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

FORM 10-Q

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

For the quarterly period ended March 31, 2019

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

Commission file number: 000-51476

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**20-2903526**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

248 Route 25A, No. 2
East Setauket, New York 11733
(Address of principal executive offices)

(631) 942-7959
(Registrant's telephone number, including area code)

Not applicable
(Former name, former address and former fiscal year, if changed since last report)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company (as defined in Rule 12b-2 of the Exchange Act).

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

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	LIXT	OTCQB

As of May 1, 2019, the Company had 67,045,814 shares of common stock, $0.0001 par value, issued and outstanding.

Documents incorporated by reference: None

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

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Forward-Looking Statements

This Quarterly Report on Form 10-Q of Lixte Biotechnology Holdings, Inc. (the "Company") contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, and Section 21E of the Securities Exchange Act of 1934. These might include statements regarding the Company's financial position, business strategy and other plans and objectives for future operations, and assumptions and predictions about future product demand, supply, manufacturing costs, marketing and pricing factors are all forward-looking statements. These statements are generally accompanied by words such as "intend," "anticipate," "believe," "estimate," "potential(ly)," "continue," "forecast," "predict," "plan," "may," "will," "could," "would," "should," "expect" or the negative of such terms or other comparable terminology. The Company believes that the assumptions and expectations reflected in such forward-looking statements are reasonable, based on information available to it on the date hereof, but the Company cannot provide assurances that these assumptions and expectations will prove to have been correct or that the Company will take any action that the Company may presently be planning. These forward-looking statements are inherently subject to known and unknown risks and uncertainties. Actual results or experience may differ materially from those expected, anticipated or implied in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, regulatory policies or changes thereto, available cash, research and development results, competition from other similar businesses, and market and general economic factors. This discussion should be read in conjunction with the condensed consolidated financial statements and notes thereto included in Item 1 of this Quarterly Report on Form 10-Q and the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018, including the section entitled "Item 1A. Risk Factors". The Company does not intend to update or revise any forward-looking statements to reflect new information, future events or otherwise.

PART I - FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,893,604	$ 4,273,012
Accrued intertest receivable	4,161	—
Prepaid expenses and other current assets	57,070	61,433
Total current assets	3,954,835	4,334,445
Prepaid expense, less current portion	—	2,293
Total assets	$ 3,954,835	$ 4,336,738
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 210,673	$ 195,211
Research and development contract liabilities	34,139	15,704
Total current liabilities	244,812	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	25,280,598	25,267,662
Accumulated deficit	(25,077,279)	(24,648,543)
Total stockholders' equity	3,710,023	4,125,823
Total liabilities and stockholders' equity	$ 3,954,835	$ 4,336,738

See accompanying notes to condensed consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,	
	2019	**2018**
Revenues	$ —	$ —
Costs and expenses:		
General and administrative costs, including $12,000 and $12,000 to related parties for the three months ended March 31, 2019 and 2018, respectively	390,428	354,070
Research and development costs, including $33,897 and $0 to Theradex for the three months ended March 31, 2019 and 2018, respectively	48,314	25,689
Total costs and expenses	438,742	379,759
Loss from operations	(438,742)	(379,759)
Interest income	10,006	599
Net loss	$ (428,736)	$ (379,160)
Net loss per common share – basic and diluted	$ (0.01)	$ (0.01)
Weighted average common shares outstanding – basic and diluted	67,045,814	58,025,814

See accompanying notes to condensed consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)

Three Months Ended March 31, 2019 and 2018

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Par Value			
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
Balance, December 31, 2017	350,000	$ 3,500,000	58,025,814	$ 5,802	$ 20,004,654	$ (22,515,415)	$ 995,041
Net loss	—	—	—	—	—	(379,160)	(379,160)
Balance, March 31, 2018	350,000	$ 3,500,000	58,025,814	$ 5,802	$ 20,004,654	$ (22,894,575)	$ 615,881

See accompanying notes to condensed consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Three Months Ended March 31,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (428,736)	$ (379,160)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense included in -		
General and administrative costs	12,936	—
Research and development costs	—	—
Changes in operating assets and liabilities:		
(Increase) decrease in -		
Accrued interest receivable	(4,161)	—
Prepaid expenses and other current assets	6,656	15,796
Increase (decrease) in -		
Accounts payable and accrued expenses	15,462	(123,546)
Research and development contract liabilities	18,435	(10,800)
Net cash used in operating activities	(379,408)	(497,710)
Cash and cash equivalents:		
Net decrease	(379,408)	(497,710)
Balance at beginning of period	4,273,012	1,305,748
Balance at end of period	$ 3,893,604	$ 808,038
Supplemental disclosures of cash flow information:		
Cash paid for -		
Interest	$ —	$ —
Income taxes	$ —	$ —

See accompanying notes to condensed consolidated financial statements.

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 March 31, 2019, and for the three months ended March 31, 2019 and 2018, 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 March 31, 2019, and the results of its operations for the three months ended March 31, 2019 and 2018, and its cash flows for the three months ended March 31, 2019 and 2018. 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, 2018 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, 2018, 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 encompasses two major categories of compounds at various stages of pre-clinical and clinical development that the Company believes have broad therapeutic potential not only for cancer but also for other debilitating and life-threatening diseases.

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

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

Going Concern

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

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

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

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

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.

At March 31, 2019, the Company had cash and cash equivalents of $3,893,604 available to fund its operations. The next step in the development of the Company's lead anti-cancer clinical compound LB-100 is to evaluate its therapeutic benefit in Phase 1b/2 clinical trials. The initial clinical trial evaluating LB-100 in myelodysplastic syndrome (MDS) began during April 2019 and is expected to complete patient accrual over a period of two years, with final analysis and reporting expected within three years. The Company's longer-term objective is to secure one or more strategic partnerships with pharmaceutical companies with major programs in cancer.

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

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

Research and Development

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

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

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

On January 10, 2010, the Company retained Theradex Systems, Inc. ("Theradex") under a Master Agreement to provide technical and advisory services to the Company with respect to clinical trial matters involving the U.S. Food and Drug Administration ("FDA"). Theradex is an international contract research organization ("CRO") that provides technical and advisory services with respect to clinical research and development of pharmaceutical compounds under the rules and regulations of the FDA. On September 21, 2012, the Company entered into a work order agreement with Theradex to manage and administer the Company's Phase 1 clinical trial of LB-100. This Phase 1 clinical trial had been substantially completed at December 31, 2017.

On September 12, 2018, the Company finalized a work order agreement with Theradex to monitor a Phase 1b/2 clinical trial that was approved by the FDA in early November 2018 to evaluate the therapeutic benefit of LB-100 in MDS. This clinical trial began during April 2019 and is expected to complete patient accrual over a period of two years, with final analysis and reporting expected within three years. The clinical trial will be managed and conducted by the Moffitt Cancer Center and Research Institute Hospital Inc., Tampa, Florida, to evaluate the therapeutic benefit of the Company's lead anti-cancer clinical compound LB-100 administered intravenously in patients with low or intermediate-1 risk myelodysplastic syndrome (MDS). This work order agreement became operational in August 2018 and is estimated to be completed by December 2021. Costs under this work order agreement are estimated to be approximately $954,000, with such payments expected to be divided approximately 94% to Theradex for services and approximately 6% for payments for pass-through costs. The costs of the upcoming Phase 1b/2 clinical trial to be paid to or through Theradex will be recorded and charged to operations based on the periodic documentation provided by the CRO. During the three months ended March 31, 2019, the Company paid Theradex $32,964 pursuant to this work order. As of March 31, 2019, total costs of $44,870 have been incurred pursuant to this work order agreement.

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

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

Patent and Licensing Costs

Due to the significant uncertainty associated with the successful development of one or more commercially viable products based on the Company's research efforts and related patent applications, all patent-related legal and filing fees and licensing-related legal fees are charged to operations as incurred. Patent and licensing costs were $190,773 and $217,659 for the three months ended March 31, 2019 and 2018, respectively. Patent and licensing costs are included in general and administrative costs in the Company's consolidated statements of operations.

Concentration of Risk

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

As discussed above at "Research and Development", the Company had retained Theradex to provide technical and advisory services to the Company with respect to clinical trial matters involving the FDA, including monitoring a Phase 1b/2 clinical trial that was approved by the FDA in early November 2018 to evaluate the therapeutic benefit of LB-100 in MDS. This clinical trial began during April 2019 and is expected to complete patient accrual over a period of two years, with final analysis and reporting expected within three years.

Costs incurred pursuant to the agreements with Theradex are included in research and development costs in the Company's consolidated statements of operations.

Income Taxes

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

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

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

The Company is subject to U.S. federal income taxes and income taxes of various state tax jurisdictions. As the Company's net operating losses have yet to be utilized, all previous tax years remain open to examination by Federal authorities and other jurisdictions in which the Company currently operates or has operated in the past. The Company had no unrecognized tax benefits as of March 31, 2019 and December 31, 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 March 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.

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

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

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

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

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

Earnings (Loss) Per Share

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

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

At March 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.

	March 31,	
	2019	**2018**
Series A Convertible Preferred Stock	4,375,000	4,375,000
Common stock warrants	9,000,000	—
Common stock options, including options issued in the form of warrants	7,750,000	7,470,000
Total	21,125,000	11,845,000

Fair Value of Financial Instruments

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

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

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

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

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

The carrying value of financial instruments (consisting of cash and 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 June 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update 2018-07, Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting ("ASU 2018-07"). ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. ASU 2018-07 also clarifies that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Revenue from Contracts with Customers (Topic 606). ASU 2018-07 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 in the quarter beginning January 1, 2019. The adoption of ASU 2018-07 did not have any impact on the Company's financial statement presentation or disclosures.

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

4. Stockholders' Equity

Preferred Stock

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

Effective January 28, 2016, the Series A Convertible Preferred Stock Certificate of Designations was amended to increase the authorized shares of Series A Convertible Preferred Stock from 175,000 shares to 350,000 shares. Accordingly, as of March 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 March 31, 2019. The Company has the right to redeem the Series A Convertible Preferred Stock up to the fifth anniversary of the respective closing dates at a price per share equal to $50.00. The Series A Convertible Preferred Stock has no right to cash, except for the payment of the aforementioned dividend based on the generation of revenues by the Company and does not have any registration rights.

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

Common Stock

The Company is authorized to issue up to 100,000,000 shares of common stock (par value $0.0001). As of March 31, 2019 and December 31, 2018, the Company had 67,045,814 shares of common stock issued and outstanding.

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 three months ended March 31, 2019 is presented below.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Warrants outstanding at December 31, 2018	9,000,000	$ 1.000	
Issued	—	—	
Exercised	—	—	
Expired	—	—	
Warrants outstanding at March 31, 2019	9,000,000	$ 1.000	3.67

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

Based on a fair market value of $0.90 per share on March 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 March 31, 2019.

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 March 31, 2019 and 2018, which amounts are included in general and administrative costs in the Company's consolidated statements of operations. Beginning in late February 2017, Dr. Kovach began devoting 100% of his time to the Company's business activities.

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

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

Legal and consulting fees charged to operations for services rendered by the Eric Forman Law Office were $12,000 for the three months ended March 31, 2019 and 2018, respectively. Eric J. Forman is the son-in-law of Gil Schwartzberg, a significant stockholder of and consultant to the Company, and is the son of Dr. Stephen J. Forman, who was elected to the Company's Board of Directors on May 13, 2016. Julie Forman, the wife of Eric Forman and the daughter of Gil Schwartzberg, is Vice President of Morgan Stanley Wealth Management, where the Company maintains a banking relationship.

Stock-based compensation arrangements involving members of the Company's Board of Directors and affiliates are described at Note 6. Total stock-based compensation expense relating to directors, officers, affiliates and related parties was $12,936 and $0 for the three months ended March 31, 2019 and 2018, respectively.

6. Stock-Based Compensation

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

On June 20, 2007, the Board of Directors of the Company approved the 2007 Stock Compensation Plan (the "2007 Plan"), which provides for the granting of awards, consisting of stock options, stock appreciation rights, performance shares, or restricted shares of common stock, to employees and independent contractors, for up to 2,500,000 shares of the Company's common stock, under terms and conditions as determined by the Company's Board of Directors. The 2007 Plan terminated on June 19, 2017. As of March 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 date of grant and subsequent measurement dates using the Black-Scholes option-pricing model. The expected dividend yield assumption is based on the Company's expectation of dividend payouts. The expected volatilities are based on historical volatility of the Company's stock. The risk-free interest rate is based on the U.S. treasury yield curve in effect as of the grant date. The expected life of the stock options is the average of the vesting term and the full contractual term of the stock options.

There were no stock options requiring an assessment of value during the three months ended March 31, 2019 and 2018.

Effective August 4, 2018, in conjunction with their appointments as directors of the Company, the Company granted to Dr. Winson Sze Chun Ho and Dr. Yun Yen stock options for each person to purchase an aggregate of 200,000 shares of the Company's common stock, exercisable for a period of five years from the vesting date at $0.28 per share, which was the approximate fair market value of the Company's common stock on such date. One-half of such stock options (100,000 shares each) vested on August 4, 2018 and the remaining one-half of such stock options (100,000 shares each) will vest on August 4, 2019. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $104,920 ($0.2623 per share), of which $52,460 was attributable to the stock options fully-vested on August 4, 2018 and was therefore was charged to operations on that date. The remaining unvested portion of the fair value of the stock options will be charged to operations ratably from August 4, 2018 through August 4, 2019. During the three months ended March 31, 2019, the Company recorded a charge to operations of $12,936 with respect to these stock options.

Total stock-based compensation expense was $12,936 and $0 for the three months ended March 31, 2019 and 2018, respectively.

A summary of stock option activity, including options issued in the form of warrants, during the three months ended March 31, 2019 is presented below.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Stock options outstanding at December 31, 2018	7,750,000	$ 0.583	
Granted	—	—	
Exercised	—	—	
Expired	—	—	
Stock options outstanding at March 31, 2019	7,750,000	$ 0.538	3.43
Stock options exercisable at March 31, 2019	7,550,000	$ 0.545	3.41

Total deferred compensation expense for the outstanding value of unvested stock options was approximately $18,000 at March 31, 2019, which will be recognized subsequent to March 31, 2018 over a weighted-average period of approximately four months.

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

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

The intrinsic value of exercisable but unexercised in-the-money stock options at March 31, 2019 was approximately $3,283,000, based on a fair market value of $0.90 per share on March 31, 2019.

Outstanding options to acquire 200,000 shares of the Company's common stock had not vested at March 31, 2019.

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 March 31, 2019, the Company was not subject to any pending or threatened legal claims or actions.

Significant agreements and contracts

Effective October 18, 2013, the Company entered into a Materials Cooperative Research and Development Agreement (M-CRADA) with the National Institute of Neurological Disorders and Stroke (NINDS) of the National Institutes of Health (NIH) for a term of four years. The Surgical Neurology Branch of NINDS is conducting research characterizing a variety of compounds proprietary to the Company and is examining the potential of the compounds for anti-cancer activity, reducing neurological deficit due to ischemia and brain injury, and stabilizing catalytic function of misfolded proteins for inborn brain diseases. Under an M-CRADA, a party provides research material, in this case proprietary compounds from the Company's pipeline, for study by scientists at NIH. The exchange of material 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 was charged to research and development costs in the consolidated statement of operations on such date. The second installment of $50,000 was scheduled to be paid on the June 14, 2018 anniversary date of the amendment and was accreted ratably through such date and included in research and development contract liabilities in the Company's consolidated balance sheet. Pursuant to revised and updated collaboration plans, on November 3, 2018, the NINDS and the Company agreed to a cancellation of the second installment payment of $50,000. Accordingly, the previously accreted charge of $50,000, of which $25,000 was recorded during the six months ended June 30, 2018, was reversed during the fourth quarter of the year ended December 31, 2018. During the three months ended March 31, 2018, $12,500, was included in research and development costs in the consolidated statement of operations.

On December 24, 2013, the Company entered into an agreement with NDA Consulting Corp. ("NDA") for consultation and advice in the field of oncology research and drug development. As part of the agreement, NDA also agreed to cause its president, Dr. Daniel D. Von Hoff, M.D., to become a member of the Company's Scientific Advisory Committee. The term of the agreement was for one year and provided for a quarterly cash fee of $4,000. In 2014, 2015, 2016, 2017 and 2018, the agreement was automatically renewed on its anniversary date for an additional one-year term. Consulting and advisory fees charged to operations pursuant to this agreement were $4,000 during the three months ended March 31, 2019 and 2018.

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

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

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

Effective April 2, 2018, the Company entered into a consulting agreement for a term of two years with Liberi Life Sciences Consultancy BV, located in The Netherlands, for consulting and advisory services with respect to sales and licensing, as well as the procurement of investors in China, Japan and South Korea (the "Consulting Agreement"). The Consulting Agreement provided for the payment of a fixed, one-time retainer of EURO 15,000 (US $18,348), which was paid on April 5, 2018, and 2.5% of the net payments received by the Company from sales of products or licensing activities arising directly and exclusively from leads generated by the advisor during the term of the Consulting Agreement, and any investors introduced to the Company by the advisor that results in an investment in the Company during the term of the Consulting Agreement. The Company recorded the payment of the retainer as a prepaid expense in the Company's consolidated balance sheet. The Company is amortizing the retainer payment over the two-year life of the Consulting Agreement, as a result of which the Company recorded a charge to operations of $2,294 during the three months ended March 31, 2019. At March 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. At December 31, 2018, the unamortized balance of the retainer payment was $11,468, of which $9,175 was classified as a current asset and $2,293 was classified as a non-current asset in the Company's consolidated balance sheet at such date.

Effective August 20, 2018 (the "Effective Date"), the Company and the Moffitt Cancer Center and Research Institute Hospital Inc., Tampa, Florida ("Moffitt") entered into an Exclusive License Agreement (the "License Agreement"). Pursuant to the License Agreement, Moffitt granted the Company an exclusive license under certain patents owned by Moffitt (the "Licensed Patents") relating to the treatment of MDS and a non-exclusive license under inventions, concepts, processes, information, data, know-how, research results, clinical data, and the like (other than the Licensed Patents) necessary or useful for the practice of any claim under the Licensed Patents or the use, development, manufacture or sale of any product for the treatment of MDS which would otherwise infringe a valid claim under the Licensed Patents. The Company is obligated to pay Moffitt a non-refundable license issue fee of $25,000 after the first patient is entered into a Phase 1b/2 clinical trial to be managed and conducted by Moffitt. This clinical trial began during April 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 March 31, 2019, the Company recorded a charge to operations of $15,274 in connection with these license agreements.

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

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

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

On September 12, 2018, the Company finalized a work order agreement with Theradex to monitor the Phase 1b/2 clinical trial being conducted by Moffitt that began during April 2019. The clinical trial will be managed and conducted by Moffitt to evaluate the therapeutic benefit of the Company's lead anti-cancer clinical compound LB-100 administered intravenously in patients with low or intermediate-1 risk MDS. This work order agreement became operational in August 2018 and is estimated to be completed by December 2021. Costs under this work order agreement are estimated to be approximately $954,000. During the three months ended March 31, 2019, the Company paid Theradex $32,964 pursuant to this work order. As of March 31, 2019, total costs of $44,870 have been incurred pursuant to this work order agreement.

8. Subsequent Events

Effective March 8, 2019, the Company entered into a Master Services Agreement with Triligent International ("Triligent") for services associated with certain of the Company's projected, current and/or future pre-clinical and/or clinical studies, for a period of three years and renewable for an additional three-year term, and terminable by either party. Triligent will invoice the Company for time and expenses on a monthly basis.

Effective April 5, 2019, pursuant to the terms of the Master Services Agreement, the Company finalized a work order agreement with Triligent to assist the Company in pre-study commencement medical writing projects, including the development of study protocols and model informed consent forms in connection with a clinical research proposal. The total cost of this work order is not expected to exceed $10,500.

Effective April 9, 2019, the Company entered into a consulting agreement with Theradex for consulting services associated with the Company's worldwide development of LB-100, which is expected to be completed by July 1, 2020. Pursuant to the terms of the consulting agreement, Theradex will invoice the Company for time and expenses on a monthly basis.

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**.**

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

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

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

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

Going Concern

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

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

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

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

At March 31, 2019, the Company had cash and cash equivalents of $3,893,604 available to fund its operations. The next step in the development of the Company's lead anti-cancer clinical compound LB-100 is to evaluate its therapeutic benefit in a Phase 1b/2 clinical trial. This clinical trial began during April 2019 and is expected to complete patient accrual over a period of two years, with final analysis and reporting expected within three years. The Company's longer-term objective is to secure one or more strategic partnerships with pharmaceutical companies with major programs in cancer.

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

Recent Accounting Pronouncements

Information with respect to recent accounting pronouncements is provided at Note 3 to the condensed consolidated financial statements for the three months ended March 31, 2019 and 2018 included elsewhere in this document.

Concentration of Risk

Information with respect to concentration of risk is provided at Note 3 to the condensed consolidated financial statements for the three months ended March 31, 2019 and 2018 included elsewhere in this document.

Critical Accounting Policies and Estimates

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

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

Research and Development

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

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

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

On January 10, 2010, the Company retained Theradex Systems, Inc. ("Theradex") under a Master Agreement to provide technical and advisory services to the Company with respect to clinical trial matters involving the U.S. Food and Drug Administration ("FDA"). Theradex is an international contract research organization ("CRO") that provides technical and advisory services with respect to clinical research and development of pharmaceutical compounds under the rules and regulations of the FDA. On September 21, 2012, the Company entered into a work order agreement with Theradex to manage and administer the Company's Phase 1 clinical trial of LB-100. This Phase 1 clinical trial had been substantially completed at December 31, 2017.

On September 12, 2018, the Company finalized a work order agreement with Theradex to monitor a Phase 1b/2 clinical trial that was approved by the FDA in early November 2018 to evaluate the therapeutic benefit of LB-100 in MDS. This clinical trial began during April 2019 and is expected to complete patient accrual over a period of two years, with final analysis and reporting expected within three years. The clinical trial will be managed and conducted by the Moffitt Cancer Center and Research Institute Hospital Inc., Tampa, Florida, to evaluate the therapeutic benefit of the Company's lead anti-cancer clinical compound LB-100 administered intravenously in patients with low or intermediate-1 risk myelodysplastic syndrome (MDS). This work order agreement became operational in August 2018 and is estimated to be completed by December 2021. Costs under this work order agreement are estimated to be approximately $954,000, with such payments expected to be divided approximately 94% to Theradex for services and approximately 6% for payments for pass-through costs. The costs of the upcoming Phase 1b/2 clinical trial to be paid to or through Theradex will be recorded and charged to operations based on the periodic documentation provided by the CRO. During the three months ended March 31, 2019, the Company paid Theradex $32,964 pursuant to this work order. As of March 31, 2019, total costs of $44,870 have been incurred pursuant to this work order agreement.

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

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

Patent and Licensing Costs

Due to the significant uncertainty associated with the successful development of one or more commercially viable products based on the Company's research efforts and related patent applications, all patent-related legal and filing fees and licensing-related legal fees are charged to operations as incurred. Patent and licensing costs were $190,773 and $217,659 for the three months ended March 31, 2019 and 2018, respectively. Patent and licensing costs are included in general and administrative costs in the Company's consolidated statements of operations.

Stock-Based Compensation

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

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

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

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

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

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

Plan of Operation

Overview of Plans

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

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

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

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

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

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

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

Operating Plans

LB-100 Anti-Cancer Targets and Recent Developments

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

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

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

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

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

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

Near-Term Objectives

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

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

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

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

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

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

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

Results of Operations

At March 31, 2019, the Company had not yet commenced any revenue-generating operations, does not have any positive cash flows from operations, and is dependent on its ability to raise equity capital to fund its operating requirements.

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

	Three Months Ended March 31,	
	2019	2018
Revenues	$ —	$ —
Costs and expenses:		
General and administrative costs	390,428	354,070
Research and development costs	48,314	25,689
Total costs and expenses	438,742	379,759
Loss from operations	(438,742)	(379,759)
Interest income	10,006	599
Net loss	$ (428,736)	$ (379,160)
Net loss per common share – basic and diluted	$ (0.01)	$ (0.01)
Weighted average common shares outstanding – basic and diluted	67,045,814	58,025,814

Three Months Ended March 31, 2019 and 2018

Revenues. The Company did not have any revenues for the three months ended March 31, 2019 and 2018.

General and Administrative Costs. For the three months ended March 31, 2019, general and administrative costs were $390,428, which consisted of patent and licensing legal fees and costs of $190,773, other consulting and professional fees of $125,461, the fair value of vested stock options issued to directors of $12,936, insurance expense of $13,546, officer's salary and related costs of $17,028, licensing fees of $15,274, stock transfer fees of $3,345, listing fees of $3,000, filing fees of $5,000, and other operating costs of $4,065.

For the three months ended March 31, 2018, general and administrative costs were $354,070, which consisted of patent and licensing legal fees and costs of $217,659, other consulting and professional fees of $90,246, insurance expense of $12,796, officer's salary and related costs of $16,965, stock transfer fees of $3,924, listing fees of $3,000, filing fees of $6,294, and other operating costs of $3,186.

General and administrative costs increased by $36,358 or 10.3% in 2019 as compared to 2018, primarily as a result of an increase in other consulting and professional fees of $35,215, licensing fees of $15,274 and the fair value of stock options issued to directors of $12,936, offset by a decrease in patent and licensing fees of $26,886

Research and Development Costs. For the three months ended March 31, 2019, research and development costs were $48,314, which consisted entirely of contractor costs, primarily in connection with the Company's pre-clinical research focused on the development of additional novel anti-cancer compounds to add to its clinical pipeline, including $32,964 to Theradex in connection with the Phase 1b/2 clinical trial of LB-100, and $10,000 to BioPharma Works.

For the three months ended March 31, 2018, research and development costs were $25,689, which consisted entirely of contractor costs, primarily in connection with the Company's pre-clinical research focused on the development of additional novel anti-cancer compounds to add to its clinical pipeline, including $10,000 to BioPharma Works, and $12,500 to the National Cancer Institute in connection with Amendment No. 1 to the M-CRADA.

Research and development costs increased by $22,625 or 88.1% in 2019 as compared to 2018, as a result of an increase in contractor costs primarily to Theradex in connection with the Phase 1b/2 clinical trial of LB-100.

Interest Income. For the three months ended March 31, 2019, the Company had interest income of $10,006, as compared to interest income of $599 for the three months ended March 31, 2018, as a result of the Company investing the majority of its cash resources in short-term federally insured certificates of deposit beginning in 2019.

Net Loss. For the three months ended March 31, 2019, the Company incurred a net loss of $428,736, as compared to a net loss of $379,160 for the three months ended March 31, 2018.

Liquidity and Capital Resources – March 31, 2019

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

At March 31, 2019, the Company had working capital of $3,710,023, as compared to working capital of $4,123,530 at December 31, 2018, reflecting a decrease in working capital of $413,507 for the three months ended March 31, 2019. The decrease in working capital during the three months ended March 31, 2019 was the result of working capital being utilized to fund the Company's research and development activities and ongoing operating expenses, including maintaining and developing the Company's patent portfolio.

At March 31, 2019, the Company had cash and cash equivalents of $3,893,604 available to fund its operations. The next step in the development of the Company's lead anti-cancer clinical compound LB-100 is to evaluate its therapeutic benefit in Phase 1b/2 clinical trials. The initial clinical trial evaluating LB-100 in myelodysplastic syndrome (MDS) began during April 2019 and is expected to complete patient accrual over a period of two years, with final analysis and reporting expected within three years. The Company's longer-term objective is to secure one or more strategic partnerships with pharmaceutical companies with major programs in cancer.

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

Operating Activities. For the three months ended March 31, 2019, operating activities utilized cash of $379,408, as compared to utilizing cash of $497,710 for the three months ended March 31, 2018, to fund the Company's ongoing research and development activities and to fund its other ongoing operating expenses, including maintaining and developing its patent portfolio.

Investing Activities. For the three months ended March 31, 2019 and 2018, the Company had no investing activities.

Financing Activities. For the three months ended March 31, 2019 and 2018, the Company had no financing activities.

Principal Commitments

Effective October 18, 2013, the Company entered into a Materials Cooperative Research and Development Agreement (M-CRADA) with the National Institute of Neurological Disorders and Stroke (NINDS) of the National Institutes of Health (NIH) for a term of four years. The Surgical Neurology Branch of NINDS is conducting research characterizing a variety of compounds proprietary to the Company and is examining the potential of the compounds for anti-cancer activity, reducing neurological deficit due to ischemia and brain injury, and stabilizing catalytic function of misfolded proteins for inborn brain diseases. Under an M-CRADA, a party provides research material, in this case proprietary compounds from the Company's pipeline, for study by scientists at NIH. The exchange of material 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 was charged to research and development costs in the consolidated statement of operations on such date. The second installment of $50,000 was scheduled to be paid on the June 14, 2018 anniversary date of the amendment and was accreted ratably through such date and included in research and development contract liabilities in the Company's consolidated balance sheet. Pursuant to revised and updated collaboration plans, on November 3, 2018, the NINDS and the Company agreed to a cancellation of the second installment payment of $50,000. Accordingly, the previously accreted charge of $50,000, of which $25,000 was recorded during the six months ended June 30, 2018, was reversed during the fourth quarter of the year ended December 31, 2018. During the three months ended March 31, 2018, $12,500, was included in research and development costs in the consolidated statement of operations.

On December 24, 2013, the Company entered into an agreement with NDA Consulting Corp. ("NDA") for consultation and advice in the field of oncology research and drug development. As part of the agreement, NDA also agreed to cause its president, Dr. Daniel D. Von Hoff, M.D., to become a member of the Company's Scientific Advisory Committee. The term of the agreement was for one year and provided for a quarterly cash fee of $4,000. In 2014, 2015, 2016, 2017 and 2018, the agreement was automatically renewed on its anniversary date for an additional one-year term. Consulting and advisory fees charged to operations pursuant to this agreement were $4,000 during the three months ended March 31, 2019 and 2018.

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

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

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

Effective April 2, 2018, the Company entered into a consulting agreement for a term of two years with Liberi Life Sciences Consultancy BV, located in The Netherlands, for consulting and advisory services with respect to sales and licensing, as well as the procurement of investors in China, Japan and South Korea (the "Consulting Agreement"). The Consulting Agreement provided for the payment of a fixed, one-time retainer of EURO 15,000 (US $18,348), which was paid on April 5, 2018, and 2.5% of the net payments received by the Company from sales of products or licensing activities arising directly and exclusively from leads generated by the advisor during the term of the Consulting Agreement, and any investors introduced to the Company by the advisor that results in an investment in the Company during the term of the Consulting Agreement. The Company recorded the payment of the retainer as a prepaid expense in the Company's consolidated balance sheet. The Company is amortizing the retainer payment over the two-year life of the Consulting Agreement, as a result of which the Company recorded a charge to operations of $2,294 during the three months ended March 31, 2019. At March 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. At December 31, 2018, the unamortized balance of the retainer payment was $11,468, of which $9,175 was classified as a current asset and $2,293 was classified as a non-current asset in the Company's consolidated balance sheet at such date.

Effective August 20, 2018 (the "Effective Date"), the Company and the Moffitt Cancer Center and Research Institute Hospital Inc., Tampa, Florida ("Moffitt") entered into an Exclusive License Agreement (the "License Agreement"). Pursuant to the License Agreement, Moffitt granted the Company an exclusive license under certain patents owned by Moffitt (the "Licensed Patents") relating to the treatment of MDS and a non-exclusive license under inventions, concepts, processes, information, data, know-how, research results, clinical data, and the like (other than the Licensed Patents) necessary or useful for the practice of any claim under the Licensed Patents or the use, development, manufacture or sale of any product for the treatment of MDS which would otherwise infringe a valid claim under the Licensed Patents. The Company is obligated to pay Moffitt a non-refundable license issue fee of $25,000 after the first patient is entered into a Phase 1b/2 clinical trial to be managed and conducted by Moffitt. This clinical trial began during April 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 March 31, 2019, the Company recorded a charge to operations of $15,274 in connection with these license agreements.

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

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

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

On September 12, 2018, the Company finalized a work order agreement with Theradex to monitor the Phase 1b/2 clinical trial being conducted by Moffitt that began during April 2019. The clinical trial will be managed and conducted by Moffitt to evaluate the therapeutic benefit of the Company's lead anti-cancer clinical compound LB-100 administered intravenously in patients with low or intermediate-1 risk MDS. This work order agreement became operational in August 2018 and is estimated to be completed by December 2021. Costs under this work order agreement are estimated to be approximately $954,000. During the three months ended March 31, 2019, the Company paid Theradex $32,964 pursuant to this work order. As of March 31, 2019, total costs of $44,870 have been incurred pursuant to this work order agreement.

Off-Balance Sheet Arrangements

At March 31, 2019, the Company did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures

The Company carried out an evaluation, under the supervision and with the participation of its management, consisting of its principal executive officer and principal financial officer (who is the same person), of the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act (defined below)). Based upon that evaluation, the Company's principal executive officer and principal financial officer concluded that, as of the end of the period covered in this report, the Company's disclosure controls and procedures were effective to ensure that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the required time periods and is accumulated and communicated to the Company's management, consisting of the Company's principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

The Company's management, consisting of its principal executive officer and principal financial officer, does not expect that its disclosure controls and procedures or its internal controls will prevent all error or fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Furthermore, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Due to the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. In addition, as conditions change over time, so too may the effectiveness of internal controls. However, management believes that the consolidated financial statements included in this report fairly present, in all material respects, the Company's financial condition, results of operations and cash flows for the periods presented.

(b) Changes in Internal Controls Over Financial Reporting

The Company's management, consisting of its principal executive officer and principal financial officer, has determined that no change in the Company's internal control over financial reporting (as that term is defined in Rules 13(a)-15(f) and 15(d)-15(f) of the Securities Exchange Act of 1934) occurred during or subsequent to the end of the period covered in this report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The Company is not currently subject to any pending or threatened legal actions or claims.

ITEM 1A. RISK FACTORS

As of the date of this filing, there have been no material changes to the Risk Factors included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018, as filed with the Securities and Exchange Commission on March 25, 2019 (the "2018 Form 10-K"). The Risk Factors set forth in the 2018 Form 10-K should be read carefully in connection with evaluating the Company's business and in connection with the forward-looking statements contained in this Quarterly Report on Form 10-Q. Any of the risks described in the 2018 Form 10-K could materially adversely affect the Company's business, financial condition or future results and the actual outcome of matters as to which forward-looking statements are made. These are not the only risks that the Company faces. Additional risks and uncertainties not currently known to the Company or that the Company currently deems to be immaterial also may materially adversely affect the Company's business, financial condition and/or operating results.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

A list of exhibits required to be filed as part of this report is set forth in the Index to Exhibits, which is presented elsewhere in this document, and is incorporated herein by reference.

SIGNATURES

In accordance with the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
(Registrant)

Date: May 9, 2019

By: */s/ JOHN S. KOVACH*
John S. Kovach
Chief Executive Officer and Chief Financial Officer
(Principal financial and accounting officer)

INDEX TO EXHIBITS

The following documents are filed as part of this report:

Exhibit Number	Description of Document
31.1*	Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Officer's Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document

* Filed herewith.

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

Exhibit 31.1

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

I, John S. Kovach, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 9, 2019

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

Exhibit 32.1

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

I, John S. Kovach, the Chief Executive Officer and Chief Financial Officer of Lixte Biotechnology Holdings, Inc. (the "Company"), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that:

(i) The Quarterly Report on Form 10-Q of the Company for the quarterly period ended March 31, 2019 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

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

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

Date: May 9, 2019

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