantial doubt about our ability to continue as a going concern.

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

Recent Accounting Pronouncements

Recently Adopted Accounting Standards

In June 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 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 was effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. We adopted the provisions of ASU 2018-07 effective January 1, 2019. The adoption of ASU 2018-07 did not have any impact on our financial statement presentation or disclosures subsequent to its adoption.

Recently Issued Accounting Standards

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"). ASU 2019-12 simplifies the accounting for income taxes by removing certain exceptions and enhances and simplifies various aspects of the income tax accounting guidance in ASC 740. ASU 2019-12 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The adoption of ASU 2018-07 is not expected to have any impact on our financial statement presentation or disclosures subsequent to its adoption.

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

Concentration of Risk

We periodically contract with vendors and consultants to provide services related to our research and development activities. Agreements for these services can be for a specific time period (typically one year) or for a specific project or task.

As of July 31, 2019, we entered into a Collaboration Agreement for an Investigator-Initiated Clinical Trial with the Spanish Sarcoma Group (Grupo Español de Investigación en Sarcomas or "GEIS"), Madrid, Spain, to carry out a study entitled "Randomized phase I/II trial of LB-100 plus doxorubicin vs. doxorubicin alone in first line of advanced soft tissue sarcoma". Costs incurred pursuant to the agreement with GEIS are included in research and development costs in our consolidated statements of operations.

During the year ended December 31, 2019, we incurred costs of $87,471 pursuant to the GEIS agreement, reflecting 10.7% of total research and development costs for such period. We did not have any other contract costs that represented 10% or more of general and administrative costs or research and development costs during the years ended December 31, 2019 or 2018. During the six months ended June 30, 2020, we incurred costs of $43,411 pursuant to the GEIS agreement, reflecting 20.4% of total research and development costs.

General and administrative costs for the six months ended June 30, 2020 and 2019 include charges from a legal firm for general licensing and patent prosecution costs relating to our intellectual properties representing 50.5% and 33.0%, respectively, of total general and administrative costs for those periods.

Research and development costs for the six months ended June 30, 2020 include charges from four vendors and consultants representing 28.3%, 20.4%, 15.1%, and 11.9%, respectively, of total research and development costs for that period. Research and development costs for the six months ended June 30, 2019 include charges from four vendors and consultants representing 39.9%, 31.1%, 14.1% and 10.3%, respectively, of total research and development costs for that period.

Critical Accounting Policies and Estimates

The preparation of our 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 reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions. 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.

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

Research and Development

Research and development costs consist primarily of fees paid to consultants and contractors, and other expenses relating to the acquisition, design, development and testing of our 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 with milestone provisions are recognized as charges to research and development costs in our consolidated statement of operations based on the achievement of such milestones, as specified in the agreement. 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 our consolidated balance sheet, with a corresponding charge to research and development costs in our consolidated statement of operations.

Payments made pursuant to research and development contracts are initially recorded as advances on research and development contract services in our consolidated balance sheet and then charged to research and development costs in our 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 our consolidated balance sheet, with a corresponding charge to research and development costs in our consolidated statement of operations. We review the status of our research and development contracts on a quarterly basis.

Patent and Licensing Related Legal and Filing Costs

Due to the significant uncertainty associated with the successful development of one or more commercially viable products based on our 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 related legal and filing costs are included in general and administrative costs in our consolidated statements of operations.

Stock-Based Compensation

We periodically issue common stock and stock options to officers, directors, employees, Scientific Advisory Committee members, contractors and consultants for services rendered. Options vest and expire according to terms established at the issuance date of each grant. Stock grants, which are generally time vested, are measured at the grant date fair value and charged to operations ratably over the vesting period.

Through December 31, 2018, we accounted 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 our financial statements over the vesting period of the awards. We accounted 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 was reached or (b) at the date at which the necessary performance to earn the equity instruments was complete.

In accordance with our adoption of Accounting Standards Update 2018-07, Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, effective January 1, 2019, stock options granted to members of our Scientific Advisory Committee and to outside consultants are now accounted for consistent with the accounting for stock-based payments to officers and directors, as described above, 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 our financial statements over the vesting period of the awards.

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. Estimated volatility is based on the historical volatility of our common stock, calculated utilizing a one-year look-back period, as we believe that such measurement period provides a more accurate and meaningful volatility factor given the changes in our research and development program and capital requirements over the past several years. 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 the common stock is determined by reference to the quoted market price of our common stock on the grant date.

We recognize the fair value of stock-based compensation awards in general and administrative costs and in research and development costs, as appropriate, in our consolidated statements of operations. We issue new shares of common stock to satisfy stock option exercises.

Summary of Business Activities and Plans

We have two classes of drugs under development for the treatment of cancer, consisting of protein phosphatase inhibitors designated as the LB-100 series of compounds, and histone deacetylase inhibitors, designated 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. LB-200 has not yet advanced to the clinical stage and would require additional capital to fund further development. Accordingly, because of our focus on the clinical development of LB-100 and analogs for cancer therapy, we have decided not to actively pursue the pre-clinical development of its LB-200 series of compounds at this time and will only maintain its composition of matter patents for LB-200.

For clinical development, we selected LB-100, an inhibitor of an enzyme, protein phosphatase 2A (PP2A), that is important to many aspects of the regulation normal and abnormal cellular growth. This novel compound enhances the effectiveness of cytotoxic anti-cancer drugs and radiation therapy without enhancing toxicity in many animal models and was found to have potential anti-cancer activity without limiting toxicity in its initial Phase 1 clinical trial. We believe this first-in-class compound may be potentially useful for the treatment of a number of cancers in combination with existing standard chemotherapy regimens and with the evolving targeted cytotoxic therapies of personalized cancer medicine.

Our immediate objective is to demonstrate significant therapeutic benefit of treatment with LB-100 in cancers shown to be vulnerable to PP2A inhibition in animal models (Hong 2015; Mazhar, 2019). The selection of cancer targets is also based on the ability of the caring physician to detect potential significant benefit early into therapy. In this regard, we are currently studying LB-100 in myelodysplastic syndrome, a disease of bone marrow failure and severe anemia requiring frequent blood transfusions, an easily measurable parameter reflecting potential benefit or failure of a new treatment. We are also pursuing evaluation of LB-100 plus standard cytotoxic drugs in two aggressive cancers: advanced undifferentiated sarcomas for which standard treatment is associated with a median time to progression of only ~4.5 months and in small cell lung cancer for which "best" therapy is associated with a median survival of ~9.0 months. Because of the rapid progression of these diseases, readout of success or failure is achieved quite rapidly. Evidence of benefit of a new treatment in such aggressive diseases even in early Phase 2 clinical trials would generate enthusiasm in both clinicians and large pharmaceutical companies.

There are additional clues to the potential value of LB-100 or one of its analogs as additions to immuno-blockers and metabolic modifiers for the treatment of different types of cancers. 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 require further preclinical studies that we are not in a position to pursue at this time. We are seeking potential collaborators to explore the intriguing possibility that LB-100 may have a place in enhancing the burgeoning field of solid tumor immunotherapy.

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, we have allocated resources to expand the breadth and depth of our patent portfolio. Our 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. Our longer-term objective is to secure one or more strategic partnerships or licensing agreements with pharmaceutical companies with major programs in cancer.

Impact of the Novel Coronavirus (COVID-19) on our Business Operations

The global outbreak of the novel coronavirus (COVID-19) has led to severe disruptions in general economic activities worldwide, as businesses and governments have taken broad actions to mitigate this public health crisis. In light of the uncertain and continually evolving situation relating to the spread of COVID-19, this pandemic could pose a risk to us. The extent to which the coronavirus may impact our business operations will depend on future developments, which are highly uncertain and cannot be predicted at this time. We intend to continue to monitor the situation and may adjust our current business plans as more information and guidance become available.

The coronavirus pandemic presents a challenge to medical facilities worldwide. As our clinical trials are conducted on an outpatient basis, it is not currently possible to predict the full impact of this developing health crisis on such clinical trials, which could include delays in and increased costs of such clinical trials. Current indications from the clinical research organizations conducting the clinical trials for us are that such clinical trials are being delayed or extended for at least three to six months as a result of the coronavirus pandemic.

There is also significant uncertainty as to the affect that the coronavirus may have on the amount and type of financing available to us in the future.

Results of Operations

At June 30, 2020 and December 31, 2019, we had not yet commenced any revenue-generating operations, did not have any positive cash flows from operations, and are dependent on our ability to raise equity capital to fund our operating requirements.

Years Ended December 31, 2019 and 2018

Our consolidated statements of operations for the years ended December 31, 2019 and 2018, as discussed herein, are presented below.

	Years Ended December 31,	
	2019	**2018**
Revenues	$ —	$ —
Costs and expenses:		
General and administrative costs	1,669,160	2,097,348
Research and development costs	820,906	40,703
Total costs and expenses	2,490,066	2,138,051
Loss from operations	(2,490,066)	(2,138,051)
Interest income	49,723	4,923
Net loss	$ (2,440,343)	$ (2,133,128)
Net loss per common share – basic and diluted	$ (0.22)	$ (0.22)
Weighted average common shares outstanding – basic and diluted	11,174,302	9,799,352

Revenues. We did not have any revenues for the years ended December 31, 2019 and 2018.

General and Administrative Costs. For the year ended December 31, 2019, general and administrative costs were $1,669,160, which consisted of the fair value of vested stock options issued to directors and a consultant of $314,631, patent and licensing legal fees and costs of $742,918, other consulting and professional fees of $350,534, insurance expense of $55,935, officer's salary and related costs of $67,684, licensing fees of $80,669, stock transfer fees of $10,202, listing fees of $12,000, filing fees of $10,016, and other operating costs of $24,571.

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, listing fees of $12,000, filing fees of $7,490, and other operating costs of $16,734.

General and administrative costs decreased by $428,188 or 20.4% in 2019 as compared to 2018, primarily as a result of decreases in the fair value of stock options issued to directors and consultants of $470,981, and patent and licensing legal fees and costs of $99,407, offset by increases in licensing fees of $80,669, and other consulting and professional fees of $49,885.

Research and Development Costs. For the year ended December 31, 2019, research and development costs were $820,906, which consisted of the fair value of vested stock options issued to a consultant of $434,024, and contractor costs, primarily in connection with our pre-clinical research focused on the development of additional novel anti-cancer compounds to add to its clinical pipeline, including $87,471 with respect to GEIS, and $100,000 to BioPharmaWorks.

For the year ended December 31, 2018, research and development costs were $40,703, which consisted entirely of contractor costs, primarily in connection with our pre-clinical research focused on the development of additional novel anti-cancer compounds to add to its clinical pipeline, including $10,000 to BioPharmaWorks, and is stated net of a credit of $25,000 for a reversal of an obligation to the NCI in connection with Amendment No. 3 to the M-CRADA, which updated collaboration plans between the NCI and us.

Research and development costs increased by $780,203 in 2019 as compared to 2018, as a result of an increase in the fair value of vested stock options issued to a consultant of $434,024, and contractor costs, primarily in connection with our pre-clinical research focused on the development of additional novel anti-cancer compounds to add to its clinical pipeline, including $87,471 with respect to GEIS, and $90,000 to BioPharmaWorks.

Interest Income. For the year ended December 31, 2019, we had interest income of $49,723, as compared to interest income of $4,923 for the year ended December 31, 2018, as a result of our investing the majority of our cash resources in short-term federally insured certificates of deposit beginning in 2019.

Net Loss. For the year ended December 31, 2019, we incurred a net loss of $2,440,343, as compared to a net loss of $2,133,128 for the year ended December 31, 2018.

Six Months Ended June 30, 2020 and 2019

Our condensed consolidated statements of operations for the six months ended June 30, 2020 and 2019, as discussed herein, are presented below.

	Six Months Ended June 30,	
	2020	**2019**
Revenues	$ —	$ —
Costs and expenses:		
General and administrative costs	547,928	938,191
Research and development costs	212,618	128,437
Total costs and expenses	760,546	1,066,628
Loss from operations	(760,546)	(1,066,628)
Interest income	4,246	27,428
Net loss	$ (756,300)	$ (1,039,200)
Net loss per common share – basic and diluted	$ (0.07)	$ (0.09)
Weighted average common shares outstanding – basic and diluted	11,134,302	11,134,302

Revenues. We did not have any revenues for the six months ended June 30, 2020 and 2019.

General and Administrative Costs. For the six months ended June 30, 2020, general and administrative costs were $547,928, which consisted of patent and licensing legal fees and costs of $276,912, other consulting and professional fees of $171,919, insurance expense of $28,416, officer's salary and related costs of $33,892, licensing fees of $12,398, stock transfer fees of $6,386, listing fees of $6,000, filing fees of $6,294, travel of $718, and other operating costs of $4,993.

For the six months ended June 30, 2019, general and administrative costs were $938,191, which consisted of the fair value of vested stock options issued to directors and consultants of $309,601, patent and licensing legal fees and costs of $309,906, other consulting and professional fees of $185,348, insurance expense of $27,092, officer's salary and related costs of $33,880, licensing fees of $43,067, stock transfer fees of $5,732, listing fees of $6,000, filing fees of $6,593, travel of $3,242, and other operating costs of $7,730.

General and administrative costs decreased by $390,263 or 41.6% in 2020 as compared to 2019, primarily as a result of decreases in the fair value of stock options issued to directors and consultants of $309,601, patent and licensing legal fees and costs of $32,994, other consulting and professional fees of $13,429, and licensing fees of $30,669.

Research and Development Costs. For the six months ended June 30, 2020, research and development costs were $212,618, which consisted of contractor costs, primarily in connection with our pre-clinical research focused on the development of additional novel anti-cancer compounds to add to its clinical pipeline, including $43,411 to GEIS, $25,364 to Moffitt, $20,076 to Theradex, and $60,201 to BioPharmaWorks.

For the six months ended June 30, 2019, research and development costs were $128,437, which consisted of contractor costs, primarily in connection with our pre-clinical research focused on the development of additional novel anti-cancer compounds to add to its clinical pipeline, including $13,253 to Moffitt, $51,261 to Theradex, and $40,000 to BioPharmaWorks.

Research and development costs increased by $84,181 in 2020 as compared to 2019, as a result of an increase in contractor costs, primarily in connection with our pre-clinical research focused on the development of additional novel anti-cancer compounds to add to its clinical pipeline, including $43,411 to GEIS.

Interest Income. For the six months ended June 30, 2020, we had interest income of $4,246, as compared to interest income of $27,428 for the six months ended June 30, 2019, as a result of a reduction in our cash resources previously invested in short-term federally insured certificates of deposit.

Net Loss. For the six months ended June 30, 2020, we incurred a net loss of $756,300, as compared to a net loss of $1,039,200 for the six months ended June 30, 2019.

Liquidity and Capital Resources

Our 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. We have not generated any revenues from operations to date and do not expect to do so in the foreseeable future. Furthermore, we have experienced recurring operating losses and negative operating cash flows since inception and have financed our working capital requirements during this period primarily through the recurring sale of our 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 our ability to continue as a going concern within one year of the date that the consolidated financial statements are being issued. In addition, our independent registered public accounting firm, in their report on our consolidated financial statements for the year ended December 31, 2019, has also expressed substantial doubt about our ability to continue as a going concern (see “Going Concern” above).

At December 31, 2019, we had working capital of $2,434,135, as compared to working capital of $4,123,530 at December 31, 2018, reflecting a decrease in working capital of $1,689,395 for the year ended December 31, 2019. The decrease in working capital during the year ended December 31, 2019 was the result of working capital being utilized to fund our research and development activities and ongoing operating expenses, including maintaining and developing our patent portfolio.

At December 31, 2019, we had cash and cash equivalents of $2,598,864 available to fund its operations. Because we are currently engaged in Phase 2 clinical trials, it is expected that it will take a significant amount of time to develop any product or intellectual property capable of generating sustainable revenues. Accordingly, our 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 we are able to generate revenues through licensing our technologies or through product sales, there can be no assurance that we will be able to achieve positive earnings and operating cash flows.

At June 30, 2020, we had working capital of $1,590,985, as compared to working capital of $2,434,135 at December 31, 2019, reflecting a decrease in working capital of $843,150 for the six months ended June 30, 2020. The decrease in working capital during the six months ended June 30, 2020 was the result of working capital being utilized to fund our research and development activities and ongoing operating expenses, including maintaining and developing our patent portfolio.

At June 30, 2020, we had cash and cash equivalents of $1,774,332 available to fund its operations. Because we are currently engaged in Phase 2 clinical trials, it is expected that it will take a significant amount of time to develop any product or intellectual property capable of generating sustainable revenues. Accordingly, our 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 we are able to generate revenues through licensing its technologies or through product sales, there can be no assurance that we will be able to achieve positive earnings and operating cash flows.

This offering is expected to generate gross proceeds of $9,375,000 (or net proceeds of approximately $7,875,000) based on an offering price of $6.25 per share, the mid-point of the range set forth on the cover page of this prospectus. We intend to use the net proceeds from this offering as described in the section of this prospectus titled “Use of Proceeds”.

The amounts that we actually spend for any specific purpose may vary significantly and will depend on a number of factors, including, but not limited to, our research and development activities and programs, clinical testing, regulatory approval, market conditions, and changes in or revisions to our research and development plans and clinical trial programs. Investors will be relying on the judgment of our management regarding the application of the proceeds from the sale of our common stock in this offering.

We believe that the net proceeds from this offering, combined with our existing cash resources, will be sufficient to fund our projected operating requirements for at least 24 months subsequent to the closing of this offering. However, the expected net proceeds from this offering are not expected to be sufficient for us to be able to complete the development and commercialization of any of our drug compounds.

The amount and timing of future cash requirements will depend on the pace and design of our clinical trial program. Current indications from the clinical research organizations conducting the clinical trials for us indicate that such clinical trials are being delayed or extended for at least three to six months as a result of the coronavirus pandemic. As market conditions present uncertainty as to our ability to secure additional funds, there can be no assurances that we will be able to secure additional financing on acceptable terms, or at all, as and when necessary to continue to conduct operations. The impact of the coronavirus on capital markets may affect the amount and type of financing available to us in the future.

If cash resources are insufficient to satisfy our ongoing cash requirements, we would be required to scale back or discontinue our clinical trial program and our technology and product development efforts, or obtain funds, if available (although there can be no certainty), through strategic alliances that may require us to relinquish rights to certain of our compounds, or to curtail or discontinue our operations entirely.

Our longer-term objective is to secure one or more strategic partnerships or licensing agreements with pharmaceutical companies with major programs in cancer.

Operating Activities. For the year ended December 31, 2019, operating activities utilized cash of $1,674,148, as compared to utilizing cash of $1,511,034 for the year ended December 31, 2018, to fund our ongoing research and development activities and to fund our other ongoing operating expenses, including maintaining and developing our patent portfolio.

For the six months ended June 30, 2020, operating activities utilized cash of $768,682, as compared to utilizing cash of $709,056 for the six months ended June 30, 2019, to fund our ongoing research and development activities and to fund its other ongoing operating expenses, including maintaining and developing its patent portfolio.

Investing Activities. We had no investing activities for the years ended December 31, 2019 and 2018, or for the six months ended June 30, 2020 and 2019.

Financing Activities. For the year ended December 31, 2019, we had no financing activities. For the year ended December 31, 2018, financing activities consisted of net proceeds from the sale of 1,500,000 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 3,333 shares of our common stock at an exercise price of $0.90 per share.

For the six months ended June 30, 2020, financing activities consisted of the payment of deferred offering costs of $55,850. We had no financing activities for the six months ended June 30, 2019.

Principal Commitments

Clinical Trial Agreements

Moffitt. Effective August 20, 2018, we entered into a Clinical Trial Research Agreement with the Moffitt Cancer Center and Research Institute Hospital Inc., Tampa, Florida, effective for a term of five years, unless terminated earlier by us pursuant to 30 days written notice. Pursuant to the Clinical Trial Research Agreement, Moffitt agreed to conduct and manage a Phase 1b/2 clinical trial to evaluate the therapeutic benefit of our lead anti-cancer clinical compound LB-100 to be administered intravenously in patients with low or intermediate-1 risk myelodysplastic syndrome (MDS).

In November 2018, we received approval from the U.S. FDA for our Investigational New Drug Application to conduct a Phase 1b/2 clinical trial to evaluate the therapeutic benefit of LB-100 in patients with low and intermediate-1 risk MDS who have failed or are intolerant of standard treatment. Patients with MDS, although usually older, are generally well except for severe anemia requiring frequent blood transfusions. This Phase 1b/2 clinical trial utilizes LB-100 as a single agent in the treatment of patients with low and intermediate-1 risk MDS, including patients with del(5q) myelodysplastic syndrome (del5qMDS) failing first line therapy. The bone marrow cells of patients with del5qMDS are deficient in PP2A by virtue of an acquired mutation and are especially vulnerable to further inhibition of PP2A by LB-100. The clinical trial began at a single site in April 2019 and the first patient was entered into the clinical trial in July 2019. A total enrollment of 41 patients is planned. An interim analysis will be done after the first 21 patients are entered. If there are 3 or more responders but fewer than 7, an additional 20 patients will be entered. If at any point there are 7 or more responders, this will be sufficient evidence to support continued development of LB-100 for the treatment of low and intermediate-1 risk MDS. Recruitment has been slow and the Covid-19 pandemic has further reduced recruitment of patients into the protocol. At the current rate of accrual, the trial would be completed over a period of four years from its initiation, with the final analysis and reporting expected by July 2023. However, with additional funds, our objective would be to add two additional MDS centers to the Phase 2 portion of the study to accelerate patient accrual, with the goal of an earlier reporting date.

During the six months ended June 30, 2020 and 2019, we paid Moffitt $25,365 and $13,253, respectively, pursuant to this agreement. As of June 30, 2020, total costs of $70,458 have been incurred pursuant to this agreement.

GEIS. As of July 31, 2019, we entered into a Collaboration Agreement for an Investigator-Initiated Clinical Trial with the Spanish Sarcoma Group (Grupo Español de Investigación en Sarcomas or “GEIS”), Madrid, Spain, to carry out a study entitled “Randomized phase I/II trial of LB-100 plus doxorubicin vs. doxorubicin alone in first line of advanced soft tissue sarcoma”. The purpose of this clinical trial is to obtain information about the efficacy and safety of LB-100 combined with doxorubicin in soft tissue sarcomas. Doxorubicin is the global standard for initial treatment of advanced soft tissue sarcomas (“ASTS”). Doxorubicin alone has been the mainstay of first line treatment of ASTS for over 40 years, with little therapeutic gain from adding cytotoxic compounds to or substituting other cytotoxic compounds for doxorubicin. In animal models, LB-100 consistently enhances the anti-tumor activity of doxorubicin without apparent increases in toxicity.

GEIS has a network of referral centers in Spain and across Europe that have an impressive track record of efficiently conducting innovative studies in ASTS. We agreed to provide GEIS with a supply of LB-100 to be utilized in the conduct of this clinical trial, as well as to provide funding for the clinical trial. The goal was to enter the first patient during the quarter ending December 31, 2020, with approximately 150 patients to be enrolled over two years. Advanced sarcoma is a very aggressive disease. The design of the study assumes a median progression free survival (PFS, no evidence of disease progression or death from any cause) of 4.5 months in the doxorubicin arm and an alternative median PFS of 7.5 months in the doxorubicin plus LB-100 arm to demonstrate a statistically significant decrease in relative risk of progression or death by adding LB-100. There is a planned interim analysis of the primary endpoint when about half of the 102 events required for final analysis is reached.

We had previously expected that this clinical trial would commence during the quarter ended June 30, 2020. However, during July 2020, a Spanish regulatory body advised us that although it had approved the scientific and ethical basis of the protocol, it required that we manufacture a new inventory of LB-100 under current Spanish pharmaceutical manufacturing standards. These regulations were adopted subsequent to the production of our existing LB-100 inventory. We are in the process of determining how soon new inventory of LB-100 meeting Spanish specifications can be produced. Accordingly, the clinical trial is now estimated to begin during the quarter ending September 30, 2021 and to be completed by the quarter ending September 30, 2024. The interim analysis expected in June 2023 could indicate either inferiority or superiority of the LB-100 plus doxorubicin arm compared to doxorubicin alone. A positive study would have the potential to change the standard therapy for this disease after four decades of failure to improve the marginal benefit of doxorubicin alone.

Our agreement with GEIS provides for various payments based on achieving specific milestones over the term of the agreement. On February 18, 2020, we advanced $43,411 to GEIS towards a second milestone payment obligation of $87,471, which was expected to become due and payable during the quarter ended June 30, 2020 based on the anticipated achievement of the second milestone, and which was therefore recorded as an advance on our balance sheet at March 31, 2020. However, as a result of the substantial delay in commencing the clinical trial as described above, the achievement of the second milestone was delayed until mid-2021 and we therefore determined to charge such advance to research and development costs in our statement of operations at June 30, 2020.

Accordingly, during the six months ended June 30, 2020, we incurred costs of $43,411 pursuant to this agreement. As of June 30, 2020, total costs of $130,882 have been incurred pursuant to this agreement.

Our aggregate commitments pursuant to the aforementioned clinical trial agreements, less amounts previously paid to date under these agreements, totaled approximately $4,795,000 as of June 30, 2020, consisting of approximately $4,162,000 relating to the GEIS clinical trial and approximately $633,000 relating to the Moffit clinical trial, which are expected to be incurred over the next five years through June 30, 2025.

Clinical Trial Monitoring Agreements

On September 12, 2018, we finalized a work order agreement with Theradex Systems, Inc., an international contract research organization, to monitor the Phase 1b/2 clinical trial being managed and conducted by Moffitt. The clinical trial began in April 2019 and the first patient was entered into the clinical trial in July 2019. At the current rate of accrual, the trial would be completed over a period of four years from its initiation, with the final analysis and reporting expected by July 2023.

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 6% for payments for pass-through costs. The costs of the Phase 1b/2 clinical trial being paid to or through Theradex are being recorded and charged to operations based on the periodic documentation provided by the CRO. During the six months ended June 30, 2020 and 2019, we incurred costs of $11,476 and $48,493, respectively, pursuant to this work order. As of June 30, 2020, total costs of $74,968 have been incurred pursuant to this work order agreement.

Our aggregate commitments pursuant to this clinical trial monitoring agreement, less amounts previously paid to date under this agreement, totaled approximately $876,000 as of June 30, 2020, which are expected to be incurred over the next five years through June 30, 2025.

Patent and License Agreements

On March 22, 2018, we entered into a Patent Assignment and Exploitation Agreement with INSERM TRANSFERT SA, acting as delegatee of the French National Institute of Health and Medical Research, for the assignment to us 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 us 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 with us to allow INSERM to conduct research on our proprietary compound LB-100 and/or its analogs for the treatment of depressive or stress disorders in humans. Pursuant to the Agreement, we have 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. We also agreed to pay INSERM certain commercial royalties on net sales of products attributed to the Agreement. Our 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 us. As there can be no assurances that we will be able to obtain the capital or business resources necessary to focus on the exploitation of this patent, it is uncertain as to when, if at all, we may reach any of the development or commercialization milestones under the Agreement. As of June 30, 2020 and December 31, 2019, no amounts were due under this agreement.

Effective April 2, 2018, we 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 us 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 us by the advisor that results in an investment in us during the term of the Consulting Agreement. We recorded the payment of the retainer as a prepaid expense in our consolidated balance sheet, and are amortizing the retainer payment over the two-year life of the Consulting Agreement, as a result of which we recorded charges to operations of $2,294 and $4,588 during the six months ended June 30, 2020 and 2019, respectively. As of June 30, 2020, the prepaid consulting fee had been fully amortized. At December 31, 2019, the unamortized balance of the retainer payment was $9,174, all of which was classified as a current asset in our consolidated balance sheet at such date. On March 1, 2020, the Consulting Agreement was extended to April 2, 2021 without any additional consideration.

Effective August 20, 2018, we entered into an Exclusive License Agreement with Moffitt. Pursuant to the License Agreement, Moffitt granted us an exclusive license under certain patents owned by Moffitt 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. We were obligated to pay Moffitt a non-refundable license issue fee of $25,000 after the first patient is entered into a Phase 1b/2 clinical trial to be managed and conducted by Moffitt. The clinical trial began at a single site in April 2019 and the first patient was entered into the clinical trial in July 2019. We are 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 we commence payment of minimum royalty payments. We have also agreed to pay non-refundable milestone payments to Moffitt, which cannot be credited against earned royalties payable by us, 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. During the six months ended June 30, 2020 and 2019, we recorded charges to operations of $12,398 and $43,067, respectively, in connection with our obligations under the License Agreement. As of June 30, 2020, no milestones had yet been attained.

We 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. Our 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.

Employment Agreements

Dr. John Kovach. On July 15, 2020, we entered into an employment agreement with Dr. John Kovach pursuant to which Dr. Kovach is to continue to act as our President, Chief Scientific Officer, and Chief Executive Officer. His responsibilities shall be for the oversight of our entire operations and strategic planning, and shall be the primary contact between our executive team and the Board of Directors, to whom he shall report. Dr. Kovach shall supervise all scientific endeavors, providing guidance to the Chief Medical Officer. He shall be the principal spokesperson for us. Dr. Kovach will receive an annual salary of $250,000, payable monthly. The effective date of the agreement is October 1, 2020, and shall remain in effect until the earlier of (i) one year from the effective date, automatically renewable for additional one-year periods unless terminated by either party upon 60 days written notice prior to the end of the applicable one-year period, (ii) his death, or (iii) termination for cause.

Eric Forman. On July 15, 2020, as amended on August 12, 2020, we entered into an employment agreement with Eric Forman, pursuant to which Mr. Forman will act as our Chief Administrative Officer reporting directly to our Chief Executive Officer. His primary function shall be to oversee our internal operations, including IT, licensing, legal, personnel, marketing, and corporate governance. Mr. Forman will receive an annual salary of $120,000, payable monthly. He will also receive options for 58,333 shares of common stock. The options can be exercised on a cashless basis. The options will have a term of 5 years and an exercise price of $7.14 per share, which was equal to the closing price of our common stock on the grant date. The options will vest as to 25% on August 12, 2020, and 25% vesting on each of the first, second and third anniversaries of the grant date. The effective date of the agreement is October 1, 2020, and shall remain in effect until the earlier of (i) one year from the effective date, automatically renewable for additional one-year periods unless terminated by either party upon 60 days written notice prior to the end of the applicable one-year period, (ii) his death, or (iii) termination for cause.

Dr. James Miser. On August 1, 2020, we entered into an employment agreement with Dr. James Miser, M.D., pursuant to which Dr. Miser was appointed as our Chief Medical Officer. Under the employment agreement, Dr. Miser will play a leadership role in planning, implementation and oversight of clinical trials. He will be responsible for assisting and developing strategic clinical goals and the implementation and safety monitoring of investigational studies. He will be the primary medical monitor for all clinical investigational studies and for the oversight of third party CRO monitors. He will work closely with our Chief Executive Officer on the development of specific goals needed to ensure the timely implementation of appropriate clinical studies needed for successful registration of therapeutic products and new drug development. Dr. Miser will be required to devote at least 50% of his business time to our activities. Dr. Miser will receive an annual salary of $150,000. He will also receive options for 83,333 shares of our common stock. The options will have a term of five years and an exercise price of $7.14 per share, which was equal to the closing price of our common stock on the effective date of the employment agreement. The options can be exercised on a cashless basis. The options will vest as to 25% on the effective date, and 25% on each of the first, second and third anniversaries of the effective date. The effective date of the agreement is August 1, 2020. The agreement shall remain in effect until the earlier of (i) one year from the effective date, automatically renewable for additional one-year periods unless terminated by either party upon 60 days written notice prior to the end of the applicable one-year period, (ii) his death, or (iii) termination for cause.

Robert Weingarten. On August 12, 2020, we entered into an employment agreement with Robert N. Weingarten pursuant to which Mr. Weingarten was appointed as our Vice-President and Chief Financial Officer. Mr. Weingarten will receive an annual salary of $120,000. He will also receive options for 58,333 shares of common stock. The options can be exercised on a cashless basis. The options will have a term of five years and an exercise price of $7.14 per share, which was equal to the closing price of our common stock on the effective date of the employment agreement. The options will vest as to 25% on the effective date, and 25% on each of the first, second and third anniversaries of the effective date. The effective date of the agreement is August 12, 2020. The agreement shall remain in effect until the earlier of (i) one year from the effective date, automatically renewable for additional one-year periods unless terminated by either party upon 60 days written notice prior to the end of the applicable one-year period, (ii) his death, or (iii) termination for cause.

Other Significant Agreements and Contracts

On December 24, 2013, we entered into an agreement with NDA Consulting Corp. 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 our Scientific Advisory Committee. The term of the agreement was for one year and provided for a quarterly cash fee of $4,000. The agreement has been automatically renewed for additional one-year terms on its anniversary date since 2014. Consulting and advisory fees charged to operations pursuant to this agreement were $8,000 and $8,000 for the six months ended June 30, 2020 and 2019, respectively, which were included in research and development costs in the consolidated statements of operations.

Effective September 14, 2015, we entered into a Collaboration Agreement with BioPharmaWorks, pursuant to which we engaged BioPharmaWorks to perform certain services for us. Those services included, among other things: (a) assisting us to (i) commercialize its products and strengthen its 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. 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, we agreed to pay BioPharmaWorks a monthly fee of $10,000, subject to our right to pay a negotiated hourly rate in lieu of the monthly payment and agreed to issue to BioPharmaWorks certain equity-based compensation. In April 2018, it was 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, we subsequently agreed to resume the Collaboration Agreement with BioPharmaWorks effective March 1, 2019, and the Collaboration Agreement is currently in effect. We recorded charges to operations pursuant to this Collaboration Agreement of $60,000 and $40,000 for the six months ended June 30, 2020 and 2019, respectively, which were included in research and development costs in the consolidated statements of operations.

Off-Balance Sheet Arrangements

At June 30, 2020 and December 31, 2019, we did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

Trends, Events and Uncertainties

Research and development of new pharmaceutical compounds is, by its nature, unpredictable. Although we will undertake research and development efforts with commercially reasonable diligence, there can be no assurance that the net proceeds from this offering will be sufficient to enable us to develop our pharmaceutical compounds to the extent needed to create future sales to sustain operations as contemplated herein.

There can be no assurances that one or more of our pharmaceutical compounds will obtain the regulatory approvals and market acceptance to achieve sustainable revenues sufficient to support our operations. Even if we are able to generate revenues, there can be no assurances that we will be able to achieve operating profitability or positive operating cash flows. There can be no assurances that we will be able to secure additional financing, to the extent required, on acceptable terms or at all. If cash resources are insufficient to satisfy our ongoing cash requirements, we would be required to reduce or discontinue our research and development programs, or attempt to obtain funds, if available (although there can be no assurances), through strategic alliances that may require us to relinquish rights to certain of our pharmaceutical compounds, or to curtail or discontinue our operations entirely.

Other than as discussed above and elsewhere in this prospectus, we are not currently aware of any trends, events or uncertainties that are likely to have a material effect on our financial condition in the near term, although it is possible that new trends or events may develop in the future that could have a material effect on our financial condition.

BUSINESS

Company Overview

We are 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. Our product pipeline is primarily focused on inhibitors of protein phosphatases, used alone and in combination with cytotoxic agents and/or x-ray and immune checkpoint blockers, and encompasses two major categories of compounds at various stages of pre-clinical and clinical development that we believe have broad therapeutic potential not only for cancer but also for other debilitating and life-threatening diseases.

We have developed two series of pharmacologically active drugs, the LB-100 series and the LB-200 series. We believe 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, our compounds will improve therapeutic benefit without enhancing toxicity in humans.

Our activities are subject to significant risks and uncertainties, including the need for additional capital, as described below. We have 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; Research; Clinical Trial Activities

Our primary focus is developing new treatments for human cancers for which better therapies are urgently needed.

Our 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. We design 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. We seek 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 us as the LB-100 series of compounds, and histone deacetylase inhibitors (HDACi), designated by us 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.

We have 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 or CRADA with the National Institute of Neurologic Disorders and Stroke or NINDS of the National Institutes of Health or 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 our 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, pheochromocytomas 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, we believe the LB-100 series of compounds may be useful against most, if not all, cancer types.

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, we have demonstrated that our HDACi have broad activity against many cancer types, have neuroprotective activity, and have anti-fungal activity. In addition, these compounds have low toxicity. LB-200 has not yet advanced to the clinical stage and would require additional capital to fund further development. Accordingly, because of our focus on the clinical development of LB-100 and analogs for cancer therapy as described below in more detail, we have decided not to actively pursue the pre-clinical development of its LB-200 series of compounds at this time. At this time, we intend to only maintain its composition of matter patents for LB-200.

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 of a series of serine/threonine phosphatase (s/t ptase) inhibitors designed by us. 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 we have 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. 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.

We completed a Phase 1 clinical trial of LB-100 to evaluate its safety that showed it is associated with antitumor 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, we were 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.

Clinical Trial Agreements

Moffitt Cancer Center Clinical Trial Research Agreement

Effective August 20, 2018, we entered into a Clinical Trial Research Agreement with the Moffitt Cancer Center and Research Institute Hospital Inc., Tampa, Florida, effective for a term of five years, unless terminated earlier by us pursuant to 30 days written notice. Pursuant to the Clinical Trial Research Agreement, Moffitt agreed to conduct and manage a Phase 1b/2 clinical trial to evaluate the therapeutic benefit of our lead anti-cancer clinical compound LB-100 to be administered intravenously in patients with low or intermediate-1 risk myelodysplastic syndrome (MDS).

In November 2018, we received approval from the FDA for our Investigational New Drug Application to conduct a Phase 1b/2 clinical trial to evaluate the therapeutic benefit of LB-100 in patients with low and intermediate-1 risk MDS who have failed or are intolerant of standard treatment. Patients with MDS, although usually older, are generally well except for severe anemia requiring frequent blood transfusions. This Phase 1b/2 clinical trial utilizes LB-100 as a single agent in the treatment of patients with low and intermediate-1 risk MDS, including patients with del(5q) myelodysplastic syndrome (del5qMDS) failing first line therapy. The bone marrow cells of patients with del5qMDS are deficient in PP2A by virtue of an acquired mutation and are especially vulnerable to further inhibition of PP2A by LB-100. The clinical trial began at a single site in April 2019 and the first patient was entered into the clinical trial in July 2019. A total enrollment of 41 patients is planned. An interim analysis will be done after the first 21 patients are entered. If there are 3 or more responders but fewer than 7, an additional 20 patients will be entered. If at any point there are 7 or more responders, this will be sufficient evidence to support continued development of LB-100 for the treatment of low and intermediate-1 risk MDS. Recruitment has been slow and the Covid-19 pandemic has further reduced recruitment of patients into the protocol. At the current rate of accrual, the trial would be completed over a period of four years from its initiation, with the final analysis and reporting expected by July 2023. However, with additional funds, our objective would be to add two additional MDS centers to the Phase 2 portion of the study to accelerate patient accrual, with the goal of an earlier reporting date.

Spanish Sarcoma Group Collaboration Agreement

As of July 31, 2019, we entered into a Collaboration Agreement for an Investigator-Initiated Clinical Trial with the Spanish Sarcoma Group (Grupo Español de Investigación en Sarcomas or "GEIS"), Madrid, Spain, to carry out a study entitled "Randomized phase I/II trial of LB-100 plus doxorubicin vs. doxorubicin alone in first line of advanced soft tissue sarcoma". The purpose of this clinical trial is to obtain information about the efficacy and safety of LB-100 combined with doxorubicin in soft tissue sarcomas. Doxorubicin is the global standard for initial treatment of advanced soft tissue sarcomas ("ASTS"). Doxorubicin alone has been the mainstay of first line treatment of ASTS for over 40 years, with little therapeutic gain from adding cytotoxic compounds to or substituting other cytotoxic compounds for doxorubicin. In animal models, LB-100 consistently enhances the anti-tumor activity of doxorubicin without apparent increases in toxicity.

GEIS has a network of referral centers in Spain and across Europe that have an impressive track record of efficiently conducting innovative studies in ASTS. We agreed to provide GEIS with a supply of LB-100 to be utilized in the conduct of this clinical trial, as well as to provide funding for the clinical trial. The goal was to enter the first patient during the quarter ending December 31, 2020, with approximately 150 patients to be enrolled over two years. Advanced sarcoma is a very aggressive disease. The design of the study assumes a median progression free survival (PFS, no evidence of disease progression or death from any cause) of 4.5 months in the doxorubicin arm and an alternative median PFS of 7.5 months in the doxorubicin plus LB-100 arm to demonstrate a statistically significant decrease in relative risk of progression or death by adding LB-100. There is a planned interim analysis of the primary endpoint when about half of the 102 events required for final analysis is reached.

We had previously expected that this clinical trial would commence during the quarter ended June 30, 2020. However, during July 2020, the Spanish regulatory body known as the Agency for Medicine and Health Products (Agencia Española de Medicamentos y Productos Sanitarios or "AEMPS") advised us that although it had approved the scientific and ethical basis of the protocol, it required that we manufacture a new inventory of LB-100 under current Spanish pharmaceutical manufacturing standards. These regulations were adopted subsequent to the production of our existing LB-100 inventory. We are in the process of determining how soon new inventory of LB-100 meeting Spanish specifications can be produced. Accordingly, the clinical trial is now estimated to begin during the quarter ending September 30, 2021 and to be completed by the quarter ending September 30, 2024. The interim analysis expected in June 2023 could indicate either inferiority or superiority of the LB-100 plus doxorubicin arm compared to doxorubicin alone. A positive study would have the potential to change the standard therapy for this disease after four decades of failure to improve the marginal benefit of doxorubicin alone.

NCI Pharmacologic Study

During the fourth quarter of 2019, the National Cancer Institute (NCI) enrolled the first two patients of a planned eight patient pharmacologic study of the ability of LB-100 to enter the brain and penetrate recurrent brain tumors in patients where surgical removal of the cancers is indicated (clinical trials registry NCT03027388). This study is being conducted and funded by the NCI under a Cooperative Research and Development Agreement with us; additional information will be reported by us as it is provided by the NCI.

Primary malignant brain tumors (gliomas) are very challenging to treat. Radiation combined with the chemotherapeutic drug temozolomide has been the mainstay of therapy of the most aggressive gliomas (glioblastoma multiforme or GBM) for decades, with some further benefit gained by the addition of one or more anti-cancer drugs, but without major advances in overall survival for the majority of patients. In animal models of GBM, our novel protein phosphatase inhibitor LB-100 enhances the effectiveness of radiation, temozolomide chemotherapy treatments and immunotherapy, raising the possibility that LB-100 may improve outcomes of standard GBM treatment in the clinic. Although LB-100 has proven safe in patients at doses associated with apparent anti-tumor activity against several human cancers arising outside the brain, the ability of LB-100 to penetrate tumor tissue arising in the brain is not known. Unfortunately, many drugs potentially useful for GBM treatment do not enter the brain in amounts necessary for anti-cancer action.

The NCI study is designed to determine the extent to which LB-100 enters recurrent malignant gliomas. Patients having surgery to remove one or more tumors will receive one dose of LB-100 prior to surgery and have blood and tumor tissue analyzed to determine the amount of LB-100 present and to determine whether the cells in the tumors show the biochemical changes expected to be present if LB-100 reaches its molecular target. The goal is to obtain data in up to eight patients. As a result of the innovative design of the NCI study, data from so few patients should be sufficient to provide a sound rationale for conducting a larger clinical trial to determine the effectiveness of adding LB-100 to the standard treatment regimen for GBMs.

Clinical Trial Monitoring Agreements

On September 12, 2018, we finalized a work order agreement with Theradex Systems, Inc, an international contract research organization, to monitor the Phase 1b/2 clinical trial being managed and conducted by Moffitt. The clinical trial began in April 2019 and the first patient was entered into the clinical trial in July 2019. At the current rate of accrual, the trial would be completed over a period of four years from its initiation, with the final analysis and reporting expected by July 2023. 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 6% for payments for pass-through costs.

Patent and License Agreements

On March 22, 2018, we entered into a Patent Assignment and Exploitation Agreement with INSERM TRANSFERT SA, acting as delegatee of the French National Institute of Health and Medical Research, for the assignment to us 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 us as co-owners on February 19, 2016 and granted on December 5, 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 with us to allow INSERM to conduct research on our proprietary compound LB-100 and/or its analogs for the treatment of depressive or stress disorders in humans. Pursuant to the Agreement, we have 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. We also agreed to pay INSERM certain commercial royalties on net sales of products attributed to the Agreement. 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 us. As there can be no assurances that we will be able to obtain the capital or business resources necessary to focus on the exploitation of this patent, it is uncertain when we may reach any of the development or commercialization milestones under the Agreement, if at all.

Effective April 2, 2018, we 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 was extended for an additional period of one year. 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 us 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 us by the advisor that results in an investment in us during the term of the Consulting Agreement.

Effective August 20, 2018, we entered into an Exclusive License Agreement with Moffitt. Pursuant to the License Agreement, Moffitt granted us an exclusive license under certain patents owned by Moffitt 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. We were obligated to pay Moffitt a non-refundable license issue fee of $25,000 after the first patient is entered into a Phase 1b/2 clinical trial to be managed and conducted by Moffitt. The clinical trial began at a single site in April 2019 and the first patient was entered into the clinical trial in July 2019. We are 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 we commence payment of minimum royalty payments. We have also agreed to pay non-refundable milestone payments to Moffitt, which cannot be credited against earned royalties payable by us, 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. As of June 30, 2020, no milestones had yet been attained.

We 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. Our 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.

Other Significant Agreements and Contracts

Effective October 18, 2013, we entered into a Materials Cooperative Research and Development Agreement (M-CRADA) with the NINDS of the NIH for a term of four years. The Surgical Neurology Branch of NINDS is conducting research characterizing a variety of compounds proprietary to us 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 our pipeline, for study by scientists at NIH. The exchange of material was for research only and did 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 December 24, 2013, we entered into an agreement with NDA Consulting Corp. 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 our Scientific Advisory Committee. The term of the agreement was for one year and provided for a quarterly cash fee of $4,000. The agreement has been automatically renewed for additional one-year terms on its anniversary date since 2014. Consulting and advisory fees charged to operations pursuant to this agreement for the years ended December 31, 2019 and 2018 were $16,000 and $16,000, respectively.

Effective September 14, 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. 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, we agreed to pay BioPharmaWorks a monthly fee of $10,000, subject to our right to pay a negotiated hourly rate in lieu of the monthly payment and agreed to issue to BioPharmaWorks certain equity-based compensation. 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. 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, we subsequently agreed to resume the Collaboration Agreement with BioPharmaWorks effective March 1, 2019, and the Collaboration Agreement is currently in effect.

Effective August 12, 2020, we entered into a Master Service Agreement with the Foundation for Angelman Syndrome Therapy (FAST) to collaborate in supporting preclinical studies of the potential benefit of LB-100 in a mouse model of Angelman Syndrome (AS) as reported in The Proceedings of The National Academy of Science (Wang et al, June 3, 2019). The preclinical studies will take place at The University of California - Davis under the direction of Dr. David Segal, an internationally recognized leader in AS research. If the preclinical studies confirm that LB-100 reduces AS signs in rodent models, we have agreed to enter into discussions with FAST with respect to possible collaborations to most efficiently assess the benefit of LB-100 in patients with AS, which is a rare disease affecting an estimated one out of 12,000 to one out of 20,000 persons in the United States. The genetic cause of AS, reduced function of a specific maternal gene called Ube3, has been understood for some time, but the molecular abnormality resulting from the genetic lesion has now been shown to be increased concentrations of protein phosphatase 2A (PP2A), a molecular target of our investigational compound, LB-100. We agreed to provide FAST with a supply of LB-100 to be utilized in the conduct of this study, which is initially expected to be completed within three years. Conditioned on FAST's completion of this study, we have agreed to pay FAST five percent (5%) of all proceeds, as defined in the Master Service Agreement, received by us, up to a maximum of $250,000 from the exploitation of the study results.

Future Clinical Trials

Presented below are clinical trials that we would currently consider conducting over the next few years. We expect that these potential clinical trials, and the details thereof, will change over time as we obtain more clinical information on LB-100. Our ability to conduct these clinical trials is subject to the availability of sufficient additional 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/atezolizumab, 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 began in April 2019, and/or partnering relationships with other pharmaceutical companies, in order for us to undertake and complete such clinical studies. We are in discussions with various parties with respect to the financing of these clinical studies, although there can be no assurances that we will be able to obtain such financing and/or partnering relationships on acceptable terms or at all. Our longer-term objective is to secure one or more strategic partnerships with pharmaceutical companies with major programs in cancer research and drug development.

Intellectual Property

Our products will ultimately be based on our intellectual property and are expected to be covered by our 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. We have also filed patent applications for the use of certain homologs of both series of drugs for the 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 patent applications for the use of homologs of the LB-200 series for the treatment of serious systemic fungal infections and for the treatment of common fungal infections of the skin and nails.

Patent applications 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, and by the European Patent Office and the Eurasian Patent Office.

Our portfolio of domestic and international patents issued is summarized below, of which patents were issued during the year ended December 31, 2019. We have 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	1/19/2014	2/6/2028
AZ 023804	2/6/2008	7/29/2016	2/6/2028
BR 0806365	2/6/2008	1/21/2020	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	4/1/2015	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	2/20/2030
US 8,541,458	8/1/2008	9/24/2013	7/17/2029
US 8,822,461	2/6/2007	9/2/2014	2/6/2028
US 9,079,917	2/6/2007	7/14/2015	2/6/2028
US 10,023,587	2/6/2007	7/17/2018	2/6/2028
US 10,399,993	2/6/2007	9/3/2019	2/6/2028

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	8/28/2029

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 104619710	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
HK 1209424	6/28/2013	10/11/2019	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
AU 2016219853	2/19/2016	5/16/2019	2/19/2036
US 9,833,450	2/19/2015	12/5/2017	2/19/2036
US 10,413,541	2/19/2015	9/17/2019	2/19/2036

HDAC Inhibitors

Patent	Priority Date or International Filing Date (non-U.S. applications)	Issue/Grant Date	Expiration Date
CA 270857	10/1/2008	8/2/2016	10/1/2028
CN 10185480	10/1/2008	7/3/2014	10/1/2028
EP 2200439	10/1/2008	3/22/2017	10/1/2028
HK 1145420	10/1/2008	1/26/2018	10/1/2028
US 8,143,445	10/1/2007	3/27/2012	8/23/2029
US 8,455,688	10/1/2007	6/4/2013	10/1/2028

abicycloheptanes 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	6/29/2012	12/11/2018	12/7/2033
US 10,668,062	6/29/2012	6/2/2020	6/28/2033

Formulations of Oxabicycloheptanes and Oxabicycloheptenes

Patent	Priority Date or International Filing Date (non-U.S. applications)	Issue/Grant Date	Expiration Date
AU 2014251087	4/8/2014	5/2/2019	4/8/2034
CN 105209036	4/8/2014	10/26/2018	4/8/2034
IL 241945	4/8/2014	4/30/2019	4/8/2034
US 10,532,050	4/9/2013	1/14/2020	7/5/2034

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
JP 6453441	7/23/2015	1/16/2019	7/23/2035
US 10,071,094	7/24/2014	9/11/2018	7/23/2035
US 10,434,100	7/24/2014	10/8/2019	7/23/2035

Oxabicycloheptane Prodrugs

Patent	Priority Date or International Filing Date (non-U.S. applications)	Issue/Grant Date	Expiration Date
AU 2016263079	5/12/2016	8/15/2019	5/12/2036
EP 3294287	5/12/2016	4/8/2020	5/12/2036
IL 255516	5/12/2016	2/27/2020	5/12/2036
US 9,988,394	5/15/2015	6/5/2018	5/13/2036
US 10,364,252	5/15/2015	7/30/2019	5/13/2036
US 10,618,908	5/15/2015	4/14/2020	5/13/2036

The Market

Anti-Cancer Drugs

We have developed two series of pharmacologically active drugs, the LB-100 series and the LB-200 series. We believe 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, our compounds will improve therapeutic benefit without enhancing toxicity in humans.

Marketing Plan

Our primary goal to date has been to take our primary compound, LB-100, through Phase 2 clinical trials. Because of the novelty and spectrum of activity of LB-100, we believe it is reasonably likely we may find a partner in the pharmaceutical industry with interest in this compound at some stage of its clinical development. However, we would prefer to delay the partnering/licensing decision until the potential value of our products are 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 our 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 our most valuable resources is our 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

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

Competition

The life sciences industry is highly competitive and subject to rapid and profound technological change. 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. Additionally, 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 we do. 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 other organizations will not develop technologies with significant advantages over those that we are seeking to develop. Any such development could harm our business.

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 that we ultimately commercialize relative to competing products;
- the ease of use and ready availability of any product that we bring to market; and
- the relative speed with which we are able to bring any product resulting from its research to market in our target markets.

If we are unable to distinguish our products from competing products, or if competing products reach the market first, we may be unable to compete successfully with current or future competitors.

Employees

As of October 31, 2020, we had two full-time employees and two part-time employees.

Facilities

As of October 31, 2020, we do not operate any facilities, but contract out research, development, drug marketing, and storage to various commercial laboratories, drug manufacturers and storage facilities.

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.

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

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

Legal Proceedings

We may be involved from time to time in ordinary litigation, negotiation, and settlement matters that will not have a material effect on our operations or finances. We are not currently party to any material legal proceedings, and we are not aware of any pending or threatened litigation against us.

MANAGEMENT

Directors and Executive Officers

The following table and text set forth the names of all of our directors and executive officers as of October 31, 2020. 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. 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 and our consultants.

Our directors and executive officer are as follows:

Name	Age	Position(s) Held with the Registrant
Dr. John S. Kovach	83	President, Chief Executive Officer, and Director
Dr. James S. Miser	73	Chief Medical Officer
Robert N. Weingarten	68	Vice President and Chief Financial Officer
Eric Forman	40	Chief Administrative Officer
Dr. Philip F. Palmedo	85	Director
Dr. Stephen J. Forman	72	Director
Dr. Winson Sze Chun Ho	35	Director
Dr. Yun Yen	65	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 our business activities since that date.

Dr. James S. Miser

James S. Miser, M.D., is a pediatric hematologist/oncologist, internationally recognized as an expert in the study and treatment of childhood cancers. His outstanding career includes leadership positions as Clinical Director, Department of Pediatrics, Division of Pediatric Hematology/Oncology, Children's Hospital and Medical Center and Associate Member, Fred Hutchinson Cancer Research Center, Seattle, Washington; Chairman, Division of Pediatrics, Director, Department of Pediatric Hematology/Oncology, President and Chief Executive Officer, and Chief Medical Officer, all at City of Hope National Medical Center, Duarte, California. Since 2009, he has been a member of the Active Staff, Department of Pediatrics at City of Hope, most recently part-time, and Chair Professor, College of Medical Sciences and Technology, Taipei Medical University, Taipei, Taiwan.

Dr. Miser has extensive experience in the clinical development of new anti-cancer drugs for pediatric malignancies, leading many clinical trials at institutional and national cancer study groups. He is expert in the design and monitoring of clinical cancer trials and was a member of the Soft Tissue Sarcoma Strategy Group, and Member of the New Agents Executive and Steering Committee, Phase II Coordinator Children's Cancer Group and Chairman, Data Monitoring Committee, National Wilms Tumor Society. He has authored more than a 100 peer reviewed articles dealing primarily with pediatric clinical cancer studies.

Robert N. Weingarten

We have entered into an Employment Agreement with Mr. Weingarten to serve as our Vice President and Chief Financial Officer effective August 12, 2020. Mr. Weingarten is an experienced business consultant and advisor with a consulting practice focusing on accounting and SEC compliance issues. Since 1979, Mr. Weingarten has provided such financial consulting and advisory services, has acted as chief financial officer, and has served on the boards of directors of numerous public companies in various stages of development, operation or reorganization. Mr. Weingarten has experience in a variety of industries, including the pharmaceutical industry.

Mr. Weingarten has been a Director of Guardion Health Sciences, Inc. since June 2015 and Chairman of the board of directors since July 2020. Previously, Mr. Weingarten served as Lead Director on Guardion's board of directors from January 2017 to March 2020. From July 2017 to June 2018, Mr. Weingarten was the Chief Financial Officer of Alltemp, Inc. From April 2013 to February 2017, Mr. Weingarten served on the board of directors of RespireRx Pharmaceuticals Inc. and also served as Vice President and Chief Financial Officer. Mr. Weingarten received a B.A. in Accounting from the University of Washington in 1974, a M.B.A. in Finance from the University of Southern California in 1975, and is a Certified Public Accountant (inactive) in the State of California.

Eric Forman, J.D.

Mr. Forman has led our business development as a consultant since 2013. Effective as of October 1, 2020, Mr. Forman was appointed as our Chief Administrative Officer. In his capacity as a consultant, and in his role as Chief Administrative Officer, his responsibilities include overseeing all internal operations, the development of science/business collaborations, and the management of our growing intellectual property portfolio. Prior to his involvement with our company, he served as Counsel and Senior Project Manager at Shore Group Associates managing in-house legal, tax, and regulatory affairs and supervising client relations for financial software and mobile application development teams.

As an attorney, Mr. Forman has represented and advised both technology and biotechnology companies, entrepreneurs, non-profits, and start-ups with a focus on intellectual property, licensing, corporate structure and transactions.

Mr. Forman earned a B.A. degree Cum Laude from Loyola Marymount University and a J.D. from the Benjamin N. Cardozo School of Law. He has an active law license and is a member of the New York State Bar Association.

Dr. Philip F. Palmedo

Philip F. Palmedo, Ph.D., is a physicist, entrepreneur and corporate manager. Dr. Palmedo joined our 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 us 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 our 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 was established to advise our management in three areas: human molecular pathology; the clinical management of human brain tumors; and medicinal chemistry. Our 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 our 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 us. Our Committee currently is comprised as follows:

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.

KEY CONSULTANT

Gil Schwartzberg

Gil Schwartzberg, JD, ScD (hon) has been a consultant to our company since its inception. Prior to which he was Chairman of the Board, President and CEO of the City of Hope National Medical Center, one of the nation's leading biomedical research and treatment facilities and a National Cancer Institute (NCI) Comprehensive Cancer Center. Following his departure, the Graduate School of Biological Science of The Beckman Research Institute at the City of Hope awarded him the degree of Doctor of Science, honoring his work in the advancement of science through programmatic development and the growth of the Graduate School. This was the first ScD. degree awarded by the Beckman Graduate School., which received its full academic accreditation during Mr. Schwartzberg's tenure as the school's president. He is now City of Hope Chairman Emeritus for life.

Prior to his joining the City of Hope Mr. Schwartzberg was Vice Chairman of the Board of Sterling Bank of Los Angeles, of which he was a founder and where he served for many years as the Chairman of the Loan Committee until the bank's sale. Additionally, he was a founding shareholder of Skechers USA, Inc. (NYSE: SKX). He is currently a consultant to Skechers and both trustee and co-trustee of trusts that hold the controlling interest in the company.

Mr. Schwartzberg earned a Juris Doctorate awarded magna cum laude. He practiced law, specializing in business structure and transactions and remains a member in good standing of the California Bar, He is the author of two books. *Warning Toxic Business Mistakes and How to Avoid Making Them* and *Jane Austen's Persuasion Annotated, a Royal Navy Reading Companion*.

Family Relationships

Eric Forman, our appointed Chief Administrative Officer, is the son of board member Dr. Stephen Forman and son-in-law of our consultant Gil Schwartzberg.

Director Independence

Prior to the consummation of this offering, our Board of Directors undertook a review of the independence of our directors and considered whether any director has a relationship with us that could compromise that director's ability to exercise independent judgment in carrying out that director's responsibilities. Our Board of Directors has affirmatively determined that Philip Palmedo, Stephen Forman, Winson Sze Chun Ho, and Yun Yen are each an "independent director," as defined under the Nasdaq rules.

Committees of Our Board of Directors

Our Board of Directors directs the management of our business and affairs, as provided by Delaware law, and conducts its business through meetings of the Board of Directors and its standing committees. We will have a standing audit committee and compensation committee. Our entire Board of Directors will serve in place of a nominating and corporate governance committee. In addition, from time to time, special committees may be established under the direction of the Board of Directors when necessary to address specific issues.

Audit Committee

Our audit committee will be responsible for, among other things:

- Approving and retaining the independent auditors to conduct the annual audit of our financial statements;
- reviewing the proposed scope and results of the audit;
- reviewing and pre-approving audit and non-audit fees and services;

- reviewing accounting and financial controls with the independent auditors and our financial and accounting staff;
- reviewing and approving transactions between us and our directors, officers and affiliates;
- establishing procedures for complaints received by us regarding accounting matters;
- overseeing internal audit functions, if any; and
- preparing the report of the audit committee that the rules of the SEC require to be included in our annual meeting proxy statement.

Upon consummation of this offering, our audit committee will consist of Dr. Philip Palmedo, Dr. Yun Yen, and Winson Sze-Chun Ho with Dr. Palmedo serving as chair. Our Board of Directors has affirmatively determined that each of the committee members meet the definition of "independent director" under the Nasdaq rules, and that they meet the independence standards under Rule 10A-3. Each member of our audit committee meets the financial literacy requirements of the Nasdaq rules. In addition, our Board of Directors has determined that Dr. Palmedo will qualify as an "audit committee financial expert," as such term is defined in Item 407(d)(5) of Regulation S-K. Our Board of Directors has adopted a written charter for the audit committee, which is available on our principal corporate website at *www.lixte.com*.

Compensation Committee

Our compensation committee will be responsible for, among other things:

- reviewing and recommending the compensation arrangements for management, including the compensation for our president and chief executive officer;
- establishing and reviewing general compensation policies with the objective to attract and retain superior talent, to reward individual performance and to achieve our financial goals;
- administering our stock incentive plans; and
- preparing the report of the compensation committee that the rules of the SEC require to be included in our annual meeting proxy statement.

Upon the consummation of this offering, our compensation committee will consist of Yun Yen, Stephen Forman and Philip Palmedo, with Dr. Yen serving as chair. Our board has determined that all three committee members are independent directors under Nasdaq rules. Our board of directors has adopted a written charter for the compensation committee, which is available on our principal corporate website at *www.lixte.com*.

Nominating and Governance

Although our entire Board of Directors will serve in place of a nominating and corporate governance committee, our independent directors on the board will be responsible for, among other things:

- nominating members of the Board of Directors;
- developing a set of corporate governance principles applicable to our company; and
- overseeing the evaluation of our Board of Directors.

Upon the consummation of this offering, our entire Board of Directors will serve in place of a nominating and corporate governance committee. Our Board of Directors will adopt resolutions addressing, among other things, the nomination process.

Code of Ethics

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

Limitations on Liability and Indemnification Matters

Our Certificate of Incorporation contains provisions that limit the liability of our current and former directors for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- any transaction from which the director derived an improper personal benefit.

This limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our Certificate of Incorporation provides that we are authorized to indemnify our directors and officers to the fullest extent permitted by Delaware law. Our Amended and Restated Bylaws provide that we are required to indemnify our directors and executive officers to the fullest extent permitted by Delaware law. Our Amended and Restated Bylaws also provide that, upon satisfaction of certain conditions, we are required to advance expenses incurred by a director or executive officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. Our Amended and Restated Bylaws also provide our Board of Directors with discretion to indemnify our other officers and employees when determined appropriate by our Board of Directors. We expect to enter into agreements to indemnify our directors, executive officers and other employees as determined by the Board of Directors. With certain exceptions, these agreements provide for indemnification for related expenses, including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these provisions and agreements are necessary to attract and retain qualified persons as directors and officers. We also intend to obtain customary directors' and officers' liability insurance upon consummation of this offering.

The limitation of liability and indemnification provisions in our Certificate of Incorporation and Amended and Restated Bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions. At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought, and we are not aware of any threatened litigation that may result in claims for indemnification.

EXECUTIVE AND DIRECTOR COMPENSATION

Summary Compensation Table

The following table presents the compensation awarded to, earned by or paid to our only named executive officer for the years ended December 31, 2019 and 2018.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock awards ($)(	Option awards ($)	Nonequity incentive plan compensation ($)	Nonqualified deferred compensation earnings ($)	All other compensation ($)	Total ($)
John Kovach Chief Executive Officer	2019	60,000	—	—	—	—	—	—	60,000
	2018	60,000	—	—	—	—	—	—	60,000

Outstanding Equity Awards at December 31, 2019

There were no outstanding equity awards to our only named executive officer that were outstanding on December 31, 2019.

Employment Agreements; Compensation

During the years ended December 31, 2018 and 2019, we paid Dr. John S. Kovach, our 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 our 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 our business activities since that date.

Dr. Kovach is not compensated separately for his service on our Board of Directors. Dr. Kovach is reimbursed for out-of-pocket expenses.

Effective October 1, 2020, we entered into an employment agreement with Dr. Kovach as Chief Executive Officer pursuant to which Dr. Kovach is to receive an annual salary of $250,000. The term of the agreement is for an initial term of one year, which shall automatically be renewed for additional periods of one year unless notice of termination has been sent by either party not less than 60 days prior to the expiration of any one-year period.

Effective August 12, 2020, we entered into an employment agreement with Robert N. Weingarten pursuant to which Mr. Weingarten was appointed as our Vice President and Chief Financial Officer. Mr. Weingarten will receive an annual salary of $120,000 and options for 58,333 shares of common stock. The options can be exercised on a cashless basis. The options will have a term of five years and an exercise price of $7.14 per share. The options will vest as to 25% on August 12, 2020, and 25% vesting on each anniversary of the effective date of the employment agreement. The term of the agreement is for an initial term of one year, which shall be automatically renewed for additional periods of one year unless notice of termination has been sent by either party not less than 60 days prior to the expiration of any one-year period.

Effective August 1, 2020, we entered into an employment agreement with Dr. James Miser pursuant to which Dr. Miser was appointed as our Chief Medical Officer. Dr. Miser will be working on the basis of 50% of his time devoted to our company. Dr. Miser is to receive an annual salary of $150,000 and options for 83,333 shares of common stock. The options can be exercised on a cashless basis. The options will have a term of five years and an exercise price of $7.14 per share. The options will vest as to 25% on August 1, 2020, and 25% vesting on each anniversary of the effective date of the employment agreement. The term of the agreement is for an initial term of one year, which shall automatically be renewed for additional periods of one year unless notice of termination has been sent by either party not less than 60 days prior to the expiration of any one-year period.

Effective October 1, 2020, we entered into an employment agreement with Eric Forman pursuant to which Mr. Forman will serve as our Chief Administrative Officer. Mr. Forman is to receive an annual salary of $120,000 and options for 58,333 shares of common stock. The options can be exercised on a cashless basis. The options will have a term of 5 years and an exercise price of $7.14 per share. The options will vest as to 25% on August 12, 2020, and 25% vesting on each anniversary of the grant date. The term of the agreement is for an initial term of one year, which shall automatically be renewed for additional periods of one year unless notice of termination has been sent by either party not less than 60 days prior to the expiration of any one-year period.

Consulting Agreements

We have entered into various consulting agreements with Gil Schwartzberg as described at “CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS.”

Board of Director Compensation

Effective May 13, 2016, in conjunction with his appointment as our director, we granted to Dr. Stephen J. Forman stock options to purchase an aggregate of 33,333 shares of common stock under the 2007 Plan, exercisable for a period of five years from vesting date at $0.96 per share, which was the fair market value of our common stock on such date. One-half of such stock option (16,667 shares) vested on May 13, 2016 and the remaining one-half of such stock option (16,666 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 ($0.9354 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, we 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 our Board of Directors, Dr. Philip F. Palmedo was granted fully-vested stock options to purchase 8,333 shares of our common stock. The stock options are exercisable for a period of five years from the date of grant at $0.90 per share, which was the fair market value of our 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 ($0.9000 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 our Board of Directors, Dr. Stephen J. Forman was granted fully-vested stock options to purchase 8,333 shares of our common stock. The stock options are exercisable for a period of five years from the date of grant at $0.90 per share, which was the fair market value of our 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 ($0.9000 per share), which was charged to operations on the date of grant.

Effective August 4, 2018, in conjunction with their appointments as our directors, we granted to Dr. Winson Sze Chun Ho and Dr. Yun Yen stock options for each person to purchase an aggregate of 33,333 shares of our common stock, exercisable for a period of five years from the vesting date at $1.68 per share, which was the approximate fair market value of the our common stock on such date, with one-half of such stock options (16,667 shares each) vesting on August 4, 2018 and the remaining one-half of such stock options (16,666 shares each) vesting 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 ($1.5738 per share), of which $52,460 was attributable to the stock options fully-vested on August 4, 2018 and was therefore charged to operations on that date. The remaining unvested portion of the fair value of the stock options were charged to operations ratably from August 4, 2018 through August 4, 2019. During the years ended December 31, 2019 and 2018, we recorded charges to operations of $31,046 and $73,874, respectively, with respect to these stock options.

Effective May 22, 2019, in recognition with their service as directors over the past year, we granted to Dr. Winson Sze Chun Ho, Dr. Yun Yen, Dr. Stephen Forman, and Dr. Philip Palmedo, fully-vested stock options to purchase an aggregate of 33,333 shares (8,333 shares each) of our common stock, exercisable for a period of five years from the vesting date at $6.60 per share, which was the approximate fair market value of our 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 $189,060 ($5.6718 per share), which was attributable to the stock options fully vested on May 22, 2019 and was therefore charged to operations on that date.

DIRECTOR COMPENSATION TABLE

The following table describes the compensation of our directors for the year 2019.

Name and Principal Position	Year	Fees earned or paid in cash ($)	Stock Awards ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)	Change in Pension Value and Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)(2)	Total ($)
John S. Kovach Director (3)	2019	$60,000	0	0	0	0	0	60,000
Philip F. Palmedo Director	2019	0	0	$47,265	0	0	0	47,265
Stephen J. Forman Director	2019	0	0	$47,265	0	0	0	47,265
Winson Sze Chun Ho Director	2019	0	0	$47,265	0	0	0	47,265
Yun Yen Director	2019	0	0	$47,265	0	0	0	47,265

(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 our President and Chief Executive officer.

Scientific Advisory Committee Compensation

On December 24, 2013, we entered into an agreement with NDA Consulting Corp. 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 our Scientific Advisory Committee. In connection with this agreement, NDA was granted stock options to purchase 100,000 shares of our 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 our 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). We remeasured the non-vested options to fair value at the end of each reporting period. During the year ended December 31, 2017, we recorded a final charge to operations of $2,492 with respect to these stock options.

2020 Stock Incentive Plan

Summary

Our 2020 Stock Incentive Plan (the "2020 Plan") was adopted by our Board of Directors on July 14, 2020 and will be submitted to our stockholders as soon as practicable. Having an adequate number of shares available for future equity compensation grants is necessary to promote our long-term success and the creation of stockholder value by:

- Enabling us to continue to attract and retain the services of key service providers who would be eligible to receive grants;
- Aligning participants' interests with stockholders' interests through incentives that are based upon the performance of our common stock;
- Motivating participants, through equity incentive awards, to achieve long-term growth in our business, in addition to short-term financial performance; and
- Providing a long-term equity incentive program that is competitive as compared to other companies with whom we

compete for talent.

The 2020 Plan permits the discretionary award of incentive stock options ("ISOs"), non-statutory stock options ("NQSOs"), restricted stock, restricted stock units ("RSUs"), stock appreciation rights ("SARs"), other equity awards and/or cash awards to selected participants. The 2020 Plan will remain in effect until July 14, 2030.

The 2020 Plan provides for the reservation of 2,333,333 shares of common stock for issuance thereunder (the "Share Limit"), and provides that the maximum number of shares that may be issued pursuant to the exercise of ISOs is 2,333,333 (the "ISO Limit"). The number of shares available for issuance under the 2020 Plan constituted approximately 20.8% of our issued and outstanding shares of common stock as of the date of board approval.

Key Features of the 2020 Plan

Certain key features of the 2020 Plan are summarized as follows:

- If not terminated earlier by our Board of Directors, the 2020 Plan will terminate on July 14, 2030.
- Up to a maximum aggregate of 2,333,333 shares of common stock may be issued under the 2020 Plan. The maximum number of shares that may be issued pursuant to the exercise of ISOs is also 2,333,333.
- The 2020 Plan will generally be administered by a committee comprised solely of independent members of our Board of Directors. This committee will be the Compensation Committee unless otherwise designated by our Board of Directors. The board may designate a separate committee to make awards to employees who are not officers subject to the reporting requirements of Section 16 of the Exchange Act.
- Employees, consultants and board members are eligible to receive awards, provided that the Committee has the discretion to determine (i) who shall receive any awards, and (ii) the terms and conditions of such awards.
- Awards may consist of ISOs, NQSOs, restricted stock, RSUs, SARs, other equity awards and/or cash awards.
- Stock options and SARs may not be granted at a per share exercise price below the fair market value of a share of our common stock on the date of grant.
- Stock options and SARs may not be repriced or exchanged without stockholder approval.
- The maximum exercisable term of stock options and SARs may not exceed ten years.
- Awards are subject to recoupment of compensation policies adopted by us.

Eligibility to Receive Awards. Employees, consultants and our members of our Board of Directors and certain of our affiliated companies are eligible to receive awards under the 2020 Plan. The Committee determines, in its discretion, the selected participants who will be granted awards under the 2020 Plan.

Shares Subject to the 2020 Plan. The maximum number of shares of common stock that can be issued under the 2020 Plan is 14,000,000 shares.

The shares underlying forfeited or terminated awards (without payment of consideration), or unexercised awards become available again for issuance under the 2020 Plan. No fractional shares may be issued under the 2020 Plan. No shares will be issued with respect to a participant's award unless applicable tax withholding obligations have been satisfied by the participant.

Administration of the 2020 Plan. The 2020 Plan will be administered by the Compensation Committee of the Board of Directors, which shall consist of independent board members. With respect to certain awards issued under the 2020 Plan, the members of the Committee also must be "Non-Employee Directors" under Rule 16b-3 of the Exchange Act. Subject to the terms of the 2020 Plan, the Committee has the sole discretion, among other things, to:

- Select the individuals who will receive awards;
- Determine the terms and conditions of awards (for example, performance conditions, if any, and vesting schedule);

- Correct any defect, supply any omission, or reconcile any inconsistency in the 2020 Plan or any award agreement;
- Accelerate the vesting, extend the post-termination exercise term or waive restrictions of any awards at any time and under such terms and conditions as it deems appropriate, subject to the limitations set forth in the 2020 Plan;
- Permit a participant to defer compensation to be provided by an award; and
- Interpret the provisions of the 2020 Plan and outstanding awards.

The Committee may suspend vesting, settlement, or exercise of awards pending a determination of whether a selected participant's service should be terminated for cause (in which case outstanding awards would be forfeited). Awards may be subject to any policy that the Board of Directors may implement on the recoupment of compensation (referred to as a "clawback" policy). The members of the Board of Directors, the Committee and their delegates shall be indemnified by us to the maximum extent permitted by applicable law for actions taken or not taken regarding the 2020 Plan. In addition, the Committee may use the 2020 Plan to issue shares under other plans or sub-plans as may be deemed necessary or appropriate, such as to provide for participation by non-U.S. employees and those of any of our subsidiaries and affiliates.

Types of Awards.

Stock Options. A stock option is the right to acquire shares at a fixed exercise price over a fixed period of time. The Committee will determine, among other terms and conditions, the number of shares covered by each stock option and the exercise price of the shares subject to each stock option, but such per share exercise price cannot be less than the fair market value of a share of our common stock on the date of grant of the stock option. The exercise price of each stock option granted under the 2020 Plan must be paid in full at the time of exercise, either with cash, or through a broker-assisted "cashless" exercise and sale program, or net exercise, or through another method approved by the Committee. Stock options granted under the 2020 Plan may be either ISOs or NQSOs. In order to comply with Treasury Regulation Section 1.422-2(b), the 2020 Plan provides that no more than 2,333,333 shares may be issued pursuant to the exercise of ISOs.

SARs. A SAR is the right to receive, upon exercise, an amount equal to the difference between the fair market value of the shares on the date of the SAR's exercise and the aggregate exercise price of the shares covered by the exercised portion of the SAR. The Committee determines the terms of SARs, including the exercise price (provided that such per share exercise price cannot be less than the fair market value of a share of our common stock on the date of grant), the vesting and the term of the SAR. Settlement of a SAR may be in shares of common stock or in cash, or any combination thereof, as the Committee may determine. SARs may not be repriced or exchanged without stockholder approval.

Restricted Stock. A restricted stock award is the grant of shares of our common stock to a selected participant and such shares may be subject to a substantial risk of forfeiture until specific conditions or goals are met. The restricted shares may be issued with or without cash consideration being paid by the selected participant as determined by the Committee. The Committee also will determine any other terms and conditions of an award of restricted stock.

RSUs. RSUs are the right to receive an amount equal to the fair market value of the shares covered by the RSU at some future date after the grant. The Committee will determine all of the terms and conditions of an award of RSUs. Payment for vested RSUs may be in shares of common stock or in cash, or any combination thereof, as the Committee may determine. RSUs represent an unfunded and unsecured obligation for us, and a holder of a stock unit has no rights other than those of a general creditor.

Other Awards. The 2020 Plan also provides that other equity awards, which derive their value from the value of our shares or from increases in the value of our shares, may be granted. In addition, cash awards may also be issued. Substitute awards may be issued under the 2020 Plan in assumption of or substitution for or exchange for awards previously granted by an entity which we (or an affiliate) acquire.

Limited Transferability of Awards. Awards granted under the 2020 Plan generally are not transferrable other than by will or by the laws of descent and distribution. However, the Committee may in its discretion permit the transfer of awards other than ISOs.

Change in Control. In the event that we are a party to a merger or other reorganization or similar transaction, outstanding 2020 Plan awards will be subject to the agreement pertaining to such merger or reorganization. Such agreement may provide for (i) the continuation of the outstanding awards by us if we are a surviving corporation, (ii) the assumption or substitution of the outstanding awards by the surviving entity or its parent, (iii) full exercisability and/or full vesting of outstanding awards, or (iv) cancellation of outstanding awards either with or without consideration, in all cases with or without consent of the selected participant. The Committee will decide the effect of a change in control of us on outstanding awards.

Amendment and Termination of the 2020 Plan. The Board of Directors generally may amend or terminate the 2020 Plan at any time and for any reason, except that it must obtain stockholder approval of material amendments to the extent required by applicable laws, regulations or rules.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

The following includes a summary of transactions since January 1, 2018 to which we have been a party, including transactions in which the amount involved in the transaction exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described elsewhere in this prospectus. We are not otherwise a party to a current related party transaction, and no transaction is currently proposed, in which the amount of the transaction exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years and in which a related person had or will have a direct or indirect material interest.

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

On September 12, 2007, we entered into a consulting agreement with Gil Schwartzberg for Mr. Schwartzberg to provide financial advisory and consulting services to us 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 ours, and continues to be a consultant to us. Consideration under this consulting agreement, including subsequent extensions, has been paid exclusively in the form of stock options. On January 28, 2014, we entered into a second amendment to its consulting agreement with Mr. Schwartzberg to extend such agreement to January 28, 2019. In conjunction with such amendment, we granted Mr. Schwartzberg stock options to purchase an additional 666,667 shares of common stock, exercisable at $3.00 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 (333,334 shares) vesting immediately and one-half of the stock options (333,333 shares) vesting on January 28, 2015. On August 2, 2018, we entered into a third amendment to our consulting agreement with Mr. Schwartzberg to extend it to January 28, 2024, which was approved by our Board of Directors. In conjunction with such amendment, we extended the expiration date of the fully vested stock options for 666,667 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 ($1.0674 per share), which was reflected as a charge to general and administrative costs in the consolidated statement of operations for the year ended December 31, 2018.

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, 2019 and 2018, respectively. Mr. Forman is the son-in-law of Gil Schwartzberg, a significant stockholder of and consultant to us, and is the son of Dr. Stephen Forman, who was elected to our 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 we maintain a continuing banking relationship. In addition, in connection with his continuing service as a consultant, Mr. Forman was granted the following stock options:

- Effective October 16, 2017 - fully-vested stock options to purchase 16,667 shares of our common stock. The stock options are exercisable for a period of five years from the date of grant at $0.90 per share, which was the fair market value of our 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 ($0.9000 per share), which was charged to operations on the date of grant.

- Effective May 22, 2019 - fully-vested stock options to purchase 16,667 shares of our common stock, exercisable for a period of five years from the vesting date at $6.60 per share, which was the approximate fair market value of our 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 $94,525 ($5.6718 per share), which was charged to operations on the grant date.

Robert N. Weingarten was appointed as our Vice President and Chief Financial Officer on August 12, 2020. During the years ended December 31, 2019 and 2018, we paid Mr. Weingarten a total of $80,380 and $68,250, respectively, for accounting and financial consulting services rendered with respect to the preparation of our consolidated financial statements and certain other financial and compliance matters. During the six months ended June 30, 2020 and 2019, we paid Mr. Weingarten a total of $47,375 and $44,865 for similar accounting and financial consulting services rendered.

Indemnification Agreements

In connection with this offering, we entered into indemnification agreements with each of our directors and executive officers. These indemnification agreements will provide the directors and executive officers with contractual rights to indemnification and expense advancement that are, in some cases, broader than the specific indemnification provisions contained under Delaware law.

Related Person Transaction Policy

Prior to this offering, we have not had a formal policy regarding approval of transactions with related parties. Upon consummation of this offering, we shall adopt a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. The policy will become effective immediately upon the execution of the underwriting agreement for this offering. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants in which the amount involved exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of our board of directors, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant stockholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy. In addition, under our code of business conduct and ethics, our employees and directors will have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related person transactions, our audit committee, or other independent body of our board of directors, will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;

- the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;

- the availability of other sources for comparable services or products; and

- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related person transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our stockholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion.

PRINCIPAL STOCKHOLDERS

The following table sets forth, as of November 1, 2020, certain information regarding beneficial ownership of our common stock (the only class of our voting equity securities issued and outstanding) by (i) each person or entity who is known by us to own beneficially more than 5% of our outstanding shares of common stock, (ii) each of our directors, and (iii) all of our directors and executive officers as a group. As of November 1, 2020, there were 11,174,302 shares of our common stock issued and outstanding. In computing the number and percentage of shares beneficially owned by a person, shares of common stock that a person has a right to acquire within sixty (60) days of November 1, 2020 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. This table is based upon information supplied by our 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	1,519,083(1)	13.6%
Dr. Philip F. Palmedo 248 Route 25A, No. 2 East Setauket, New York 11733	302,670(2)	2.7%
Dr. Stephen J. Forman 248 Route 25A, No. 2 East Setauket, New York 11733	87,083(3)	0.8%
Dr. Yun Yen 248 Route 25A, No. 2 East Setauket, New York 11733	41,667(13)	0.4%
Dr. Winson Sze Chun Ho 248 Route 25A, No. 2 East Setauket, New York 11733	41,667(12)	0.4%
Robert Weingarten 248 Route 25A, No. 2 East Setauket, New York 11733	14,583(14)	—%
Eric J. Forman 248 Route 25A, No. 2 East Setauket, New York 11733	1,417,916(5)	12.6%
Dr. James S. Miser 248 Route 25A, No. 2 East Setauket, New York 11733	20,833(15)	0.2%
All officers and directors as a group (eight persons)	1,992,170	17.5%
John and Barbara Kovach 2015 Trust Eric J. Forman, Trustee 401 Park Avenue South, 10th Floor New York, New York 10016	1,333,333(4)	11.9%
Gil Schwartzberg 5500 Military Trail, Suite 22, Box 356 Jupiter, Florida 33458	1,936,456(6)	16.1%
Dr. Debbie Schwartzberg 5500 Military Trail, Suite 22, Box 356 Jupiter, Florida 33458	1,645,807(7)	13.8%
Dr. Arthur and Jane Riggs 4852 Saint Andres Avenue La Verne, California 91750	1,957,500(8)	16.2%
Robert and Susan Greenberg 228 Manhattan Beach Boulevard Manhattan Beach, California 90266	1,275,000(9)	11.1%
Lalit R. Bahl and Kavit K. Kinra		

3 Pheasant Run Setauket, New York 11733	1,000,000	8.8%
Lawrence J. Goldstein 1865 Palmer Avenue Larchmont, New York 10538	666,667(10)	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	1,000,000(11)	8.9%

(1) The shares are owned as of record by the John S. Kovach Trust. Dr. Kovach is a co-trustee of the Trust and has the exclusive right to control the investment of the assets of the Trust.

(2) Includes 183,333 shares of common stock and stock warrants to purchase 16,667 shares of common stock owned by the Philip Palmedo Partnership, and 11,003 shares of common stock and stock options to purchase 550,000 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.

(3) Includes 3,750 shares of common stock owned by Dr. Stephen Forman and stock options to purchase 50,000 shares of common stock which are immediately exercisable or within 60 days. Also includes 16,667 shares of common stock and stock warrants to purchase 16,667 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.

(4) Includes 1,333,333 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.

(5) Includes 16,667 shares of common stock owned by Eric J. Forman, stock options to purchase 64,583 shares of common stock and stock warrants to purchase 1,333 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 1,333,333 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 186,667 shares of common stock, stock options to purchase 291,667 shares of common stock and common stock warrants to purchase 83,333 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 6,000 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 16,667 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.

(6) Includes 375,926 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 83,333 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:

- 142,511 shares of common stock owned by the Gil Schwartzberg IRA;
- 106,352 shares of common stock owned by Continuum Capital Partners, LP, as to which Gil Schwartzberg has sole voting, dispositive and investment control;
- 186,667 shares of common stock, stock options to purchase 291,667 shares of common stock and common stock warrants to purchase 83,333 shares of common stock owned by the Julie Schwartzberg Trust, as to which Gil Schwartzberg is the co-trustee;
- 191,667 shares of common stock, stock options to purchase 291,667 shares of common stock and common stock warrants to purchase 83,333 shares of common stock owned by the David N. Sterling Trust, as to which Gil Schwartzberg is the co-trustee;
- 16,667 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;
- 33,333 shares of common stock owned by the Julie Forman 2015 Trust, David Sterling trustee.

Excludes the following:

- 417,474 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.

(7) Includes 417,474 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:

- 186,667 shares of common stock, stock options to purchase 291,667 shares of common stock and common stock warrants to purchase 83,333 shares of common stock owned by the Julie Schwartzberg Trust, as to which Debbie Schwartzberg is the co-trustee;
- 191,667 shares of common stock, stock options to purchase 291,667 shares of common stock and common stock warrants to purchase 83,333 shares of common stock owned by the David N. Sterling Trust, as to which Debbie Schwartzberg is the co-trustee;
- 16,667 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;
- 33,333 shares of common stock owned by the Julie Forman 2015 Trust, David Sterling trustee.

Excludes the following:

- 375,926 shares of common stock and stock options to purchase 83,333 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;
- 142,511 shares of common stock owned by the Gil Schwartzberg IRA;
- 106,352 shares of common stock owned by Continuum Capital Partners, LP, as to which Gil Schwartzberg has sole voting, dispositive and investment control.

(8) Includes 1,108,333 shares of common stock, 729,167 shares of common stock issuable upon conversion of 58,333 shares of Series A Convertible Preferred Stock, and common stock warrants to purchase 210,000 shares of common 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.

(9) Consists of 941,667 shares of common stock and common stock warrants to purchase 333,333 shares of common stock owned by the Greenberg Family Trust dated May 3, 1988. 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.

(10) Includes 166,667 shares of common stock owned by Lawrence J. Goldstein and common stock warrants to purchase 166,667 shares of common stock owned by Lawrence J. Goldstein. Also includes 166,667 shares of common stock and common stock warrants to purchase 166,667 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.

(11) Excludes stock options to purchase 41,667 shares of common stock owned by Dr. Winson Sze Chun Ho, a director of ours, and the son of Hung Tak Ho, as to which Hung Tak Ho disclaims beneficial ownership or control.

(12) Includes stock options to purchase 41,667 shares of common stock. Excludes 1,000,000 shares of common stock owned by Hung Tak Ho, the father of Dr. Winson Sze Chun Ho, a director of ours, as to which Dr. Winson Sze Chun Ho disclaims beneficial ownership or control.

(13) Includes stock options to purchase 41,667 shares of common stock.

(14) Consists of stock options to purchase 14,583 shares of common stock.

(15) Consists of stock options to purchase 20,833 shares of common stock.

DESCRIPTION OF CAPITAL STOCK

General

Upon completion of this offering, our authorized capital stock will consist of 100,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share.

As of October 13, 2020, there were 71 holders of record of our common stock. As of October 30, 2020, there were 11,174,302 shares of common stock issued and outstanding. In addition, as of October 30, 2020, 350,000 shares of Series A Convertible Preferred Stock, were issued and outstanding, which shares of preferred stock are convertible into an aggregate of 729,167 shares of common stock.

The following description of our capital stock and provisions of our Certificate of Incorporation and Amended and Restated Bylaws to be effective upon the completion of this offering is only a summary. You should also refer to our Certificate of Incorporation, a copy of which is filed as an exhibit to the registration statement of which this prospectus is a part, and our Amended and Restated Bylaws, a copy of which is filed as an exhibit to the registration statement of which this prospectus is a part.

Common Stock

We are authorized to issue up to a total of 100,000,000 shares of common stock, par value $0.0001 per share. Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of our stockholders. Holders of our common stock have no cumulative voting rights.

Further, holders of our common stock have no pre-emptive or conversion rights or other subscription rights. Upon our liquidation, dissolution or winding-up, holders of our common stock are entitled to share in all assets remaining after payment of all liabilities and the liquidation preferences of any of our outstanding shares of preferred stock. Subject to preferences that may be applicable to any outstanding shares of preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of our assets which are legally available. Each outstanding share of our common stock is, and all shares of common stock to be issued in this offering when they are paid for will be, fully paid and non-assessable.

The holders of a majority of the shares of our capital stock, represented in person or by proxy, are necessary to constitute a quorum for the transaction of business at any meeting. If a quorum is present, an action by stockholders entitled to vote on a matter is approved if the number of votes cast in favor of the action exceeds the number of votes cast in opposition to the action, with the exception of the election of directors, which requires a plurality of the votes cast.

Preferred Stock

Our Board of Directors will have the authority, without further action by the stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the designations, powers, preferences, privileges, and relative participating, optional, or special rights as well as the qualifications, limitations, or restrictions of the preferred stock, including dividend rights, conversion rights, voting rights, terms of redemption, and liquidation preferences, any or all of which may be greater than the rights of the common stock. Our board of directors, without stockholder approval, will be able to issue convertible preferred stock with voting, conversion, or other rights that could adversely affect the voting power and other rights of the holders of common stock. Preferred stock could be issued quickly with terms calculated to delay or prevent a change of control or make removal of management more difficult. Additionally, the issuance of preferred stock may have the effect of decreasing the market price of our common stock, and may adversely affect the voting and other rights of the holders of common stock. At present, we have no plans to issue any shares of preferred stock following this offering.

We have designated a total of 350,000 shares as our Series A Convertible Preferred Stock which are non-voting and not subject to increase without the written consent of a majority of the holders of such series. The holders of each tranche of 175,000 shares are entitled to receive a per share dividend equal to 1% of our annual net revenue divided by 175,000, until converted or redeemed. Each share of Series A Convertible Preferred Stock may be converted, at the option of the holder, into 2.083 shares of common stock (subject to customary anti-dilution provisions), and as subject to mandatory conversions at the conversion rate in the event of a merger or sale transaction resulting in gross proceeds to us of at least $21,875,000. Each share has a liquidation preference based on its assumed conversion into shares of common stock. We have a right to redeem the Series A Convertible Preferred Stock up to the fifth anniversary of their respective closing dates (March 17, 2015 and January 21, 2016) at a price per share equal to $50.

Options

Our 2020 Stock Incentive Plan provides for us to sell or issue restricted shares of common stock or to grant incentive stock options or non-qualified stock options, stock appreciation rights, and restricted stock unit awards for the purchase of shares of common stock to employees, members of the Board of Directors and consultants (see "Executive and Director Compensation - 2020 Stock Incentive Plan"). As of October 30, 2020, we had not issued any options for the purchase of shares of our common stock under the 2020 Stock Incentive Plan. As of October 30, 2020, we had options to purchase 1,508,333 shares of common stock issued and outstanding.

Anti-Takeover Provisions of Delaware Law, our Certificate of Incorporation and our Amended and Restated Bylaws

Delaware Law

We are governed by the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly traded Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A business combination includes mergers, asset sales or other transactions resulting in a financial benefit to the stockholder. An interested stockholder is a person who, together with affiliates and associates, owns (or within three years, did own) 15% or more of the corporation's voting stock, subject to certain exceptions. The statute could have the effect of delaying, deferring or preventing a change in control of our Company.

Board of Directors Vacancies

Our Certificate of Incorporation and Amended and Restated Bylaws authorize only our board of directors to fill vacant directorships. In addition, the number of directors constituting our board of directors may be set only by resolution of the majority of the incumbent directors.

Stockholder Action; Special Meeting of Stockholders

Our Certificate of Incorporation and Amended and Restated Bylaws provide that our stockholders may take action by written consent. Our Certificate of Incorporation and Amended and Restated Bylaws further provide that special meetings of our stockholders may be called by a majority of the board of directors, the Chief Executive Officer, or the Chairman of the board of directors.

Advance Notice Requirements for Stockholder Proposals and Director Nominations

Our Amended and Restated Bylaws provide that stockholders seeking to bring business before our annual meeting of stockholders, or to nominate candidates for election as directors at our annual meeting of stockholders, must provide timely notice of their intent in writing. To be timely, a stockholder's notice must be delivered to the secretary at our principal executive offices not later than the close of business on the 90^{th} day nor earlier than the close of business on the 120^{th} day prior to the first anniversary of the preceding year's annual meeting; provided, however, that in the event the date of the annual meeting is more than 30 days before or more than 60 days after such anniversary date, or if no annual meeting was held in the preceding year, notice by the stockholder to be timely must be so delivered not earlier than the close of business on the 120^{th} day prior to such annual meeting and not later than the close of business on the later of the 90^{th} day prior to such annual meeting or the 10^{th} day following the day on which a public announcement of the date of such meeting is first made by us. These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders.

Authorized but Unissued Shares

Our authorized but unissued shares of common stock and preferred stock are available for future issuance without stockholder approval and may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise. If we issue such shares without stockholder approval and in violation of limitations imposed by The Nasdaq Capital Market or any stock exchange on which our stock may then be trading, our stock could be delisted.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Limited, P.O. Box 505005, Louisville, Kentucky 40233, Batch 5005, Telephone No. 1-800-962-4284.

Stock Market Listing

Our application to have our shares of common stock listed for trading on The Nasdaq Capital Market under the symbol "LIXT" has been approved subject to notice of issuance.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of substantial amounts of our common stock in the public market, or the anticipation of these sales, could materially and adversely affect market prices prevailing from time to time, and could impair our ability to raise capital through sales of equity or equity-related securities.

Only a limited number of shares of our common stock will be available for sale in the public market for a period of several months after completion of this offering due to contractual and legal restrictions on resale described below. Nevertheless, sales of a substantial number of shares of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could materially and adversely affect the prevailing market price of our common stock. Although our application to list our common stock on The Nasdaq Capital Market has been approved, we cannot assure you that there will be an active market for our common stock.

Of the shares to be outstanding immediately after the completion of this offering, we expect that the shares to be sold in this offering and the shares of common stock sold by the selling stockholders will be freely tradable without restriction under the Securities Act unless purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act. Certain of the remaining shares of our common stock outstanding after this offering will be subject to a 180-day lock-up period under the lock-up agreements as described below. These restricted securities may be sold in the public market only if registered or pursuant to an exemption from registration, such as Rule 144 or Rule 701 under the Securities Act.

Rule 144

Affiliate Resales of Restricted Securities

Affiliates of ours must generally comply with Rule 144 if they wish to sell any shares of our common stock in the public market, whether or not those shares are "restricted securities." "Restricted securities" are any securities acquired from us or one of our affiliates in a transaction not involving a public offering. All shares of our common stock issued prior to the closing of the offering made hereby, are considered to be restricted securities. The shares of our common stock sold in this offering are not considered to be restricted securities.

Non-Affiliate Resales of Restricted Securities

Any person or entity who is not an affiliate of ours and who has not been an affiliate of ours at any time during the three months preceding a sale is only required to comply with Rule 144 in connection with sales of restricted shares of our common stock. Subject to the lock-up agreements described below, those persons may sell shares of our common stock that they have beneficially owned for at least one year without any restrictions under Rule 144 immediately following the effective date of the registration statement of which this prospectus is a part.

Further, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time such person sells shares of our common stock, and has not been an affiliate of ours at any time during the three months preceding such sale, and who has beneficially owned such shares of our common stock for at least six months but less than a year, is entitled to sell such shares so long as there is adequate current public information, as defined in Rule 144, available about us.

Resales of restricted shares of our common stock by non-affiliates are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144, described above.

Rule 701

Rule 701 generally allows a stockholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of ours during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation, or notice provisions of Rule 144.

Rule 701 also permits affiliates of ours to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required to wait until 90 days after the date of this prospectus before selling such shares pursuant to Rule 701 and until expiration of the 180-day lock-up period described below.

Equity Incentive Awards

We intend to file a registration statement on Form S-8 under the Securities Act after the closing of this offering to register the shares of common stock that are issuable pursuant to our 2020 Equity Incentive Plan. The registration statement is expected to be filed and become effective as soon as practicable after the completion of this offering. Accordingly, shares registered under the registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations and the lock-up arrangement described above, if applicable.

Lock-Up and Leak-Out Agreements

Each of our directors and executive officers and certain holders of our outstanding securities prior to this offering have entered into a Lock-Up/Leak-Out Agreement with us pursuant to which such officers, directors and stockholders have agreed to not sell their securities during such period commencing upon the date of the filing of this registration statement and ending at such time as may be determined by the underwriters in this offering; provided, however, that such lock-up period shall end no later than 180 days from the effective date of this registration statement. In addition, such officers, directors and shareholders have agreed that for a period of 48 months following the completion of our public offering they shall not transfer, sell, contract to sell, devise, gift, assign, pledge, hypothecate, distribute or grant any option to purchase or otherwise dispose of, directly or indirectly, any of their shares subject to the Lock-Up/Leak-Out Agreement; provided, however, our Board of Directors may, in its sole discretion, amend the terms of the Lock-Up/Leak-Out Agreement.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK

The following is a summary of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the ownership and disposition of our common stock but does not purport to be a complete analysis of all the potential tax considerations relating thereto. This summary is based upon the provisions of the Internal Revenue Code of 1986, as amended ("Internal Revenue Code") Treasury regulations promulgated thereunder, administrative rulings and judicial decisions, all as of the date hereof. These authorities may be changed, possibly retroactively, so as to result in U.S. federal income tax consequences different from those set forth below. No ruling on the U.S. federal, state, or local tax considerations relevant to our operations or to the purchase, ownership or disposition of our shares, has been requested from the IRS or other tax authority. No assurance can be given that the IRS would not assert, or that a court would not sustain, a position contrary to any of the tax consequences described below.

This summary also does not address the tax considerations arising under the laws of any non-U.S., state or local jurisdiction, or under U.S. federal gift and estate tax laws, except to the limited extent set forth below. In addition, this discussion does not address tax considerations applicable to an investor's particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

- banks, insurance companies or other financial institutions, regulated investment companies or real estate investment trusts;
- persons subject to the alternative minimum tax or Medicare contribution tax on net investment income;
- tax-exempt organizations or governmental organizations;
- controlled foreign corporations, passive foreign investment companies and corporations that accumulate earnings to avoid U.S. federal income tax;
- brokers or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- persons that own, or are deemed to own, more than five percent of our capital stock (except to the extent specifically set forth below);
- U.S. expatriates and certain former citizens or long-term residents of the U.S.;
- partnerships or entities classified as partnerships for U.S. federal income tax purposes or other pass-through entities (and investors therein);
- persons who hold our common stock as a position in a hedging transaction, "straddle," "conversion transaction" or other risk reduction transaction or integrated investment;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons who do not hold our common stock as a capital asset within the meaning of Section 1221 of the Internal Revenue Code; or
- persons deemed to sell our common stock under the constructive sale provisions of the Internal Revenue Code.

You are urged to consult your tax advisor with respect to the application of the U.S. federal income tax laws to your particular situation, as well as any tax consequences of the purchase, ownership and disposition of our common stock arising under the U.S. federal estate or gift tax rules or under the laws of any state, local, non-U.S., or other taxing jurisdiction or under any applicable tax treaty.

Non-U.S. Holder Defined

For purposes of this discussion, you are a non-U.S. holder (other than a partnership) if you are any holder other than:

- an individual citizen or resident of the U.S. (for U.S. federal income tax purposes);
- a corporation or other entity taxable as a corporation created or organized in the U.S. or under the laws of the U.S., any state thereof, or the District of Columbia, or other entity treated as such for U.S. federal income tax purposes;
- an estate whose income is subject to U.S. federal income tax regardless of its source; or
- a trust (x) whose administration is subject to the primary supervision of a U.S. court and which has one or more "U.S. persons" (within the meaning of Section 7701(a)(30) of the Internal Revenue Code) who have the authority to control all substantial decisions of the trust or (y) which has made a valid election to be treated as a U.S. person.

In addition, if a partnership or entity classified as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner generally will depend on the status of the partner and upon the activities of the partnership. Accordingly, partnerships that hold our common stock, and partners in such partnerships, should consult their tax advisors.

Distributions

As described in "Dividend Policy," we have never declared or paid cash dividends on our common stock and do not anticipate paying any dividends on our common stock in the foreseeable future. However, if we do make distributions on our common stock, those payments will constitute dividends for U.S. tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed both our current and our accumulated earnings and profits, they will constitute a return of capital and will first reduce your basis in our common stock, but not below zero, and then will be treated as gain from the sale of stock as described below under "— Gain on Disposition of Common Stock."

Subject to the discussion below on effectively connected income, backup withholding and foreign accounts, any dividend paid to you generally will be subject to U.S. withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty. In order to receive a reduced treaty rate, you must provide us with an IRS Form W-8BEN, IRS Form W-8BEN-E or other appropriate version of IRS Form W-8 certifying qualification for the reduced rate. A non-U.S. holder of shares of our common stock eligible for a reduced rate of U.S. withholding tax pursuant to an income tax treaty may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the non-U.S. holder's behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our paying agent, either directly or through other intermediaries.

Dividends received by you that are effectively connected with your conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, attributable to a permanent establishment maintained by you in the U.S.) are generally exempt from such withholding tax. In order to obtain this exemption, you must provide us with an IRS Form W-8ECI or other applicable IRS Form W-8 properly certifying such exemption. Such effectively connected dividends, although not subject to withholding tax, are taxed at the same graduated rates applicable to U.S. persons, net of certain deductions and credits. In addition, if you are a corporate non-U.S. holder, dividends you receive that are effectively connected with your conduct of a U.S. trade or business may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty. You should consult your tax advisor regarding any applicable tax treaties that may provide for different rules.

Gain on Disposition of Common Stock

Subject to the discussion below regarding backup withholding and foreign accounts, you generally will not be required to pay U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

- the gain is effectively connected with your conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, the gain is attributable to a permanent establishment maintained by you in the U.S.);
- you are a non-resident alien individual who is present in the U.S. for a period or periods aggregating 183 days or more during the taxable year in which the sale or disposition occurs and certain other conditions are met; or
- our common stock constitutes a U.S. real property interest by reason of our status as a "U.S. real property holding corporation," or USRPHC, for U.S. federal income tax purposes at any time within the shorter of (i) the five-year period preceding your disposition of our common stock, or (ii) your holding period for our common stock.

We believe that we are not currently and will not become a USRPHC for U.S. federal income tax purposes, and the remainder of this discussion so assumes. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, however, as long as our common stock is regularly traded on an established securities market, such common stock will be treated as U.S. real property interests only if you actually or constructively hold more than five percent of such regularly traded common stock at any time during the shorter of the five-year period preceding your disposition of, or your holding period for, our common stock.

If you are a non-U.S. holder described in the first bullet above, you will be required to pay tax on the net gain derived from the sale under regular graduated U.S. federal income tax rates, and a corporate non-U.S. holder described in the first bullet above also may be subject to the branch profits tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty. If you are an individual non-U.S. holder described in the second bullet above, you will be required to pay a flat 30% tax (or such lower rate specified by an applicable income tax treaty) on the gain derived from the sale, which gain may be offset by U.S. source capital losses for the year (provided you have timely filed U.S. federal income tax returns with respect to such losses). You should consult any applicable income tax or other treaties that may provide for different rules.

Federal Estate Tax

Our common stock beneficially owned by an individual who is not a citizen or resident of the U.S. (as defined for U.S. federal estate tax purposes) at the time of their death will generally be includable in the decedent's gross estate for U.S. federal estate tax purposes, unless an applicable estate tax treaty provides otherwise. The test for whether an individual is a resident of the U.S. for U.S. federal estate tax purposes differs from the test used for U.S. federal income tax purposes. Some individuals, therefore, may be non-U.S. holders for U.S. federal income tax purposes, but not for U.S. federal estate tax purposes, and vice versa.

Backup Withholding and Information Reporting

Generally, we must report annually to the IRS the amount of dividends paid to you, your name and address and the amount of tax withheld, if any. A similar report will be sent to you. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in your country of residence.

Payments of dividends or of proceeds on the disposition of stock made to you may be subject to information reporting and backup withholding at a current rate of 28% unless you establish an exemption, for example, by properly certifying your non-U.S. status on an IRS Form W-8BEN, IRS Form W-8BEN-E or another appropriate version of IRS Form W-8.

Backup withholding is not an additional tax; rather, the U.S. federal income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of taxes, a refund or credit may generally be obtained from the IRS, provided that the required information is furnished to the IRS in a timely manner.

Foreign Account Tax Compliance

The Foreign Account Tax Compliance Act, or FATCA, imposes withholding tax at a rate of 30% on dividends on and gross proceeds from the sale or other disposition of our common stock paid to "foreign financial institutions" (as specially defined under these rules), unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding the U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or otherwise establishes an exemption. FATCA also generally imposes a U.S. federal withholding tax of 30% on dividends on and gross proceeds from the sale or other disposition of our common stock paid to a "non-financial foreign entity" (as specially defined for purposes of these rules) unless such entity provides the withholding agent with a certification identifying certain substantial direct and indirect U.S. owners of the entity, certifies that there are none or otherwise establishes an exemption. The withholding provisions under FATCA generally apply to dividends on our common stock, and under current transition rules, are expected to apply with respect to the gross proceeds from the sale or other disposition of our common stock on or after January 1, 2019. An intergovernmental agreement between the U.S. and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their tax advisors regarding the possible implications of this legislation on their investment in our common stock.

Each prospective investor should consult its tax advisor regarding the particular U.S. federal, state and local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, including the consequences of any proposed change in applicable laws.

UNDERWRITING

WestPark Capital, Inc., or WestPark Capital, is acting as the representative of the underwriters of this offering. Under the terms of an underwriting agreement, which is filed as an exhibit to the registration statement, each of the underwriters named below has severally agreed to purchase from us the respective number of shares of common stock shown opposite its name below:

Underwriters	Number of Shares
WestPark Capital, Inc.	
WallachBeth Capital, LLC	

The underwriting agreement provides that the underwriters' obligation to purchase shares of common stock depends on the satisfaction of the conditions contained in the underwriting agreement including:

- the representations and warranties made by us to the underwriters are true;
- there is no material change in our business or the financial markets; and
- we deliver customary closing documents to the underwriters.

Commissions and Expenses

The following table shows the public offering price, underwriting discount and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option.

	Per Share	Total with no Over-Allotment	Total with Over-Allotment
Public offering price	$ 6.25	$ 9,375,000	$ 10,781,250
Underwriting discount (7.5%)	$ 0.46875	$ 703,125	$ 808,594
Non-accountable expense allowance (1.7%)[(1)]	$ 0.10625	$ 159,375	$ 183,281
Proceeds, before expenses, to us	$ 5.675	$ 8,512,500	$ 9,789,375

(1) We have agreed to pay a non-accountable expense allowance to the representative equal to 1.7% of the gross proceeds received in this offering.

We have paid an advance of $50,000 to the representative, which will be applied against actual out-of-pocket accountable expenses and reimbursed to us to the extent any portion thereof is not actually incurred in compliance with FINRA Rule 5110(f)(2)(C).

The underwriters propose to offer the shares of common stock directly to the public at the public offering price on the cover of this prospectus and to selected dealers, which may include the underwriters, at such offering price less a selling concession not in excess of $0.____ per share.

The expenses of this offering that are payable by us are estimated to be approximately $375,000 (which excludes estimated underwriting discounts and commissions and the non-accountable expense allowance payable to the underwriters). We will be responsible for all of the underwriters expenses related to this offering, including filing fees and communication expenses for the registration of the shares, all filing fees associated with the review of this offering by FINRA, fees and expenses relating to the listing of the shares on The Nasdaq Capital Market, fees relating to background checks (up to a maximum of $5,000), fees relating to the registration, qualification or exemptions of the shares under securities laws of foreign jurisdictions, cost of making and printing the underwriting documents, cost and expenses of a public relations firm, cost of preparing, printing and delivering stock certificates, fees and expenses of the transfer agent, and fees and expenses of our legal counsel, road show expenses for this offering, and fees and expenses of the underwriters legal counsel, not to exceed $75,000. The maximum amount of fees, costs and expenses incurred by the underwriters that we shall be responsible for may not exceed $130,000.

Option to Purchase Additional Shares

We have granted the underwriters an option exercisable for 45 days after the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of 225,000 shares from us at the public offering price, less underwriting discounts and commissions and the non-accountable expense allowance payable to the underwriters. To the extent that this option is exercised, each underwriter will be obligated, subject to certain conditions, to purchase its pro rata portion of these additional shares based on the underwriter's percentage underwriting commitment in this offering as indicated in the table at the beginning of this Underwriting Section.

Lock-Up Agreements

All of our directors, executive officers and principal shareholders have agreed that, for a period of 180 days after the date of this prospectus and subject to certain limited exceptions, we and they will not, directly or indirectly, without the prior written consent of WestPark Capital (i) offer for sale, sell, pledge, or otherwise dispose of (or enter into any transaction or device that is designed to, or could be expected to, result in the disposition by any person at any time in the future of) any shares of common stock (including, without limitation, shares of common stock that may be deemed to be beneficially owned by us or them in accordance with the rules and regulations of the SEC and shares of common stock that may be issued upon exercise of any options or warrants) or securities convertible into or exercisable or exchangeable for common stock, (ii) enter into any swap or other derivatives transaction that transfers to another, in whole or in part, any of the economic benefits or risks of ownership of shares of common stock, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of common stock or other securities, in cash or otherwise, (iii) make any demand for or exercise any right or file or cause to be filed a registration statement, including any amendments thereto, with respect to the registration of any shares of common stock or securities convertible into or exercisable or exchangeable for common stock or any of our other securities, or (iv) publicly disclose the intention to do any of the foregoing.

WestPark Capital, in its sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time. When determining whether or not to release common stock and other securities from lock-up agreements, WestPark Capital will consider, among other factors, the holder's reasons for requesting the release, the number of shares of common stock and other securities for which the release is being requested and market conditions at the time.

Underwriters' Warrants

We have also agreed to issue to the underwriters or their designees at the closing of this offering, warrants (the "Underwriters' Warrants") to purchase an aggregate of 150,000 shares of common stock (10% of the number of shares sold in the offering, excluding the over-allotment option). The Underwriters' Warrants will be exercisable at any time and from time to time, in whole or in part, during a period commencing six months from the effective date of this offering and expiring five years from the effective date of the offering. The Underwriters' Warrants will be exercisable at a price equal to 120% of the public offering price per share of common stock and such warrants shall be exercisable on a cash basis, provided that if a registration statement registering the common stock underlying the Underwriters' Warrants is not effective, the Underwriters' Warrants may be exercised on a cashless basis. The Underwriters' Warrants have been deemed compensation by FINRA and are, therefore, subject to a 180-day lock-up pursuant to Rule 5110(g)(1) of FINRA. The underwriters or their permitted assignees under this Rule 5110(g)(1) shall not sell, transfer, assign, pledge or hypothecate the Underwriters' Warrants, nor engage in any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the Underwriters' Warrants, for a period of 180 days from the effective date of the offering, except that they may be assigned, in whole or in part, as specifically set forth in the underwriting agreement. The Underwriters' Warrants will provide for customary anti-dilution provisions (for stock dividends, splits and recapitalizations and the like) consistent with FINRA Rule 5110, and the number of shares underlying the Underwriters' Warrants shall be reduced, or the exercise price increased, if necessary, to comply with FINRA rules or regulations. Further, the Underwriters' Warrants will provide for a one-time demand registration right and unlimited piggyback rights. The Underwriters' Warrants and underlying shares are included in this prospectus.

Offering Price Determination

The actual offering price of the shares of our common stock we are offering will be negotiated between us and the underwriters based upon, among other things, the trading of our shares prior to the offering.

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make for these liabilities.

Stabilization, Short Positions and Penalty Bids

The underwriters may engage in stabilizing transactions, short sales and purchases to cover positions created by short sales, and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of the common stock, in accordance with Regulation M under the Exchange Act:

- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.

- A short position involves a sale by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase in the offering, which creates the syndicate short position. This short position may be either a covered short position or a naked short position. In a covered short position, the number of shares involved in the sales made by the underwriters in excess of the number of shares they are obligated to purchase is not greater than the number of shares that they may purchase by exercising their option to purchase additional shares. In a naked short position, the number of shares involved is greater than the number of shares in their option to purchase additional shares. The underwriters may close out any short position by either exercising their option to purchase additional shares and/or purchasing shares in the open market. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through their option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.

- Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions.

- Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of the common stock. As a result, the price of the common stock may be higher than the price that might otherwise exist in the open market. These transactions may be effected on The Nasdaq Capital Market or otherwise and, if commenced, may be discontinued at any time.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of the common stock. In addition, neither we nor any of the underwriters make any representation that the underwriters will engage in these stabilizing transactions or that any transaction, once commenced, will not be discontinued without notice.

Electronic Distribution

A prospectus in electronic format may be made available on the Internet sites or through other online services maintained by one or more of the underwriters and/or selling group members participating in this offering, or by their affiliates. In those cases, prospective investors may view offering terms online and, depending upon the particular underwriter or selling group member, prospective investors may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations.

Other than the prospectus in electronic format, the information on any underwriter's or selling group member's web site and any information contained in any other web site maintained by an underwriter or selling group member is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter or selling group member in its capacity as underwriter or selling group member and should not be relied upon by investors.

Listing on The Nasdaq Capital Market

Our application has been approved to have our common stock listed on The Nasdaq Capital Market under the symbol "LIXT" subject to notice of issuance.

Discretionary Sales

The underwriters have informed us that they do not expect to sell more than 5% of the common stock in the aggregate to accounts over which they exercise discretionary authority.

Other Relationships

Certain of the underwriters and their affiliates may in the future provide various investment banking, commercial banking and other financial services for us and our affiliates for which they may in the future receive customary fees.

WestPark Capital and certain of its officers and principals hold, collectively, 214,596 shares of our common stock, representing an aggregate 1.92% of the outstanding shares of common stock immediately prior to this offering.

Selling Restrictions

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Notice to prospective investors in the European Economic Area and the United Kingdom

In relation to each Member State of the European Economic Area and the United Kingdom (each a "Relevant State"), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of shares may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

(a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the underwriters; or

(c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the underwriters and us that it is a "qualified investor" within the meaning of Article 2(e) of the Prospectus Regulation. In the case of any shares being offered to a financial intermediary as that term is used in the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Relevant State to qualified investors as so defined or in circumstances in which the prior consent of the underwriters have been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an "offer to the public" in relation to shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

Notice to prospective investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the Prospectus Regulation) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order") and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons") or otherwise in circumstances which have not resulted and will not result in an offer to the public of the shares in the United Kingdom within the meaning of the Financial Services and Markets Act 2000.

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons.

Notice to prospective investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (the "SIX") or on any other stock exchange or regulated trading facility in Switzerland. This document does not constitute a prospectus within the meaning of, and has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (the "FINMA"), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (the "CISA"). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to prospective investors in France

This prospectus (including any amendment, supplement or replacement thereto) is not being distributed in the context of a public offering in France within the meaning of Article L. 411-1 of the French Monetary and Financial Code (Code monétaire et financier). This prospectus has not been and will not be submitted to the French Autorité des marchés financiers (the "AMF") for approval in France and accordingly may not and will not be distributed to the public in France.

Pursuant to Article 211-3 of the AMF General Regulation, French residents are hereby informed that:

1. the transaction does not require a prospectus to be submitted for approval to the AMF;

2. persons or entities referred to in Point 2°, Section II of Article L. 411-2 of the Monetary and Financial Code may take part in the transaction solely for their own account, as provided in Articles D. 411-1, D. 734-1, D. 744-1, D. 754-1 and D. 764-1 of the Monetary and Financial Code; and

3. the financial instruments thus acquired cannot be distributed directly or indirectly to the public otherwise than in accordance with Articles L. 411-1, L. 411-2, L. 412-1 and L. 621-8 to L. 621-8-3 of the Monetary and Financial Code.

This prospectus is not to be further distributed or reproduced (in whole or in part) in France by the recipients of this prospectus. This prospectus has been distributed on the understanding that such recipients will only participate in the issue or sale of our common stock for their own account and undertake not to transfer, directly or indirectly, our common stock to the public in France, other than in compliance with all applicable laws and regulations and in particular with Articles L. 411-1 and L. 411-2 of the French Monetary and Financial Code.

Notice to Prospective Investors in Germany

Our common stock may be offered and sold in the Federal Republic of Germany only in compliance with the Prospectus Regulation, the Commission Delegated Regulations (EU) 2019/979 and (EU) 2019/980, each as of March 14, 2019 and the German Securities Prospectus Act (Wertpapierprospektgesetz), as amended, or any other laws applicable in Germany governing the issue, offering and sale of securities. This prospectus has not been approved under the Prospectus Regulation and, accordingly, our common stock may not be offered publicly in the Federal Republic of Germany. Our common stock will only be offered in the Federal Republic of Germany in reliance on an exemption from the requirement to publish an approved securities prospectus under the Prospectus Regulation. Any resale of our common stock in Germany may only be made in accordance with the Prospectus Regulation and other applicable laws.

Notice to Prospective Investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) (the "SFO") of Hong Kong and any rules made thereunder; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong) (the "CO") or which do not constitute an offer to the public within the meaning of the CO. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made thereunder.

Notice to Prospective Investors in China

This prospectus will not be circulated or distributed in the PRC and the shares will not be offered or sold, and will not be offered or sold to any person for re-offering or resale directly or indirectly to any residents of the PRC except pursuant to any applicable laws and regulations of the PRC. Neither this prospectus nor any advertisement or other offering material may be distributed or published in the PRC, except under circumstances that will result in compliance with applicable laws and regulations.

LEGAL MATTERS

The validity of the issuance of the common stock offered by us in this offering will be passed upon for us TroyGould PC, Los Angeles, California. Certain legal matters in connection with this offering will be passed upon for the underwriters by Sheppard, Mullin, Richter & Hampton LLP, New York, New York.

EXPERTS

The consolidated financial statements of Lixte Biotechnology Holdings, Inc. as of December 31, 2019 and 2018 and for each of the years then ended included in this Registration Statement, of which this prospectus forms a part, have been so included in reliance on the report of Weinberg & Company, P.A., an independent registered public accounting firm (the report on the consolidated financial statements contains an explanatory paragraph regarding our ability to continue as a going concern) appearing elsewhere herein, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission a registration statement on Form S-1 under the Securities Act with respect to the common stock offered by this prospectus. This prospectus, which is part of the registration statement, omits certain information, exhibits, schedules and undertakings set forth in the registration statement. For further information pertaining to us and our common stock, reference is made to the registration statement and the exhibits and schedules to the registration statement. Statements contained in this prospectus as to the contents or provisions of any documents referred to in this prospectus are not necessarily complete, and in each instance where a copy of the document has been filed as an exhibit to the registration statement, reference is made to the exhibit for a more complete description of the matters involved.

The registration statement is available at the Securities and Exchange Commission's website at *www.sec.gov*. The registration statement, including all exhibits and amendments to the registration statement, has been filed electronically with the Securities and Exchange Commission. we will become subject to the information and periodic reporting requirements of the Securities Exchange Act of 1934, as amended, and, accordingly, will be required to file annual reports containing financial statements audited by an independent public accounting firm, quarterly reports containing unaudited financial data, current reports, proxy statements and other information with the Securities and Exchange Commission. You will be able to inspect and copy such periodic reports, proxy statements and other information at the website of the Securities and Exchange Commission referred to above.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

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

Years Ended December 31, 2019 and 2018

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, 2019 and 2018, 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, 2019 and 2018, 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 audits 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, an 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, 2020

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2019	**2018**
ASSETS		
Current assets:		
Cash	$ 2,598,864	$ 4,273,012
Accrued interest receivable	14,367	—
Prepaid expenses and other current assets	58,802	61,433
Total current assets	2,672,033	4,334,445
Prepaid expense, less current portion	—	2,293
Total assets	$ 2,672,033	$ 4,336,738
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 143,549	$ 195,211
Research and development contract liabilities	94,349	15,704
Total current liabilities	237,898	210,915
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	6,704	6,704
Additional paid-in capital	26,016,317	25,267,662
Accumulated deficit	(27,088,886)	(24,648,543)
Total stockholders' equity	2,434,135	4,125,823
Total liabilities and stockholders' equity	$ 2,672,033	$ 4,336,738

See accompanying notes to consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,	
	2019	**2018**
Revenues	$ —	$ —
Costs and expenses:		
General and administrative costs, including $362,631 and $833,612 to related parties for the years ended December 31, 2019 and 2018, respectively	1,669,160	2,097,348
Research and development costs	820,906	40,703
Total costs and expenses	2,490,066	2,138,051
Loss from operations	(2,490,066)	(2,138,051)
Interest income	49,723	4,923
Net loss	$ (2,440,343)	$ (2,133,128)
Net loss per common share – basic and diluted	$ (0.04)	$ (0.04)
Weighted average common shares outstanding – basic and diluted	67,045,814	58,796,115

See accompanying notes to consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

Years Ended December 31, 2019 and 2018

	Series A Convertible Preferred Stock		Common Stock		Additional		Total
	Shares	Amount	Shares	Par Value	Paid-in Capital	Accumulated Deficit	Stockholders' Equity
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	—	—	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
Stock-based compensation expense	—	—	—	—	748,655	—	748,655
Net loss	—	—	—	—	—	(2,440,343)	(2,440,343)
Balance, December 31, 2019	350,000	$3,500,000	67,045,814	$ 6,704	$26,016,317	$ (27,088,886)	$ 2,434,135

See accompanying notes to consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (2,440,343)	$ (2,133,128)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense included in -		
General and administrative costs	314,631	785,612
Research and development costs	434,024	—
Changes in operating assets and liabilities:		
(Increase) decrease in -		
Accrued interest receivable	(14,367)	—
Prepaid expenses and other current assets	4,924	(1,409)
Increase (decrease) in -		
Accounts payable and accrued expenses	(51,662)	(116,823)
Research and development contract liabilities	78,645	(45,286)
Net cash used in operating activities	(1,674,148)	(1,511,034)
Cash flows from financing activities:		
Exercise of common stock options	—	3,000
Proceeds from sale of common stock and common stock units	—	4,500,000
Costs incurred in connection with the sale of common stock units	—	(24,702)
Net cash provided by financing activities	—	4,478,298
Cash:		
Net increase (decrease)	(1,674,148)	2,967,264
Balance at beginning of period	4,273,012	1,305,748
Balance at end of period	$ 2,598,864	$ 4,273,012
Supplemental disclosures of cash flow information:		
Cash paid for -		
Interest	$ —	$ —
Income taxes	$ —	$ —

See accompanying notes to consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2019 and 2018

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 is primarily focused on inhibitors of protein phosphatases, used alone and in combination with cytotoxic agents and/or x-ray and immune checkpoint blockers, and 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, 2019, 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.

At December 31, 2019, the Company had cash and cash equivalents of $2,598,864 available to fund its operations. Because the Company is currently engaged in Phase 2 clinical trials, it is expected that it will 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 Company's longer-term objective is to secure one or more strategic partnerships or licensing agreements with pharmaceutical companies with major programs in cancer. The Company expects that it will need to begin to raise additional capital no later than the fourth quarter of 2020.

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. There is also significant uncertainty as to the affect that the coronavirus may have on the availability, amount and type of financing in the future.

If cash resources are insufficient to satisfy the Company's ongoing cash requirements, the Company would be required to scale back or discontinue its clinical trial program and its technology and product development efforts, 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 and Cash Equivalents

Cash and cash equivalents include cash and short-term certificates of deposit. The Company maintains its cash balances with financial institutions with high credit ratings and in accounts insured by the Federal Deposit Insurance Corporation (the "FDIC"). The Company may periodically have cash balances in banks in excess of FDIC insurance limits. The Company has not experienced any losses to date resulting from this practice.

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.

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 are 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 Related Legal and Filing 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-related legal and filing costs were $742,918 and $842,325 for the years ended December 31, 2019 and 2018, respectively. Patent and licensing related legal and filing costs are included in general and administrative costs in the Company's consolidated statements of operations.

Concentration of Risk

The Company periodically contracts with vendors and consultants to provide services related to the Company's research and development activities. Agreements for these services can be for a specific time period (typically one year) or for a specific project or task. The only such contract that represented 10% or more of general and administrative costs or research and development costs for the years ended December 31, 2019 and 2018 is described below.

As discussed at Note 7, effective as of July 31, 2019, the Company entered into a Collaboration Agreement for an Investigator-Initiated Clinical Trial with GEIS to carry out a clinical trial entitled "Randomized phase I/II trial of LB-100 plus doxorubicin vs. doxorubicin alone in first line of advanced soft tissue sarcoma". The Company estimates that this clinical trial will be completed and results will be published by June 2023. Costs incurred pursuant to the agreement with GEIS are included in research and development costs in the Company's consolidated statements of operations. During the year ended December 31, 2019, the Company incurred costs of $87,471 pursuant to this agreement, reflecting 10.7% of total research and development costs for such period.

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, 2019 and 2018 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, 2019, 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.

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

Through December 31, 2018, the Company accounted 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 accounted 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 was reached or (b) at the date at which the necessary performance to earn the equity instruments was complete.

In accordance with the Company's adoption of Accounting Standards Update 2018-07, Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting (see "Recent Accounting Pronouncements" below), effective January 1, 2019, stock options granted to members of the Company's Scientific Advisory Committee and to outside consultants are now accounted for consistent with the accounting for stock-based payments to officers and directors, as described above, 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 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. Estimated volatility is based on the historical volatility of the Company's common stock, calculated utilizing a one-year look-back period, as the Company believes that such measurement period provides a more accurate and meaningful volatility factor given the changes in the Company's research and development program and capital requirements over the past several years. 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 the common stock is determined by reference to the quoted market price of the Company's common stock on the grant date.

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 was the same for all periods presented because all preferred shares, warrants and stock options outstanding were anti-dilutive.

At December 31, 2019 and 2018, 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,	
	2019	**2018**
Series A Convertible Preferred Stock	4,375,000	4,375,000
Common stock warrants	9,000,000	9,000,000
Common stock options, including options issued in the form of warrants	7,850,000	7,750,000
Total	21,225,000	21,125,000

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 cash equivalents, 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 June 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 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 was effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company adopted the provisions of ASU 2018-07 effective January 1, 2019 (see "Stock-Based Compensation" above). The adoption of ASU 2018-07 did not have any impact on the Company's financial statement presentation or disclosures subsequent to its adoption.

Recently Issued Accounting Standards

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"). ASU 2019-12 simplifies the accounting for income taxes by removing certain exceptions and enhances and simplifies various aspects of the income tax accounting guidance in ASC 740. ASU 2019-12 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The adoption of ASU 2018-07 is not expected to have any impact on the Company's financial statement presentation or disclosures subsequent to its adoption.

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 is authorized to issue 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 has designated a total of 350,000 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. As of December 31, 2019, 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, 2019. The Company has the right to redeem the Series A Convertible Preferred Stock up to the fifth anniversary of their respective closing dates (March 17, 2015 and January 21, 2016) at a price per share equal to $50.00. The Series A Convertible Preferred Stock has no right to cash, except with respect to 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 has 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 a total of 100,000,000 shares of common stock (par value $0.0001). As of December 31, 2019 and 2018, the Company had 67,045,814 shares of common stock issued and outstanding.

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.

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, during the years ended December 31, 2019 and 2018 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	
Issued	—	—	
Exercised	—	—	
Expired	—	—	
Warrants outstanding at December 31, 2019	9,000,000	$ 1.000	2.92

At December 31, 2019, all outstanding warrants are exercisable at $1.000 per common share.

Based on a fair market value of $0.68 per share on December 31, 2019, 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, 2019.

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, 2019 and 2018, respectively, which amounts are included in general and administrative costs in the Company's consolidated statements of operations.

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 such agreement 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) vesting immediately and one-half of the stock options (2,000,000 shares) vesting 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, the Company entered into a third amendment to its consulting agreement with Mr. Schwartzberg to extend it to January 28, 2024, which was approved by the Company's Board of Directors. 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 reflected as a charge to general and administrative costs in the consolidated statement of operations for the year ended December 31, 2018.

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, 2019 and 2018, respectively. Eric 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 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 continuing banking relationship.

A summary of related party costs for the years ended December 31, 2019 and 2018 is as follows:

	Years Ended December 31,	
	2019	**2018**
Related party costs:		
Cash-based	$ 48,000	$ 48,000
Stock-based	314,631	785,612
Total	$ 362,631	$ 833,612

Stock-based compensation arrangements involving members of the Company's Board of Directors and affiliates are described at Note 5.

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 provided for the granting of awards, consisting of stock options, stock appreciation rights, performance shares, and 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, 2019, 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 grant date using the Black-Scholes option-pricing model. The risk-free interest rate is based on the U.S. treasury yield curve in effect as of the grant date. The expected dividend yield assumption is based on the Company's expectation of dividend payouts and is assumed to be zero. The expected volatility is based on the historical volatility of the Company's common stock. The expected life of the stock option is considered its full contractual term. The fair market value of the common stock is determined by reference to the quoted market price of the common stock on the grant date.

For stock options requiring an assessment of value during the year ended December 31, 2019, the fair value of each stock option award was estimated using the Black-Scholes option-pricing model with the following assumptions:

Risk-free interest rate	1.47% to 1.85%
Expected dividend yield	0%
Expected volatility	133.01% to 171.87%
Expected life	5 years

For stock options requiring an assessment of value during the year ended December 31, 2018, the fair value of each stock option award was estimated using the Black-Scholes option-pricing model with 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

Effective August 4, 2018, in conjunction with their appointments as directors of the Company, the Company granted stock options to each of Dr. Winson Sze Chun Ho and Dr. Yun Yen 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, with one-half of such stock options (100,000 shares for each director) vesting on August 4, 2018 and the remaining one-half of such stock options (100,000 shares for each director) vesting on August 4, 2019. The aggregate 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 charged to operations on that date. The remaining unvested portion of the fair value of the stock options was charged to operations ratably from August 4, 2018 through August 4, 2019. During the years ended December 31, 2019 and 2018, the Company recorded charges to operations of $31,046 and $73,874, respectively, with respect to these stock options.

Effective May 22, 2019, in recognition with their service as directors of the Company over the past year, the Company granted to each of Dr. Winson Sze Chun Ho, Dr. Yun Yen, Dr. Stephen Forman, and Dr. Philip Palmedo, fully-vested stock options to purchase an aggregate of 200,000 shares (50,000 shares for each director) of the Company's common stock, exercisable for a period of five years from the vesting date at $1.10 per share, which was the approximate 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 $189,060 ($0.9453 per share), which was charged to operations on the grant date.

Effective May 22, 2019, in recognition of his continuing service as consultant to the Company, the Company granted to Eric Forman fully-vested stock options to purchase 100,000 shares of the Company's common stock, exercisable for a period of five years from the vesting date at $1.10 per share, which was the approximate 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 $94,525 ($0.9453 per share), which was charged to operations on the grant date.

Effective July 23, 2019, the Company granted Francis Johnson, a consultant to the Company, fully vested stock options to purchase 500,000 shares of the Company's common stock in recognition of Mr. Johnson's continuing contributions to the development of the Company's proprietary compounds. The stock options are exercisable for a period of five years from the date of grant at $1.00 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 determined to be $434,024 ($0.8680 per share), which was attributable to the stock options fully vested on July 23, 2019 and was therefore charged to operations on that date.

A summary of stock-based compensation costs for the years ended December 31, 2019 and 2018 is as follows:

	Years Ended December 31,	
	2019	2018
Related parties	$ 314,631	$ 785,612
Non-related parties	434,024	—
Total stock-based compensation costs	$ 748,655	$ 785,612

A summary of stock option activity, including options issued in the form of warrants, during the years ended December 31, 2019 and 2018 is presented below.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
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	0.583	
Granted	800,000	1.038	
Exercised	—	—	
Expired	(700,000)	0.321	
Stock options outstanding at December 31, 2019	7,850,000	$ 0.608	3.14
Stock options exercisable at December 31, 2018	7,550,000	$ 0.545	
Stock options exercisable at December 31, 2019	7,850,000	$ 0.608	3.14

There was no deferred compensation expense for the outstanding value of unvested stock options at December 31, 2019.

The exercise prices of common stock options outstanding and exercisable, including options issued in the form of warrants, at December 31, 2019 are as follows:

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
$ 0.280	400,000	400,000
$ 0.500	4,200,000	4,200,000
$ 1.000	1,000,000	1,000,000
$ 1.100	300,000	300,000
$ 2.000	500,000	500,000
	7,850,000	7,850,000

The intrinsic value of exercisable but unexercised in-the-money stock options at December 31, 2019 was approximately $1,664,950, based on a fair market value of $0.68 per share on December 31, 2019.

All outstanding options to acquire shares of the Company's common stock were vested at December 31, 2019.

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, 2019 and 2018 are summarized below.

	December 31,	
	2019	2018
Start-up and organization costs	$ 10,000	$ 14,000
Research credits	359,000	351,000
Stock-based compensation	799,000	626,000
Net operating loss carryforwards	4,879,000	4,395,000
Total deferred tax assets	6,047,000	5,386,000
Valuation allowance	(6,047,000)	(5,386,000)
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, 2019 and 2018, 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, 2019 and 2018 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, 2019 and 2018.

	Years Ended December 31,	
	2019	2018
U. S. federal statutory tax rate	(21.0)%	(21.0)%
State income taxes, net of federal tax benefit	(6.0)%	(6.0)%
Expirations related to stock-based compensation	1.2%	0.2%
Adjustment to deferred tax asset	(0.3)%	(1.3)%
Change in valuation allowance	26.1%	28.1%
Effective tax rate	0.0%	0.0%

At December 31, 2019, the Company has available net operating loss carryforwards for federal and state income tax purposes of approximately $17,088,000 and $17,987,000, respectively. Federal net operating losses, if not utilized earlier, expire through 2039. 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 losses incurred in post-2015 tax years may be utilized in future tax years. Post-2015 New York net operating losses expire through 2039. As the Company's net operating losses have yet to be utilized, all previous tax years since 2006 remain open to examination by Federal authorities and other jurisdictions in which the Company currently operates or has operated in the past.

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, 2019, the Company was not subject to any pending or threatened legal claims or actions.

Clinical Trial Agreements

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 agreed to conduct and manage a Phase 1b/2 clinical trial to evaluate the 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 myelodysplastic syndrome (MDS).

In 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 therapeutic benefit of LB-100 in patients with low and intermediate-1 risk MDS who have failed or are intolerant of standard treatment. This clinical trial began in April 2019 and the first patient was entered into the clinical trial in July 2019. The clinical trial is expected to be completed over a period of two years, with final analysis and reporting expected within three years. This Phase 1b/2 clinical trial utilizes 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. During the years ended December 31, 2019 and 2018, the Company paid Moffitt $45,093 and $0, respectively, pursuant to this agreement. As of December 31, 2019, total costs of $45,093 have been incurred pursuant to this agreement.

Effective as of July 31, 2019, the Company entered into a Collaboration Agreement for an Investigator-Initiated Clinical Trial with the Spanish Sarcoma Group (Grupo Espanol de Investigacion en Sarcomas or "GEIS"), Madrid, Spain, to carry out a clinical trial entitled "Randomized phase I/II trial of LB-100 plus doxorubicin vs. doxorubicin alone in first line of advanced soft tissue sarcoma". The purpose of this clinical trial is to obtain information about the efficacy and safety of the Company's lead anti-cancer clinical compound LB-100 combined with doxorubicin in soft tissue sarcomas. Doxorubicin is the global standard for initial treatment of advanced soft tissue sarcomas (ASTA). Doxorubicin alone has been the mainstay of first line treatment of ASTS for over 40 years, with little therapeutic gain from adding cytotoxic compounds to or substituting other cytotoxic compounds for doxorubicin. In animal models, LB-100 consistently enhances the antitumor activity of doxorubicin without apparent increases in toxicity. GEIS has a network of referral centers in Spain and across Europe that have an impressive track record of efficiently conducting innovative studies in ASTS. The Company has agreed to provide GEIS with a supply of LB-100 to be utilized in the conduct of this clinical trial, as well as to provide funding for the clinical trial. The goal is to enter the first patient into this clinical trial during the quarter ending June 30, 2020, with approximately 170 patients to be subsequently enrolled over a period of two years. The Company estimates that this clinical trial will be completed and results will be published by June 30, 2023. The original start date for patient entry was delayed due to longer than expected processing of formal approval of importation of LB-100 into the European Union. This approval was originally expected to be received in the quarter ended September 30, 2019, but was delayed and is now expected to be received during the quarter ending June 30, 2020. During the year ended December 31, 2019, the Company incurred costs of $87,471 pursuant to this agreement. As of December 31, 2019, total costs of $87,471 have been incurred pursuant to this agreement.

The Company's aggregate commitments pursuant to these clinical trial agreements, less amounts previously incurred to date under these agreements, totaled approximately $5,000,000 as of December 31, 2019, which are expected to be incurred over the next five years through 2024.

Clinical Trial Monitoring Agreements

On September 12, 2018, the Company finalized a work order agreement with Theradex Systems, Inc. (Theradex"), an international contract research organization ("CRO"), to monitor the Phase 1b/2 clinical trial being managed and conducted by Moffitt. The clinical trial is expected to be completed over a period of two years, with final analysis and reporting expected within three years. 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 6% for payments for pass-through costs. The costs of the Phase 1b/2 clinical trial being paid to or through Theradex are being recorded and charged to operations based on the periodic documentation provided by the CRO. During the years ended December 31, 2019 and 2018, the Company incurred costs of $51,586 and $11,906, respectively, pursuant to this work order. As of December 31, 2019, total costs of $63,492 have been incurred pursuant to this work order agreement.

The Company expects to enter into a separate work order agreement with Theradex to monitor the GEIS clinical trial as described above.

Patent and License Agreements

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 as to when the Company may reach any of the development or commercialization milestones under the Agreement, if at all. As of December 31, 2019 and 2018, no amounts were due under this agreement.

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, and is amortizing the retainer payment over the two-year life of the Consulting Agreement, as a result of which the Company recorded charges to operations of $9,174 and $6,881 during the years ended December 31, 2019 and 2018, respectively. At December 31, 2019, the unamortized balance of the retainer payment was $2,294, all of which was classified as a current asset in the Company's consolidated balance sheet at such date. 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 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 after the first patient is entered into a Phase 1b/2 clinical trial to be managed and conducted by Moffitt. The clinical trial began in April 2019 and the first patient was entered into the clinical trial in July 2019. The clinical trial is expected to be completed over a period of two years, with final analysis and reporting expected within three years. 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. During the years ended December 31, 2019 and 2018, the Company recorded charges to operations of $80,669 and $0, respectively, in connection with its obligations under the License Agreement. As of December 31, 2019, no milestones had yet been attained.

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.

Other 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 was for research only and did 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 which 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 year ended December 31, 2018, was reversed during the year ended December 31, 2018.

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. The agreement has been automatically renewed for additional one-year terms on its anniversary date since 2014. Consulting and advisory fees charged to operations pursuant to this agreement for the years ended December 31, 2019 and 2018 were $16,000 and $16,000, respectively, which were included in research and development costs in the consolidated statements of operations.

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 included, 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. 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. 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, and the Collaboration Agreement is currently in effect. The Company recorded charges to operations pursuant to this Collaboration Agreement for the years ended December 31, 2019 and 2018 of $100,000 and $10,000, respectively, which were included in research and development costs in the consolidated statements of operations.

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.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

INDEX TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

Three Months and Six Months Ended June 30, 2020 and 2019

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2020	December 31, 2019
	(Unaudited)	
ASSETS		
Current assets:		
Cash	$ 1,774,332	$ 2,598,864
Accrued interest receivable	—	14,367
Prepaid expenses and other current assets	30,618	58,802
Total current assets	1,804,950	2,672,033
Deferred offering costs	86,850	—
Total assets	$ 1,891,800	$ 2,672,033
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 189,868	$ 143,549
Research and development contract liabilities	24,097	94,349
Total current liabilities	213,965	237,898
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, 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	6,704	6,704
Additional paid-in capital	26,016,317	26,016,317
Accumulated deficit	(27,845,186)	(27,088,886)
Total stockholders' equity	1,677,835	2,434,135
Total liabilities and stockholders' equity	$ 1,891,800	$ 2,672,033

See accompanying notes to condensed consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Revenues	$ —	$ —	$ —	$ —
Costs and expenses:				
General and administrative costs, including $27,000 and $323,665 to related parties for the three months ended June 30, 2020 and 2019, respectively, and $54,000 and $363,601 to related parties for the six months ended June 30, 2020 and 2019, respectively	255,443	547,763	547,928	938,191
Research and development costs	117,946	80,123	212,618	128,437
Total costs and expenses	373,389	627,886	760,546	1,066,628
Loss from operations	(373,389)	(627,886)	(760,546)	(1,066,628)
Interest income	264	17,422	4,246	27,428
Net loss	$ (373,125)	$ (610,464)	$ (756,300)	$ (1,039,200)
Net loss per common share – basic and diluted	$ (0.01)	$ (0.01)	$ (0.01)	$ (0.02)
Weighted average common shares outstanding – basic and diluted	67,045,814	67,045,814	67,045,814	67,045,814

See accompanying notes to condensed consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)

Three Months and Six Months Ended June 30, 2020 and 2019

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Par Value			
Balance, December 31, 2019	350,000	$ 3,500,000	67,045,814	$ 6,704	$ 26,016,317	$ (27,088,886)	$ 2,434,135
Net loss	—	—	—	—	—	(383,175)	(383,175)
Balance, March 31, 2020	350,000	3,500,000	67,045,814	6,704	26,016,317	(27,472,061)	2,050,960
Net loss	—	—	—	—	—	(373,125)	(373,125)
Balance, June 30, 2020	350,000	$ 3,500,000	67,045,814	$ 6,704	$ 26,016,317	$ (27,845,186)	$ 1,677,835
Balance, December 31, 2018	350,000	$ 3,500,000	67,045,814	$ 6,704	$ 25,267,662	$ (24,648,543)	$ 4,125,823
Stock-based compensation expense	—	—	—	—	12,936	—	12,936
Net loss	—	—	—	—	—	(428,736)	(428,736)
Balance, March 31, 2019	350,000	3,500,000	67,045,814	6,704	25,280,598	(25,077,279)	3,710,023
Stock-based compensation expense	—	—	—	—	296,665	—	296,665
Net loss	—	—	—	—	—	(610,464)	(610,464)
Balance, June 30, 2019	350,000	$ 3,500,000	67,045,814	$ 6,704	$ 25,577,263	$ (25,687,743)	$ 3,396,224

See accompanying notes to condensed consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Six Months Ended June 30,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (756,300)	$ (1,039,200)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense included in -		
General and administrative costs	—	309,601
Changes in operating assets and liabilities:		
(Increase) decrease in -		
Accrued interest receivable	14,367	(17,071)
Prepaid expenses and other current assets	28,184	25,495
Increase (decrease) in -		
Accounts payable and accrued expenses	15,319	(11,329)
Research and development contract liabilities	(70,252)	23,448
Net cash used in operating activities	(768,682)	(709,056)
Cash flows from financing activities:		
Payment of deferred offering costs	(55,850)	—
Net cash used in financing activities	(55,850)	—
Cash:		
Net decrease	(824,532)	(709,056)
Balance at beginning of period	2,598,864	4,273,012
Balance at end of period	$ 1,774,332	$ 3,563,956
Supplemental disclosures of cash flow information:		
Cash paid for -		
Interest	$ —	$ —
Income taxes	$ —	$ —
Noncash investing and financing activities:		
Accrual of deferred offering costs	$ 31,000	$ —

See accompanying notes to condensed consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

Three Months and Six Months Ended June 30, 2020 and 2019

1. Organization and Basis of Presentation

The condensed consolidated financial statements of Lixte Biotechnology Holdings, Inc., a Delaware corporation ("Holdings"), including its wholly-owned Delaware subsidiary, Lixte Biotechnology, Inc. ("Lixte") (collectively, the "Company"), at June 30, 2020, and for the three months and six months ended June 30, 2020 and 2019, are unaudited. In the opinion of management of the Company, all adjustments, including normal recurring accruals, have been made that are necessary to present fairly the financial position of the Company as of June 30, 2020, and the results of its operations for the three months and six months ended June 30, 2020 and 2019, and its cash flows for the six months ended June 30, 2020 and 2019. Operating results for the interim periods presented are not necessarily indicative of the results to be expected for a full fiscal year. The consolidated balance sheet at December 31, 2019 has been derived from the Company's audited consolidated financial statements at such date.

The condensed consolidated financial statements and related notes have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been omitted pursuant to such rules and regulations. These condensed consolidated financial statements should be read in conjunction with the financial statements and other information included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as filed with the SEC.

2. Business

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 is primarily focused on inhibitors of protein phosphatases, used alone and in combination with cytotoxic agents and/or x-ray and immune checkpoint blockers, and 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. 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.

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, 2019, 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. The Company expects that it will need to begin to raise additional capital by no later than early 2021.

At June 30, 2020, the Company had cash and cash equivalents of $1,774,332 available to fund its operations. Because the Company is currently engaged in Phase 2 clinical trials, it is expected that it will 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. Current indications from the clinical research organizations conducting the clinical trials for the Company indicate that such clinical trials are being delayed or extended for at least three to six months as a result of the coronavirus pandemic. 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. There is also significant uncertainty as to the affect that the coronavirus may have on the amount and type of financing available to the Company in the future.

If cash resources are insufficient to satisfy the Company's ongoing cash requirements, the Company would be required to scale back or discontinue its clinical trial program and its technology and product development efforts, 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.

3. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying condensed 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. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions. 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 and Cash Equivalents

Cash and cash equivalents include cash and short-term certificates of deposit. The Company maintains its cash balances with financial institutions with high credit ratings and in accounts insured by the Federal Deposit Insurance Corporation (the "FDIC"). The Company may periodically have cash balances in banks in excess of FDIC insurance limits. The Company has not experienced any losses to date resulting from this practice.

Research and Development

Research and development costs consist primarily of fees paid to consultants and contractors, 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 with milestone provisions are recognized as charges to research and development costs in the Company's consolidated statement of operations based on the achievement of such milestones, as specified in the agreement. 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.

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 are 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.

Deferred Offering Costs

Deferred offering costs consist of payments with respect to pending equity financing transactions, including legal fees. Such costs are deferred and charged to additional paid-in capital upon the successful completion of such financings and are charged to operations if such financings are abandoned or terminated.

Patent and Licensing Related Legal and Filing 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-related legal and filing costs were $143,444 and $119,133 for the three months ended June 30, 2020 and 2019, and $276,911 and $309,906 for the six months ended June 30, 2020 and 2019, respectively. Patent and licensing related legal and filing costs are included in general and administrative costs in the Company's consolidated statements of operations.

Concentration of Risk

The Company periodically contracts with vendors and consultants to provide services related to the Company's operations. Charges incurred for these services can be for a specific time period (typically one year) or for a specific project or task. Costs and expenses incurred that represented 10% or more of general and administrative costs or research and development costs for the three months and six months ended June 30, 2020 and 2019 is described as follows.

General and administrative costs for the three months ended June 30, 2020 and 2019 include charges from a legal firm for general licensing and patent prosecution costs relating to the Company's intellectual properties representing 56.2% and 21.7%, respectively, of total general and administrative costs for those periods.

General and administrative costs for the six months ended June 30, 2020 and 2019 include charges from a legal firm for general licensing and patent prosecution costs relating to the Company's intellectual properties representing 50.5% and 33.0%, respectively, of total general and administrative costs for those periods.

Research and development costs for the three months ended June 30, 2020 include charges from three vendors and consultants representing 36.8%, 25.6% and 10.5%, respectively, of total research and development costs for that period. Research and development costs for the three months ended June 30, 2019 include charges from four vendors and consultants representing 37.4%, 21.7%, 21.1% and 16.5%, respectively, of total research and development costs for that period.

Research and development costs for the six months ended June 30, 2020 include charges from four vendors and consultants representing 28.3%, 20.4%, 15.1%, and 11.9%, respectively, of total research and development costs for that period. Research and development costs for the six months ended June 30, 2019 include charges from four vendors and consultants representing 39.9%, 31.1%, 14.1% and 10.3%, respectively, of total research and development costs for that period.

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 June 30, 2020 or December 31, 2019 and does not anticipate any material amount of unrecognized tax benefits within the 12 months subsequent to June 30, 2020.

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. The Company had not recorded any liability for uncertain tax positions as of June 30, 2020 or December 31, 2019. Subsequent to June 30, 2020, any interest and penalties related to uncertain tax positions will be recognized as a component of income tax expense.

Stock-Based Compensation

The Company periodically issues common stock and stock options to officers, directors, employees, Scientific Advisory Committee members, contractors and consultants for services rendered. Options vest and expire according to terms established at the issuance date of each grant. Stock grants, which are generally time vested, are measured at the grant date fair value and charged to operations ratably over the vesting period.

The Company accounts for stock-based payments to officers, directors, employees, Scientific Advisory Committee members contractors and consultants 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 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. Estimated volatility is based on the historical volatility of the Company's common stock, calculated utilizing a one-year look-back period, as the Company believes that such measurement period provides a more accurate and meaningful volatility factor given the changes in the Company's research and development program and capital requirements over the past several years. 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 the common stock is determined by reference to the quoted market price of the Company's common stock on the grant date.

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 was the same for all periods presented because all preferred shares, warrants and stock options outstanding were anti-dilutive.

At June 30, 2020 and 2019, 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.

	June 30,	
	2020	2019
Series A Convertible Preferred Stock	4,375,000	4,375,000
Common stock warrants	9,000,000	9,000,000
Common stock options, including options issued in the form of warrants	7,850,000	7,550,000
Total	21,225,000	20,925,000

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 cash equivalents, 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

In December 2019, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes (“ASU 2019-12”). ASU 2019-12 simplifies the accounting for income taxes by removing certain exceptions and enhances and simplifies various aspects of the income tax accounting guidance in ASC 740. ASU 2019-12 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The adoption of ASU 2019-12 is not expected to have any impact on the Company’s financial statement presentation or disclosures subsequent to its adoption.

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.

4. Stockholders' Equity

Preferred Stock

The Company is authorized to issue 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 has designated a total of 350,000 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. As of June 30, 2020 and December 31, 2019, 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 June 30, 2020 and December 31, 2019. The Company has the right to redeem the Series A Convertible Preferred Stock up to the fifth anniversary of their respective closing dates (March 17, 2015 and January 21, 2016) at a price per share equal to $50.00. Accordingly, as of June 30, 2020, the Company has the right to redeem the 175,000 shares of Series A Convertible Preferred Stock that were issued on January 21, 2016 at an aggregate cash redemption value of $8,750,000. The Series A Convertible Preferred Stock has no right to cash, except with respect to the payment of the aforementioned dividend based on the generation of revenues by the Company. The shares of Series A Convertible Preferred Stock do not have any registration rights.

Based on the attributes of the Series A Convertible Preferred Stock as previously described, 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 a total of 100,000,000 shares of common stock, par value $0.0001 per share. As of June 30, 2020 and December 31, 2019, the Company had 67,045,814 shares of common stock issued and outstanding.

Common Stock Warrants

A summary of common stock warrant activity during the six months ended June 30, 2020 is presented below.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Warrants outstanding at December 31, 2019	9,000,000	$ 1.000	
Issued	—	—	
Exercised	—	—	
Expired	—	—	
Warrants outstanding at June 30, 2020	9,000,000	$ 1.000	2.42

At June 30, 2020, all outstanding warrants are exercisable at $1.000 per common share.

Based on a fair market value of $0.90 per share on June 30, 2020, 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 June 30, 2020.

Information with respect to the issuance of common stock in connection with various stock-based compensation arrangements is provided at Note 6.

5. Related Party Transactions

The Company's Chairman and major stockholder, Dr. John Kovach, was paid a salary of $15,000 for the three months ended June 30, 2020 and 2019, and $30,000 for the six months ended June 30, 2020 and 2019, respectively, which amounts are included in general and administrative costs in the Company's consolidated statements of operations.

In September 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 stockholders. In January 2014 and August 2018, the Company entered into respective amendments to this consulting agreement, which have extended the consulting agreement through January 28, 2024. Consideration under this consulting agreement, including amendments, has been paid exclusively in the form of stock options. Mr. Schwartzberg is currently a significant stockholder of the Company and continues to be a consultant to the Company.

Legal and consulting fees charged to operations for services rendered by the Eric Forman Law Office were $12,000 and $12,000 for the three months ended June 30, 2020 and 2019, respectively, and $24,000 and $24,000 for the six months ended June 30, 2020 and 2019, respectively. Eric 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 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 continuing banking relationship.

A summary of related party costs for the three months and six months ended June 30, 2020 and 2019 is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Related party costs:				
Cash-based	$ 27,000	$ 27,000	$ 54,000	$ 54,000
Stock-based	—	296,665	—	309,601
Total	$ 27,000	$ 323,665	$ 54,000	$ 363,601

Stock-based compensation arrangements involving members of the Company's Board of Directors and affiliates are described at Note 6.

Additional information with respect to cash-based compensation arrangements are described at Note 6.

6. Stock-Based Compensation

The Company issues common stock and stock options as incentive compensation to directors and as compensation for the services of employees, 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 provided for the granting of awards, consisting of stock options, stock appreciation rights, performance shares, and restricted shares of common stock, to employees and consultants, 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 June 30, 2020, 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 grant date using the Black-Scholes option-pricing model. The risk-free interest rate is based on the U.S. treasury yield curve in effect as of the grant date. The expected dividend yield assumption is based on the Company's expectation of dividend payouts and is assumed to be zero. The expected volatility is based on the historical volatility of the Company's common stock. The expected life of the stock option is considered its full contractual term. The fair market value of the common stock is determined by reference to the quoted market price of the common stock on the grant date.

There were no stock options requiring an assessment of value during the six months ended June 30, 2020 and 2019.

Effective August 4, 2018, in conjunction with their appointments as directors of the Company, the Company granted stock options to each of Dr. Winson Sze Chun Ho and Dr. Yun Yen 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, with one-half of such stock options (100,000 shares for each director) vesting on August 4, 2018 and the remaining one-half of such stock options (100,000 shares for each director) vesting on August

4, 2019. The aggregate 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 charged to operations on that date. The remaining unvested portion of the fair value of the stock options was charged to operations ratably from August 4, 2018 through August 4, 2019. During the three months and six months ended June 30, 2019, the Company recorded a charge to operations of $13,080 and $26,016, respectively, with respect to these stock options.

Effective May 22, 2019, in recognition with their service as directors of the Company over the past year, the Company granted to each of Dr. Winson Sze Chun Ho, Dr. Yun Yen, Dr. Stephen Forman, and Dr. Philip Palmedo, fully-vested stock options to purchase an aggregate of 200,000 shares (50,000 shares for each director) of the Company's common stock, exercisable for a period of five years from the vesting date at $1.10 per share, which was the approximate 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 $189,060 ($0.9453 per share), which was charged to operations on the grant date.

Effective May 22, 2019, in recognition of his continuing service as consultant to the Company, the Company granted to Eric Forman fully-vested stock options to purchase 100,000 shares of the Company's common stock, exercisable for a period of five years from the vesting date at $1.10 per share, which was the approximate 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 $94,525 ($0.9453 per share), which was charged to operations on the grant date.

A summary of stock-based compensation costs for the three months and six months ended June 30, 2020 and 2019 is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Related parties	$ —	$ 296,665	$ —	$ 309,601
Non-related parties	—	—	—	—
Total stock-based compensation costs	$ —	$ 296,665	$ —	$ 309,601

A summary of stock option activity, including options issued in the form of warrants, during the six months ended June 30, 2020 is presented below.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Stock options outstanding at December 31, 2019	7,850,000	$ 0.608	
Granted	—	—	
Exercised	—	—	
Expired	—	—	
Stock options outstanding at June 30, 2020	7,850,000	$ 0.608	2.64
Stock options exercisable at June 30, 2020	7,850,000	$ 0.608	2.64

There was no deferred compensation expense for the outstanding value of unvested stock options at June 30, 2020.

The exercise prices of common stock options outstanding and exercisable, including options issued in the form of warrants, at June 30, 2020 are as follows:

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
$ 0.280	400,000	400,000
$ 0.500	4,200,000	4,200,000
$ 1.000	1,000,000	1,000,000
$ 1.100	300,000	300,000
$ 2.000	500,000	500,000
	7,850,000	7,850,000

The intrinsic value of exercisable but unexercised in-the-money stock options at June 30, 2020 was approximately $3,002,000, based on a fair market value of $0.90 per share on June 30, 2020.

All outstanding stock options to acquire shares of the Company's common stock were vested at June 30, 2020.

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

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 June 30, 2020, the Company was not subject to any pending or threatened legal claims or actions.

Clinical Trial Agreements

Moffitt. Effective August 20, 2018, the Company entered into a Clinical Trial Research Agreement (the "Clinical Trial Research Agreement") with the Moffitt Cancer Center and Research Institute Hospital Inc., Tampa, Florida ("Moffitt"), 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 agreed to conduct and manage a Phase 1b/2 clinical trial to evaluate the 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 myelodysplastic syndrome (MDS).

In November 2018, the Company received approval from the U.S. Food and Drug Administration ("FDA") for its Investigational New Drug ("IND") Application to conduct a Phase 1b/2 clinical trial to evaluate the therapeutic benefit of LB-100 in patients with low and intermediate-1 risk MDS who have failed or are intolerant of standard treatment. Patients with MDS, although usually older, are generally well except for severe anemia requiring frequent blood transfusions. This Phase 1b/2 clinical trial utilizes LB-100 as a single agent in the treatment of patients with low and intermediate-1 risk MDS, including patients with del(5q) myelodysplastic syndrome (del5qMDS) failing first line therapy. The bone marrow cells of patients with del5qMDS are deficient in PP2A by virtue of an acquired mutation and are especially vulnerable to further inhibition of PP2A by LB-100. The clinical trial began at a single site in April 2019 and the first patient was entered into the clinical trial in July 2019. A total enrollment of 41 patients is planned. An interim analysis will be done after the first 21 patients are entered. If there are 3 or more responders but fewer than 7, an additional 20 patients will be entered. If at any point there are 7 or more responders, this will be sufficient evidence to support continued development of LB-100 for the treatment of low and intermediate-1 risk MDS. Recruitment has been slow and the Covid-19 pandemic has further reduced recruitment of patients into the protocol. At the current rate of accrual, the trial would be completed over a period of four years from its initiation, with the final analysis and reporting expected by July 2023. However, with additional funds, the Company's objective would be to add two additional MDS centers to the Phase 2 portion of the study to accelerate patient accrual, with the goal of an earlier reporting date.

During the three months ended June 30, 2020 and 2019, the Company paid Moffitt $11,698 and $13,253, respectively, pursuant to this agreement. During the six months ended June 30, 2020 and 2019, the Company paid Moffitt $25,365 and $13,253, respectively, pursuant to this agreement. As of June 30, 2020, total costs of $70,458 have been incurred pursuant to this agreement.

GEIS. Effective July 31, 2019, the Company entered into a Collaboration Agreement for an Investigator-Initiated Clinical Trial with the Spanish Sarcoma Group (Grupo Español de Investigación en Sarcomas or "GEIS"), Madrid, Spain, to carry out a study entitled "Randomized phase I/II trial of LB-100 plus doxorubicin vs. doxorubicin alone in first line of advanced soft tissue sarcoma". The purpose of this clinical trial is to obtain information about the efficacy and safety of LB-100 combined with doxorubicin in soft tissue sarcomas. Doxorubicin is the global standard for initial treatment of advanced soft tissue sarcomas ("ASTS"). Doxorubicin alone has been the mainstay of first line treatment of ASTS for over 40 years, with little therapeutic gain from adding cytotoxic compounds to or substituting other cytotoxic compounds for doxorubicin. In animal models, LB-100 consistently enhances the anti-tumor activity of doxorubicin without apparent increases in toxicity.

GEIS has a network of referral centers in Spain and across Europe that have an impressive track record of efficiently conducting innovative studies in ASTS. The Company agreed to provide GEIS with a supply of LB-100 to be utilized in the conduct of this clinical trial, as well as to provide funding for the clinical trial. The goal was to enter the first patient during the quarter ending December 31, 2020, with approximately 150 patients to be enrolled over two years. Advanced sarcoma is a very aggressive disease. The design of the study assumes a median progression free survival (PFS, no evidence of disease progression or death from any cause) of 4.5 months in the doxorubicin arm and an alternative median PFS of 7.5 months in the doxorubicin plus LB-100 arm to demonstrate a statistically significant decrease in relative risk of progression or death by adding LB-100. There is a planned interim analysis of the primary endpoint when about half of the 102 events required for final analysis is reached.

The Company had previously expected that this clinical trial would commence during the quarter ended June 30, 2020. However, during July 2020, the Spanish regulatory body known as the Agency for Medicine and Health Products (Agencia Española de Medicamentos y Productos Sanitarios or "AEMPS") advised the Company that although it had approved the scientific and ethical basis of the protocol, it required that the Company manufacture a new inventory of LB-100 under current Spanish pharmaceutical manufacturing standards. These regulations were adopted subsequent to the production of the Company's existing LB-100 inventory. The Company is in the process of determining how soon new inventory of LB-100 meeting Spanish specifications can be produced. Accordingly, the clinical trial is now estimated to begin during the quarter ending September 30, 2021 and to be completed by the quarter ending September 30, 2024. The interim analysis expected in June 2023 could indicate either inferiority or superiority of the LB-100 plus doxorubicin arm compared to doxorubicin alone. A positive study would have the potential to change the standard therapy for this disease after four decades of failure to improve the marginal benefit of doxorubicin alone.

The Company's agreement with GEIS provides for various payments based on achieving specific milestones over the term of the agreement. On February 18, 2020, the Company advanced $43,411 to GEIS towards a second milestone payment obligation of $87,471, which was expected to become due and payable during the quarter ended June 30, 2020 based on the anticipated achievement of the second milestone, and which was therefore recorded as an advance on the Company's balance sheet at March 31, 2020. However, as a result of the substantial delay in commencing the clinical trial as described above, the achievement of the second milestone was delayed until mid-2021 and the Company therefore determined to charge such advance to research and development costs in the Company's statement of operations at June 30, 2020.

Accordingly, during the three months and six months ended June 30, 2020, the Company incurred costs of $43,411 pursuant to this agreement. As of June 30, 2020, total costs of $130,882 have been incurred pursuant to this agreement.

The Company's aggregate commitments pursuant to the aforementioned clinical trial agreements, less amounts previously paid to date under these agreements, totaled approximately $4,795,000 as of June 30, 2020, consisting of approximately $4,162,000 relating to the GEIS clinical trial and approximately $633,000 relating to the Moffit clinical trial, which are expected to be incurred over the next five years through June 30, 2025.

Clinical Trial Monitoring Agreements

On September 12, 2018, the Company finalized a work order agreement with Theradex Systems, Inc. (Theradex"), an international contract research organization ("CRO"), to monitor the Phase 1b/2 clinical trial being managed and conducted by Moffitt. The clinical trial began in April 2019 and the first patient was entered into the clinical trial in July 2019. At the current rate of accrual, the trial would be completed over a period of four years from its initiation, with the final analysis and reporting expected by July 2023.

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 6% for payments for pass-through costs. The costs of the Phase 1b/2 clinical trial being paid to or through Theradex are being recorded and charged to operations based on the periodic documentation provided by the CRO. During the three months ended June 30, 2020 and 2019, the Company incurred costs of $5,790 and $15,529, respectively, pursuant to this work order. During the six months ended June 30, 2020 and 2019, the Company incurred costs of $11,476 and $48,493, respectively, pursuant to this work order. As of June 30, 2020, total costs of $74,968 have been incurred pursuant to this work order agreement.

The Company's aggregate commitments pursuant to this clinical trial monitoring agreement, less amounts previously paid to date under this agreement, totaled approximately $876,000 as of June 30, 2020, which are expected to be incurred over the next five years through June 30, 2025.

Patent and License Agreements

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 as to when, if at all, the Company may reach any of the development or commercialization milestones under the Agreement. As of June 30, 2020 and December 31, 2019, no amounts were due under this agreement.

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, and is amortizing the retainer payment over the two-year life of the Consulting Agreement, as a result of which the Company recorded charges to operations of $0 and $2,294 during the three months ended June 30, 2020 and 2019, and $2,294 and $4,588 during the six months ended June 30, 2020 and 2019, respectively. As of June 30, 2020, the prepaid consulting fee had been fully amortized. At December 31, 2019, the unamortized balance of the retainer payment was $9,174, all of which was classified as a current asset in the Company's consolidated balance sheet at such date. On March 1, 2020, the Consulting Agreement was extended to April 2, 2021 without any additional consideration.

Effective August 20, 2018 (the "Effective Date"), the Company entered into an Exclusive License Agreement (the "License Agreement") with Moffitt. 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 was obligated to pay Moffitt a non-refundable license issue fee of $25,000 after the first patient is entered into a Phase 1b/2 clinical trial to be managed and conducted by Moffitt. The clinical trial began at a single site in April 2019 and the first patient was entered into the clinical trial in July 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. During the three months ended June 30, 2020 and 2019, the Company recorded charges to operations of $6,233 and $27,793, respectively, in connection with its obligations under the License Agreement. During the six months ended June 30, 2020 and 2019, the Company recorded charges to operations of $12,398 and $43,067, respectively, in connection with its obligations under the License Agreement. As of June 30, 2020, no milestones had yet been attained.

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.

Other Significant Agreements and Contracts

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. The agreement has been automatically renewed for additional one-year terms on its anniversary date since 2014. Consulting and advisory fees charged to operations pursuant to this agreement were $4,000 and $4,000 for the three months ended June 30, 2020 and 2019, respectively, and $8,000 and $8,000 for the six months ended June 30, 2020 and 2019, respectively, which were included in research and development costs in the consolidated statements of operations.

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 included, 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. In April 2018, it was 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, and the Collaboration Agreement is currently in effect. The Company recorded charges to operations pursuant to this Collaboration Agreement of $30,000 and $30,000 for the three months ended June 30, 2020 and 2019, respectively, and $60,000 and $40,000 for the six months ended June 30, 2020 and 2019, respectively, which were included in research and development costs in the consolidated statements of operations.

Impact of the Novel Coronavirus (COVID-19) on the Company's Business Operations

The global outbreak of the novel coronavirus (COVID-19) has led to severe disruptions in general economic activities worldwide, as businesses and governments have taken broad actions to mitigate this public health crisis. In light of the uncertain and continually evolving situation relating to the spread of COVID-19, this pandemic could pose a risk to the Company. The extent to which the coronavirus may impact the Company's business operations will depend on future developments, which are highly uncertain and cannot be predicted at this time. The Company intends to continue to monitor the situation and may adjust its current business plans as more information and guidance become available.

The coronavirus pandemic presents a challenge to medical facilities worldwide. As the Company's clinical trials are conducted on an outpatient basis, it is not currently possible to predict the full impact of this developing health crisis on such clinical trials, which could include delays in and increased costs of such clinical trials. Current indications from the clinical research organizations conducting the clinical trials for the Company are that such clinical trials are being delayed or extended for at least three to six months as a result of the coronavirus pandemic.

There is also significant uncertainty as to the affect that the coronavirus may have on the amount and type of financing available to the Company in the future.

8. Subsequent Events

Reverse Stock Split

On July 14, 2020, the Board of Directors of the Company approved a 1-for-6 reverse split of the Company's outstanding shares of common stock. Holders of a majority of shares of the Company's common stock have provided their consent for such reverse stock split. The Company intends to implement such reverse stock split upon receiving regulatory approval for such action.

2020 Stock Incentive Plan

On July 14, 2020, the Board of Directors of the Company adopted the 2020 Stock Incentive Plan (the "2020 Plan"), which provides for the granting of equity-based awards, consisting of stock options, restricted stock, restricted stock units, stock appreciation rights, and other stock-based awards to employees, officers, directors and consultants of the Company and its affiliates for up to 14,000,000 shares of the Company's common stock, under terms and conditions as determined by the Company's Board of Directors.

Extension of Warrants

Effective September 14, 2015, in connection with the Collaboration Agreement with BioPharmaWorks as described at Note 7, the Company issued to BioPharmaWorks two stock 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 was 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 was exercisable for a period of five years from the date of grant at $2.00 per share. On July 3, 2020, the Company's Board of Directors approved an extension of the term of the outstanding warrants to acquire an aggregate of 1,000,000 shares of the Company's common stock from September 14, 2020 to September 14, 2025. The Company's closing stock price on July 2, 2020 was $0.90 per share.

Employment Agreements

Dr. John Kovach. On July 15, 2020, the Company entered into an employment agreement with Dr. John Kovach pursuant to which Dr. Kovach is to continue to act as the Company's President, Chief Scientific Officer, and Chief Executive Officer. His responsibilities shall be for the oversight of the Company's entire operations and strategic planning and shall be the primary contact between the Company's executive team and the Board of Directors, to whom he shall report. Dr. Kovach shall supervise all scientific endeavors, providing guidance to the Chief Medical Officer. He shall be the principal spokesperson for the Company. Dr. Kovach will receive an annual salary of $250,000, payable monthly. The effective date of the agreement is October 1, 2020, and shall remain in effect until the earlier of (i) one year from the effective date, automatically renewable for additional one-year periods unless terminated by either party upon 60 days written notice prior to the end of the applicable one-year period, (ii) his death, or (iii) termination for cause.

Eric Forman. On July 15, 2020, as amended on August 12, 2020, the Company entered into an employment agreement with Eric Forman, pursuant to which Mr. Forman will act as the Company's Chief Administrative Officer reporting directly to the Company's Chief Executive Officer. His primary function shall be to oversee the internal operations of the Company, including IT, licensing, legal, personnel, marketing, and corporate governance. Mr. Forman will receive an annual salary of $120,000, payable monthly. He will also receive options for 350,000 shares of common stock. The options can be exercised on a cashless basis. The options will have a term of 5 years and an exercise price of $1.19 per share, which was equal to the closing price of the Company's common stock of the grant date. The options will vest as to 25% on August 12, 2020, and 25% vesting on each of the first, second and third anniversaries of the grant date. The effective date of the agreement is October 1, 2020, and shall remain in effect until the earlier of (i) one year from the effective date, automatically renewable for additional one-year periods unless terminated by either party upon 60 days written notice prior to the end of the applicable one-year period, (ii) his death, or (iii) termination for cause.

Dr. James Miser. On August 1, 2020, the Company entered into an employment agreement with Dr. James Miser, M.D., pursuant to which Dr. Miser was appointed as the Company's Chief Medical Officer. Under the employment agreement, Dr. Miser will play a leadership role in planning, implementation and oversight of clinical trials. He will be responsible for assisting and developing strategic clinical goals and the implementation and safety monitoring of investigational studies. He will be the primary medical monitor for all clinical investigational studies and for the oversight of third party CRO monitors. He will work closely with the Company's Chief Executive Officer on the development of specific goals needed to ensure the timely implementation of appropriate clinical studies needed for successful registration of therapeutic products and new drug development. Dr. Miser will be required to devote at least 50% of his business time to Company activities. Dr. Miser will receive an annual salary of $150,000. He

will also receive options for 500,000 shares of the Company's common stock. The options will have a term of five years and an exercise price of $1.19 per share, which was equal to the closing price of the Company's common stock on the effective date of the employment agreement. The options can be exercised on a cashless basis. The options will vest as to 25% on the effective date, and 25% on each of the first, second and third anniversaries of the effective date. The effective date of the agreement is August 1, 2020. The agreement shall remain in effect until the earlier of (i) one year from the effective date, automatically renewable for additional one-year periods unless terminated by either party upon 60 days written notice prior to the end of the applicable one-year period, (ii) his death, or (iii) termination for cause.

Robert Weingarten. On August 12, 2020, the Company entered into an employment agreement with Robert N. Weingarten pursuant to which Mr. Weingarten was appointed as the Company's Vice-President and Chief Financial Officer. Mr. Weingarten will receive an annual salary of $120,000. He will also receive options for 350,000 shares of common stock. The options can be exercised on a cashless basis. The options will have a term of five years and an exercise price of $1.19 per share, which was equal to the closing price of the Company's common stock on the effective date of the employment agreement. The options will vest as to 25% on the effective date, and 25% on each of the first, second and third anniversaries of the effective date. The effective date of the agreement is August 12, 2020. The agreement shall remain in effect until the earlier of (i) one year from the effective date, automatically renewable for additional one-year periods unless terminated by either party upon 60 days written notice prior to the end of the applicable one-year period, (ii) his death, or (iii) termination for cause.

Agreement with Foundation for Angelman Syndrome Therapy

Effective August 12, 2020, the Company entered into a Master Service Agreement with the Foundation for Angelman Syndrome Therapy (FAST) to collaborate in supporting preclinical studies of the potential benefit of LB-100 in a mouse model of Angelman Syndrome (AS) as reported in The Proceedings of The National Academy of Science (Wang et al, June 3, 2019). The preclinical studies will take place at The University of California - Davis under the direction of Dr. David Segal, an internationally recognized leader in AS research. If the preclinical studies confirm that LB-100 reduces AS signs in rodent models, the Company has agreed to enter into discussions with FAST with respect to possible collaborations to most efficiently assess the benefit of LB-100 in patients with AS, which is a rare disease affecting an estimated one out of 12,000 to one out of 20,000 persons in the United States. The genetic cause of AS, reduced function of a specific maternal gene called Ube3, has been understood for some time, but the molecular abnormality resulting from the genetic lesion has now been shown to be increased concentrations of protein phosphatase 2A (PP2A), a molecular target of our investigational compound, LB-100. The Company agreed to provide FAST with a supply of LB-100 to be utilized in the conduct of this study, which is initially expected to be completed within three years. Conditioned on FAST's completion of this study, the Company has agreed to pay FAST five percent (5%) of all proceeds, as defined in the Master Service Agreement, received by the Company, up to a maximum of $250,000 from the exploitation of the study results.

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 other than those discussed above.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

Common Stock

Prospectus

, 2020

WestPark Capital, Inc. **WallachBeth Capital, LLC**
