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, 2020

[ ] 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, including Zip Code)

(631) 880-2907
(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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit 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. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer [ ]	Accelerated filer [ ]
Non-accelerated filer [ ]	Smaller reporting company [X]
	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, 2020, the Company had 67,045,814 shares of common stock, $0.0001 par value, issued and outstanding.

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 clinical trials and their timing and costs, 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, 2019, 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, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash	$ 2,184,831	$ 2,598,864
Advances on research and development contract services	43,411	—
Accrued interest receivable	285	14,367
Prepaid expenses and other current assets	47,750	58,802
Total current assets	2,276,277	2,672,033
Total assets	$ 2,276,277	$ 2,672,033
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 160,927	$ 143,549
Research and development contract liabilities	64,390	94,349
Total current liabilities	225,317	237,898
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, $0.0001 par value; authorized – 10,000,000 shares; issued and outstanding – 350,000 shares of Series A Convertible Preferred Stock, $10.00 per share stated value, $50.00 per share cash redemption value; aggregate cash redemption value – $17,500,000; liquidation preference based on assumed conversion into common shares – 4,375,000 shares	3,500,000	3,500,000
Common stock, $0.0001 par value; authorized – 100,000,000 shares; issued and outstanding – 67,045,814 shares	6,704	6,704
Additional paid-in capital	26,016,317	26,016,317
Accumulated deficit	(27,472,061)	(27,088,886)
Total stockholders' equity	2,050,960	2,434,135
Total liabilities and stockholders' equity	$ 2,276,277	$ 2,672,033

See accompanying notes to condensed consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,	
	2020	**2019**
Revenues	$ —	$ —
Costs and expenses:		
General and administrative costs, including $27,000 and $39,936 to related parties for the three months ended March 31, 2020 and 2019, respectively	292,484	390,428
Research and development costs	94,673	48,314
Total costs and expenses	387,157	438,742
Loss from operations	(387,157)	(438,742)
Interest income	3,982	10,006
Net loss	$ (383,175)	$ (428,736)
Net loss per common share – basic and diluted	$ (0.01)	$ (0.01)
Weighted average common shares outstanding – basic and diluted	67,045,814	67,045,814

See accompanying notes to condensed consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)

Three Months Ended March 31, 2020 and 2019

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Par Value			
Balance, December 31, 2019	350,000	$ 3,500,000	67,045,814	$ 6,704	$ 26,016,317	$ (27,088,886)	$ 2,434,135
Net loss	—	—	—	—	—	(383,175)	(383,175)
Balance, March 31, 2020	350,000	$ 3,500,000	67,045,814	$ 6,704	$ 26,016,317	$ (27,472,061)	$ 2,050,960
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

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,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (383,175)	$ (428,736)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense included in -		
General and administrative costs	—	12,936
Changes in operating assets and liabilities:		
(Increase) decrease in -		
Advances on research and development contract services	(43,411)	—
Accrued interest receivable	14,082	(4,161)
Prepaid expenses and other current assets	11,052	6,656
Increase (decrease) in -		
Accounts payable and accrued expenses	17,378	15,462
Research and development contract liabilities	(29,959)	18,435
Net cash used in operating activities	(414,033)	(379,408)
Cash:		
Net decrease	(414,033)	(379,408)
Balance at beginning of period	2,598,864	4,273,012
Balance at end of period	$ 2,184,831	$ 3,893,604
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, 2020, and for the three months ended March 31, 2020 and 2019, are unaudited. In the opinion of management of the Company, all adjustments, including normal recurring accruals, have been made that are necessary to present fairly the financial position of the Company as of March 31, 2020, and the results of its operations for the three months ended March 31, 2020 and 2019, and its cash flows for the three months ended March 31, 2020 and 2019. Operating results for the interim periods presented are not necessarily indicative of the results to be expected for a full fiscal year. The consolidated balance sheet at December 31, 2019 has been derived from the Company's audited consolidated financial statements at such date.

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

2. Business

The Company is a drug discovery company that uses biomarker technology to identify enzyme targets associated with serious common diseases and then designs novel compounds to attack those targets. The Company's product pipeline is primarily focused on inhibitors of protein phosphatases, used alone and in combination with cytotoxic agents and/or x-ray and immune checkpoint blockers, and encompasses two major categories of compounds at various stages of pre-clinical and clinical development that the Company believes have broad therapeutic potential not only for cancer but also for other debilitating and life-threatening diseases.

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

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

Going Concern

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

As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern within one year of the date that the consolidated financial statements are being issued. In addition, the Company's independent registered public accounting firm, in their report on the Company's consolidated financial statements for the year ended December 31, 2019, has also expressed substantial doubt about the Company's ability to continue as a going concern.

The Company's ability to continue as a going concern is dependent upon its ability to raise additional equity capital to fund its research and development activities and to ultimately achieve sustainable operating revenues and profits. The Company's consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties. The Company expects that it will need to raise additional capital in early 2021.

At March 31, 2020, the Company had cash and cash equivalents of $2,184,831 available to fund its operations. Because the Company is currently engaged in Phase 2 clinical trials, it is expected that it will take a significant amount of time to develop any product or intellectual property capable of generating sustainable revenues. Accordingly, the Company's business is unlikely to generate any sustainable operating revenues in the next several years and may never do so. In addition, to the extent that the Company is able to generate revenues through licensing its technologies or through product sales, there can be no assurance that the Company will be able to achieve positive earnings and operating cash flows.

The amount and timing of future cash requirements will depend on the pace and design of the Company's clinical trial program. Current indications from the clinical research organizations conducting the clinical trials for the Company indicate that such clinical trials will be delayed for at least three to six months as a result of the coronavirus pandemic. As market conditions present uncertainty as to the Company's ability to secure additional funds, there can be no assurances that the Company will be able to secure additional financing on acceptable terms, or at all, as and when necessary to continue to conduct operations. There is also significant uncertainty as to the affect that the coronavirus may have on the availability, amount and type of financing in the future.

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

3. Summary of Significant Accounting Policies

Principles of Consolidation

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

Use of Estimates

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

Cash and Cash Equivalents

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

Research and Development

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

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

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

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

Patent and Licensing Related Legal and Filing Costs

Due to the significant uncertainty associated with the successful development of one or more commercially viable products based on the Company's research efforts and related patent applications, all patent-related legal and filing fees and licensing-related legal fees are charged to operations as incurred. Patent and licensing-related legal and filing costs were $133,467 and $190,773 for the three months ended March 31, 2020 and 2019, respectively. Patent and licensing related legal and filing costs are included in general and administrative costs in the Company's consolidated statements of operations.

Concentration of Risk

The Company periodically contracts with vendors and consultants to provide services related to the Company's operations. Charges incurred for these services can be for a specific time period (typically one year) or for a specific project or task. Costs and expenses so incurred that represented 10% or more of general and administrative costs or research and development costs for the three months ended March 31, 2020 and 2019 is described as follows.

General and administrative costs for the three months ended March 31, 2020 and 2019 include charges from a legal firm for general licensing and patent prosecution costs relating to the Company's intellectual properties representing 45.6% and 48.9%, respectively, of total general and administrative costs for those periods.

Research and development costs for the three months ended March 31, 2020 include charges from five vendors and consultants representing 31.7%, 20.8%, 14.4%, 12.5% and 11.0%, respectively, of total research and development costs for that period. Research and development costs for the three months ended March 31, 2019 include charges from two vendors and consultants representing 68.2% and 20.7%, respectively, of total research and development costs for that period.

Income Taxes

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

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

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

The Company is subject to U.S. federal income taxes and income taxes of various state tax jurisdictions. As the Company's net operating losses have yet to be utilized, all previous tax years remain open to examination by Federal authorities and other jurisdictions in which the Company currently operates or has operated in the past. The Company had no unrecognized tax benefits as of March 31, 2020 or December 31, 2019 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, 2020, the Company had not recorded any liability for uncertain tax positions. In subsequent periods, any interest and penalties related to uncertain tax positions will be recognized as a component of income tax expense.

Stock-Based Compensation

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

The Company accounts for stock-based payments to officers, directors, Scientific Advisory Committee members, and to outside consultants by measuring the cost of services received in exchange for equity awards utilizing the grant date fair value of the awards, with the cost recognized as compensation expense on the straight-line basis in the Company's financial statements over the vesting period of the awards.

The fair value of stock options granted as stock-based compensation is determined utilizing the Black-Scholes option-pricing model, and is affected by several variables, the most significant of which are the life of the equity award, the exercise price of the stock option as compared to the fair market value of the common stock on the grant date, and the estimated volatility of the common stock. Estimated volatility is based on the historical volatility of the Company's common stock, calculated utilizing a one-year look-back period, as the Company believes that such measurement period provides a more accurate and meaningful volatility factor given the changes in the Company's research and development program and capital requirements over the past several years. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. The fair market value of the common stock is determined by reference to the quoted market price of the Company's common stock on the grant date.

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

Earnings (Loss) Per Share

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

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

At March 31, 2020 and 2019, the Company excluded the outstanding securities summarized below, which entitle the holders thereof to acquire shares of common stock, from its calculation of earnings per share, as their effect would have been anti-dilutive.

	March 31,	
	2020	**2019**
Series A Convertible Preferred Stock	4,375,000	4,375,000
Common stock warrants	9,000,000	9,000,000
Common stock options, including options issued in the form of warrants	7,850,000	7,750,000
Total	21,225,000	21,125,000

Fair Value of Financial Instruments

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

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

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

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

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

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

Recent Accounting Pronouncements

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

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

4. Stockholders' Equity

Preferred Stock

The Company is authorized to issue a total of 10,000,000 shares of preferred stock, par value $0.0001 per share. On March 17, 2015, the Company filed a Certificate of Designations, Preferences, Rights and Limitations (the "Certificate of Designations") of its Series A Convertible Preferred Stock with the Delaware Secretary of State to amend the Company's certificate of incorporation. The Company has designated a total of 350,000 shares as Series A Convertible Preferred Stock, which are non-voting and are not subject to increase without the written consent of a majority of the holders of the Series A Convertible Preferred Stock or as otherwise set forth in the Certificate of Designations. The holders of each tranche of 175,000 shares of the Series A Convertible Preferred Stock are entitled to receive a per share dividend equal to 1% of the annual net revenue of the Company divided by 175,000, until converted or redeemed. As of March 31, 2020 and December 31, 2019, 9,650,000 shares of preferred stock were undesignated and may be issued with such rights and powers as the Board of Directors may designate.

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

If fully converted, the 350,000 outstanding shares of Series A Convertible Preferred Stock would convert into 4,375,000 shares of common stock at December 31, 2019. The Company has the right to redeem the Series A Convertible Preferred Stock up to the fifth anniversary of their respective closing dates (March 17, 2015 and January 21, 2016) at a price per share equal to $50.00. The Series A Convertible Preferred Stock has no right to cash, except with respect to the payment of the aforementioned dividend based on the generation of revenues by the Company, and does not have any registration rights.

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

Common Stock

The Company is authorized to issue a total of 100,000,000 shares of common stock (par value $0.0001). As of March 31, 2020 and December 31, 2019, the Company had 67,045,814 shares of common stock issued and outstanding.

Common Stock Warrants

A summary of common stock warrant activity during the three months ended March 31, 2020 is presented below.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Warrants outstanding at December 31, 2019	9,000,000	$ 1.000	
Issued	—	—	
Exercised	—	—	
Expired	—	—	
Warrants outstanding at March 31, 2020	9,000,000	$ 1.000	2.67

At March 31, 2020, all outstanding warrants are exercisable at $1.000 per common share.

Based on a fair market value of $0.98 per share on March 31, 2020, there were no exercisable but unexercised in-the-money common stock warrants on that date. Accordingly, there was no intrinsic value attributed to exercisable but unexercised common stock warrants at March 31, 2020.

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

5. Related Party Transactions

The Company's Chairman and major stockholder, Dr. John Kovach, was paid a salary of $15,000 for the three months ended March 31, 2020 and 2019, respectively, which amounts are included in general and administrative costs in the Company's consolidated statements of operations.

In September 2007, the Company entered into a consulting agreement with Gil Schwartzberg for Mr. Schwartzberg to provide financial advisory and consulting services to the Company with respect to financing matters, capital structure and strategic development, and to assist management in communications with investors and shareholders. In January 2014 and August 2018, the Company entered into respective amendments to this consulting agreement, which have extended the consulting agreement through January 28, 2024. Consideration under this consulting agreement, including amendments, has been paid exclusively in the form of stock options. Mr. Schwartzberg is currently a significant stockholder of the Company and continues to be a consultant to the Company.

Legal and consulting fees charged to operations for services rendered by the Eric Forman Law Office were $12,000 for the three months ended March 31, 2020 and 2019, respectively. Eric Forman is the son-in-law of Gil Schwartzberg, a significant stockholder of and consultant to the Company, and is the son of Dr. Stephen Forman, who was elected to the Company's Board of Directors on May 13, 2016. Julie Forman, the wife of Eric Forman and the daughter of Gil Schwartzberg, is Vice President of Morgan Stanley Wealth Management, where the Company maintains a continuing banking relationship.

A summary of related party costs for the three months ended March 31, 2020 and 2019 is as follows:

	Three Months Ended March 31,	
	2020	2019
Related party costs:		
Cash-based	$ 27,000	$ 27,000
Stock-based	—	12,936
Total	$ 27,000	$ 39,936

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

6. Stock-Based Compensation

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

On June 20, 2007, the Board of Directors of the Company approved the 2007 Stock Compensation Plan (the "2007 Plan"), which provided for the granting of awards, consisting of stock options, stock appreciation rights, performance shares, and restricted shares of common stock, to employees and independent contractors, for up to 2,500,000 shares of the Company's common stock, under terms and conditions as determined by the Company's Board of Directors. The 2007 Plan terminated on June 19, 2017. As of March 31, 2020, unexpired stock options for 1,250,000 shares were issued and outstanding under the 2007 Plan.

The fair value of each stock option awarded is calculated on the grant date using the Black-Scholes option-pricing model. The risk-free interest rate is based on the U.S. treasury yield curve in effect as of the grant date. The expected dividend yield assumption is based on the Company's expectation of dividend payouts and is assumed to be zero. The expected volatility is based on the historical volatility of the Company's common stock. The expected life of the stock option is considered its full contractual term. The fair market value of the common stock is determined by reference to the quoted market price of the common stock on the grant date.

There were no stock options requiring an assessment of value during the three months ended March 31, 2020 and 2019.

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

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

Effective May 22, 2019, in recognition of his continuing service as consultant to the Company, the Company granted to Eric Forman fully-vested stock options to purchase 100,000 shares of the Company's common stock, exercisable for a period of five years from the vesting date at $1.10 per share, which was the approximate fair market value of the Company's common stock on such date. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $94,525 ($0.9453 per share), which was charged to operations on the grant date.

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

A summary of stock-based compensation costs for the three months ended March 31, 2020 and 2019 is as follows:

	Three Months Ended March 31,	
	2020	**2019**
Related parties	$ —	$ 12,936
Non-related parties	—	—
Total stock-based compensation costs	$ —	$ 12,936

A summary of stock option activity, including options issued in the form of warrants, during the three months ended March 31, 2020 is presented below.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Stock options outstanding at December 31, 2019	7,850,000	$ 0.608	
Granted	—	—	
Exercised	—	—	
Expired	—	—	
Stock options outstanding at March 31, 2020	7,850,000	$ 0.608	2.89
Stock options exercisable at March 31, 2020	7,850,000	$ 0.608	2.89

There was no deferred compensation expense for the outstanding value of unvested stock options at March 31, 2020.

The exercise prices of common stock options outstanding and exercisable, including options issued in the form of warrants, at March 31, 2020 are as follows:

Exercise Prices	Options Outstanding (Shares)	Options Exercisable (Shares)
$ 0.120	450,000	450,000
$ 0.150	300,000	300,000
$ 0.160	200,000	200,000
$ 0.200	500,000	500,000
$ 0.280	400,000	400,000
$ 0.500	4,200,000	4,200,000
$ 1.000	1,000,000	1,000,000
$ 1.100	300,000	300,000
$ 2.000	500,000	500,000
	7,850,000	7,850,000

The intrinsic value of exercisable but unexercised in-the-money stock options at March 31, 2020 was approximately $3,486,000, based on a fair market value of $0.98 per share on March 31, 2020.

All outstanding stock options to acquire shares of the Company's common stock were vested at March 31, 2020.

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

7. Commitments and Contingencies

Legal Claims

The Company may be subject to legal claims and actions from time to time as part of its business activities. As of March 31, 2020, the Company was not subject to any pending or threatened legal claims or actions.

Clinical Trial Agreements

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

In November 2018, the Company received approval from the FDA for its Investigational New Drug (IND) Application to conduct a Phase 1b/2 clinical trial to evaluate the therapeutic benefit of LB-100 in patients with low and intermediate-1 risk MDS who have failed or are intolerant of standard treatment. This clinical trial began in April 2019 and the first patient was entered into the clinical trial in July 2019. The clinical trial is expected to be completed over a period of two years, with final analysis and reporting expected within three years. This Phase 1b/2 clinical trial utilizes LB-100 as a single agent in the treatment of patients with del(5q) myelodysplastic syndrome (del5qMDS) failing first line therapy. The bone marrow cells of these patients are deficient in PP2A and are especially vulnerable to further inhibition of PP2A by LB-100. During the three months ended March 31, 2020 and 2019, the Company paid Moffitt $13,667 and $0, respectively, pursuant to this agreement. As of March 31, 2020, total costs of $58,760 have been incurred pursuant to this agreement.

Effective as of July 31, 2019, the Company entered into a Collaboration Agreement for an Investigator-Initiated Clinical Trial with the Spanish Sarcoma Group (Grupo Espanol de Investigacion en Sarcomas or "GEIS"), Madrid, Spain, to carry out a clinical trial entitled "Randomized phase I/II trial of LB-100 plus doxorubicin vs. doxorubicin alone in first line of advanced soft tissue sarcoma". The purpose of this clinical trial is to obtain information about the efficacy and safety of the Company's lead anti-cancer clinical compound LB-100 combined with doxorubicin in soft tissue sarcomas. Doxorubicin is the global standard for initial treatment of advanced soft tissue sarcomas (ASTA). Doxorubicin alone has been the mainstay of first line treatment of ASTS for over 40 years, with little therapeutic gain from adding cytotoxic compounds to or substituting other cytotoxic compounds for doxorubicin. In animal models, LB-100 consistently enhances the antitumor activity of doxorubicin without apparent increases in toxicity. GEIS has a network of referral centers in Span and across Europe that have an impressive track record of efficiently conducting innovative studies in ASTS. The Company has agreed to provide GEIS with a supply of LB-100 to be utilized in the conduct of this clinical trial, as well as to provide funding for the clinical trial. The goal is to enter the first patient into this clinical trial during the quarter ending June 30, 2020, with approximately 170 patients to be subsequently enrolled over a period of two years. The Company estimates that this clinical trial will be completed and results will be published by June 30, 2023. The original start date for patient entry was delayed due to longer than expected processing of formal approval of importation of LB-100 into the European Union. This approval was originally expected to be received in the quarter ended September 30, 2019 but was delayed and is now expected to be received during the quarter ending June 30, 2020. During the three months ended March 31, 2020, the Company did not incur any costs pursuant to this agreement; however, on February 18, 2020, the Company advanced $43,411 to GEIS towards an upcoming second milestone payment of $87,471. Excluding the advance made on February 18, 2020, as of March 31, 2020, total costs of $87,471 have been incurred pursuant to this agreement.

The Company's aggregate commitments pursuant to these clinical trial agreements, less amounts previously paid to date under these agreements, totaled approximately $4,806,000 as of March 31, 2020, which are expected to be incurred over the next five years through March 31, 2025.

Clinical Trial Monitoring Agreements

On September 12, 2018, the Company finalized a work order agreement with Theradex Systems, Inc. (Theradex"), an international contract research organization ("CRO"), to monitor the Phase 1b/2 clinical trial being managed and conducted by Moffitt. The clinical trial is expected to be completed over a period of two years, with final analysis and reporting expected within three years. Costs under this work order agreement are estimated to be approximately $954,000, with such payments expected to be divided approximately 94% to Theradex for services and approximately 6% for payments for pass-through costs. The costs of the Phase 1b/2 clinical trial being paid to or through Theradex are being recorded and charged to operations based on the periodic documentation provided by the CRO. During the three months ended March 31, 2020 and 2019, the Company incurred costs of $5,686 and $32,964, respectively, pursuant to this work order. As of March 31, 2020, total costs of $69,178 have been incurred pursuant to this work order agreement.

Patent and License Agreements

On March 22, 2018, the Company entered into a Patent Assignment and Exploitation Agreement (the "Agreement") with INSERM TRANSFERT SA, acting as delegatee of the French National Institute of Health and Medical Research ("INSERM"), for the assignment to the Company of INSERM'S interest in United States Patent No. 9,833,450 entitled "Oxabicyloheptanes and Oxabicycloheptenes for the Treatment of Depressive and Stress Disorders", which was filed with the United States Patent and Trademark Office in the name of INSERM and the Company as co-owners on February 19, 2015 and granted on May 12, 2017, and related patent applications and filings. INSERM is a French public institution dedicated to research in the field of health and medicine that had previously entered into a Material Transfer Agreement ("MTA") with the Company to allow INSERM to conduct research on the Company's proprietary compound LB-100 and/or its analogs for the treatment of depressive or stress disorders in humans. Pursuant to the Agreement, the Company has agreed to make certain milestone payments to INSERM aggregating up to $1,750,000 upon achievement of development milestones and up to $6,500,000 upon achievement of commercial milestones. The Company also agreed to pay INSERM certain commercial royalties on net sales of products attributed to the Agreement. The Company's current plan is to complete the validation process to evaluate LB-100 for the treatment of depressive or stress disorders in humans within three years; however, the exploitation of this patent for the treatment of depressive and stress disorders in humans will require substantial additional capital and/or a joint venture or other type of business arrangement with a pharmaceutical company with substantially greater capital and business resources than those available to the Company. As there can be no assurances that the Company will be able to obtain the capital or business resources necessary to focus on the exploitation of this patent, it is uncertain as to when the Company may reach any of the development or commercialization milestones under the Agreement, if at all. As of March 31, 2020 and December 31, 2019, no amounts were due under this agreement.

Effective April 2, 2018, the Company entered into a consulting agreement for a term of two years with Liberi Life Sciences Consultancy BV, located in The Netherlands, for consulting and advisory services with respect to sales and licensing, as well as the procurement of investors in China, Japan and South Korea (the "Consulting Agreement"). The Consulting Agreement provided for the payment of a fixed, one-time retainer of EURO 15,000 (US $18,348), which was paid on April 5, 2018, and 2.5% of the net payments received by the Company from sales of products or licensing activities arising directly and exclusively from leads generated by the advisor during the term of the Consulting Agreement, and any investors introduced to the Company by the advisor that results in an investment in the Company during the term of the Consulting Agreement. The Company recorded the payment of the retainer as a prepaid expense in the Company's consolidated balance sheet, and is amortizing the retainer payment over the two-year life of the Consulting Agreement, as a result of which the Company recorded charges to operations of $2,294 and $2,294 during the three months ended March 31, 2020 and 2019, respectively. As of March 31, 2020, the prepaid consulting fee had been fully amortized. At December 31, 2019, the unamortized balance of the retainer payment was $9,174, all of which was classified as a current asset in the Company's consolidated balance sheet at such date.

Effective August 20, 2018 (the "Effective Date"), the Company and Moffitt entered into an Exclusive License Agreement (the "License Agreement"). Pursuant to the License Agreement, Moffitt granted the Company an exclusive license under certain patents owned by Moffitt (the "Licensed Patents") relating to the treatment of MDS and a non-exclusive license under inventions, concepts, processes, information, data, know-how, research results, clinical data, and the like (other than the Licensed Patents) necessary or useful for the practice of any claim under the Licensed Patents or the use, development, manufacture or sale of any product for the treatment of MDS which would otherwise infringe a valid claim under the Licensed Patents. The Company was obligated to pay Moffitt a non-refundable license issue fee of $25,000 after the first patient is entered into a Phase 1b/2 clinical trial to be managed and conducted by Moffitt. The clinical trial began in April 2019 and the first patient was entered into the clinical trial in July 2019. The clinical trial is expected to be completed over a period of two years, with final analysis and reporting expected within three years. The Company is also obligated to pay Moffitt an annual license maintenance fee of $25,000 commencing on the first anniversary of the Effective Date and every anniversary thereafter until the Company commences payment of minimum royalty payments. The Company has also agreed to pay non-refundable milestone payments to Moffitt, which cannot be credited against earned royalties payable by the Company, based on reaching various clinical and commercial milestones aggregating $1,897,000, subject to reduction by 40% under certain circumstances relating to the status of Valid Claims, as such term is defined in the License Agreement. During the three months ended March 31, 2020 and 2019, the Company recorded charges to operations of $6,165 and $15,274, respectively, in connection with its obligations under the License Agreement. As of March 31, 2020, no milestones had yet been attained.

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

Other Significant Agreements and Contracts

On December 24, 2013, the Company entered into an agreement with NDA Consulting Corp. ("NDA") for consultation and advice in the field of oncology research and drug development. As part of the agreement, NDA also agreed to cause its president, Dr. Daniel D. Von Hoff, M.D., to become a member of the Company's Scientific Advisory Committee. The term of the agreement was for one year and provided for a quarterly cash fee of $4,000. The agreement has been automatically renewed for additional one-year terms on its anniversary date since 2014. Consulting and advisory fees charged to operations pursuant to this agreement for the three months ended March 31, 2020 and 2019 were $4,000 and $4,000, respectively, which were included in research and development costs in the consolidated statements of operations.

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

BioPharmaWorks was founded in 2015 by former Pfizer scientists with extensive multi-disciplinary research and development and drug development experience. The Collaboration Agreement was for an initial term of two years and automatically renews for subsequent annual periods unless terminated by a party not less than 60 days prior to the expiration of the applicable period. In connection with the Collaboration Agreement, the Company agreed to pay BioPharmaWorks a monthly fee of $10,000, subject to the right of the Company to pay a negotiated hourly rate in lieu of the monthly payment and agreed to issue to BioPharmaWorks certain equity-based compensation. In November 2016, it was mutually agreed to suspend services and payments under the Collaboration Agreement, without extending its term, for the period from November 1, 2016 through March 31, 2017. The Collaboration Agreement resumed as scheduled on April 1, 2017. In April 2018, it was again mutually agreed to suspend services and payments under the Collaboration Agreement, without extending its term, for the period from February 1, 2018 through the September 13, 2019 anniversary date. In February 2019, the Company and BioPharmaWorks subsequently agreed to resume the Collaboration Agreement effective March 1, 2019, and the Collaboration Agreement is currently in effect. The Company recorded charges to operations pursuant to this Collaboration Agreement for the three months ended March 31, 2020 and 2019 of $30,000 and $10,000, respectively, which were included in research and development costs in the consolidated statements of operations.

8. Subsequent Events

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

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

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

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

Recent Development

Summary of Article published in the April 27, 2020 online edition of Journal of Neuro-Oncology – Inhibition of protein phosphatase 2A (PP2A) with LB-100 enhances anti-tumor immunity against glioblastoma:

Investigators at the National Cancer Institute (NCI) and National Institute of Neurological Disorders and Stroke (NINDS) reported that LB-100, the Company's lead clinical compound, enhanced pharmacological immunotherapy of intracranial brain tumors in immune-competent mice. Glioblastoma multiforme (GBM) tumors, the most common and aggressive brain tumors of adults, are generally resistant to treatment. Radiation combined with the chemotherapeutic drug temozolomide has been the standard therapy for decades, with no major advances in overall survival for the majority of patients despite studies of many other regimens.

In recent years, a new class of anti-cancer drugs, known as immune checkpoint blockers, particularly those targeting an immune regulatory factor called programmed death protein 1 (PD-1), has been shown to induce long-term regressions of several types of cancer, but anti-PD-1 treatment of GBM has not been encouraging. The article reports that the combination of LB-100 plus a PD-1 blocker shrank the GBM cancers implanted in the brain, including elimination of tumor and development of immunity to re-challenge with the same tumor in 25% of the animals.

These investigators had previously shown that LB-100 enhances the anti-tumor activity of a PD-1 blocker in a mouse model of colon cancer, but this is the first report that inhibition of PP2A activity improves the efficacy of a PD-1 blocker in a model of GBM. The mechanism(s) by which LB-100 synergizes with an anti-PD-1 agent to cause significant tumor regression is not fully understood, but it appears that the anti-cancer activity of the combination of the two agents is mediated by activating the normal immune system to attack the cancer, rather than a direct action of LB-100 on the tumor itself. Given that the human safety profiles of several anti-PD-1 drugs and LB-100 are well established, the Company believes the new animal data justifies the conduct of a Phase 1b/2 trial of LB-100 plus a PD-1 blocker in GBM patients who have relapsed after initial standard therapy.

Going Concern

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

As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern within one year of the date that the consolidated financial statements are being issued. In addition, the Company's independent registered public accounting firm, in their report on the Company's consolidated financial statements for the year ended December 31, 2019, has also expressed substantial doubt about the Company's ability to continue as a going concern.

The Company's ability to continue as a going concern is dependent upon its ability to raise additional equity capital to fund its research and development activities and to ultimately achieve sustainable operating revenues and profits. The Company's consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties. The Company expects that it will need to raise additional capital in early 2021.

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, 2020 and 2019 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, 2020 and 2019 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 reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions. Management bases its estimates on historical experience and on various assumptions that are believed to be reasonable in relation to the financial statements taken as a whole under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Management regularly evaluates the key factors and assumptions used to develop the estimates utilizing currently available information, changes in facts and circumstances, historical experience and reasonable assumptions. After such evaluations, if deemed appropriate, those estimates are adjusted accordingly. Actual results could differ from those estimates. Significant estimates include those related to assumptions used in accruals for potential liabilities, valuing equity instruments issued for services, and the realization of deferred tax assets.

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

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 Related Legal and Filing Costs

Due to the significant uncertainty associated with the successful development of one or more commercially viable products based on the Company's research efforts and related patent applications, all patent-related legal and filing fees and licensing-related legal fees are charged to operations as incurred. Patent and licensing related legal and filing costs 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. Stock grants, which are generally time vested, are measured at the grant date fair value and charged to operations ratably over the vesting period.

The Company accounts for stock-based payments to officers, directors, Scientific Advisory Committee members, and to outside consultants by measuring the cost of services received in exchange for equity awards utilizing the grant date fair value of the awards, with the cost recognized as compensation expense on the straight-line basis in the Company's financial statements over the vesting period of the awards.

The fair value of stock options granted as stock-based compensation is determined utilizing the Black-Scholes option-pricing model, and is affected by several variables, the most significant of which are the life of the equity award, the exercise price of the stock option as compared to the fair market value of the common stock on the grant date, and the estimated volatility of the common stock. Estimated volatility is based on the historical volatility of the Company's common stock, calculated utilizing a one-year look-back period, as the Company believes that such measurement period provides a more accurate and meaningful volatility factor given the changes in the Company's research and development program and capital requirements over the past several years. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. The fair market value of the common stock is determined by reference to the quoted market price of the Company's common stock on the grant date.

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

Plan of Operation

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'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 of LB-100 and to enter into discussions with cancer centers that focus on the inhibition of PP2A as an important cancer target.

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, 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.

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

Impact of the Novel Coronavirus (COVID-19) on the Company's Business

In light of the uncertain and rapidly evolving situation relating to the spread of the novel coronavirus (COVID-19), this pandemic could pose a risk to the Company's business. The extent to which the coronavirus may impact the Company's business operations will depend on future developments, which are highly uncertain and cannot be predicted at this time. The Company intends to continue to monitor the situation and may adjust its current business plans as more information and guidance become available.

The coronavirus pandemic presents a challenge to medical facilities worldwide. As the Company's clinical trials are conducted on an outpatient basis, it is not currently possible to predict the full impact of this developing health crisis on such clinical trials, which could include delays in and increased costs of such clinical trials.

Current indications from the clinical research organizations conducting the clinical trials for the Company are that such clinical trials will be delayed for at least three to six months as a result of the coronavirus pandemic. There is also significant uncertainty as to the affect that the coronavirus may have on the availability, amount and type of financing in the future. The Company expects that it will need to begin to raise additional capital in early 2021.

Results of Operations

At March 31, 2020, the Company had not yet commenced any revenue-generating operations, does not have any positive cash flows from operations, and is dependent on its ability to raise equity capital to fund its operating requirements.

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

	Three Months Ended March 31,	
	2020	2019
Revenues	$ —	$ —
Costs and expenses:		
General and administrative costs	292,484	390,428
Research and development costs	94,673	48,314
Total costs and expenses	387,157	438,742
Loss from operations	(387,157)	(438,742)
Interest income	3,982	10,006
Net loss	$ (383,175)	$ (428,736)
Net loss per common share – basic and diluted	$ (0.01)	$ (0.01)
Weighted average common shares outstanding – basic and diluted	67,045,814	67,045,814

Three Months Ended March 31, 2020 and 2019

Revenues. The Company did not have any revenues for the three months ended March 31, 2020 and 2019.

General and Administrative Costs. For the three months ended March 31, 2020, general and administrative costs were $292,484, which consisted of patent and licensing legal fees and costs of $133,467, other consulting and professional fees of $107,742, insurance expense of $14,284, officer's salary and related costs of $17,021, licensing fees of $6,165, stock transfer fees of $3,591, listing fees of $3,000, filing fees of $5,000, and other operating costs of $2,214.

For the three months ended March 31, 2019, general and administrative costs were $390,428, which consisted of the fair value of vested stock options issued to directors and consultants of $12,936, patent and licensing legal fees and costs of $190,773, other consulting and professional fees of $125,461, 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.

General and administrative costs decreased by $97,945 or 25.1% in 2020 as compared to 2019, primarily as a result of decreases in the fair value of stock options issued to directors and consultants of $12,936, patent and licensing legal fees and costs of $57,306, other consulting and professional fees of $17,719, and licensing fees of $9,109.

Research and Development Costs. For the three months ended March 31, 2020, research and development costs were $94,673, which consisted 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 $13,667 to Moffitt, $5,685 to Theradex for oversight of the Moffitt study, and $30,000 to BioPharma Works.

For the three months ended March 31, 2019, research and development costs were $48,314, which consisted 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 for oversight of the Moffitt study, and $10,000 to BioPharma Works.

Research and development costs increased by $46,359 in 2020 as compared to 2019, as a result of an increase in 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 $13,667 to Moffitt, and $20,000 to BioPharma Works.

Interest Income. For the three months ended March 31, 2020, the Company had interest income of $3,982, as compared to interest income of $10,006 for the three months ended March 31, 2019, as a result of a reduction in the Company's cash resources previously invested in short-term federally insured certificates of deposit.

Net Loss. For the three months ended March 31, 2020, the Company incurred a net loss of $383,175, as compared to a net loss of $428,736 for the three months ended March 31, 2019.

Liquidity and Capital Resources – March 31, 2020

The Company's consolidated financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has not generated any revenues from operations to date and does not expect to do so in the foreseeable future. Furthermore, the Company has experienced recurring operating losses and negative operating cash flows since inception and has financed its working capital requirements during this period primarily through the recurring sale of its equity securities and the exercise of outstanding common stock options and purchase warrants. As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern within one year of the date that the consolidated financial statements are being issued. In addition, the Company's independent registered public accounting firm, in their report on the Company's consolidated financial statements for the year ended December 31, 2019, has also expressed substantial doubt about the Company's ability to continue as a going concern (see "Going Concern" above).

At March 31, 2020, the Company had working capital of $2,050,960, as compared to working capital of $2,434,135 at December 31, 2019, reflecting a decrease in working capital of $383,175 for the three months ended March 31, 2020. The decrease in working capital during the three months ended March 31, 2020 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, 2020, the Company had cash and cash equivalents of $2,184,831 available to fund its operations. Because the Company is currently engaged in Phase 2 clinical trials, it is expected that it will take a significant amount of time to develop any product or intellectual property capable of generating sustainable revenues. Accordingly, the Company's business is unlikely to generate any sustainable operating revenues in the next several years and may never do so. In addition, to the extent that the Company is able to generate revenues through licensing its technologies or through product sales, there can be no assurance that the Company will be able to achieve positive earnings and operating cash flows.

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

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

The Company's longer-term objective is to secure one or more strategic partnerships or licensing agreements with pharmaceutical companies with major programs in cancer. The Company expects that it will need to raise additional capital in early 2021.

Operating Activities. For the three months ended March 31, 2020, operating activities utilized cash of $414,033, as compared to utilizing cash of $379,408 for the three months ended March 31, 2019, 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, 2020 and 2019, the Company had no investing activities.

Financing Activities. For the three months ended March 31, 2020 and 2019, the Company had no financing activities.

Principal Commitments

Clinical Trial Agreements

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

In November 2018, the Company received approval from the FDA for its Investigational New Drug (IND) Application to conduct a Phase 1b/2 clinical trial to evaluate the therapeutic benefit of LB-100 in patients with low and intermediate-1 risk MDS who have failed or are intolerant of standard treatment. This clinical trial began in April 2019 and the first patient was entered into the clinical trial in July 2019. The clinical trial is expected to be completed over a period of two years, with final analysis and reporting expected within three years. This Phase 1b/2 clinical trial utilizes LB-100 as a single agent in the treatment of patients with del(5q) myelodysplastic syndrome (del5qMDS) failing first line therapy. The bone marrow cells of these patients are deficient in PP2A and are especially vulnerable to further inhibition of PP2A by LB-100. During the three months ended March 31, 2020 and 2019, the Company paid Moffitt $13,667 and $0, respectively, pursuant to this agreement. As of March 31, 2020, total costs of $58,760 have been incurred pursuant to this agreement.

Effective as of July 31, 2019, the Company entered into a Collaboration Agreement for an Investigator-Initiated Clinical Trial with the Spanish Sarcoma Group (Grupo Espanol de Investigacion en Sarcomas or "GEIS"), Madrid, Spain, to carry out a clinical trial entitled "Randomized phase I/II trial of LB-100 plus doxorubicin vs. doxorubicin alone in first line of advanced soft tissue sarcoma". The purpose of this clinical trial is to obtain information about the efficacy and safety of the Company's lead anti-cancer clinical compound LB-100 combined with doxorubicin in soft tissue sarcomas. Doxorubicin is the global standard for initial treatment of advanced soft tissue sarcomas (ASTA). Doxorubicin alone has been the mainstay of first line treatment of ASTS for over 40 years, with little therapeutic gain from adding cytotoxic compounds to or substituting other cytotoxic compounds for doxorubicin. In animal models, LB-100 consistently enhances the antitumor activity of doxorubicin without apparent increases in toxicity. GEIS has a network of referral centers in Span and across Europe that have an impressive track record of efficiently conducting innovative studies in ASTS. The Company has agreed to provide GEIS with a supply of LB-100 to be utilized in the conduct of this clinical trial, as well as to provide funding for the clinical trial. The goal is to enter the first patient into this clinical trial during the quarter ending June 30, 2020, with approximately 170 patients to be subsequently enrolled over a period of two years. The Company estimates that this clinical trial will be completed and results will be published by June 30, 2023. The original start date for patient entry was delayed due to longer than expected processing of formal approval of importation of LB-100 into the European Union. This approval was originally expected to be received in the quarter ended September 30, 2019 but was delayed and is now expected to be received during the quarter ending June 30, 2020. During the three months ended March 31, 2020, the Company did not incurred costs pursuant to this agreement, however, on February 18, 2020, the Company advanced $43,411 to GEIS towards an upcoming second milestone payment of $87,471. Excluding the advance made on February 18, 2020, as of March 31, 2020, total costs of $87,471 have been incurred pursuant to this agreement.

The Company's aggregate commitments pursuant to these clinical trial agreements, less amounts previously paid to date under these agreements, totaled approximately $4,806,000 as of March 31, 2020, which are expected to be incurred over the next five years through March 31, 2025.

Clinical Trial Monitoring Agreements

On September 12, 2018, the Company finalized a work order agreement with Theradex Systems, Inc. (Theradex"), an international contract research organization ("CRO"), to monitor the Phase 1b/2 clinical trial being managed and conducted by Moffitt. The clinical trial is expected to be completed over a period of two years, with final analysis and reporting expected within three years. Costs under this work order agreement are estimated to be approximately $954,000, with such payments expected to be divided approximately 94% to Theradex for services and approximately 6% for payments for pass-through costs. The costs of the Phase 1b/2 clinical trial being paid to or through Theradex are being recorded and charged to operations based on the periodic documentation provided by the CRO. During the three months ended March 31, 2020 and 2019, the Company incurred costs of $5,686 and $32,964, respectively, pursuant to this work order. As of March 31, 2020, total costs of $69,178 have been incurred pursuant to this work order agreement.

Patent and License Agreements

On March 22, 2018, the Company entered into a Patent Assignment and Exploitation Agreement (the "Agreement") with INSERM TRANSFERT SA, acting as delegatee of the French National Institute of Health and Medical Research ("INSERM"), for the assignment to the Company of INSERM'S interest in United States Patent No. 9,833,450 entitled "Oxabicyloheptanes and Oxabicycloheptenes for the Treatment of Depressive and Stress Disorders", which was filed with the United States Patent and Trademark Office in the name of INSERM and the Company as co-owners on February 19, 2015 and granted on May 12, 2017, and related patent applications and filings. INSERM is a French public institution dedicated to research in the field of health and medicine that had previously entered into a Material Transfer Agreement ("MTA") with the Company to allow INSERM to conduct research on the Company's proprietary compound LB-100 and/or its analogs for the treatment of depressive or stress disorders in humans. Pursuant to the Agreement, the Company has agreed to make certain milestone payments to INSERM aggregating up to $1,750,000 upon achievement of development milestones and up to $6,500,000 upon achievement of commercial milestones. The Company also agreed to pay INSERM certain commercial royalties on net sales of products attributed to the Agreement. The Company's current plan is to complete the validation process to evaluate LB-100 for the treatment of depressive or stress disorders in humans within three years; however, the exploitation of this patent for the treatment of depressive and stress disorders in humans will require substantial additional capital and/or a joint venture or other type of business arrangement with a pharmaceutical company with substantially greater capital and business resources than those available to the Company. As there can be no assurances that the Company will be able to obtain the capital or business resources necessary to focus on the exploitation of this patent, it is uncertain as to when the Company may reach any of the development or commercialization milestones under the Agreement, if at all. As of March 31, 2020 and December 31, 2019, no amounts were due under this agreement.

Effective April 2, 2018, the Company entered into a consulting agreement for a term of two years with Liberi Life Sciences Consultancy BV, located in The Netherlands, for consulting and advisory services with respect to sales and licensing, as well as the procurement of investors in China, Japan and South Korea (the "Consulting Agreement"). The Consulting Agreement provided for the payment of a fixed, one-time retainer of EURO 15,000 (US $18,348), which was paid on April 5, 2018, and 2.5% of the net payments received by the Company from sales of products or licensing activities arising directly and exclusively from leads generated by the advisor during the term of the Consulting Agreement, and any investors introduced to the Company by the advisor that results in an investment in the Company during the term of the Consulting Agreement. The Company recorded the payment of the retainer as a prepaid expense in the Company's consolidated balance sheet, and is amortizing the retainer payment over the two-year life of the Consulting Agreement, as a result of which the Company recorded charges to operations of $2,294 and $2,294 during the three months ended March 31, 2020 and 2019, respectively. As of March 31, 2020, the prepaid consulting fee had been fully amortized. At December 31, 2019, the unamortized balance of the retainer payment was $9,174, all of which was classified as a current asset in the Company's consolidated balance sheet at such date.

Effective August 20, 2018 (the "Effective Date"), the Company and Moffitt entered into an Exclusive License Agreement (the "License Agreement"). Pursuant to the License Agreement, Moffitt granted the Company an exclusive license under certain patents owned by Moffitt (the "Licensed Patents") relating to the treatment of MDS and a non-exclusive license under inventions, concepts, processes, information, data, know-how, research results, clinical data, and the like (other than the Licensed Patents) necessary or useful for the practice of any claim under the Licensed Patents or the use, development, manufacture or sale of any product for the treatment of MDS which would otherwise infringe a valid claim under the Licensed Patents. The Company was obligated to pay Moffitt a non-refundable license issue fee of $25,000 after the first patient is entered into a Phase 1b/2 clinical trial to be managed and conducted by Moffitt. The clinical trial began in April 2019 and the first patient was entered into the clinical trial in July 2019. The clinical trial is expected to be completed over a period of two years, with final analysis and reporting expected within three years. The Company is also obligated to pay Moffitt an annual license maintenance fee of $25,000 commencing on the first anniversary of the Effective Date and every anniversary thereafter until the Company commences payment of minimum royalty payments. The Company has also agreed to pay non-refundable milestone payments to Moffitt, which cannot be credited against earned royalties payable by the Company, based on reaching various clinical and commercial milestones aggregating $1,897,000, subject to reduction by 40% under certain circumstances relating to the status of Valid Claims, as such term is defined in the License Agreement. During the three months ended March 31, 2020 and 2019, the Company recorded charges to operations of $6,165 and $15,274, respectively, in connection with its obligations under the License Agreement. As of March 31, 2020, no milestones had yet been attained.

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

Other Significant Agreements and Contracts

On December 24, 2013, the Company entered into an agreement with NDA Consulting Corp. ("NDA") for consultation and advice in the field of oncology research and drug development. As part of the agreement, NDA also agreed to cause its president, Dr. Daniel D. Von Hoff, M.D., to become a member of the Company's Scientific Advisory Committee. The term of the agreement was for one year and provided for a quarterly cash fee of $4,000. The agreement has been automatically renewed for additional one-year terms on its anniversary date since 2014. Consulting and advisory fees charged to operations pursuant to this agreement for the three months ended March 31, 2020 and 2019 were $4,000 and $4,000, respectively, which were included in research and development costs in the consolidated statements of operations.

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

BioPharmaWorks was founded in 2015 by former Pfizer scientists with extensive multi-disciplinary research and development and drug development experience. The Collaboration Agreement was for an initial term of two years and automatically renews for subsequent annual periods unless terminated by a party not less than 60 days prior to the expiration of the applicable period. In connection with the Collaboration Agreement, the Company agreed to pay BioPharmaWorks a monthly fee of $10,000, subject to the right of the Company to pay a negotiated hourly rate in lieu of the monthly payment and agreed to issue to BioPharmaWorks certain equity-based compensation. In November 2016, it was mutually agreed to suspend services and payments under the Collaboration Agreement, without extending its term, for the period from November 1, 2016 through March 31, 2017. The Collaboration Agreement resumed as scheduled on April 1, 2017. In April 2018, it was again mutually agreed to suspend services and payments under the Collaboration Agreement, without extending its term, for the period from February 1, 2018 through the September 13, 2019 anniversary date. In February 2019, the Company and BioPharmaWorks subsequently agreed to resume the Collaboration Agreement effective March 1, 2019, and the Collaboration Agreement is currently in effect. The Company recorded charges to operations pursuant to this Collaboration Agreement for the three months ended March 31, 2020 and 2019 of $30,000 and $10,000, respectively, which were included in research and development costs in the consolidated statements of operations.

Off-Balance Sheet Arrangements

At March 31, 2020, 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

Evaluation of Disclosure Controls and Procedures

As required by Rule 15d-15(b) of the Securities and Exchange Commission (the "SEC"), the Company carried out an evaluation, under the supervision and with the participation of its management, consisting of the Company's principal executive and financial officer (who is the same person), of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of March 31, 2020, the end of the most recent period covered by this report.

The term "disclosure controls and procedures", as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) under the Exchange Act. The Company's internal control over financial reporting is designed to ensure that material information regarding the Company's operations is made available to management and the board of directors to provide them reasonable assurance that the published financial statements are fairly presented.

There are limitations inherent in any internal control, such as the possibility of human error and the circumvention or overriding of controls. As a result, even effective internal controls can provide only reasonable assurance with respect to financial statement preparation. As conditions change over time so too may the effectiveness of internal controls. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

The Company's management has concluded that the Company has a material weakness in its internal controls resulting from the Chief Executive Officer having almost complete responsibility for the processing of invoices and the preparation of checks, and the Company's finance department not having adequate internal staff to process the accounting information and prepare periodic financial statements and footnotes. While the Company has designed and implemented measures and systems that it believes address and mitigate these control weaknesses, through expanded bookkeeping and review procedures and the services of qualified outside consultants with expertise to perform specific accounting and finance functions, as well as review of major transactions and agreements by the Board of Directors, the Company may not be successful in such efforts, which may undermine its ability to provide accurate, timely and reliable reports on its financial and operating results. In addition, if the Company identifies additional material weaknesses in its internal control over financial reporting, the Company may not detect errors on a timely basis and its financial statements may be materially misstated. Moreover, in the future the Company may engage in business activities or transactions that could negatively affect its internal control over financial reporting and result in additional material weaknesses.

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

The Company's business, financial condition, results of operations and cash flows may be impacted by a number of factors, many of which are beyond the Company's control, including those set forth in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as filed with the Securities and Exchange Commission on March 25, 2020 (the "2019 Form 10-K").

The Risk Factors set forth in the 2019 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 2019 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.

As of the date of this filing, there have been no material changes to the Risk Factors previously disclosed in the Company's 2019 Form 10-K, except as noted below.

Impact of the Novel Coronavirus (COVID-19) on the Company's Business

In light of the uncertain and rapidly evolving situation relating to the spread of the novel coronavirus (COVID-19), this pandemic could pose a risk to the Company's business. The extent to which the coronavirus may impact the Company's business operations will depend on future developments, which are highly uncertain and cannot be predicted at this time. The Company intends to continue to monitor the situation and may adjust its current business plans as more information and guidance become available.

The coronavirus pandemic presents a challenge to medical facilities worldwide. As the Company's clinical trials are conducted on an outpatient basis, it is not currently possible to predict the full impact of this developing health crisis on such clinical trials, which could include delays in and increased costs of such clinical trials.

Current indications from the clinical research organizations conducting the clinical trials for the Company are that such clinical trials will be delayed for at least three to six months as a result of the coronavirus pandemic. There is also significant uncertainty as to the affect that the coronavirus may have on the availability, amount and type of financing in the future. The Company expects that it will need to begin to raise additional capital in early 2021.

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

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".

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 11, 2020

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

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 11, 2020

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, 2020 (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 11, 2020

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