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

FORM 10-Q

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

For the quarterly period ended March 31, 2022

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

Commission file number: 001-39717

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)

680 East Colorado Boulevard, Suite 180
Pasadena, California 91101
(Address of principal executive offices, including Zip Code)

(631) 830-7092
(Registrant's telephone number, including area code)

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, par value $0.0001 per share	LIXT	The Nasdaq Stock Market LLC
Warrants to Purchase Common Stock, par value $0.0001 per share	LIXTW	The Nasdaq Stock Market LLC

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 ☒ 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 ☒ 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 ☒
	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 ☒

As of May 2, 2022, the Company had 16,646,593 shares of common stock, $0.0001 par value, issued and outstanding.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

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PART I - FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2022 (Unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash	$ 3,777,742	$ 4,823,745
Advances on research and development contract services	147,017	150,241
Prepaid insurance	130,101	109,029
Other prepaid expenses and current assets	51,919	10,249
Total current assets	4,106,779	5,093,264
Deferred offering costs	10,906	—
Total assets	$ 4,117,685	$ 5,093,264
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses, including $32,500 and $32,500 to related parties at March 31, 2022 and December 31, 2021, respectively	$ 369,490	$ 225,965
Research and development contract liabilities	275,103	76,961
Total current liabilities	644,593	302,926
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, $0.0001 par value; authorized – 10,000,000 shares; issued and outstanding – 350,000 shares of Series A Convertible Preferred Stock, $10.00 per share stated value, liquidation preference based on assumed conversion into common shares – 729,167 shares	3,500,000	3,500,000
Common stock, $0.0001 par value; authorized – 100,000,000 shares; issued and outstanding – 13,746,593 shares	1,374	1,374
Additional paid-in capital	38,710,800	38,371,128
Accumulated deficit	(38,739,082)	(37,082,164)
Total stockholders' equity	3,473,092	4,790,338
Total liabilities and stockholders' equity	$ 4,117,685	$ 5,093,264

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,	
	2022	**2021**
Revenues	$ —	$ —
Costs and expenses:		
General and administrative costs:		
Compensation to related parties, including stock-based compensation of $339,672 and $656,032 for the three months ended March 31, 2022 and 2021, respectively	565,922	816,032
Patent and licensing legal and filing fees and costs	315,237	120,160
Other	314,743	345,462
Research and development costs	458,450	443,526
Total costs and expenses	1,654,352	1,725,180
Loss from operations	(1,654,352)	(1,725,180)
Interest income	109	146
Interest expense	(2,494)	(2,099)
Foreign currency loss	(181)	(11)
Net loss	$ (1,656,918)	$ (1,727,144)
Net loss per common share – basic and diluted	$ (0.12)	$ (0.14)
Weighted average common shares outstanding – basic and diluted	13,746,593	12,768,201

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, 2022 and 2021

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Par Value			
Balance, December 31, 2021	350,000	$ 3,500,000	13,746,593	$ 1,374	$ 38,371,128	$ (37,082,164)	$ 4,790,338
Stock-based compensation expense	—	—	—	—	339,672	—	339,672
Net loss	—	—	—	—	—	(1,656,918)	(1,656,918)
Balance, March 31, 2022	350,000	$ 3,500,000	13,746,593	$ 1,374	$ 38,710,800	$ (38,739,082)	$ 3,473,092
Balance, December 31, 2020	350,000	$ 3,500,000	12,402,157	$ 1,240	$ 31,864,479	$ (30,353,768)	$ 5,011,951
Proceeds from sale of common stock in direct equity offering, net of offering costs	—	—	1,133,102	113	3,689,648	—	3,689,761
Exercise of warrants	—	—	3,000	1	17,099	—	17,100
Stock-based compensation expense	—	—	—	—	656,032	—	656,032
Net loss	—	—	—	—	—	(1,727,144)	(1,727,144)
Balance, March 31, 2021	350,000	$ 3,500,000	13,538,259	$ 1,354	$ 36,227,258	$ (32,080,912)	$ 7,647,700

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,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (1,656,918)	$ (1,727,144)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense included in -		
General and administrative costs	339,672	656,032
Changes in operating assets and liabilities:		
(Increase) decrease in -		
Advances on research and development contract services	3,224	63,905
Prepaid insurance	(21,072)	(7,973)
Other prepaid expenses and current assets	(41,670)	(47,500)
Increase (decrease) in -		
Accounts payable and accrued expenses	143,525	(41,421)
Research and development contract liabilities	198,142	77,764
Net cash used in operating activities	(1,035,097)	(1,026,337)
Cash flows from financing activities:		
Proceeds from sale of common stock in direct equity offering, net of offering costs	—	3,689,761
Exercise of common stock warrants	—	17,100
Payment of deferred offering costs	(10,906)	(10,467)
Net cash provided by (used in) financing activities	(10,906)	3,696,394
Cash:		
Net increase (decrease)	(1,046,003)	2,670,057
Balance at beginning of period	4,823,745	5,069,266
Balance at end of period	$ 3,777,742	$ 7,739,323
Supplemental disclosures of cash flow information:		
Cash paid for -		
Interest	$ 2,494	$ 2,099
Income taxes	$ —	$ —

See accompanying notes to condensed consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

Three Months Ended March 31, 2022 and 2021

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, 2022, and for the three months ended March 31, 2022 and 2021, 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, 2022, and the results of its operations for the three months ended March 31, 2022 and 2021, and its cash flows for the three months ended March 31, 2022 and 2021. 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, 2021 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, 2021, 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.

Sale of Common Stock

Effective April 12, 2022, the Company completed the sale of 2,900,000 shares of common stock at a price of $2.00 per share in a registered direct equity offering, generating gross proceeds of $5,800,000. The total cash costs of this offering were approximately $633,840, resulting in net proceeds of approximately $5,166,160. Pursuant to the placement agents' agreement, the Company granted to the placement agents warrants to purchase up to 290,000 shares of common stock expiring on April 14, 2027, at an exercise price of $2.00 per share.

Going Concern

At March 31, 2022, the Company had cash of $3,777,742 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 and resources 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. Even if the Company is able to generate revenues through licensing its technologies or through product sales, there can be no assurance that the Company will be able to achieve positive earnings and operating cash flows.

The Company's consolidated financial statements have been presented on the basis that it will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has no recurring source of revenue and has experienced negative operating cash flows since inception. The Company has financed its working capital requirements primarily through the recurring sale of its equity securities.

As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern. The Company's independent registered public accounting firm, in its report on the Company's consolidated financial statements for the year ended December 31, 2021, has also expressed substantial doubt about the Company's ability to continue as a going concern. The Company's consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 profitability. The amount and timing of future cash requirements depends on the pace and design of the Company's clinical trial program, which, in turn, depends on the availability of operating capital to fund such activities.

Based on current operating plans, the Company estimates that existing cash resources, together with the proceeds of the April 12, 2022 registered direct equity offering, will provide sufficient working capital to fund the current clinical trial program with respect to the development of the Company's lead anti-cancer clinical compound LB-100 for approximately 18 months, through September 30, 2023. However, existing cash resources will not be sufficient to complete development of and obtain regulatory approval for the Company's product candidate, and the Company will need to raise significant additional capital to do so. In addition, the Company's operating plan may change as a result of many factors currently unknown, and additional funds may be needed sooner than planned.

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, as and when necessary, to continue to conduct operations. There is also significant uncertainty as to the effect that the coronavirus pandemic may have on the Company's clinical trial schedule and the amount and type of financing available to the Company in the future.

If cash resources are insufficient to satisfy the Company's ongoing cash requirements, the Company would be required to scale back or discontinue its clinical trial program, as well as its licensing and patent prosecution efforts and its technology and product development efforts, or obtain funds, if available, through strategic alliances or joint ventures that could require the Company to relinquish rights to and/or control of LB-100, or to discontinue operations entirely.

3. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying condesned 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

Cash is primarily held in a cash bank deposit program maintained by a major financial institution. The Company's policy is to maintain its cash balances with financial institutions with high credit ratings and in accounts insured by the Federal Deposit Insurance Corporation (the "FDIC") and/or by the Securities Investor Protection Corporation (the "SIPC"). The Company may periodically have cash balances in financial institutions in excess of the FDIC and SIPC insurance limits of $250,000 and $500,000, respectively. The financial institution that currently holds the Company's cash balances also maintains supplemental insurance coverage for its customers' cash balances. The Company has not experienced any losses to date resulting from this practice.

Research and Development

Research and development costs consist primarily of fees paid to consultants and contractors, and other expenses relating to the acquisition, design, development and clinical trials with respect to the Company's compounds and product candidates. Research and development costs also include the costs to produce the compounds used in research and clinical trials, which are charged to operations as incurred.

Research and development costs are generally charged to operations ratably over the life of the underlying contracts, unless the achievement of milestones, the completion of contracted work, the termination of an agreement, or other information indicates that a different expensing schedule is more appropriate. However, payments for research and development costs that are contractually defined as non-refundable are charged to operations as incurred.

Obligations incurred with respect to mandatory scheduled payments under research agreements with milestone provisions are recognized as charges to research and development costs in the Company's consolidated statement of operations based on the achievement of such milestones, as specified in the agreement. Obligations incurred with respect to mandatory scheduled payments under research agreements without milestone provisions are accounted for when due, 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.

Prepaid Insurance

Prepaid insurance represents the premiums paid for directors and officers insurance coverage and for general liability insurance coverage in excess of the amortization of the total policy premium charged to operations at each balance sheet date. Such amortization is determined by amortizing the total policy premium charged on a straight-line basis over the respective policy periods. As the policy premiums incurred are amortizable in the ensuing twelve-month period, they are recorded as a current asset in the Company's consolidated balance sheet at each reporting date and amortized to the Company's consolidated statement of operations for each reporting period.

Patent and Licensing Legal and Filing Fees and 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 and licensing legal and filing fees and costs related to the development and protection of its intellectual property are charged to operations as incurred. Patent and licensing legal and filing fees and costs were $315,237 and $120,160 for the three months ended March 31, 2022 and 2021, respectively. Patent and licensing legal and filing fees and costs are included in general and administrative costs in the Company's consolidated statements of operations.

Concentration of Risk

The Company periodically contracts with vendors and consultants to provide services related to the Company's operations. Charges incurred for these services can be for a specific time period (typically one year) or for a specific project or task. Costs and expenses incurred that represented 10% or more of general and administrative costs or research and development costs for the three months ended March 31, 2022 and 2021 are described as follows.

General and administrative costs for the three months ended March 31, 2022 and 2021 include charges from legal firms and other vendors for general licensing and patent prosecution costs relating to the Company's intellectual properties representing 29.3% of total general and administrative costs. General and administrative costs for the three months ended March 31, 2022 and 2021 also included charges for the fair value of stock options granted to directors and corporate officers representing 31.0% and 51.2%, respectively, of total general and administrative costs for those periods.

Research and development costs for the three months ended March 31, 2022 include charges from two vendors and consultants representing 63.8%, and 11.8%, respectively, of total research and development costs for that period. Research and development costs for the three months ended March 31, 2021 include charges from three vendors and consultants representing 54.2%, 15.9% and 13.9%, respectively, 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 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. 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, 2022 or 2021 and does not anticipate any material amount of unrecognized tax benefits within the 12 months subsequent to March 31, 2022.

The Company accounts for uncertainties in income tax law under a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns as prescribed by GAAP. The tax effects of a position are recognized only if it is "more-likely-than-not" to be sustained by the taxing authority as of the reporting date. If the tax position is not considered "more-likely-than-not" to be sustained, then no benefits of the position are recognized. The Company had not recorded any liability for uncertain tax positions as of March 31, 2022 or 2021. Subsequent to March 31, 2022, any interest and penalties related to uncertain tax positions will be recognized as a component of income tax expense.

Stock-Based Compensation

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

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

The fair value of stock options granted as stock-based compensation is determined utilizing the Black-Scholes option-pricing model, and is affected by several variables, the most significant of which are the expected life of the stock option, 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. Unless sufficient historical exercise data is available, the expected life of the stock option is calculated as the mid-point between the vesting period and the contractual term (the "simplified method"). The estimated volatility is based on the historical volatility of the Company's common stock, calculated utilizing a look-back period approximately equal to the contractual life of the stock option being granted. 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 expected dividend yield is based on the Company's expectation of dividend payouts and is assumed to be zero.

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, 2022 and 2021, 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,	
	2022	**2021**
Series A Convertible Preferred Stock	729,167	729,167
Common stock warrants	3,110,310	3,110,310
Common stock options, including options issued in the form of warrants	2,666,667	1,675,000
Total	6,506,144	5,514,477

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 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 August 2020, the FASB issued ASU 2020-06, Debt — Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU 2020-06"). ASU 2020-06 simplifies the accounting for convertible debt by eliminating the beneficial conversion and cash conversion accounting models. Upon adoption of ASU 2020-06, convertible debt proceeds, unless issued with a substantial premium or an embedded conversion feature that is not clearly and closely related to the host contract, will no longer be allocated between debt and equity components. This modification will reduce the issue discount and result in less non-cash interest expense in financial statements. ASU 2020-06 also updates the earnings per share calculation and requires entities to assume share settlement when the convertible debt can be settled in cash or shares. For contracts in an entity's own equity, the type of contracts primarily affected by ASU 2020-06 are freestanding and embedded features that are accounted for as derivatives under the current guidance due to a failure to meet the settlement assessment by removing the requirements to (i) consider whether the contract would be settled in registered shares, (ii) consider whether collateral is required to be posted, and (iii) assess shareholder rights. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, and only if adopted as of the beginning of such fiscal year. The Company adopted ASU 2020-06 effective January 1, 2021. The adoption of ASU 2020-06 did not have any impact on the Company's consolidated financial statement presentation or disclosures.

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt — Modifications and Extinguishments (Subtopic 470-50), Compensation — Stock Compensation (Topic 718), and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options ("ASU 2021-04"). ASU 2021-04 provides guidance as to how an issuer should account for a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option (i.e., a warrant) that remains classified after modification or exchange as an exchange of the original instrument for a new instrument. An issuer should measure the effect of a modification or exchange as the difference between the fair value of the modified or exchanged warrant and the fair value of that warrant immediately before modification or exchange and then apply a recognition model that comprises four categories of transactions and the corresponding accounting treatment for each category (equity issuance, debt origination, debt modification, and modifications unrelated to equity issuance and debt origination or modification). ASU 2021-04 is effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply the guidance provided in ASU 2021-04 prospectively to modifications or exchanges occurring on or after the effective date. The Company adopted ASU 2021-04 effective January 1, 2022. The adoption of ASU 2021-04 did not have any impact on the Company's consolidated financial statement presentation or disclosures.

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

4. Stockholders' Equity

Preferred Stock

The Company 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 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 Preferences, Rights and Limitations. 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, 2022 and December 31, 2021, the Company had 9,650,000 shares of undesignated preferred stock which 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 2.0833 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 729,167 shares of common stock at March 31, 2022 and December 31, 2021. The Series A Convertible Preferred Stock has no right to cash, except with respect to the payment of the aforementioned dividend based on the generation of revenues by the Company. The shares of Series A Convertible Preferred Stock do not have any registration rights.

Based on the attributes of the Series A Convertible Preferred Stock as previously described, the Company has accounted for the Series A Convertible Preferred Stock as a permanent component of stockholders' equity.

Common Stock

The Company is authorized to issue a total of 100,000,000 shares of common stock, par value $0.0001 per share. As of March 31, 2022 and December 31, 2021, the Company had 13,746,593 shares of common stock issued, issuable and outstanding.

During February and March 2021, the Company issued 3,000 shares of common stock upon the exercise of 3,000 warrants at $5.70 per share and received cash proceeds of $17,100.

Effective March 2, 2021, the Company completed the sale of 1,133,102 shares of common stock at a price of $3.70 per share in a registered direct equity offering, generating gross proceeds of $4,192,478. The total cash costs of this offering were $502,717, resulting in net cash proceeds of $3,689,761. Pursuant to the placement agents' agreement, the Company granted warrants to the placement agents to purchase up to 113,310 shares of common stock commencing on March 2, 2021 and expiring on March 2, 2026, at an exercise price of $3.70 per share.

Common Stock Warrants

A summary of common stock warrant activity during the three months ended March 31, 2022 is presented below.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Warrants outstanding at December 31, 2021	3,110,310	$ 5.772	
Issued	—	—	
Exercised	—	—	
Expired	—	—	
Warrants outstanding at March 31, 2022	3,110,310	$ 5.772	2.23

At March 31, 2022, the outstanding warrants are exercisable at the following prices per common share:

Exercise Prices	Warrants Outstanding (Shares)
$ 3.700	113,310
$ 5.700	1,497,000
$ 6.000	1,500,000
	3,110,310

Based on a fair market value of $1.23 per share on March 31, 2022, there was no intrinsic value attributed to exercisable but unexercised common stock warrants at March 31, 2022.

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

Related party transactions include transactions with the Company's officers, directors and affiliates.

Employment Agreements with Officers

During July and August 2020, the Company entered into one-year employment agreements with its executive officers, consisting of Dr. John S. Kovach, Eric J. Forman, Dr. James S. Miser, and Robert N. Weingarten, payable monthly, as described below. The employment agreements are automatically renewable for additional one-year periods unless terminated by either party upon 60 days written notice prior to the end of the applicable one-year period, or by death, or by termination for cause. These employment agreements were automatically renewed for an additional one-year period in July and August 2021.

The Company entered into an employment agreement with Dr. Kovach dated July 15, 2020, effective October 1, 2020, for Dr. Kovach to continue to act as the Company's President, Chief Executive Officer and Chief Scientific Officer with an annual salary of $250,000. During the three months ended March 31, 2022 and 2021, the Company paid $62,500 and $62,500, respectively, to Dr. Kovach under this employment agreement, which are included in general and administrative costs in the Company's consolidated statements of operations for such periods.

The Company entered into an employment agreement with Dr. James S. Miser, M.D., effective August 1, 2020 to act as the Company's Chief Medical Officer with an annual salary of $150,000. Effective May 1, 2021, Dr. Miser's annual salary was increased to $175,000. Dr. Miser is required to devote at least 50% of his business time to the Company's activities. During the three months ended March 31, 2022 and 2021, the Company paid $43,750 and $37,500, respectively, to Dr. Miser under this employment agreement, which are included in general and administrative costs in the Company's consolidated statements of operations for such periods.

The Company entered into an employment agreement with Eric J. Forman effective July 15, 2020, as amended on August 12, 2020, to act as the Company's Chief Administrative Officer with an annual salary of $120,000. Eric Forman is the son-in-law of Gil Schwartzberg, a member of the Company's Board of Directors, and a significant stockholder of and consultant to the Company, and is the son of Dr. Stephen Forman, a member of the Company's Board of Directors. Julie Forman, the wife of Eric Forman and the daughter of Gil Schwartzberg, is Vice President of Morgan Stanley Wealth Management, at which firm the Company's cash is on deposit and the Company maintains a continuing banking relationship. Effective May 1, 2021, Mr. Forman's annual salary was increased to $175,000. During the three months ended March 31, 2022 and 2021, the Company paid $43,750 and $30,000, respectively, to Mr. Forman under this employment agreement, which are included in general and administrative costs in the Company's consolidated statements of operations for such periods.

The Company entered into an employment agreement with Robert N. Weingarten effective August 12, 2020 to act as the Company's Vice President and Chief Financial Officer with an annual salary of $120,000. Effective May 1, 2021, Mr. Weingarten's annual salary was increased to $175,000. During the three months ended March 31, 2022 and 2021, the Company paid $43,750 and $30,000, respectively, to Mr. Weingarten under this employment agreement which are included in general and administrative costs in the Company's consolidated statements of operations for such periods.

Compensatory Arrangements for Board of Directors

Effective April 9, 2021, the Board of Directors approved a comprehensive cash and equity compensation package for the members of the Board of Directors and committee members.

The Board of Directors approved the following cash compensation for non-officer independent directors, payable quarterly:

Base director compensation - $20,000 per year
Chairman of audit committee - additional $10,000 per year
Chairman of any other committees - additional $5,000 per year
Member of audit committee - additional $5,000 per year
Member of any other committees - additional $2,500 per year

Total cash compensation paid to independent directors was $32,500 for the three months ended March 31, 2022.

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

A summary of related party costs, including compensation under employment and consulting agreements and fees paid to non-officer directors for their services on the Board of Directors, for the three months ended March 31, 2022 and 2021 is presented below.

	Three Months Ended March 31,	
	2022	2021
Related party costs:		
Cash-based	$ 226,250	$ 160,000
Stock-based	339,672	656,032
Total	$ 565,922	$ 816,032

6. Stock-Based Compensation

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

On July 14, 2020, the Board of Directors of the Company adopted the 2020 Stock Incentive Plan (the "2020 Plan"), which provides for the granting of equity-based awards, consisting of stock options, restricted stock, restricted stock units, stock appreciation rights, and other stock-based awards to employees, officers, directors and consultants of the Company and its affiliates for up to 2,333,333 shares of the Company's common stock, under terms and conditions as determined by the Company's Board of Directors. Stockholders holding a majority of the voting power of the common stock of the Company approved the 2020 Plan pursuant to an action by written consent dated July 31, 2020. Stockholders of the Company were notified of such action by written consent pursuant to an Information Statement dated August 31, 2020 and mailed to stockholders on or about September 3, 2020. As of March 31, 2022, unexpired stock options for 1,400,000 shares were issued and outstanding under the 2020 Plan and 933,333 shares were available for issuance under the 2020 Plan.

Effective April 9, 2021, the Board of Directors approved a comprehensive cash and equity compensation package for the members of the Board of Directors and committee members. Cash-based features of the compensation package are described at Notes 5 and 8.

Stock-based features of the compensation package consisted of the annual granting of stock options to each non-officer director to purchase 100,000 shares of common stock at the closing market price on the earlier of the date of the annual meeting of shareholders or the last business day of the month ending June 30, vesting 12.5% on the last day of each subsequent calendar quarter-end until fully vested, and the granting of stock options to a new director to purchase 250,000 shares of common stock, exercisable at the closing market price on the grant date for a period of five years, vesting 50% on the grant date and the remainder vesting 12.5% on the last day of each subsequent calendar quarter-end until fully vested.

The fair value of a stock option award 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 estimated volatility is based on the historical volatility of the Company's common stock, calculated utilizing a look-back period approximately equal to the contractual life of the stock option being granted. Unless sufficient historical exercise data is available, the expected life of the stock option is calculated as the mid-point between the vesting period and the contractual term (the "simplified method"). 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, 2022.

For stock options requiring an assessment of value during the three months ended March 31, 2021, the fair value of each stock option award was estimated using the Black-Scholes option-pricing model with the following assumptions:

Risk-free interest rate	0.80%
Expected dividend yield	0%
Expected volatility	201.47%
Expected life	2.5 years

On July 15, 2020, as amended on August 12, 2020, in connection with the employment agreement entered into with Eric J. Forman, Mr. Forman was granted options for 58,333 shares of the Company's common stock. The options can be exercised on a cashless basis. The options have a term of five years and an exercise price of $7.14 per share, which was equal to the closing market price of the Company's common stock on the grant date. The options vested as to 25% on August 12, 2020 and August 12, 2021, and will vest 25% on each of the second and third anniversaries of the grant date. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $400,855 ($6.8718 per share), of which $100,214 was attributable to the stock options fully-vested on August 12, 2020 and was therefore charged to operations on that date. The remaining unvested portion of the fair value of the stock options is being charged to operations ratably from August 12, 2020 through August 12, 2023. During the three months ended March 31, 2022 and 2021, the Company recorded charges to general and administrative costs in the consolidated statement of operations of $24,710 and $24,710, respectively, with respect to these stock options.

On August 1, 2020, in connection with an employment agreement entered into with Dr. James S. Miser, M.D., Dr. Miser was granted options for 83,334 shares of the Company's common stock. The options can be exercised on a cashless basis. The options have a term of five years and an exercise price of $7.14 per share, which was equal to the closing market price of the Company's common stock on the effective date of the employment agreement. The options vested as to 25% on August 1, 2020 and August 1, 2021, and will vest 25% on each of the second and third anniversaries of the effective date. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $572,650 ($6.8718 per share), of which $143,163 was attributable to the stock options fully-vested on August 1, 2020 and was therefore charged to operations on that date. The remaining unvested portion of the fair value of the stock options is being charged to operations ratably from August 1, 2020 through August 1, 2023. During the three months ended March 31, 2022 and 2021, the Company recorded charges to general and administrative costs in the consolidated statement of operations of $35,300 and $35,300, respectively, with respect to these stock options.

On August 12, 2020, in connection with the employment agreement entered into with Robert N. Weingarten, Mr. Weingarten was granted options for 58,333 shares of the Company's common stock. The options can be exercised on a cashless basis. The options have a term of five years and an exercise price of $7.14 per share, which was equal to the closing market price of the Company's common stock on the grant date. The options vested as to 25% on August 12, 2020 and August 12, 2021, and will vest 25% on each of the second and third anniversaries of the grant date. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $400,855 ($6.8718 per share), of which $100,214 was attributable to the stock options fully-vested on August 12, 2020 and was therefore charged to operations on that date. The remaining unvested portion of the fair value of the stock options is being charged to operations ratably from August 12, 2020 through August 12, 2023. During the three months ended March 31, 2022 and 2021, the Company recorded charges to general and administrative costs in the consolidated statement of operations of $24,710 and $24,710, respectively, with respect to these stock options.

Effective January 6, 2021, in recognition of their service as directors of the Company over the past year, the Company granted fully-vested stock options to purchase 50,000 shares of common stock to each of Dr. Winson Sze Chun Ho, Dr. Yun Yen, Dr. Stephen Forman, and Dr. Philip Palmedo (an aggregate of 200,000 shares), exercisable for a period of five years from the grant date at $3.21 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 $571,312 ($2.8566 per share) and was charged to general and administrative costs in the consolidated statement of operations on the grant date.

On April 9, 2021, Winson Sze Chun Ho resigned from the Company's Board of Directors to focus on clinical and pre-clinical cancer research in academic medicine. Concurrent with his resignation, the Board of Directors appointed Gil Schwartzberg to fill the vacancy created by Dr. Ho's resignation. In connection with his appointment to the Board of Directors, and in accordance with the Company's cash and equity compensation package for members of the Board of Directors, Mr. Schwartzberg was granted options exercisable for a period of five years to purchase 250,000 shares of the Company's common stock at an exercise price of $3.20 per share (the closing market price on the grant date), vesting 50% on the grant date and the remainder vesting 12.5% on the last day of each subsequent calendar quarter-end until fully vested. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $753,611 ($3.0144 per share), of which $376,800 was attributable to the stock options fully-vested on April 9, 2021 and was therefore charged to operations on that date. The remaining unvested portion of the fair value of the stock options is being charged to operations ratably from April 9, 2021 through June 30, 2023. During the three months ended March 31, 2022, the Company recorded a charge to general and administrative costs in the consolidated statement of operations of $41,764 with respect to these stock options.

On May 11, 2021, the Board of Directors appointed Regina Brown to the Board of Directors. In connection with her appointment to the Board of Directors, and in accordance with the Company's cash and equity compensation package for members of the Board of Directors, Ms. Brown was granted options exercisable for a period of five years to purchase 250,000 shares of the Company's common stock at an exercise price of $2.80 per share (the closing market price on the grant date), vesting 50% on the grant date and the remainder vesting 12.5% on the last day of each subsequent calendar quarter-end until fully vested. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $658,363 ($2.6335 per share), of which $329,188 was attributable to the stock options fully-vested on May 11, 2021 and was therefore charged to operations on that date. The remaining unvested portion of the fair value of the stock options is being charged to operations ratably from May 11, 2021 through June 30, 2023. During the three months ended March 31, 2022, the Company recorded a charge to general and administrative costs in the consolidated statement of operations of $37,983 with respect to these stock options.

On June 30, 2021, the Board of Directors, in accordance with the recently adopted cash and equity compensation package for the members of the Board of Directors, granted to each of the five non-officer directors of the Company stock options exercisable for a period of five years to purchase 100,000 shares (a total of 500,000 shares) of the Company's common stock at an exercise price of $3.03 per share (the closing market price on the grant date), vesting 12.5% on the last day of each subsequent calendar quarter-end until fully vested. The total fair value of the 500,000 stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $1,421,095 ($2.84225 per share), which is being charged to operations ratably from July 1, 2021 through June 30, 2023. During the three months ended March 31, 2022, the Company recorded a charge to general and administrative costs in the consolidated statement of operations of $175,205 with respect to these stock options.

A summary of stock-based compensation costs for the three months ended March 31, 2022 and 2021 is as follows:

	Three Months Ended March 31,	
	2022	**2021**
Related parties	$ 339,672	$ 656,032
Non-related parties	—	—
Total stock-based compensation costs	$ 339,672	$ 656,032

A summary of stock option activity, including options issued in the form of warrants, during the three months ended March 31, 2022 is presented below.

	Number of Shares	**Weighted Average Exercise Price**	**Weighted Average Remaining Contractual Life (in Years)**
Stock options outstanding at December 31, 2021	2,666,667	$ 3.738	
Granted	—	—	
Exercised	—	—	
Expired	—	—	
Stock options outstanding at March 31, 2022	2,666,667	$ 3.738	3.17
Stock options exercisable at March 31, 2022	2,097,917	$ 3.737	2.94

Total deferred compensation expense for the outstanding value of unvested stock options was approximately $1,757,000 at March 31, 2022, which will be recognized subsequent to March 31, 2022 over a weighted-average period of approximately 15 months.

The exercise prices of common stock options outstanding and exercisable, including options issued in the form of warrants, at March 31, 2022 are as follows:

Exercise Prices	Options Outstanding (Shares)	Options Exercisable (Shares)
$ 0.900	33,333	33,333
$ 1.680	66,667	66,667
$ 2.060	200,000	200,000
$ 2.800	250,000	171,875
$ 3.000	666,667	666,667
$ 3.030	500,000	187,500
$ 3.200	250,000	171,875
$ 3.210	200,000	200,000
$ 6.000	166,667	166,667
$ 6.600	50,000	50,000
$ 7.140	200,000	100,000
$ 12.000	83,333	83,333
	2,666,667	2,097,917

The intrinsic value of exercisable but unexercised in-the-money stock options at March 31, 2022 was approximately $11,000, based on a fair market value of $1.23 per share on March 31, 2022.

Outstanding stock options to acquire 568,750 shares of the Company's common stock had not vested at March 31, 2022.

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

7. Income Taxes

During the three months ended March 31, 2022 and 2021, the Company did not record any provision for income taxes as the Company incurred losses during those periods. Deferred tax assets and liabilities reflect the net tax effect of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company has recorded a full valuation allowance against its deferred tax assets for all periods presented as the Company believes it is more likely than not the deferred tax assets will not be realized.

8. 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, 2022, the Company was not subject to any pending or threatened legal claims or actions.

Principal Commitments

Clinical Trial Agreements

At March 31, 2022, the Company's contractual commitments pursuant to clinical trial agreements, clinical trial monitoring agreements, and agreements for the production of LB-100 for clinical use, as described below, aggregated $8,399,000, which are currently scheduled to be incurred through December 31, 2025. The Company's ability to conduct and fund these contractual commitments is subject to the timely availability of sufficient capital to fund such expenditures, as well as any changes in the allocation or reallocation of such funds to the Company's current or future clinical trial programs. The Company expects that the full amount of these expenditures will be incurred only if such clinical trial programs are conducted as originally designed and their respective enrollments and duration are not modified or reduced. Clinical trial programs, such as the types that the Company is engaged in, can be highly variable and can frequently involve a series of changes and modifications over time as clinical data is obtained and analyzed, and are frequently modified, suspended or terminated before the clinical trial endpoint. Accordingly, such contractual commitments as discussed herein should be considered as estimates only based on current clinical assumptions and conditions, and are typically subject to significant revisions over time.

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

In November 2018, the Company received approval from the U.S. Food and Drug Administration for its Investigational New Drug Application ("IND") to conduct a Phase 1b/2 clinical trial to evaluate the therapeutic benefit of LB-100 in patients with low and intermediate-1 risk MDS who have failed or are intolerant of standard treatment. Patients with MDS, although usually older, are generally well except for severe anemia requiring frequent blood transfusions. This Phase 1b/2 clinical trial utilizes LB-100 as a single agent in the treatment of patients with low and intermediate-1 risk MDS, including patients with del(5q) myelodysplastic syndrome (del5qMDS) failing first line therapy. The bone marrow cells of patients with del5qMDS are deficient in PP2A by virtue of an acquired mutation and are especially vulnerable to further inhibition of PP2A by LB-100. The clinical trial began at a single site in April 2019 and the first patient was entered into the clinical trial in July 2019. A total enrollment of 41 patients is planned. An interim analysis will be done after the first 21 patients are entered. If there are 3 or more responders but fewer than 7, an additional 20 patients will be entered. If at any point there are 7 or more responders, this will be sufficient evidence to support continued development of LB-100 for the treatment of low and intermediate-1 risk MDS. Recruitment has been slow and the Covid-19 pandemic has further reduced recruitment of patients into the protocol. At the current rate of accrual, the clinical trial is expected to be completed by June 30, 2025. However, with additional funds, the Company would consider adding two additional MDS centers to the Phase 2 portion of the study to accelerate patient accrual.

During the three months ended March 31, 2022 and 2021, the Company incurred costs of $3,332 and $7,384, respectively, pursuant to this agreement, which have been included in research and development costs in the Company's consolidated statements of operations. As of March 31, 2022, total costs of $108,009 have been incurred pursuant to this agreement. The Company's aggregate commitment pursuant to this agreement, less amounts previously paid to date, totaled approximately $600,000 as of March 31, 2022, which is expected to be incurred through December 31, 2025.

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

GEIS has a network of referral centers in Spain and across Europe that have an impressive track record of efficiently conducting innovative studies in ASTS. The Company agreed to provide GEIS with a supply of LB-100 to be utilized in the conduct of this clinical trial, as well as to provide funding for the clinical trial. The goal was to enter approximately 150 patients in this clinical trial over a period of two years. As advanced sarcoma is a very aggressive disease, the design of the study assumes a median progression free survival (PFS, no evidence of disease progression or death from any cause) of 4.5 months in the doxorubicin arm and an alternative median PFS of 7.5 months in the doxorubicin plus LB-100 arm to demonstrate a statistically significant decrease in relative risk of progression or death by adding LB-100. There is a planned interim analysis of the primary endpoint when approximately 50% of the 102 events required for final analysis is reached.

The Company had previously expected that this clinical trial would commence during the quarter ended June 30, 2020. However, during July 2020, the Spanish regulatory authority advised the Company that although it had approved the scientific and ethical basis of the protocol, it required that the Company manufacture new inventory of LB-100 under current Spanish pharmaceutical manufacturing standards. These standards were adopted subsequent to the production of the Company's existing LB-100 inventory.

A new batch of LB 100 has been prepared and is now undergoing the multitude of analytical studies of the formulated product necessary to gain approval for use in the European Union. Regulatory reviews by the European Union have been delayed, as a result of which the final review of the clinical product by Spanish regulatory authorities will also be delayed. Accordingly, the clinical trial is now estimated to begin during the quarter ending June 30, 2022 and be completed by June 30, 2025.

The interim analysis of this clinical trial could indicate either inferiority or superiority of LB-100 plus doxorubicin as compared to doxorubicin alone. A positive study would have the potential to change the standard therapy for this disease after four decades of failure to improve the marginal benefit of doxorubicin alone.

The Company's agreement with GEIS provides for various payments based on achieving specific milestones over the term of the agreement. Through March 31, 2022, the Company has paid GEIS an aggregate of $67,582 towards the second milestone payment for current work being done under this agreement.

During the three months ended March 31, 2022 and 2021, the Company incurred costs of $0 and $24,171, respectively, pursuant to this agreement, which have been included in research and development costs in the Company's consolidated statements of operations. As of March 31, 2022, total costs of $155,053 have been incurred pursuant to this agreement. The Company's aggregate commitment pursuant to this agreement, less amounts previously paid to date, totaled approximately $4,166,000 as of March 31, 2022, which is expected to be incurred through December 31, 2025.

In order to manufacture a new inventory supply of LB-100 for the GEIS clinical trial, the Company has engaged a number of vendors to carry out the multiple tasks needed to make and gain approval of a new clinical product for investigational study in Spain. These tasks include the synthesis under good manufacturing practices (GMP) of the active pharmacologic ingredient (API), with documentation of each of the steps involved by an independent auditor. The API is then transferred to a vendor that prepares the clinical drug product, also under GMP conditions documented by an independent auditor. The clinical drug product is then sent to a vendor to test for purity and sterility, provide appropriate labels, store the drug, and distribute the drug to the clinical centers for use in the clinical trials. A formal application documenting all steps taken to prepare the clinical drug product for clinical use must be submitted to the appropriate regulatory authorities for review and approval before being used in a clinical trial.

On November 2, 2021, the Company entered into a Development Agreement with Famar Health Care Services Madrid SA ("Famar") to prepare a new batch of clinical LB-100 for use in clinical trials to be conducted in the European Union. During the three months ended March 31, 2022, the Company incurred costs of $292,293, pursuant to this agreement, which has been included in research and development costs in the Company's consolidated statements of operations. The Company's aggregate commitment pursuant to this agreement, less amounts previously paid to date, totaled approximately $29,000 as of March 31, 2022, which is expected to be incurred through June 30, 2022.

As of March 31, 2022, the Company estimates that this program to provide new inventory of the clinical drug product for the Spanish sarcoma study, and potentially for subsequent multiple trials within the European Union will cost approximately $1,153,000. The Company's aggregate commitments under this program, less amounts previously paid to date, totaled approximately $206,000 as of March 31, 2022, which are expected to be incurred through December 31, 2022. As the production of the new inventory of the clinical drug product is being conducted in Europe and is paid for in Euros, final costs are subject to foreign currency fluctuations between the United States Dollar and the Euro.

City of Hope. Effective January 18, 2021, the Company executed a Clinical Research Support Agreement with the City of Hope National Medical Center, an NCI-designated comprehensive cancer center, and City of Hope Medical Foundation (collectively, "City of Hope"), to carry out a Phase 1b clinical trial of LB-100, the Company's first-in-class protein phosphatase inhibitor, combined with a standard regimen for treatment of untreated extensive- stage disease small cell lung cancer (ED-SCLC). LB-100 will be given in combination with carboplatin, etoposide and atezolizumab, an FDA-approved but marginally effective regimen, to previously untreated ED-SCLC patients. The dose of LB-100 will be escalated with the standard fixed doses of the 3-drug regimen to reach a recommended Phase 2 dose (RP2D). Patient entry will be expanded so that a total of 12 patients will be evaluable at the RP2D to confirm the safety of the LB-100 combination and to look for potential therapeutic activity as assessed by objective response rate, duration of overall response, progression-free-survival and overall survival.

The clinical trial was initiated on March 9, 2021, with patient accrual expected to take approximately two years to complete. If LB-100 does potentiate the benefit of the standard regimen, some evidence could be noted at 12 months into the clinical trial, but an assessment of potential increased activity is likely to require at least 24 months. The Company is currently seeking to add two additional centers to increase the rate of accrual. The Company expects this clinical trial to be completed by June 30, 2024.

During the three months ended March 31, 2022 and 2021, the Company incurred costs of $0 and $240,508, respectively, pursuant to this agreement. The Company's aggregate commitment pursuant to this agreement, less amounts previously paid to date, totaled approximately $2,433,000 as of March 31, 2022, which is expected to be incurred through December 31, 2024, based upon a target of 42 enrollees. If a significant number of patients fail during the dose-escalation process, an increase of up to 12 patients would likely be necessary, at an estimated additional cost of approximately $800,000. The Company currently expects that enrollment in this clinical trial will range from approximately 18 to 30 enrollees, with 24 enrollees as the most likely number. Should fewer than 42 enrollees be required, the Company has agreed to compensate City of Hope on a per enrollee basis.

National Cancer Institute Pharmacologic Clinical Trial. In May 2019, the National Cancer Institute (NCI) initiated a glioblastoma (GBM) pharmacologic clinical trial. During the fourth quarter of 2019, the NCI enrolled the first two patients of a planned eight patient pharmacologic study of the ability of LB-100 to enter the brain and penetrate recurrent brain tumors in patients where surgical removal of the cancers is indicated (clinical trials registry NCT03027388). This study is being conducted and funded by the NCI under a Cooperative Research and Development Agreement, with the Company being required to provide the LB-100 clinical compound.

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

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

The neurosurgical unit at the NCI, which had been closed due to the Covid-19 epidemic, has reopened, and patient accrual has resumed. Patient entry remains at two, with the goal to enter eight patients before analyzing results. There is an urgent need to improve therapy for this type of aggressive brain tumor. If the NCI study shows that LB-100 does penetrate the brain, a clinical study of LB-100 in combination with standard therapy for GBM, the drug temozolomide and radiation, both of which have been well documented in pre-clinical studies to be significantly enhanced by LB-100, would be of significant interest to neuro-oncologists frustrated by decades of limited advances in therapy for this common brain tumor in adults.

Clinical Trial Monitoring Agreements

Moffitt. On September 12, 2018, the Company finalized a work order agreement with Theradex Systems, Inc. ("Theradex"), an international contract research organization ("CRO"), to monitor the Phase 1b/2 clinical trial being managed and conducted by Moffitt. The clinical trial began in April 2019 and the first patient was entered into the clinical trial in July 2019. At the current rate of accrual, the clinical trial is expected to be completed by June 30, 2025.

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, 2022 and 2021, the Company incurred costs of $3,281 and $941, respectively, pursuant to this work order. As of March 31, 2022, total costs of $95,166 have been incurred pursuant to this work order agreement. The Company's aggregate commitment pursuant to this clinical trial monitoring agreement, less amounts previously paid to date, totaled approximately $864,000 as of March 31, 2022, which is expected to be incurred through June 30, 2025.

City of Hope. On February 5, 2021, the Company signed a new work order agreement with Theradex to monitor the City of Hope investigator-initiated clinical trial in small cell lung cancer in accordance with FDA requirements for oversight by the sponsoring party. During the three months ended March 31, 2022 and 2021, the Company incurred costs of $4,500 and $3,540, respectively, pursuant to this work order. As of March 31, 2022, total costs of $29,126 have been incurred pursuant to this work order agreement. The Company's aggregate commitment pursuant to this clinical trial monitoring agreement, less amounts previously paid to date, totaled approximately $307,000 as of March 31, 2022, which is expected to be incurred through June 30, 2025.

Patent and License Agreements

On March 22, 2018, the Company entered into a Patent Assignment and Exploitation Agreement with INSERM TRANSFERT SA, acting as delegatee of the French National Institute of Health and Medical Research, for the assignment to 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 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 initial plan was to complete the validation process to evaluate LB-100 for the treatment of depressive or stress disorders in humans within three years; however, the exploitation of this patent for the treatment of depressive and stress disorders in humans will require substantial additional capital and/or a joint venture or other type of business arrangement with a pharmaceutical company with substantially greater capital and business resources than those available to the Company. As there can be no assurances that the Company will be able to obtain the capital or business resources necessary to focus on the exploitation of this patent, it is uncertain as to when, if at all, the Company may reach any of the development or commercialization milestones under the Agreement. As of March 31, 2022 and December 31, 2021, no amounts were due under this agreement.

Effective August 20, 2018, the Company entered into an Exclusive License Agreement with Moffitt. Pursuant to the License Agreement, Moffitt granted the Company an exclusive license under certain patents owned by Moffitt (the "Licensed Patents") relating to the treatment of MDS and a non-exclusive license under inventions, concepts, processes, information, data, know-how, research results, clinical data, and the like (other than the Licensed Patents) necessary or useful for the practice of any claim under the Licensed Patents or the use, development, manufacture or sale of any product for the treatment of MDS which would otherwise infringe a valid claim under the Licensed Patents. The Company was obligated to pay Moffitt a non-refundable license issue fee of $25,000 after the first patient is entered into a Phase 1b/2 clinical trial to be managed and conducted by Moffitt. The clinical trial began at a single site in April 2019 and the first patient was entered into the clinical trial in July 2019. The Company is also obligated to pay Moffitt an annual license maintenance fee of $25,000 commencing on the first anniversary of the Effective Date and every anniversary thereafter until the Company commences payment of minimum royalty payments. The Company has also agreed to pay non-refundable milestone payments to Moffitt, which cannot be credited against earned royalties payable by the Company, based on reaching various clinical and commercial milestones aggregating $1,897,000, subject to reduction by 40% under certain circumstances relating to the status of Valid Claims, as such term is defined in the License Agreement. During the three months ended March 31, 2022 and 2021, the Company recorded charges to operations of $6,165 and $6,164, respectively, in connection with its obligations under the License Agreement. As of March 31, 2022, 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.

Employment Agreements with Officers

During July and August 2020, the Company entered into one-year employment agreements with its executive officers, consisting of Dr. John S. Kovach, Eric J. Forman, Dr. James S. Miser, and Robert N. Weingarten, which provided for aggregate annual compensation of $640,000, payable monthly (see Note 5). The employment agreements are automatically renewable for additional one-year periods unless terminated by either party upon 60 days written notice prior to the end of the applicable one-year period, or by death, or by termination for cause. These employment agreements were automatically renewed for an additional one-year period in July and August 2021.

On April 9, 2021, the Board of Directors increased the annual compensation of Eric J. Forman, the Company's Chief Administrative Officer, Dr. James S. Miser, the Company's Chief Medical Officer, and Robert N. Weingarten, the Company's Chief Financial Officer, under the employment agreements such that the total aggregate annual compensation of all officers increased to $775,000, effective May 1, 2021.

Other Significant Agreements and Contracts

On December 24, 2013, the Company entered into an agreement with NDA Consulting Corp. for consultation and advice in the field of oncology research and drug development. As part of the agreement, NDA also agreed to cause its president, Dr. Daniel D. Von Hoff, M.D., to become a member of the Company's Scientific Advisory Committee. The term of the agreement was for one year and provided for a quarterly cash fee of $4,000. The agreement has been automatically renewed for additional one-year terms on its anniversary date since 2014. Consulting and advisory fees charged to operations pursuant to this agreement were $4,000 and $4,000 for the three months ended March 31, 2022 and 2021, 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. The Company recorded charges to operations pursuant to this Collaboration Agreement of $30,000 and $30,000 for the three months ended March 31, 2022 and 2021, respectively, which were included in research and development costs in the consolidated statements of operations.

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

The research team at the University of California, Davis recently completed their pre-clinical study of the potential benefit of LB-100 in a mouse model of AS, and the results are currently under review by FAST. The preliminary analysis indicates that the positive results previously reported by Chinese investigators were not confirmed in the US model. The Company is awaiting input from FAST as to whether it intends to continue to pursue pre-clinical studies of LB 100.

On October 8, 2021, the Company entered into a Development Collaboration Agreement with the Netherlands Cancer Institute, Amsterdam (NKI), one of the world's leading comprehensive cancer centers, and Oncode Institute, Utrecht, a major independent cancer research center, to identify the most promising drugs to be combined with LB-100, and potentially LB-100 analogues, to be used to treat a range of cancers, as well as to identify the specific molecular mechanisms underlying the identified combinations. The Company has agreed to fund the study and provide a sufficient supply of LB-100 to conduct the study. The study is expected to take approximately two years to conduct. During the three months ended March 31, 2022, the Company incurred charges in the amount of $54,230 with respect to this agreement, which amount is included in research and development costs in the Company's consolidated statements of operations. As of March 31, 2022, total costs of $109,478 have been incurred pursuant to this collaboration agreement. The Company's aggregate commitment pursuant to this collaboration agreement, less amounts previously paid to date, totaled approximately $380,000 as of March 31, 2022, which is expected to be incurred through June 30, 2025.

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

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

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

The Company is continuing to monitor the situation and will adjust its current business and financing plans as more information and guidance become available.

9. Subsequent Events

The Company performed an evaluation of subsequent events through the date of filing of these condensed consolidated financial statements with the SEC. Other than those matters described below, there were no material subsequent events which affected, or could affect, the amounts or disclosures in the condensed consolidated financial statements.

Sale of Common Stock

Effective April 12, 2022, the Company completed the sale of 2,900,000 shares of common stock at a price of $2.00 per share in a registered direct equity offering, generating gross proceeds of $5,800,000. The total cash costs of this offering were approximately $633,840, resulting in net proceeds of approximately $5,166,160. Pursuant to the placement agents' agreement, the Company granted to the placement agents warrants to purchase up to 290,000 shares of common stock expiring on April 14, 2027, at an exercise price of $2.00 per share.

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

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, 2021, 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.

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

The 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, relies on stock-based compensation for a substantial portion of employee and consultant compensation, does not have positive cash flows from operations, and is dependent on periodic infusions of equity capital to fund its operating requirements.

Recent Developments

The following is a summary of recent developments, including information contained in recent news releases issued by the Company:

January 12, 2022 - The Company reported that its recent collaboration with the Netherlands Cancer Institute (NKI), Amsterdam, one of the world's leading comprehensive cancer centers, and Stichting Oncode Institute (Oncode Institute), Utrecht, a major independent cancer research center, has led to an initial joint patent application covering LB-100 combination therapy with one of several other investigational compounds. The Company, NKI and Oncode Institute believe that the combination therapy would provide unexpectedly strong synergistic anti-cancer effects in cancer patients. The Company previously announced its entry into a collaboration with the NKI and the Oncode Institute to identify the most promising drugs to be used in combination with the Company's LB-100 or with one of the Company's LB-100 analogues to treat a range of cancers, as well as to identify the specific molecular mechanisms underlying the identified combinations.

March 22, 2022 – The Company noted findings by a team of physician-scientists led by principal investigator Dr. Amir Jazaeri, professor of Gynecologic Oncology and Reproductive Medicine at The University of Texas MD Anderson Cancer Center, and reported at the annual meeting of Society of Gynecologic Oncology (SGO) in Phoenix, Arizona, that a subset of patients with ovarian clear cell carcinoma (OCCC) treated with immune checkpoint inhibitors lived significantly longer (had increased overall survival) than most patients with the same disease treated with the same regimens.

Dr. Emily Hinchcliff (now at Northwestern University Cancer Center), the lead author of the report, noted that based on observations in two exceptional survivors, her team became interested in survival outcomes in patients with inactivating somatic tumor mutations in PPP2R1A, the major scaffold subunit of the protein phosphatase 2A (PP2A) multimeric enzyme. This presentation included preliminary results of 28 recurrent, platinum-resistant OCCC patients enrolled on an ongoing clinical trial testing the efficacy of CTLA4- and PD-L1-targeting immune checkpoint inhibitors (clinicaltrials.gov identifier: NCT03026062). Median overall survival was not reached in seven patients with hotspot inactivation mutations in PPP2R1A versus 6.4 months in the 21 patients without such mutations (p=0.018; HR=0.13 (95% CI: 0.02-0.95). Of note in several patients, response or prolonged disease stabilization leading to longer survival occurred after initial progression. Inactivating mutations in PPP2R1A are known to reduce the enzymatic activity of PP2A.

April 12, 2022 – The Company announced that Professor René Bernards, Netherlands Cancer Institute (NKI), Amsterdam, presented new data from promising drug combinations of the Company's lead clinical cancer compound, LB-100, at the Annual Meeting of American Association for Cancer Research (AACR) in New Orleans, Lousiana, on April 11, 2022.

In brief, the Company's first-in-class lead clinical compound and protein phosphatase 2A (PP2A) inhibitor, LB-100, induces further activation of oncogenic signaling in a number of KRAS-mutant cancers, rendering them particularly vulnerable to anti-cancer therapy. Professor Bernards' presentation, entitled "Unconventional Approaches to the Treatment of Cancer", was delivered as part of the events celebrating Professor Bernards' selection as the awardee of the 2022 AACR Princess Takamatsu Memorial Lectureship. The AACR stated that this award "recognizes an individual scientist whose novel and significant work has had or may have a far-reaching impact on the detection, diagnosis, treatment, or prevention of cancer, and who embodies the dedication of [Princess Takamatsu] to multinational collaborations." AACR is the largest cancer research organization in the world, with more than 50,000 members residing in 129 countries and territories.

Professor Bernards discussed his paradoxical approach to developing more effective cancer therapies. The initial studies, done in collaboration with the Company, reveal that the vigorous activation of several oncogenic signaling pathways by LB-100 is associated with marked increases in DNA damage and mitotic stress. CRISPR-based genetic screening and screening of selected investigational compounds both showed that LB-100 is synthetically lethal in combination with inhibitors of the mitotic entry kinase WEE1. Results were confirmed in a group of colorectal cancer cell lines bearing diverse mutations. The mechanisms responsible for these unexpected activities of LB-100 combined with WEE1 kinase inhibitors were presented.

Sale of Common Stock

Effective April 12, 2022, the Company completed the sale of 2,900,000 shares of common stock at a price of $2.00 per share in a registered direct equity offering, generating gross proceeds of $5,800,000. The total cash costs of this offering were approximately $633,840, resulting in net proceeds of approximately $5,166,160. Pursuant to the placement agents' agreement, the Company granted to the placement agents warrants to purchase up to 290,000 shares of common stock expiring on April 14, 2027, at an exercise price of $2.00 per share.

Going Concern

At March 31, 2022, the Company had cash of $3,777,742 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 and resources 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. Even if the Company is able to generate revenues through licensing its technologies or through product sales, there can be no assurance that the Company will be able to achieve positive earnings and operating cash flows.

The Company's consolidated financial statements have been presented on the basis that it will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has no recurring source of revenue and has experienced negative operating cash flows since inception. The Company has financed its working capital requirements primarily through the recurring sale of its equity securities.

As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern. The Company's independent registered public accounting firm, in its report on the Company's consolidated financial statements for the year ended December 31, 2021, has also expressed substantial doubt about the Company's ability to continue as a going concern. The Company's consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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, 2022 and 2021 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, 2022 and 2021 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. There were no changes to the critical accounting policies described in the consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 that impacted the Company's condensed consolidated financial statements and related notes for the three months ended March 31, 2022.

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 contractors, and other expenses relating to the acquisition, design, development and clinical trials with respect to the Company's compounds and product candidates. Research and development costs also include the costs to produce the compounds used in research and clinical trials, which are charged to operations as incurred.

Research and development costs are generally charged to operations ratably over the life of the underlying contracts, unless the achievement of milestones, the completion of contracted work, the termination of an agreement, or other information indicates that a different expensing schedule is more appropriate. However, payments for research and development costs that are contractually defined as non-refundable are charged to operations as incurred.

Obligations incurred with respect to mandatory scheduled payments under research agreements with milestone provisions are recognized as charges to research and development costs in the Company's consolidated statement of operations based on the achievement of such milestones, as specified in the agreement. Obligations incurred with respect to mandatory scheduled payments under research agreements without milestone provisions are accounted for when due, 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 Legal and Filing Fees and 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 and licensing legal and filing fees and costs are charged to operations as incurred. Patent and licensing legal and filing fees and costs are included in general and administrative costs in the Company's consolidated statements of operations.

During the three months ended March 31, 2022 and 2021, patent and licensing legal and filing fees and costs related to the development and protection of its intellectual property were $315,237 and $120,160, respectively, an increase of $195,077, or 162.3% in 2022, as compared to 2021.

In late 2021, the Company engaged a new patent law firm highly regarded for its expertise in biotechnology. This firm conducted a comprehensive analysis of the Company's extensive patent portfolio in order to implement a program to maximize the Company's intellectual property protection, both domestically and internationally. In addition, several new patents were recently filed, reflecting potential new uses of the Company's unique lead clinical compound LB-100 in cancer therapy. These activities have resulted in an increase in patent and licensing legal and filing fees and costs in 2022 as compared to 2021, and the Company expects that such patent and licensing related legal and filing costs will continue, and may increase, in 2022 and thereafter as the Company continues to develop and expand its patent portfolio related to the clinical development of LB-100.

Stock-Based Compensation

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

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

The fair value of stock options granted as stock-based compensation is determined utilizing the Black-Scholes option-pricing model, and is affected by several variables, the most significant of which are the expected life of the stock option, 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. Unless sufficient historical exercise data is available, the expected life of the stock option is calculated as the mid-point between the vesting period and the contractual term (the "simplified method"). The estimated volatility is based on the historical volatility of the Company's common stock, calculated utilizing a look-back period approximately equal to the contractual life of the stock option being granted. 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 expected dividend yield is based on the Company's expectation of dividend payouts and is assumed to be zero.

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.

Summary of Business Activities and Plans

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

Product Candidates

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

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

The LB-200 series consists of histone deacetylase inhibitors (HDACi). Many pharmaceutical companies are also developing drugs of this type, and at least two companies have HDACi approved for clinical use, in both cases for the treatment of a type of lymphoma. Despite this significant competition, the Company has demonstrated that its HDACi have broad activity against many cancer types, have neuroprotective activity, and have anti-fungal activity. In addition, these compounds have low toxicity. LB-200 has not yet advanced to the clinical stage and would require additional capital to fund further development. Accordingly, because of the Company's focus on the clinical development of LB-100 and analogs for cancer therapy as described below in more detail, the Company have decided not to actively pursue the pre-clinical development of our LB-200 series of compounds at this time. At this time, the Company intend to only maintain composition of matter patents for LB-200.

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

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

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

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 Activities

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

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

The Company is continuing to monitor the situation and will adjust its current business and financing plans as more information and guidance become available.

Results of Operations

At March 31, 2022, 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,	
	2022	**2021**
Revenues	$ —	$ —
Costs and expenses:		
General and administrative costs:		
Compensation to related parties	565,922	816,032
Patent and licensing legal and filing fees and costs	315,237	120,160
Other	314,743	345,462
Research and development costs	458,450	443,526
Total costs and expenses	1,654,352	1,725,180
Loss from operations	(1,654,352)	(1,725,180)
Interest income	109	146
Interest expense	(2,494)	(2,099)
Foreign currency loss	(181)	(11)
Net loss	$ (1,656,918)	$ (1,727,144)
Net loss per common share – basic and diluted	$ (0.12)	$ (0.14)
Weighted average common shares outstanding – basic and diluted	13,746,593	12,768,201

Three Months Ended March 31, 2022 and 2021

Revenues. The Company did not have any revenues for the three months ended March 31, 2022 and 2021.

General and Administrative Costs. For the three months ended March 31, 2022, general and administrative costs were $1,195,902, which consisted of the fair value of vested stock options issued to directors and officers of $339,672, patent and licensing legal and filing fees and costs of $315,237, other consulting and professional fees of $137,715, insurance expense of $117,135, officer's salary and related costs of $210,867, cash-based director and committee fees of $32,500, licensing fees of $6,165, shareholder reporting costs of $2,954, listing fees of $14,875, filing fees of $5,324, taxes and licenses of $4,069, and other operating costs of $9,389.

For the three months ended March 31, 2021, general and administrative costs were $1,281,654, which consisted of the fair value of vested stock options issued to directors and officers of $656,032, patent and licensing legal and filing fees and costs of $120,160, other consulting and professional fees of $194,882, insurance expense of $87,757, officer's salary and related costs of $173,582, licensing fees of $6,164, shareholder reporting costs of $10,386, listing fees of $14,500, filing fees of $9,574, taxes and licenses of $4,669, and other operating costs of $3,948.

General and administrative costs decreased by $85,752, or 6.7%, in 2022 as compared to 2021, primarily as a result of a decrease in the fair value of vested stock options issued to directors and officers of $316,360, and a decrease in other consulting and professional fees of $57,167, offset by an increase in patent and licensing legal and filing fees and costs of $195,077, an increase in cash-based director and committee fees of $32,500, an increase in insurance expense of $29,378, and an increase in officer's salary and related costs of $37,285.

Research and Development Costs. For the three months ended March 31, 2022, research and development costs were $458,450, which consisted of contractor costs incurred in connection with the synthesis work done to develop a new supply of LB-100 of $332,713, clinical and related oversight costs of $11,113, and pre-clinical research focused on development of additional novel anti-cancer compounds to add to the Company's clinical pipeline of $114,624.

For the three months ended March 31, 2021, research and development costs were $443,526, which consisted of contractor costs incurred in connection with the synthesis work done to develop a new supply of LB-100 of $132,286, clinical and related oversight costs of $276,544, which included an upfront payment to City of Hope of $240,508 upon execution of the Clinical Research Support Agreement in January 2021, and pre-clinical research focused on development of additional novel anti-cancer compounds to add to the Company's clinical pipeline of $34,696.

Research and development costs increased by $14,924, or 3.4%, in 2022 as compared to 2021, primarily as a result of an increase in contractor costs incurred in connection with the synthesis work done to develop a new supply of LB-100 of $200,427, and an increase in pre-clinical research focused on development of additional novel anti-cancer compounds to add to the Company's clinical pipeline of $79,928. These costs were offset by a decrease in clinical and related oversight costs of $265,431, including an upfront payment to City of Hope of $240,508 upon execution of the Clinical Research Support Agreement in January 2021. The absence of costs associated with ongoing clinical trials during the three months ended March 31, 2022 and 2021 reflects the slow accrual of patients into such clinical trials.

Interest Income. For the three months ended March 31, 2022, the Company had interest income of $109, as compared to interest income of $146 for the three months ended March 31, 2021, related to the investment of funds generated by the Company's financing activities.

Interest Expense. For the three months ended March 31, 2022, the Company had interest expense of $2,494, as compared to interest expense of $2,099 for the three months ended March 31, 2021, related to the financing of its directors and officers liability insurance policy premium.

Foreign Currency Loss. For the three months ended March 31, 2022, the Company had a loss from foreign currency transactions of $181, as compared to a loss from foreign current transactions of $11 for the three months ended March 31, 2021.

Net Loss. For the three months ended March 31, 2022, the Company incurred a net loss of $1,656,918, as compared to a net loss of $1,727,144 for the three months ended March 31, 2021.

Liquidity and Capital Resources – March 31, 2022

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

	Three Months Ended March 31,	
	2022	2021
Net cash used in operating activities	$ (1,035,097)	$ (1,026,337)
Net cash provided by (used in) investing activities	—	—
Net cash provided by (used in) financing activities	(10,906)	3,696,394
Net increase (decrease) in cash	$ (1,046,003)	$ 2,670,057

At March 31, 2022, the Company had working capital of $3,462,186, as compared to working capital of $4,790,338 at December 31, 2021, reflecting a decrease in working capital of $1,328,152 for the three months ended March 31, 2022. The decrease in working capital during the three months ended March 31, 2022 was the result of funding the Company's research and development activities and ongoing operating expenses, including the Company's clinical trial program and maintaining and developing its patent portfolio. At March 31, 2022, the Company had cash of $3,777,742 available to fund its operations.

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 profitability. The amount and timing of future cash requirements depends on the pace and design of the Company's clinical trial program, which, in turn, depends on the availability of operating capital to fund such activities.

Effective April 12, 2022, the Company completed the sale of 2,900,000 shares of common stock at a price of $2.00 per share in a registered direct equity offering, generating gross proceeds of $5,800,000. The total cash costs of this offering were approximately $633,840, resulting in net proceeds of approximately $5,166,160.

Based on current operating plans, the Company estimates that existing cash resources, together with the proceeds of the April 12, 2022 registered direct equity offering, will provide sufficient working capital to fund the current clinical trial program with respect to the development of the Company's lead anti-cancer clinical compound LB-100 for approximately 18 months, through September 30, 2023. However, existing cash resources will not be sufficient to complete development of and obtain regulatory approval for the Company's product candidate, and the Company will need to raise significant additional capital to do so. In addition, the Company's operating plan may change as a result of many factors currently unknown, and additional funds may be needed sooner than planned.

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, as and when necessary, to continue to conduct operations. There is also significant uncertainty as to the effect that the coronavirus pandemic may have on the Company's clinical trial schedule and the amount and type of financing available to the Company in the future.

If cash resources are insufficient to satisfy the Company's ongoing cash requirements, the Company would be required to scale back or discontinue its clinical trial program, as well as its licensing and patent prosecution efforts and its technology and product development efforts, or obtain funds, if available, through strategic alliances or joint ventures that could require the Company to relinquish rights to and/or control of LB-100, or to discontinue operations

Operating Activities. For the three months ended March 31, 2022, operating activities utilized cash of $1,035,097, as compared to utilizing cash of $1,026,337 for the three months ended March 31, 2021, 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, 2022 and 2021, the Company had no investing activities.

Financing Activities. For the three months March 31, 2022, financing activities consisted of the payment of deferred offering costs of $10,906. For the three months ended March 31, 2021, financing activities consisted of the gross proceeds from the sales of common stock in the Company's direct equity offering of $4,192,478, reduced by offering costs of $502,717, and $17,100 from the exercise of common stock warrants. The Company also paid offering costs of $10,467 during the three months ended March 31, 2021.

Principal Commitments

Clinical Trial Agreements

At March 31, 2022, the Company's contractual commitments pursuant to clinical trial agreements, clinical trial monitoring agreements, and agreements for the production of LB-100 for clinical use, as described below, aggregated $8,399,000, which are currently scheduled to be incurred through December 31, 2025. The Company's ability to conduct and fund these contractual commitments is subject to the timely availability of sufficient capital to fund such expenditures, as well as any changes in the allocation or reallocation of such funds to the Company's current or future clinical trial programs. The Company expects that the full amount of these expenditures will be incurred only if such clinical trial programs are conducted as originally designed and their respective enrollments and duration are not modified or reduced. Clinical trial programs, such as the types that the Company is engaged in, can be highly variable and can frequently involve a series of changes and modifications over time as clinical data is obtained and analyzed, and are frequently modified, suspended or terminated before the clinical trial endpoint. Accordingly, such contractual commitments as discussed herein should be considered as estimates only based on current clinical assumptions and conditions, and are typically subject to significant revisions over time.

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

In November 2018, the Company received approval from the U.S. Food and Drug Administration for its Investigational New Drug Application ("IND") to conduct a Phase 1b/2 clinical trial to evaluate the therapeutic benefit of LB-100 in patients with low and intermediate-1 risk MDS who have failed or are intolerant of standard treatment. Patients with MDS, although usually older, are generally well except for severe anemia requiring frequent blood transfusions. This Phase 1b/2 clinical trial utilizes LB-100 as a single agent in the treatment of patients with low and intermediate-1 risk MDS, including patients with del(5q) myelodysplastic syndrome (del5qMDS) failing first line therapy. The bone marrow cells of patients with del5qMDS are deficient in PP2A by virtue of an acquired mutation and are especially vulnerable to further inhibition of PP2A by LB-100. The clinical trial began at a single site in April 2019 and the first patient was entered into the clinical trial in July 2019. A total enrollment of 41 patients is planned. An interim analysis will be done after the first 21 patients are entered. If there are 3 or more responders but fewer than 7, an additional 20 patients will be entered. If at any point there are 7 or more responders, this will be sufficient evidence to support continued development of LB-100 for the treatment of low and intermediate-1 risk MDS. Recruitment has been slow and the Covid-19 pandemic has further reduced recruitment of patients into the protocol. At the current rate of accrual, the clinical trial is expected to be completed by June 30, 2025. However, with additional funds, the Company would consider adding two additional MDS centers to the Phase 2 portion of the study to accelerate patient accrual.

During the three months ended March 31, 2022 and 2021, the Company incurred costs of $3,332 and $7,384, respectively, pursuant to this agreement, which have been included in research and development costs in the Company's consolidated statements of operations. As of March 31, 2022, total costs of $108,009 have been incurred pursuant to this agreement. The Company's aggregate commitment pursuant to this agreement, less amounts previously paid to date, totaled approximately $600,000 as of March 31, 2022, which is expected to be incurred through December 31, 2025.

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

GEIS has a network of referral centers in Spain and across Europe that have an impressive track record of efficiently conducting innovative studies in ASTS. The Company agreed to provide GEIS with a supply of LB-100 to be utilized in the conduct of this clinical trial, as well as to provide funding for the clinical trial. The goal was to enter approximately 150 patients in this clinical trial over a period of two years. As advanced sarcoma is a very aggressive disease, the design of the study assumes a median progression free survival (PFS, no evidence of disease progression or death from any cause) of 4.5 months in the doxorubicin arm and an alternative median PFS of 7.5 months in the doxorubicin plus LB-100 arm to demonstrate a statistically significant decrease in relative risk of progression or death by adding LB-100. There is a planned interim analysis of the primary endpoint when approximately 50% of the 102 events required for final analysis is reached.

The Company had previously expected that this clinical trial would commence during the quarter ended June 30, 2020. However, during July 2020, the Spanish regulatory authority advised the Company that although it had approved the scientific and ethical basis of the protocol, it required that the Company manufacture new inventory of LB-100 under current Spanish pharmaceutical manufacturing standards. These standards were adopted subsequent to the production of the Company's existing LB-100 inventory.

A new batch of LB 100 has been prepared and is now undergoing the multitude of analytical studies of the formulated product necessary to gain approval for use in the European Union. Regulatory reviews by the European Union have been delayed, as a result of which the final review of the clinical product by Spanish regulatory authorities will also be delayed. Accordingly, the clinical trial is now estimated to begin during the quarter ending June 30, 2022 and be completed by June 30, 2025.

The interim analysis of this clinical trial could indicate either inferiority or superiority of LB-100 plus doxorubicin as compared to doxorubicin alone. A positive study would have the potential to change the standard therapy for this disease after four decades of failure to improve the marginal benefit of doxorubicin alone.

The Company's agreement with GEIS provides for various payments based on achieving specific milestones over the term of the agreement. Through March 31, 2022, the Company has paid GEIS an aggregate of $67,582 towards the second milestone payment for current work being done under this agreement.

During the three months ended March 31, 2022 and 2021, the Company incurred costs of $0 and $24,171, respectively, pursuant to this agreement, which have been included in research and development costs in the Company's consolidated statements of operations. As of March 31, 2022, total costs of $155,053 have been incurred pursuant to this agreement. The Company's aggregate commitment pursuant to this agreement, less amounts previously paid to date, totaled approximately $4,166,000 as of March 31, 2022, which is expected to be incurred through December 31, 2025.

In order to manufacture a new inventory supply of LB-100 for the GEIS clinical trial, the Company has engaged a number of vendors to carry out the multiple tasks needed to make and gain approval of a new clinical product for investigational study in Spain. These tasks include the synthesis under good manufacturing practices (GMP) of the active pharmacologic ingredient (API), with documentation of each of the steps involved by an independent auditor. The API is then transferred to a vendor that prepares the clinical drug product, also under GMP conditions documented by an independent auditor. The clinical drug product is then sent to a vendor to test for purity and sterility, provide appropriate labels, store the drug, and distribute the drug to the clinical centers for use in the clinical trials. A formal application documenting all steps taken to prepare the clinical drug product for clinical use must be submitted to the appropriate regulatory authorities for review and approval before being used in a clinical trial.

On November 2, 2021, the Company entered into a Development Agreement with Famar Health Care Services Madrid SA ("Famar") to prepare a new batch of clinical LB-100 for use in clinical trials to be conducted in the European Union. During the three months ended March 31, 2022, the Company incurred costs of $292,293, pursuant to this agreement, which has been included in research and development costs in the Company's consolidated statements of operations. The Company's aggregate commitment pursuant to this agreement, less amounts previously paid to date, totaled approximately $29,000 as of March 31, 2022, which is expected to be incurred through June 30, 2022.

As of March 31, 2022, the Company estimates that this program to provide new inventory of the clinical drug product for the Spanish sarcoma study, and potentially for subsequent multiple trials within the European Union will cost approximately $1,153,000. The Company's aggregate commitments under this program, less amounts previously paid to date, totaled approximately $206,000 as of March 31, 2022, which are expected to be incurred through December 31, 2022. As the production of the new inventory of the clinical drug product is being conducted in Europe and is paid for in Euros, final costs are subject to foreign currency fluctuations between the United States Dollar and the Euro.

City of Hope. Effective January 18, 2021, the Company executed a Clinical Research Support Agreement with the City of Hope National Medical Center, an NCI-designated comprehensive cancer center, and City of Hope Medical Foundation (collectively, "City of Hope"), to carry out a Phase 1b clinical trial of LB-100, the Company's first-in-class protein phosphatase inhibitor, combined with a standard regimen for treatment of untreated extensive- stage disease small cell lung cancer (ED-SCLC). LB-100 will be given in combination with carboplatin, etoposide and atezolizumab, an FDA-approved but marginally effective regimen, to previously untreated ED-SCLC patients. The dose of LB-100 will be escalated with the standard fixed doses of the 3-drug regimen to reach a recommended Phase 2 dose (RP2D). Patient entry will be expanded so that a total of 12 patients will be evaluable at the RP2D to confirm the safety of the LB-100 combination and to look for potential therapeutic activity as assessed by objective response rate, duration of overall response, progression-free-survival and overall survival.

The clinical trial was initiated on March 9, 2021, with patient accrual expected to take approximately two years to complete. If LB-100 does potentiate the benefit of the standard regimen, some evidence could be noted at 12 months into the clinical trial, but an assessment of potential increased activity is likely to require at least 24 months. The Company is currently seeking to add two additional centers to increase the rate of accrual. The Company expects this clinical trial to be completed by June 30, 2024.

During the three months ended March 31, 2022 and 2021, the Company incurred costs of $0 and $240,508, respectively, pursuant to this agreement. The Company's aggregate commitment pursuant to this agreement, less amounts previously paid to date, totaled approximately $2,433,000 as of March 31, 2022, which is expected to be incurred through December 31, 2024, based upon a target of 42 enrollees. If a significant number of patients fail during the dose-escalation process, an increase of up to 12 patients would likely be necessary, at an estimated additional cost of approximately $800,000. The Company currently expects that enrollment in this clinical trial will range from approximately 18 to 30 enrollees, with 24 enrollees as the most likely number. Should fewer than 42 enrollees be required, the Company has agreed to compensate City of Hope on a per enrollee basis.

National Cancer Institute Pharmacologic Clinical Trial. In May 2019, the National Cancer Institute (NCI) initiated a glioblastoma (GBM) pharmacologic clinical trial. During the fourth quarter of 2019, the NCI enrolled the first two patients of a planned eight patient pharmacologic study of the ability of LB-100 to enter the brain and penetrate recurrent brain tumors in patients where surgical removal of the cancers is indicated (clinical trials registry NCT03027388). This study is being conducted and funded by the NCI under a Cooperative Research and Development Agreement, with the Company being required to provide the LB-100 clinical compound.

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

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

The neurosurgical unit at the NCI, which had been closed due to the Covid-19 epidemic, has reopened, and patient accrual has resumed. Patient entry remains at two, with the goal to enter eight patients before analyzing results. There is an urgent need to improve therapy for this type of aggressive brain tumor. If the NCI study shows that LB-100 does penetrate the brain, a clinical study of LB-100 in combination with standard therapy for GBM, the drug temozolomide and radiation, both of which have been well documented in pre-clinical studies to be significantly enhanced by LB-100, would be of significant interest to neuro-oncologists frustrated by decades of limited advances in therapy for this common brain tumor in adults.

Clinical Trial Monitoring Agreements

Moffitt. On September 12, 2018, the Company finalized a work order agreement with Theradex Systems, Inc. ("Theradex"), an international contract research organization ("CRO"), to monitor the Phase 1b/2 clinical trial being managed and conducted by Moffitt. The clinical trial began in April 2019 and the first patient was entered into the clinical trial in July 2019. At the current rate of accrual, the clinical trial is expected to be completed by June 30, 2025.

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, 2022 and 2021, the Company incurred costs of $3,281 and $941, respectively, pursuant to this work order. As of March 31, 2022, total costs of $95,166 have been incurred pursuant to this work order agreement. The Company's aggregate commitment pursuant to this clinical trial monitoring agreement, less amounts previously paid to date, totaled approximately $864,000 as of March 31, 2022, which is expected to be incurred through June 30, 2025.

City of Hope. On February 5, 2021, the Company signed a new work order agreement with Theradex to monitor the City of Hope investigator-initiated clinical trial in small cell lung cancer in accordance with FDA requirements for oversight by the sponsoring party. During the three months ended March 31, 2022 and 2021, the Company incurred costs of $4,500 and $3,540, respectively, pursuant to this work order. As of March 31, 2022, total costs of $29,126 have been incurred pursuant to this work order agreement. The Company's aggregate commitment pursuant to this clinical trial monitoring agreement, less amounts previously paid to date, totaled approximately $307,000 as of March 31, 2022, which is expected to be incurred through June 30, 2025.

Patent and License Agreements

On March 22, 2018, the Company entered into a Patent Assignment and Exploitation Agreement with INSERM TRANSFERT SA, acting as delegatee of the French National Institute of Health and Medical Research, for the assignment to 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 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 initial plan was to complete the validation process to evaluate LB-100 for the treatment of depressive or stress disorders in humans within three years; however, the exploitation of this patent for the treatment of depressive and stress disorders in humans will require substantial additional capital and/or a joint venture or other type of business arrangement with a pharmaceutical company with substantially greater capital and business resources than those available to the Company. As there can be no assurances that the Company will be able to obtain the capital or business resources necessary to focus on the exploitation of this patent, it is uncertain as to when, if at all, the Company may reach any of the development or commercialization milestones under the Agreement. As of March 31, 2022 and December 31, 2021, no amounts were due under this agreement.

Effective August 20, 2018, the Company entered into an Exclusive License Agreement with Moffitt. Pursuant to the License Agreement, Moffitt granted the Company an exclusive license under certain patents owned by Moffitt (the "Licensed Patents") relating to the treatment of MDS and a non-exclusive license under inventions, concepts, processes, information, data, know-how, research results, clinical data, and the like (other than the Licensed Patents) necessary or useful for the practice of any claim under the Licensed Patents or the use, development, manufacture or sale of any product for the treatment of MDS which would otherwise infringe a valid claim under the Licensed Patents. The Company was obligated to pay Moffitt a non-refundable license issue fee of $25,000 after the first patient is entered into a Phase 1b/2 clinical trial to be managed and conducted by Moffitt. The clinical trial began at a single site in April 2019 and the first patient was entered into the clinical trial in July 2019. The Company is also obligated to pay Moffitt an annual license maintenance fee of $25,000 commencing on the first anniversary of the Effective Date and every anniversary thereafter until the Company commences payment of minimum royalty payments. The Company has also agreed to pay non-refundable milestone payments to Moffitt, which cannot be credited against earned royalties payable by the Company, based on reaching various clinical and commercial milestones aggregating $1,897,000, subject to reduction by 40% under certain circumstances relating to the status of Valid Claims, as such term is defined in the License Agreement. During the three months ended March 31, 2022 and 2021, the Company recorded charges to operations of $6,165 and $6,164, respectively, in connection with its obligations under the License Agreement. As of March 31, 2022, 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.

Employment Agreements with Officers

During July and August 2020, the Company entered into one-year employment agreements with its executive officers, consisting of Dr. John S. Kovach, Eric J. Forman, Dr. James S. Miser, and Robert N. Weingarten, which provided for aggregate annual compensation of $640,000, payable monthly. The employment agreements are automatically renewable for additional one-year periods unless terminated by either party upon 60 days written notice prior to the end of the applicable one-year period, or by death, or by termination for cause. These employment agreements were automatically renewed for an additional one-year period in July and August 2021.

On April 9, 2021, the Board of Directors increased the annual compensation of Eric J. Forman, the Company's Chief Administrative Officer, Dr. James S. Miser, the Company's Chief Medical Officer, and Robert N. Weingarten, the Company's Chief Financial Officer, under the employment agreements such that the total aggregate annual compensation of all officers increased to $775,000, effective May 1, 2021.

Other Significant Agreements and Contracts

On December 24, 2013, the Company entered into an agreement with NDA Consulting Corp. for consultation and advice in the field of oncology research and drug development. As part of the agreement, NDA also agreed to cause its president, Dr. Daniel D. Von Hoff, M.D., to become a member of the Company's Scientific Advisory Committee. The term of the agreement was for one year and provided for a quarterly cash fee of $4,000. The agreement has been automatically renewed for additional one-year terms on its anniversary date since 2014. Consulting and advisory fees charged to operations pursuant to this agreement were $4,000 and $4,000 for the three months ended March 31, 2022 and 2021, 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. The Company recorded charges to operations pursuant to this Collaboration Agreement of $30,000 and $30,000 for the three months ended March 31, 2022 and 2021, respectively, which were included in research and development costs in the consolidated statements of operations.

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

The research team at the University of California, Davis recently completed their pre-clinical study of the potential benefit of LB-100 in a mouse model of AS, and the results are currently under review by FAST. The preliminary analysis indicates that the positive results previously reported by Chinese investigators were not confirmed in the US model. The Company is awaiting input from FAST as to whether it intends to continue to pursue pre-clinical studies of LB 100.

On October 8, 2021, the Company entered into a Development Collaboration Agreement with the Netherlands Cancer Institute, Amsterdam (NKI), one of the world's leading comprehensive cancer centers, and Oncode Institute, Utrecht, a major independent cancer research center, to identify the most promising drugs to be combined with LB-100, and potentially LB-100 analogues, to be used to treat a range of cancers, as well as to identify the specific molecular mechanisms underlying the identified combinations. The Company has agreed to fund the study and provide a sufficient supply of LB-100 to conduct the study. The study is expected to take approximately two years to conduct. During the three months ended March 31, 2022, the Company incurred charges in the amount of $54,230 with respect to this agreement, which amount is included in research and development costs in the Company's consolidated statements of operations. As of March 31, 2022, total costs of $109,478 have been incurred pursuant to this collaboration agreement. The Company's aggregate commitment pursuant to this collaboration agreement, less amounts previously paid to date, totaled approximately $380,000 as of March 31, 2022, which is expected to be incurred through June 30, 2025.

Off-Balance Sheet Arrangements

At March 31, 2022, the Company did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

Trends, Events and Uncertainties

Research and development of new pharmaceutical compounds is, by its nature, unpredictable. Although the Company undertakes research and development efforts with commercially reasonable diligence, there can be no assurance that the Company's cash position will be sufficient to enable it to develop pharmaceutical compounds to the extent needed to create future revenues sufficient to sustain operations.

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

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

The Company's management is responsible for establishing and maintaining a system of disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), that is designed to ensure that information required to be disclosed by the 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 rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive officer and principal financial officer, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

In accordance with Exchange Act Rules 13a-15 and 15d-15, an evaluation was completed under the supervision and with the participation of the Company's management, including its Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of and for the three months ended March 31, 2022, the end of the most recent fiscal period covered by this report. Based on that evaluation, the Company's management has concluded that the Company's disclosure controls and procedures were effective in providing reasonable assurance that information required to be disclosed in the Company's reports filed or submitted under the Exchange Act was recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission (the "SEC").

Limitations on Effectiveness of Disclosure Controls and Procedures

In designing and evaluating disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. In addition, the design of disclosure controls and procedures must reflect that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Changes in Internal Control Over Financial Reporting

The Company's management, including its Chief Executive Officer and Chief Financial Officer, has determined that no change in the Company's internal control over financial reporting (as that term is defined in Rules 13(a)-15(f) and 15(d)-15(f) of the Securities Exchange Act of 1934) occurred during or subsequent to the three months ended March 31, 2022 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

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, 2021, as filed with the Securities and Exchange Commission on March 21, 2022 (the "2021 Form 10-K").

The Risk Factors set forth in the 2021 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 2021 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, except as disclosed herein, there have been no material changes to the Risk Factors previously disclosed in the Company's 2021 Form 10-K.

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.
31.2*	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.
32.2*	Officer's Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document (does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL document and included in Exhibit 101.INS)

* Filed herewith.

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, 2022

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

Date: May 11, 2022

By: */s/ ROBERT N. WEINGARTEN*
Robert N. Weingarten
Chief Financial Officer

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE 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, 2022

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

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Robert N. Weingarten, 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, 2022

By: */s/ ROBERT N. WEINGARTEN*
Robert N. Weingarten
Chief Financial Officer

Exhibit 32.1

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

I, John S. Kovach, the Chief Executive 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, 2022 (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, 2022

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

Exhibit 32.2

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

I, Robert N. Weingarten, the 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, 2022 (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, 2022

By: */s/ ROBERT N. WEINGARTEN*
Robert N. Weingarten
Chief Financial Officer