

---

---

**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 September 30, 2020**

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

**Commission file number: 000-51476**

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**20-2903526**  
(I.R.S. Employer  
Identification Number)

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

**(631) 880-2907**  
(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  
Yes  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

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

As of November 1, 2020, the Company had 67,045,814 shares of common stock, \$0.0001 par value, issued and outstanding.

---

---

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
AND SUBSIDIARY**

**TABLE OF CONTENTS**

	<b><u>Page Number</u></b>
<b><u>PART I - FINANCIAL INFORMATION</u></b>	
<u>Item 1. Condensed Consolidated Financial Statements</u>	4
<u>Condensed Consolidated Balance Sheets – September 30, 2020 (Unaudited) and December 31, 2019</u>	4
<u>Condensed Consolidated Statements of Operations (Unaudited) – Three Months and Nine Months Ended September 30, 2020 and 2019</u>	5
<u>Condensed Consolidated Statements of Stockholders' Equity (Unaudited) – Three Months and Nine Months Ended September 30, 2020 and 2019</u>	6
<u>Condensed Consolidated Statements of Cash Flows (Unaudited) – Nine Months Ended September 30, 2020 and 2019</u>	7
<u>Notes to Condensed Consolidated Financial Statements (Unaudited) – Three Months and Nine Months Ended September 30, 2020 and 2019</u>	8
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	25
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	37
<u>Item 4. Controls and Procedures</u>	37
<b><u>PART II - OTHER INFORMATION</u></b>	
<u>Item 1. Legal Proceedings</u>	39
<u>Item 1A. Risk Factors</u>	39
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	39
<u>Item 3. Defaults Upon Senior Securities</u>	39
<u>Item 4. Mine Safety Disclosures</u>	39
<u>Item 5. Other Information</u>	39
<u>Item 6. Exhibits</u>	40
<u>SIGNATURES</u>	41

## Forward-Looking Statements

This Quarterly Report on Form 10-Q of Lixte Biotechnology Holdings, Inc. (the “Company”) contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, and Section 21E of the Securities Exchange Act of 1934. These might include statements regarding the Company’s financial position, business strategy and other plans and objectives for future operations, and assumptions and predictions about future clinical trials and their timing and costs, product demand, supply, manufacturing costs, marketing and pricing factors are all forward-looking statements. These statements are generally accompanied by words such as “intend”, “anticipate”, “believe”, “estimate”, “potential(ly)”, “continue”, “forecast”, “predict”, “plan”, “may”, “will”, “could”, “would”, “should”, “expect” or the negative of such terms or other comparable terminology. The Company believes that the assumptions and expectations reflected in such forward-looking statements are reasonable, based on information available to it on the date hereof, but the Company cannot provide assurances that these assumptions and expectations will prove to have been correct or that the Company will take any action that the Company may presently be planning. These forward-looking statements are inherently subject to known and unknown risks and uncertainties. Actual results or experience may differ materially from those expected, anticipated or implied in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, regulatory policies or changes thereto, available cash, research and development results, competition from other similar businesses, and market and general economic factors. This discussion should be read in conjunction with the condensed consolidated financial statements and notes thereto included in Item 1 of this Quarterly Report on Form 10-Q and the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2019, including the section entitled “Item 1A. Risk Factors”. The Company does not intend to update or revise any forward-looking statements to reflect new information, future events or otherwise.

PART I - FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2020 (Unaudited)	December 31, 2019
<b>ASSETS</b>		
Current assets:		
Cash	\$ 1,076,248	\$ 2,598,864
Advances on research and development contract services	29,792	—
Accrued interest receivable	—	14,367
Prepaid insurance	69,091	34,508
Other prepaid expenses and current assets	13,000	24,294
Total current assets	1,188,131	2,672,033
Deferred offering costs	174,253	—
Total assets	<u>\$ 1,362,384</u>	<u>\$ 2,672,033</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 115,518	\$ 143,549
Accrued offering costs	44,009	—
Research and development contract liabilities	61,931	94,349
Total current liabilities	<u>221,458</u>	<u>237,898</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, \$0.0001 par value; authorized – 10,000,000 shares; issued and outstanding – 350,000 shares of Series A Convertible Preferred Stock, \$10.00 per share stated value, liquidation preference based on assumed conversion into common shares – 4,375,000 shares	3,500,000	3,500,000
Common stock, \$0.0001 par value; authorized – 100,000,000 shares; issued and outstanding – 67,045,814 shares	6,704	6,704
Additional paid-in capital	27,081,063	26,016,317
Accumulated deficit	(29,446,841)	(27,088,886)
Total stockholders' equity	<u>1,140,926</u>	<u>2,434,135</u>
Total liabilities and stockholders' equity	<u>\$ 1,362,384</u>	<u>\$ 2,672,033</u>

See accompanying notes to condensed consolidated financial statements.

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
AND SUBSIDIARY**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
(Unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues	\$ —	\$ —	\$ —	\$ —
Costs and expenses:				
General and administrative costs, including \$464,483 and \$32,030 to related parties for the three months ended September 30, 2020 and 2019, respectively, and \$518,483 and \$395,631 to related parties for the nine months ended September 30, 2020 and 2019, respectively	802,273	522,360	1,350,201	1,460,551
Research and development costs, including \$670,715 of stock-based compensation costs to consultant for the three months and nine months ended September 30, 2020	799,420	570,601	1,012,038	699,038
Total costs and expenses	<u>1,601,693</u>	<u>1,092,961</u>	<u>2,362,239</u>	<u>2,159,589</u>
Loss from operations	(1,601,693)	(1,092,961)	(2,362,239)	(2,159,589)
Interest income	38	13,889	4,284	41,317
Net loss	<u>\$ (1,601,655)</u>	<u>\$ (1,079,072)</u>	<u>\$ (2,357,955)</u>	<u>\$ (2,118,272)</u>
Net loss per common share – basic and diluted	<u>\$ (0.02)</u>	<u>\$ (0.02)</u>	<u>\$ (0.04)</u>	<u>\$ (0.03)</u>
Weighted average common shares outstanding – basic and diluted	<u>67,045,814</u>	<u>67,045,814</u>	<u>67,045,814</u>	<u>67,045,814</u>

See accompanying notes to condensed consolidated financial statements.

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
AND SUBSIDIARY**

**CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY  
(Unaudited)**

**Three Months and Nine Months Ended September 30, 2020 and 2019**

	<b>Series A Convertible Preferred Stock</b>		<b>Common Stock</b>		<b>Additional Paid-in Capital</b>	<b>Accumulated Deficit</b>	<b>Total Stockholders' Equity</b>
	<b>Shares</b>	<b>Amount</b>	<b>Shares</b>	<b>Par Value</b>			
Balance, December 31, 2019	350,000	\$ 3,500,000	67,045,814	\$ 6,704	\$ 26,016,317	\$ (27,088,886)	\$ 2,434,135
Net loss	—	—	—	—	—	(383,175)	(383,175)
Balance, March 31, 2020	350,000	3,500,000	67,045,814	6,704	26,016,317	(27,472,061)	2,050,960
Net loss	—	—	—	—	—	(373,125)	(373,125)
Balance, June 30, 2020	350,000	3,500,000	67,045,814	6,704	26,016,317	(27,845,186)	1,677,835
Stock-based compensation expense	—	—	—	—	1,064,746	—	1,064,746
Net loss	—	—	—	—	—	(1,601,655)	(1,601,655)
Balance, September 30, 2020	<u>350,000</u>	<u>\$ 3,500,000</u>	<u>67,045,814</u>	<u>\$ 6,704</u>	<u>\$ 27,081,063</u>	<u>\$ (29,446,841)</u>	<u>\$ 1,140,926</u>
Balance, December 31, 2018	350,000	\$ 3,500,000	67,045,814	\$ 6,704	\$ 25,267,662	\$ (24,648,543)	\$ 4,125,823
Stock-based compensation expense	—	—	—	—	12,936	—	12,936
Net loss	—	—	—	—	—	(428,736)	(428,736)
Balance, March 31, 2019	350,000	3,500,000	67,045,814	6,704	25,280,598	(25,077,279)	3,710,023
Stock-based compensation expense	—	—	—	—	296,665	—	296,665
Net loss	—	—	—	—	—	(610,464)	(610,464)
Balance, June 30, 2019	350,000	3,500,000	67,045,814	6,704	25,577,263	(25,687,743)	3,396,224
Stock-based compensation expense	—	—	—	—	439,054	—	439,054
Net loss	—	—	—	—	—	(1,079,072)	(1,079,072)
Balance, September 30, 2019	<u>350,000</u>	<u>\$ 3,500,000</u>	<u>67,045,814</u>	<u>\$ 6,704</u>	<u>\$ 26,016,317</u>	<u>\$ (26,766,815)</u>	<u>\$ 2,756,206</u>

See accompanying notes to condensed consolidated financial statements.

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
AND SUBSIDIARY**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
(Unaudited)**

	Nine Months Ended September 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	\$ (2,357,955)	\$ (2,118,272)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense included in -		
General and administrative costs	394,031	314,631
Research and development costs	670,715	434,024
Changes in operating assets and liabilities:		
(Increase) decrease in -		
Advances on research and development contract services	(29,792)	—
Accrued interest receivable	14,367	(2,678)
Prepaid insurance	(34,583)	(19,296)
Other prepaid expenses and current assets	11,294	(3,415)
Increase (decrease) in -		
Accounts payable and accrued expenses	(28,031)	78,322
Research and development contract liabilities	(32,418)	20,074
Net cash used in operating activities	(1,392,372)	(1,296,610)
Cash flows from financing activities:		
Payment of deferred offering costs	(130,244)	—
Net cash used in financing activities	(130,244)	—
Cash:		
Net decrease	(1,522,616)	(1,296,610)
Balance at beginning of period	2,598,864	4,273,012
Balance at end of period	\$ 1,076,248	\$ 2,976,402
Supplemental disclosures of cash flow information:		
Cash paid for -		
Interest	\$ —	\$ —
Income taxes	\$ —	\$ —
Noncash investing and financing activities:		
Accrual of deferred offering costs	\$ 44,009	\$ —

See accompanying notes to condensed consolidated financial statements.

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(Unaudited)**

**Three Months and Nine Months Ended September 30, 2020 and 2019**

**1. Organization and Basis of Presentation**

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

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

**2. Business**

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

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

***Going Concern***

At September 30, 2020, the Company had cash and cash equivalents of \$1,076,248 available to fund its operations. Because the Company is currently engaged in Phase 2 clinical trials, it is expected that it will take a significant amount of time to develop any product or intellectual property capable of generating sustainable revenues. Accordingly, the Company’s business is unlikely to generate any sustainable operating revenues in the next several years and may never do so. In addition, to the extent that the Company is able to generate revenues through licensing its technologies or through product sales, there can be no assurance that the Company will be able to achieve positive earnings and operating cash flows.

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

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

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

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. If the Company is able to complete the proposed public offering as discussed below in the approximate amount indicated, the Company estimates that such funding would provide sufficient working capital resources to fund the Company's clinical trial program with respect to the development of its lead anti-cancer clinical compound LB-100 through at least December 2022. If the Company is not able to complete the proposed public offering as discussed below, the Company would attempt to raise additional capital to fund its clinical trial program through alternative financing sources.

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 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 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.

#### ***Proposed Public Offering and Listing on The Nasdaq Capital Market***

On November 2, 2020, the Company filed Amendment No. 2 to its Registration Statement on Form S-1 with the SEC to register and sell newly-issued shares of common stock in an underwritten public offering, currently estimated to generate gross proceeds of approximately \$9,375,000, to fund the Company's operating capital requirements for at least the next two years. However, there can be no assurances that such public offering will be completed, or that if completed, that such public offering will generate gross proceeds of approximately \$9,375,000.

On October 21, 2020, the Company's application to have its shares of common stock listed for trading on The Nasdaq Capital Market under the symbol "LIXT" was approved, subject to notice of issuance of the shares in the public offering.

#### ***Reverse Stock Split***

On July 14, 2020, the Board of Directors of the Company approved a 1-for-6 reverse split of the Company's outstanding shares of common stock. Holders of a majority of shares of the Company's common stock have provided their consent for such reverse stock split. The Company intends to implement such reverse stock split upon receiving regulatory approval for such action, and concurrently with the completion of the public offering.

All common share and per share amounts presented herein are on a pre-split basis.

### **3. Summary of Significant Accounting Policies**

#### ***Principles of Consolidation***

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

### *Use of Estimates*

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

### *Cash and Cash Equivalents*

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

### *Research and Development*

Research and development costs consist primarily of fees paid to consultants and contractors, and other expenses relating to the acquisition, design, development and testing of the Company's compounds and product candidates. Research and development costs also include costs to produce the compounds used in research and clinical trials.

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

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

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

### *Prepaid Insurance*

Prepaid insurance represents the premiums paid for directors and officers insurance and for general liability insurance coverage in excess of the amortization of the total policy premium charged to operations to 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.

As of September 30, 2020, total insurance policy premiums, in excess of premiums paid to date, amounted to \$261,625, and will be payable with interest at 5.27% per annum, in nine monthly installments of \$29,767 through June 2021. As of December 31, 2019, there was no unpaid insurance premium obligation.

#### ***Deferred Offering Costs***

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

#### ***Patent and Licensing Related Legal and Filing Costs***

Due to the significant uncertainty associated with the successful development of one or more commercially viable products based on the Company's research efforts and related patent applications, all patent-related legal and filing fees and licensing-related legal fees are charged to operations as incurred. Patent and licensing-related legal and filing costs were \$163,987 and \$362,755 for the three months ended September 30, 2020 and 2019, and \$440,899 and \$672,661 for the nine months ended September 30, 2020 and 2019, respectively. Patent and licensing related legal and filing costs are included in general and administrative costs in the Company's consolidated statements of operations.

#### ***Concentration of Risk***

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

General and administrative costs for the three months ended September 30, 2020 and 2019 include charges from a legal firm for general licensing and patent prosecution costs relating to the Company's intellectual properties representing 20.4% and 69.4%, respectively, of total general and administrative costs for those periods. General and administrative costs for the three months ended September 30, 2020 also includes charges for the amortized value of stock options granted to three corporate officers representing 49.1% of total general and administrative costs for that period.

General and administrative costs for the nine months ended September 30, 2020 and 2019 include charges from a legal firm for general licensing and patent prosecution costs relating to the Company's intellectual properties representing 32.7% and 46.1%, respectively, of total general and administrative costs for those periods. General and administrative costs for the nine months ended September 30, 2020 also includes charges for the amortized value of stock options granted to three corporate officers representing 29.2% of total general and administrative costs for that period.

Research and development costs for the three months ended September 30, 2020 include charges from a consultant, and the value associated with extending stock options previously granted to that consultant, representing 87.7% of total research and development costs for that period. Research and development costs for the three months ended September 30, 2019 include charges for the value associated with fully vested stock options granted to a consultant representing 76.1% of total research and development costs, and charges from a vendor representing 15.3% of total research and development costs, respectively, for that period.

Research and development costs for the nine months ended September 30, 2020 include charges from a consultant, and the value extending stock options previously granted to that consultant, representing 75.2% of total research and development costs for that period. Research and development costs for the nine months ended September 30, 2019 include charges for the value of fully vested stock options granted to a consultant representing 62.1% of total research and development costs, and charges from a consultant and from a vendor representing 12.5% and 10.0% of total research and development costs, 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. Likewise, should the Company determine that it would not be able to realize all or part of its deferred tax assets in the future, an adjustment to the deferred tax assets would be charged to operations in the period such determination was made.

The Company is subject to U.S. federal income taxes and income taxes of various state tax jurisdictions. As the Company's net operating losses have yet to be utilized, all previous tax years remain open to examination by Federal authorities and other jurisdictions in which the Company currently operates or has operated in the past. The Company had no unrecognized tax benefits as of September 30, 2020 or December 31, 2019 and does not anticipate any material amount of unrecognized tax benefits within the 12 months subsequent to September 30, 2020.

The Company accounts for uncertainties in income tax law under a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns as prescribed by GAAP. The tax effects of a position are recognized only if it is "more-likely-than-not" to be sustained by the taxing authority as of the reporting date. If the tax position is not considered "more-likely-than-not" to be sustained, then no benefits of the position are recognized. The Company had not recorded any liability for uncertain tax positions as of September 30, 2020 or December 31, 2019. Subsequent to September 30, 2020, any interest and penalties related to uncertain tax positions will be recognized as a component of income tax expense.

## ***Stock-Based Compensation***

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

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

The fair value of stock options granted as stock-based compensation is determined utilizing the Black-Scholes option-pricing model, and is affected by several variables, the most significant of which are the 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"). Estimated volatility is based on the historical volatility of the Company's common stock, calculated utilizing a look-back period approximately equal to the estimated 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 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 September 30, 2020 and 2019, the Company excluded the outstanding securities summarized below, which entitle the holders thereof to acquire shares of common stock, from its calculation of earnings per share, as their effect would have been anti-dilutive.

	<b>September 30,</b>	
	<b>2020</b>	<b>2019</b>
Series A Convertible Preferred Stock	4,375,000	4,375,000
Common stock warrants	9,000,000	9,000,000
Common stock options, including options issued in the form of warrants	9,050,000	8,050,000
Total	<u>22,425,000</u>	<u>21,425,000</u>

### **Fair Value of Financial Instruments**

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

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

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

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

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

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

### **Recent Accounting Pronouncements**

In June 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2016-13, Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). ASU 2016-13 significantly changes how entities measure credit losses for most financial assets, including accounts and notes receivables. ASU 2016-13 will replace the current "incurred loss" approach with an "expected loss" model, under which companies will recognize allowances based on expected rather than incurred losses. Entities will apply the provisions of ASU 2016-13 as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which ASU 2016-13 is effective. ASU 2016-13 will be effective for the Company for interim and annual reporting periods beginning after December 15, 2022. Management is currently in the process of assessing the impact of the adoption of ASU-2016-13 on the Company's consolidated financial statement presentation and disclosures subsequent to its adoption.

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

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 will simplify the accounting for convertible instruments by reducing the number of accounting models for convertible debt instruments and convertible preferred stock. Limiting the accounting models results in fewer embedded conversion features being separately recognized from the host contract as compared with current GAAP. Convertible instruments that continue to be subject to separation models are (1) those with embedded conversion features that are not clearly and closely related to the host contract, that meet the definition of a derivative, and that do not qualify for a scope exception from derivative accounting and (2) convertible debt instruments issued with substantial premiums for which the premiums are recorded as paid-in capital. ASU 2020-06 also amends the guidance for the derivatives scope exception for contracts in an entity’s own equity to reduce form-over-substance-based accounting conclusions. ASU 2020-06 will be effective for public companies for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. Management has not yet evaluated the effect that the adoption of ASU 2020-06 will have on the Company’s consolidated financial statement presentation or disclosures subsequent to its adoption.

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

#### **4. Stockholders’ Equity**

##### *Preferred Stock*

The Company is authorized to issue a total of 10,000,000 shares of preferred stock, par value \$0.0001 per share. On March 17, 2015, the Company filed a Certificate of Designations, Preferences, Rights and Limitations 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 September 30, 2020 and December 31, 2019, 9,650,000 shares of preferred stock were undesignated and may be issued with such rights and powers as the Board of Directors may designate.

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

If fully converted, the 350,000 outstanding shares of Series A Convertible Preferred Stock would convert into 4,375,000 shares of common stock at September 30, 2020 and December 31, 2019. The Company has the right to redeem the Series A Convertible Preferred Stock up to the fifth anniversary of their respective closing dates (March 17, 2015 and January 21, 2016) at a price per share equal to \$50.00. Accordingly, as of September 30, 2020, the Company has the right to redeem the 175,000 shares of Series A Convertible Preferred Stock that were issued on January 21, 2016 at an aggregate cash redemption value of \$8,750,000. The Series A Convertible Preferred Stock has no right to cash, except with respect to the payment of the aforementioned dividend based on the generation of revenues by the Company. The shares of Series A Convertible Preferred Stock do not have any registration rights.

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

### Common Stock

The Company is authorized to issue a total of 100,000,000 shares of common stock, par value \$0.0001 per share. As of September 30, 2020 and December 31, 2019, the Company had 67,045,814 shares of common stock issued and outstanding.

### Common Stock Warrants

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

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

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

Based on a fair market value of \$1.17 per share on September 30, 2020, the intrinsic value attributable to exercisable but unexercised in-the-money common stock warrants on that date was \$1,530,000.

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

### 5. Related Party Transactions

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

The Company's Chairman and major stockholder, Dr. John Kovach, was paid a salary of \$15,000 for the three months ended September 30, 2020 and 2019, and \$45,000 for the nine months ended September 30, 2020 and 2019, respectively, which amounts are included in general and administrative costs in the Company's consolidated statements of operations.

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

Legal and consulting fees charged to operations for services rendered by the Eric Forman Law Office were \$14,000 and \$12,000 for the three months ended September 30, 2020 and 2019, respectively, and \$38,000 and \$36,000 for the nine months ended September 30, 2020 and 2019, respectively. Eric Forman is the son-in-law of Gil Schwartzberg, a significant stockholder of and consultant to the Company, and is the son of Dr. Stephen Forman, who was elected to the Company's Board of Directors on May 13, 2016. Julie Forman, the wife of Eric Forman and the daughter of Gil Schwartzberg, is Vice President of Morgan Stanley Wealth Management, where the Company maintains a continuing banking relationship.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Related party costs:				
Cash-based	\$ 70,452	\$ 27,000	\$ 124,452	\$ 81,000
Stock-based	394,031	5,030	394,031	314,631
Total	<u>\$ 464,483</u>	<u>\$ 32,030</u>	<u>\$ 518,483</u>	<u>\$ 395,631</u>

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

Additional information with respect to cash-based compensation arrangements are described at Note 7.

## 6. Stock-Based Compensation

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

On June 20, 2007, the Board of Directors of the Company approved the 2007 Stock Compensation Plan (the "2007 Plan"), which provided for the granting of awards, consisting of stock options, stock appreciation rights, performance shares, and restricted shares of common stock, to employees and consultants, for up to 2,500,000 shares of the Company's common stock, under terms and conditions as determined by the Company's Board of Directors. The 2007 Plan terminated on June 19, 2017. As of September 30, 2020, unexpired stock options for 1,250,000 shares were issued and outstanding under the 2007 Plan.

On July 14, 2020, the Board of Directors of the Company adopted the 2020 Stock Incentive Plan (the "2020 Plan"), which provides for the granting of equity-based awards, consisting of stock options, restricted stock, restricted stock units, stock appreciation rights, and other stock-based awards to employees, officers, directors and consultants of the Company and its affiliates for up to 14,000,000 shares of the Company's common stock, under terms and conditions as determined by the Company's Board of Directors.

The fair value of each stock option awarded is calculated on the grant date using the Black-Scholes option-pricing model. The risk-free interest rate is based on the U.S. Treasury yield curve in effect as of the grant date. The expected dividend yield assumption is based on the Company's expectation of dividend payouts and is assumed to be zero. The expected volatility is based on the historical volatility of the Company's common stock, calculated utilizing a look-back period approximately equal to the estimated 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.

For stock options requiring an assessment of value during the nine months ended September 30, 2020, 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	0.23% to 0.31%
Expected dividend yield	0%
Expected volatility	207.67%
Expected life	4 to 5 years

For stock options requiring an assessment of value during the nine months ended September 30, 2019, the fair value of each stock option award was estimated using the Black-Scholes option-pricing model with the following assumptions:

Risk-free interest rate	1.47% to 1.85%
Expected dividend yield	0%
Expected volatility	133.01% to 171.87%
Expected life	4 years

Effective August 4, 2018, in conjunction with their appointments as directors of the Company, the Company granted stock options to each of Dr. Winson Sze Chun Ho and Dr. Yun Yen to purchase an aggregate of 200,000 shares of the Company's common stock, exercisable for a period of five years from the vesting date at \$0.28 per share, which was the approximate fair market value of the Company's common stock on such date, with one-half of such stock options (100,000 shares for each director) vesting on August 4, 2018 and the remaining one-half of such stock options (100,000 shares for each director) vesting on August 4, 2019. The aggregate fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$104,920 (\$0.2623 per share), of which \$101,475 was attributable to the stock options fully-vested on August 4, 2018 and was therefore charged to operations on that date. The remaining unvested portion of the fair value of the stock options was charged to operations ratably from August 4, 2018 through August 4, 2019. During the three months and nine months ended September 30, 2019, the Company recorded a charge to operations of \$5,030 and \$31,046, respectively, with respect to these stock options.

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

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

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

Effective September 14, 2015, in connection with the Collaboration Agreement with BioPharmaWorks as described at Note 7, the Company issued to BioPharmaWorks two stock options, in the form of warrants, to purchase 1,000,000 shares (500,000 shares per warrant) of the Company's common stock. The first warrant vested on September 14, 2016 and was exercisable for a period of five years from the date of grant at \$1.00 per share. The second warrant vested on September 14, 2017 and was exercisable for a period of five years from the date of grant at \$2.00 per share. On July 3, 2020, the Company's Board of Directors approved an extension of the term of the outstanding warrants to acquire an aggregate of 1,000,000 shares of the Company's common stock from September 14, 2020 to September 14, 2025. The Company's closing stock price on July 2, 2020 was \$0.90 per share. The fair value of the extension of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was measured for accounting purposes as the difference in the fair value of the stock options immediately before and immediately after the extension date, and was determined to be \$670,715 (\$0.6707 per share), which was reflected as a charge to general and administrative costs in the consolidated statement of operations on that date.

On July 15, 2020, as amended on August 12, 2020, in connection with the employment agreement entered into with Eric Forman, Mr. Forman was granted options for 350,000 shares of the Company's common stock. The options can be exercised on a cashless basis. The options have a term of 5 years and an exercise price of \$1.19 per share, which was equal to the closing price of the Company's common stock on the grant date. The options vested as to 25% on August 12, 2020, and will vest 25% on each of the first, 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 (\$1.1453 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 will be charged to operations ratably from August 12, 2020 through August 12, 2023. During the three months and nine months ended September 30, 2020, the Company recorded a charge to operations of \$113,667 with respect to these stock options.

On August 1, 2020, in connection with an employment agreement entered into with Dr. James Miser, M.D., Dr. Miser was granted options for 500,000 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 \$1.19 per share, which was equal to the closing price of the Company's common stock on the effective date of the employment agreement. The options vested as to 25% on the effective date, and will vest 25% on each of the first, 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 (\$1.1453 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 will be charged to operations ratably from August 1, 2020 through August 1, 2023. During the three months and nine months ended September 30, 2020, the Company recorded a charge to operations of \$166,697 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 350,000 shares of the Company's common stock. The options can be exercised on a cashless basis. The options have a term of 5 years and an exercise price of \$1.19 per share, which was equal to the closing price of our common stock on the grant date. The options vested as to 25% on August 12, 2020, and will vest 25% on each of the first, 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 (\$1.1453 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 will be charged to operations ratably from August 12, 2020 through August 12, 2023. During the three months and nine months ended September 30, 2020, the Company recorded a charge to operations of \$113,667, with respect to these stock options.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Related parties	\$ 394,031	\$ 5,030	\$ 394,031	\$ 314,631
Non-related parties	670,715	434,024	670,715	434,024
Total stock-based compensation costs	<u>\$ 1,064,746</u>	<u>\$ 439,054</u>	<u>\$ 1,064,746</u>	<u>\$ 748,655</u>

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

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Life (in Years)</u>
Stock options outstanding at December 31, 2019	7,850,000	\$ 0.608	
Granted	1,200,000	1.190	
Exercised	—	—	
Expired	—	—	
Stock options outstanding at September 30, 2020	<u>9,050,000</u>	<u>\$ 0.685</u>	<u>3.27</u>
Stock options exercisable at September 30, 2020	<u>8,150,000</u>	<u>\$ 0.629</u>	<u>3.10</u>

Total deferred compensation expense for the outstanding value of unvested stock options was approximately \$980,000 at September 30, 2020, which will be recognized subsequent to September 30, 2020 over a weighted-average period of approximately thirty-four months.

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

<u>Exercise Prices</u>	<u>Options Outstanding (Shares)</u>	<u>Options Exercisable (Shares)</u>
\$ 0.120	450,000	450,000
\$ 0.150	300,000	300,000
\$ 0.160	200,000	200,000
\$ 0.200	500,000	500,000
\$ 0.280	400,000	400,000
\$ 0.500	4,200,000	4,200,000
\$ 1.000	1,000,000	1,000,000
\$ 1.100	300,000	300,000
\$ 1.190	1,200,000	300,000
\$ 2.000	500,000	500,000
	<u>9,050,000</u>	<u>8,150,000</u>

The intrinsic value of exercisable but unexercised in-the-money stock options at September 30, 2020 was approximately \$5,496,500, based on a fair market value of \$1.17 per share on September 30, 2020.

Outstanding options to acquire 900,000 shares of the Company's common stock had not vested at September 30, 2020.

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

## 7. Commitments and Contingencies

### *Legal Claims*

The Company may be subject to legal claims and actions from time to time as part of its business activities. As of September 30, 2020, the Company was not subject to any pending or threatened legal claims or actions.

### *Clinical Trial Agreements*

**Moffitt.** Effective August 20, 2018, the Company entered into a Clinical Trial Research Agreement 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 trial would be completed over a period of four years from its initiation, with the final analysis and reporting expected by July 2023. However, with additional funds, the Company’s objective would be to add two additional MDS centers to the Phase 2 portion of the study to accelerate patient accrual, with the goal of an earlier reporting date.

During the three months ended September 30, 2020 and 2019, the Company paid Moffitt \$10,643 and \$9,996, respectively, pursuant to this agreement. During the nine months ended September 30, 2020 and 2019, the Company paid Moffitt \$36,008 and \$23,249, respectively, pursuant to this agreement. As of September 30, 2020, total costs of \$81,101 have been incurred pursuant to this agreement.

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

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

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

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

Accordingly, during the three months ended September 30, 2020 and 2019, the Company incurred costs of \$0 and \$87,471, respectively, and during the nine months ended September 30, 2020 and 2019, the Company incurred costs of \$43,411 and \$87,471, respectively, pursuant to this agreement. As of September 30, 2020, total costs of \$130,882 have been incurred pursuant to this agreement.

The Company's aggregate commitments pursuant to the aforementioned clinical trial agreements, less amounts previously paid to date under these agreements, totaled approximately \$5,049,000 as of September 30, 2020, consisting of approximately \$4,428,000 relating to the GEIS clinical trial and approximately \$621,000 relating to the Moffitt clinical trial, which are expected to be incurred over the next five years through June 30, 2025.

#### ***Clinical Trial Monitoring Agreements***

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

Costs under this work order agreement are estimated to be approximately \$954,000, with such payments expected to be divided approximately 94% to Theradex for services and approximately 6% for payments for pass-through costs. The costs of the Phase 1b/2 clinical trial being paid to or through Theradex are being recorded and charged to operations based on the periodic documentation provided by the CRO. During the three months ended September 30, 2020 and 2019, the Company incurred costs of \$917 and \$3,190, respectively, pursuant to this work order. During the nine months ended September 30, 2020 and 2019, the Company incurred costs of \$12,393 and \$51,683, respectively, pursuant to this work order. As of September 30, 2020, total costs of \$75,885 have been incurred pursuant to this work order agreement.

The Company's aggregate commitments pursuant to this clinical trial monitoring agreement, less amounts previously paid to date under this agreement, totaled approximately \$875,000 as of September 30, 2020, which are expected to be incurred over the next five years through June 30, 2025.

#### ***Other Clinical Agreements***

As of September 30, 2020, the Company was committed to two other partially completed short-term clinical study agreements. The Company's aggregate commitments pursuant to these clinical study agreements, less amounts previously paid to date under these agreements, totaled approximately \$258,000 as of September 30, 2020, which is expected to be incurred over the next five months. During the three months and nine months ended September 30, 2020, the Company incurred costs of \$41,625, pursuant to these agreements.

#### ***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 "Oxabicycloheptanes 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 current plan is to complete the validation process to evaluate LB-100 for the treatment of depressive or stress disorders in humans within three years; however, the exploitation of this patent for the treatment of depressive and stress disorders in humans will require substantial additional capital and/or a joint venture or other type of business arrangement with a pharmaceutical company with substantially greater capital and business resources than those available to the Company. As there can be no assurances that the Company will be able to obtain the capital or business resources necessary to focus on the exploitation of this patent, it is uncertain as to when, if at all, the Company may reach any of the development or commercialization milestones under the Agreement. As of September 30, 2020 and December 31, 2019, no amounts were due under this agreement.

Effective April 2, 2018, the Company entered into a consulting agreement for a term of two years with Liberi Life Sciences Consultancy BV, located in The Netherlands, for consulting and advisory services with respect to sales and licensing, as well as the procurement of investors in China, Japan and South Korea. The Consulting Agreement provided for the payment of a fixed, one-time retainer of EURO 15,000 (US \$18,348), which was paid on April 5, 2018, and 2.5% of the net payments received by the Company from sales of products or licensing activities arising directly and exclusively from leads generated by the advisor during the term of the Consulting Agreement, and any investors introduced to the Company by the advisor that results in an investment in the Company during the term of the Consulting Agreement. The Company recorded the payment of the retainer as a prepaid expense in the Company's consolidated balance sheet, and is amortizing the retainer payment over the two-year life of the Consulting Agreement, as a result of which the Company recorded charges to operations of \$0 and \$2,294 during the three months ended September 30, 2020 and 2019, and \$2,294 and \$6,882 during the nine months ended September 30, 2020 and 2019, respectively. As of September 30, 2020, the prepaid consulting fee had been fully amortized. At December 31, 2019, the unamortized balance of the retainer payment was \$9,174, all of which was classified as a current asset in the Company's consolidated balance sheet at such date. On March 1, 2020, the Consulting Agreement was extended to April 2, 2021 without any additional consideration.

Effective August 20, 2018, the 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 September 30, 2020 and 2019, the Company recorded charges to operations of \$6,301 and \$31,301, respectively, in connection with its obligations under the License Agreement. During the nine months ended September 30, 2020 and 2019, the Company recorded charges to operations of \$18,699 and \$74,368, respectively, in connection with its obligations under the License Agreement. As of September 30, 2020, no milestones had yet been attained.

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

## *Employment Agreements*

**Dr. John Kovach.** On July 15, 2020, the Company entered into an employment agreement with Dr. John Kovach pursuant to which Dr. Kovach is to continue to act as the Company's President, Chief Scientific Officer, and Chief Executive Officer. His responsibilities shall be for the oversight of the Company's entire operations and strategic planning, and shall be the primary contact between the Company's executive team and the Board of Directors, to whom he shall report. Dr. Kovach shall supervise all scientific endeavors, providing guidance to the Chief Medical Officer. He shall be the principal spokesperson for the Company. Dr. Kovach will receive an annual salary of \$250,000, payable monthly. The effective date of the agreement is October 1, 2020, and shall remain in effect until the earlier of (i) one year from the effective date, automatically renewable for additional one-year periods unless terminated by either party upon 60 days written notice prior to the end of the applicable one-year period, (ii) his death, or (iii) termination for cause. During the three months and nine months ended September 30, 2020, the Company did not incur any charges for salary with respect to this agreement.

**Eric Forman.** On July 15, 2020, as amended on August 12, 2020, the Company entered into an employment agreement with Eric Forman, pursuant to which Mr. Forman will act as the Company's Chief Administrative Officer reporting directly to the Company's Chief Executive Officer. Mr. Forman's primary function shall be to oversee the Company's internal operations, including IT, licensing, legal, personnel, marketing, and corporate governance. Mr. Forman will receive an annual salary of \$120,000, payable monthly. Mr. Forman was also granted options to acquire 350,000 shares of the Company's common stock, which are further described in Note 6. The effective date of the agreement is October 1, 2020, and shall remain in effect until the earlier of (i) one year from the effective date, automatically renewable for additional one-year periods unless terminated by either party upon 60 days written notice prior to the end of the applicable one-year period, (ii) his death, or (iii) termination for cause. During the three months and nine months ended September 30, 2020, the Company did not incur any charges for salary with respect to this agreement.

**Dr. James Miser.** On August 1, 2020, the Company entered into an employment agreement with Dr. James Miser, M.D., pursuant to which Dr. Miser was appointed as the Company's Chief Medical Officer. Under the employment agreement, Dr. Miser will play a leadership role in planning, implementation and oversight of clinical trials. Dr. Miser will be responsible for assisting and developing strategic clinical goals and the implementation and safety monitoring of investigational studies. Dr. Miser will be the primary medical monitor for all clinical investigational studies and for the oversight of third party CRO monitors. Dr. Miser will work closely with the Company's Chief Executive Officer on the development of specific goals needed to ensure the timely implementation of appropriate clinical studies needed for successful registration of therapeutic products and new drug development. Dr. Miser will be required to devote at least 50% of his business time to the Company's activities. Dr. Miser will receive an annual salary of \$150,000. Dr. Miser was also granted options to acquire 500,000 shares of the Company's common stock, which are further described in Note 6. The effective date of the agreement is August 1, 2020. The agreement shall remain in effect until the earlier of (i) one year from the effective date, automatically renewable for additional one-year periods unless terminated by either party upon 60 days written notice prior to the end of the applicable one-year period, (ii) his death, or (iii) termination for cause. During the three months and nine months ended September 30, 2020, the Company incurred charges for salary in the amount of \$25,000 with respect to this agreement.

**Robert Weingarten.** On August 12, 2020, the Company entered into an employment agreement with Robert N. Weingarten pursuant to which Mr. Weingarten was appointed as the Company's Vice-President and Chief Financial Officer. Mr. Weingarten will receive an annual salary of \$120,000. Mr. Weingarten was also granted options to acquire 350,000 shares of the Company's common stock, which are further described in Note 6. The effective date of the agreement is August 12, 2020. The agreement shall remain in effect until the earlier of (i) one year from the effective date, automatically renewable for additional one-year periods unless terminated by either party upon 60 days written notice prior to the end of the applicable one-year period, (ii) his death, or (iii) termination for cause. During the three months and nine months ended September 30, 2020, the Company incurred charges for salary in the amount of \$16,452 with respect to this agreement.

## *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 September 30, 2020 and 2019, respectively, and \$12,000 and \$12,000 for the nine months ended September 30, 2020 and 2019, respectively, which were included in research and development costs in the consolidated statements of operations.

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

BioPharmaWorks was founded in 2015 by former Pfizer scientists with extensive multi-disciplinary research and development and drug development experience. The Collaboration Agreement was for an initial term of two years and automatically renews for subsequent annual periods unless terminated by a party not less than 60 days prior to the expiration of the applicable period. In connection with the Collaboration Agreement, the Company agreed to pay BioPharmaWorks a monthly fee of \$10,000, subject to the right of the Company to pay a negotiated hourly rate in lieu of the monthly payment and agreed to issue to BioPharmaWorks certain equity-based compensation. In April 2018, it was mutually agreed to suspend services and payments under the Collaboration Agreement, without extending its term, for the period from February 1, 2018 through the September 13, 2019 anniversary date. In February 2019, the Company and BioPharmaWorks subsequently agreed to resume the Collaboration Agreement effective March 1, 2019, and the Collaboration Agreement is currently in effect. The Company recorded charges to operations pursuant to this Collaboration Agreement of \$30,000 and \$30,000 for the three months ended September 30, 2020 and 2019, respectively, and \$90,000 and \$70,000 for the nine months ended September 30, 2020 and 2019, 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 preclinical studies of the potential benefit of LB-100 in a mouse model of Angelman Syndrome (AS) as reported in The Proceedings of The National Academy of Science (Wang et al, June 3, 2019). The preclinical studies will take place at The University of California - Davis under the direction of Dr. David Segal, an internationally recognized leader in AS research. If the preclinical studies confirm that LB-100 reduces AS signs in rodent models, the Company has agreed to enter into discussions with FAST with respect to possible collaborations to most efficiently assess the benefit of LB-100 in patients with AS, which is a rare disease affecting an estimated one out of 12,000 to one out of 20,000 persons in the United States. The genetic cause of AS, reduced function of a specific maternal gene called Ube3, has been understood for some time, but the molecular abnormality resulting from the genetic lesion has now been shown to be increased concentrations of protein phosphatase 2A (PP2A), a molecular target of 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.

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

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

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

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

#### **8. Subsequent Events**

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

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

### Overview

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

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

### Proposed Public Offering and Listing on The Nasdaq Capital Market

On November 2, 2020, the Company filed Amendment No. 2 to its Registration Statement on Form S-1 with the SEC to register and sell newly-issued shares of common stock in an underwritten public offering, currently estimated to generate gross proceeds of approximately \$9,375,000, to fund the Company's operating capital requirements for at least the next two years. However, there can be no assurances that such public offering will be completed, or that if completed, that such public offering will generate gross proceeds of approximately \$9,375,000.

On October 21, 2020, the Company's application to have its shares of common stock listed for trading on The Nasdaq Capital Market under the symbol "LIXT" was approved, subject to notice of issuance of the shares in the public offering.

### Reverse Stock Split

On July 14, 2020, the Board of Directors of the Company approved a 1-for-6 reverse split of the Company's outstanding shares of common stock. Holders of a majority of shares of the Company's common stock have provided their consent for such reverse stock split. The Company intends to implement such reverse stock split upon receiving regulatory approval for such action, and concurrently with the completion of the public offering.

All common share and per share amounts presented herein are on a pre-split basis.

### Going Concern

At September 30, 2020, the Company had cash and cash equivalents of \$1,076,248 available to fund its operations. Because the Company is currently engaged in Phase 2 clinical trials, it is expected that it will take a significant amount of time to develop any product or intellectual property capable of generating sustainable revenues. Accordingly, the Company's business is unlikely to generate any sustainable operating revenues in the next several years and may never do so. In addition, to the extent that the Company is able to generate revenues through licensing its technologies or through product sales, there can be no assurance that the Company will be able to achieve positive earnings and operating cash flows.

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

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

The Company's ability to continue as a going concern is dependent upon its ability to raise additional equity capital to fund its research and development activities and to ultimately achieve sustainable operating revenues and profitability. The Company's consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties (see "Liquidity and Capital Resources – September 30, 2020" below).

#### **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 and nine months ended September 30, 2020 and 2019 included elsewhere in this document.

#### **Concentration of Risk**

Information with respect to concentration of risk is provided at Note 3 to the condensed consolidated financial statements for the three months and nine months ended September 30, 2020 and 2019 included elsewhere in this document.

#### **Critical Accounting Policies and Estimates**

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

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

#### **Research and Development**

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

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

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

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

## **Patent and Licensing Related Legal and Filing Costs**

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

## **Stock-Based Compensation**

The Company periodically issues common stock and stock options to officers, directors, 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"). Estimated volatility is based on the historical volatility of the Company's common stock, calculated utilizing a look-back period approximately equal to the estimated 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 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 model systems. The enhancement of anti-cancer activity of these anti-cancer drugs occurs at doses of LB-100 that do not significantly increase toxicity in animals. It is therefore hoped that, when combined with standard anti-cancer regimens against many tumor types, the Company's compounds will improve therapeutic benefit without enhancing toxicity in humans.

## *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 Operations

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

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

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

### Results of Operations

At September 30, 2020, the Company had not yet commenced any revenue-generating operations, does not have any positive cash flows from operations, and is dependent on its ability to raise equity capital to fund its operating requirements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues	\$ —	\$ —	\$ —	\$ —
Costs and expenses:				
General and administrative costs	802,273	522,360	1,350,201	1,460,551
Research and development costs	799,420	570,601	1,012,038	699,038
Total costs and expenses	1,601,693	1,092,961	2,362,239	2,159,589
Loss from operations	(1,601,693)	(1,092,961)	(2,362,239)	(2,159,589)
Interest income	38	13,889	4,284	41,317
Net loss	\$ (1,601,655)	\$ (1,079,072)	\$ (2,357,955)	\$ (2,118,272)
Net loss per common share – basic and diluted	\$ (0.02)	\$ (0.02)	\$ (0.04)	\$ (0.03)
Weighted average common shares outstanding – basic and diluted	67,045,814	67,045,814	67,045,814	67,045,814

### Three Months Ended September 30, 2020 and 2019

Revenues. The Company did not have any revenues for the three months ended September 30, 2020 and 2019.

General and Administrative Costs. For the three months ended September 30, 2020, general and administrative costs were \$802,273, which consisted of the fair value of vested stock options issued to officers and consultants of \$394,031, patent and licensing legal fees and costs of \$163,987, other consulting and professional fees of \$139,379, insurance expense of \$26,403, officer's salary and related costs of \$61,833, licensing fees of \$6,301, stock transfer fees of \$3,353, listing fees of \$3,000, filing fees of \$598, and other operating costs of \$3,388.

For the three months ended September 30, 2019, general and administrative costs were \$522,360, which consisted of the fair value of vested stock options issued to officers and consultants of \$5,030, patent and licensing legal fees and costs of \$362,755, other consulting and professional fees of \$75,184, insurance expense of \$13,796, officer's salary and related costs of \$16,888, licensing fees of \$31,301, stock transfer fees of \$2,719, listing fees of \$3,000, filing fees of \$3,124, and other operating costs of \$8,563.

General and administrative costs increased by \$279,913 or 53.6% in 2020 as compared to 2019, primarily as a result of increases in the fair value of stock options issued to directors and consultants of \$389,001, other consulting and professional fees of \$64,195, officer's salary and related costs of \$44,945, and insurance expense of \$12,607, offset by a decreases of \$198,768 in patent and licensing legal fees and costs and \$25,000 in licensing fees.

Research and Development Costs. For the three months ended September 30, 2020, research and development costs were \$799,420, which consisted of the fair value of vested stock options issued to consultants of \$670,715, and contractor costs, primarily in connection with the Company's pre-clinical research focused on the development of additional novel anti-cancer compounds to add to its clinical pipeline, including \$10,643 to Moffitt, \$6,042 to Theradex, \$30,000 to BioPharmaWorks and \$82,020 to various other contractors.

For the three months ended September 30, 2019, research and development costs were \$570,601, which consisted of the fair value of vested stock options issued to consultants of \$434,024, and contractor costs, primarily in connection with the Company's pre-clinical research focused on the development of additional novel anti-cancer compounds to add to its clinical pipeline, including \$87,471 to GEIS, \$9,996 to Moffitt, \$5,030 to Theradex, \$30,000 to BioPharmaWorks and \$4,080 to various other contractors.

Research and development costs increased by \$228,819 in 2020 as compared to 2019, primarily as a result of an increase in the fair value of vested stock options issued to consultants of \$236,691.

Interest Income. For the three months ended September 30, 2020, the Company had interest income of \$38, as compared to interest income of \$13,889 for the three months ended September 30, 2019, as a result of a reduction in the Company's cash resources previously invested in short-term federally insured certificates of deposit.

Net Loss. For the three months ended September 30, 2020, the Company incurred a net loss of \$1,601,655, as compared to a net loss of \$1,079,072 for the three months ended September 30, 2019.

#### **Nine Months Ended September 30, 2020 and 2019**

Revenues. The Company did not have any revenues for the nine months ended September 30, 2020 and 2019.

General and Administrative Costs. For the nine months ended September 30, 2020, general and administrative costs were \$1,350,201, which consisted of the fair value of vested stock options issued to officers and consultants of \$394,031, patent and licensing legal fees and costs of \$440,899, other consulting and professional fees of \$311,298, insurance expense of \$54,818, officer's salary and related costs of \$95,724, licensing fees of \$18,699, stock transfer fees of \$9,739, listing fees of \$9,000, filing fees of \$6,892, travel of \$718, and other operating costs of \$8,383.

For the nine months ended September 30, 2019, general and administrative costs were \$1,460,551, which consisted of the fair value of vested stock options issued to officers and consultants of \$314,631, patent and licensing legal fees and costs of \$672,661, other consulting and professional fees of \$260,532, insurance expense of \$40,889, officer's salary and related costs of \$50,769, licensing fees of \$74,368, stock transfer fees of \$8,451, listing fees of \$9,000, filing fees of \$9,717, travel of \$4,271, and other operating costs of \$15,262.

General and administrative costs decreased by \$110,350 or 7.6% in 2020 as compared to 2019, primarily as a result of a decrease in patent and licensing legal fees and costs of \$231,762, offset by increases in fair value of vested stock options issued to officers and consultants of \$79,400, and other consulting and professional fees of \$50,766.

Research and Development Costs. For the nine months ended September 30, 2020, research and development costs were \$1,012,038, which consisted of the fair value of vested stock options issued to consultants of \$670,715, and contractor costs, primarily in connection with the Company's pre-clinical research focused on the development of additional novel anti-cancer compounds to add to its clinical pipeline, including \$43,411 to GEIS, \$36,008 to Moffitt, \$26,118 to Theradex, \$90,201 to BioPharmaWorks and \$145,585 to various other contractors.

For the nine months ended September 30, 2019, research and development costs were \$699,038, which consisted of the fair value of vested stock options issued to consultants of \$434,024, and contractor costs, primarily in connection with the Company's pre-clinical research focused on the development of additional novel anti-cancer compounds to add to its clinical pipeline, including \$87,471 to GEIS, \$23,249 to Moffitt, \$56,290 to Theradex, \$70,000 to BioPharmaWorks and \$28,004 to various other contractors.

Research and development costs increased by \$313,000 in 2020 as compared to 2019, primarily as a result of an increase in the fair value of vested stock options issued to consultants of \$236,691 and an increase in contractor costs, primarily in connection with the Company's pre-clinical research focused on the development of additional novel anti-cancer compounds to add to its clinical pipeline.

Interest Income. For the nine months ended September 30, 2020, the Company had interest income of \$4,284, as compared to interest income of \$41,317 for the nine months ended September 30, 2019, as a result of a reduction in the Company's cash resources previously invested in short-term federally insured certificates of deposit.

Net Loss. For the nine months ended September 30, 2020, the Company incurred a net loss of \$2,357,955, as compared to a net loss of \$2,118,272 for the nine months ended September 30, 2019.

#### **Liquidity and Capital Resources – September 30, 2020**

At September 30, 2020, the Company had working capital of \$966,673, as compared to working capital of \$2,434,135 at December 31, 2019, reflecting a decrease in working capital of \$1,467,462 for the nine months ended September 30, 2020. The decrease in working capital during the nine months ended September 30, 2020 was the result of working capital being utilized to fund the Company's research and development activities and ongoing operating expenses, including maintaining and developing the Company's patent portfolio. At September 30, 2020, the Company had cash and cash equivalents of \$1,076,248 available to fund its operations.

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. If the Company is able to complete the proposed public offering as discussed above in the approximate amount indicated, the Company estimates that such funding would provide sufficient working capital resources to fund the Company's clinical trial program with respect to the development of its lead anti-cancer clinical compound LB-100 through at least December 2022. If the Company is not able to complete the proposed public offering as discussed below, the Company would attempt to raise additional capital to fund its clinical trial program through alternative financing sources.

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 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 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.

Operating Activities. For the nine months ended September 30, 2020, operating activities utilized cash of \$1,392,372, as compared to utilizing cash of \$1,296,610 for the nine months ended September 30, 2019, to fund the Company's ongoing research and development activities and to fund its other ongoing operating expenses, including maintaining and developing its patent portfolio.

Investing Activities. For the nine months ended September 30, 2020 and 2019, the Company had no investing activities.

Financing Activities. For the nine months ended September 30, 2020, financing activities consisted of the payment of deferred offering costs of \$130,244. The Company had no financing activities for the nine months ended September 30, 2019.

## Principal Commitments

### *Clinical Trial Agreements*

**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 (“Moffitt”), effective for a term of five years, unless terminated earlier by the Company pursuant to 30 days written notice. Pursuant to the Clinical Trial Research Agreement, Moffitt agreed to conduct and manage a Phase 1b/2 clinical trial to evaluate the therapeutic benefit of the Company’s lead anti-cancer clinical compound LB-100 to be administered intravenously in patients with low or intermediate-1 risk myelodysplastic syndrome (MDS).

In November 2018, the Company received approval from the U.S. Food and Drug Administration 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 trial would be completed over a period of four years from its initiation, with the final analysis and reporting expected by July 2023. However, with additional funds, the Company’s objective would be to add two additional MDS centers to the Phase 2 portion of the study to accelerate patient accrual, with the goal of an earlier reporting date.

During the three months ended September 30, 2020 and 2019, the Company paid Moffitt \$10,643 and \$9,996, respectively, pursuant to this agreement. During the nine months ended September 30, 2020 and 2019, the Company paid Moffitt \$36,008 and \$23,249, respectively, pursuant to this agreement. As of September 30, 2020, total costs of \$81,101 have been incurred pursuant to this agreement.

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

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

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

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

Accordingly, during the three months ended September 30, 2020 and 2019, the Company incurred costs of \$0 and \$87,471, respectively, and during the nine months ended September 30, 2020 and 2019, the Company incurred costs of \$43,411 and \$87,471, respectively, pursuant to this agreement. As of September 30, 2020, total costs of \$130,882 have been incurred pursuant to this agreement.

The Company's aggregate commitments pursuant to the aforementioned clinical trial agreements, less amounts previously paid to date under these agreements, totaled approximately \$5,049,000 as of September 30, 2020, consisting of approximately \$4,428,000 relating to the GEIS clinical trial and approximately \$621,000 relating to the Moffitt clinical trial, which are expected to be incurred over the next five years through June 30, 2025.

#### ***Clinical Trial Monitoring Agreements***

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

Costs under this work order agreement are estimated to be approximately \$954,000, with such payments expected to be divided approximately 94% to Theradex for services and approximately 6% for payments for pass-through costs. The costs of the Phase 1b/2 clinical trial being paid to or through Theradex are being recorded and charged to operations based on the periodic documentation provided by the CRO. During the three months ended September 30, 2020 and 2019, the Company incurred costs of \$917 and \$3,190, respectively, pursuant to this work order. During the nine months ended September 30, 2020 and 2019, the Company incurred costs of \$12,393 and \$51,683, respectively, pursuant to this work order. As of September 30, 2020, total costs of \$75,885 have been incurred pursuant to this work order agreement.

The Company's aggregate commitments pursuant to this clinical trial monitoring agreement, less amounts previously paid to date under this agreement, totaled approximately \$875,000 as of September 30, 2020, which are expected to be incurred over the next five years through June 30, 2025.

#### ***Other Clinical Agreements***

As of September 30, 2020, the Company was committed to two other partially completed short-term clinical study agreements. The Company's aggregate commitments pursuant to these clinical study agreements, less amounts previously paid to date under these agreements, totaled approximately \$258,000 as of September 30, 2020, which is expected to be incurred over the next five months. During the three months and nine months ended September 30, 2020, the Company incurred costs of \$41,625, pursuant to these agreements.

## *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 "Oxabicycloheptanes and Oxabicycloheptenes for the Treatment of Depressive and Stress Disorders", which was filed with the United States Patent and Trademark Office in the name of INSERM and the Company as co-owners on February 19, 2015 and granted on May 12, 2017, and related patent applications and filings. INSERM is a French public institution dedicated to research in the field of health and medicine that had previously entered into a Material Transfer Agreement ("MTA") with the Company to allow INSERM to conduct research on the Company's proprietary compound LB-100 and/or its analogs for the treatment of depressive or stress disorders in humans. Pursuant to the Agreement, the Company has agreed to make certain milestone payments to INSERM aggregating up to \$1,750,000 upon achievement of development milestones and up to \$6,500,000 upon achievement of commercial milestones. The Company also agreed to pay INSERM certain commercial royalties on net sales of products attributed to the Agreement. The Company's current plan is to complete the validation process to evaluate LB-100 for the treatment of depressive or stress disorders in humans within three years; however, the exploitation of this patent for the treatment of depressive and stress disorders in humans will require substantial additional capital and/or a joint venture or other type of business arrangement with a pharmaceutical company with substantially greater capital and business resources than those available to the Company. As there can be no assurances that the Company will be able to obtain the capital or business resources necessary to focus on the exploitation of this patent, it is uncertain as to when, if at all, the Company may reach any of the development or commercialization milestones under the Agreement. As of September 30, 2020 and December 31, 2019, no amounts were due under this agreement.

Effective April 2, 2018, the Company entered into a consulting agreement for a term of two years with Liberi Life Sciences Consultancy BV, located in The Netherlands, for consulting and advisory services with respect to sales and licensing, as well as the procurement of investors in China, Japan and South Korea. The Consulting Agreement provided for the payment of a fixed, one-time retainer of EURO 15,000 (US \$18,348), which was paid on April 5, 2018, and 2.5% of the net payments received by the Company from sales of products or licensing activities arising directly and exclusively from leads generated by the advisor during the term of the Consulting Agreement, and any investors introduced to the Company by the advisor that results in an investment in the Company during the term of the Consulting Agreement. The Company recorded the payment of the retainer as a prepaid expense in the Company's consolidated balance sheet, and is amortizing the retainer payment over the two-year life of the Consulting Agreement, as a result of which the Company recorded charges to operations of \$0 and \$2,294 during the three months ended September 30, 2020 and 2019, and \$2,294 and \$6,882 during the nine months ended September 30, 2020 and 2019, respectively. As of September 30, 2020, the prepaid consulting fee had been fully amortized. At December 31, 2019, the unamortized balance of the retainer payment was \$9,174, all of which was classified as a current asset in the Company's consolidated balance sheet at such date. On March 1, 2020, the Consulting Agreement was extended to April 2, 2021 without any additional consideration.

Effective August 20, 2018, the 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 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 September 30, 2020 and 2019, the Company recorded charges to operations of \$6,301 and \$31,301, respectively, in connection with its obligations under the License Agreement. During the nine months ended September 30, 2020 and 2019, the Company recorded charges to operations of \$18,699 and \$74,368, respectively, in connection with its obligations under the License Agreement. As of September 30, 2020, no milestones had yet been attained.

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

#### **Employment Agreements**

**Dr. John Kovach.** On July 15, 2020, the Company entered into an employment agreement with Dr. John Kovach pursuant to which Dr. Kovach is to continue to act as the Company's President, Chief Scientific Officer, and Chief Executive Officer. His responsibilities shall be for the oversight of the Company's entire operations and strategic planning and shall be the primary contact between the Company's executive team and the Board of Directors, to whom he shall report. Dr. Kovach shall supervise all scientific endeavors, providing guidance to the Chief Medical Officer. He shall be the principal spokesperson for the Company. Dr. Kovach will receive an annual salary of \$250,000, payable monthly. The effective date of the agreement is October 1, 2020, and shall remain in effect until the earlier of (i) one year from the effective date, automatically renewable for additional one-year periods unless terminated by either party upon 60 days written notice prior to the end of the applicable one-year period, (ii) his death, or (iii) termination for cause. During the three months and nine months ended September 30, 2020, the Company did not incur any charges for salary with respect to this agreement.

**Eric Forman.** On July 15, 2020, as amended on August 12, 2020, the Company entered into an employment agreement with Eric Forman, pursuant to which Mr. Forman will act as the Company's Chief Administrative Officer reporting directly to the Company's Chief Executive Officer. Mr. Forman's primary function shall be to oversee the Company's internal operations, including IT, licensing, legal, personnel, marketing, and corporate governance. Mr. Forman will receive an annual salary of \$120,000, payable monthly. Mr. Forman was also granted options to acquire 350,000 shares of the Company's common stock. The effective date of the agreement is October 1, 2020, and shall remain in effect until the earlier of (i) one year from the effective date, automatically renewable for additional one-year periods unless terminated by either party upon 60 days written notice prior to the end of the applicable one-year period, (ii) his death, or (iii) termination for cause. During the three months and nine months ended September 30, 2020, the Company did not incur any charges for salary with respect to this agreement.

**Dr. James Miser.** On August 1, 2020, the Company entered into an employment agreement with Dr. James Miser, M.D., pursuant to which Dr. Miser was appointed as the Company's Chief Medical Officer. Under the employment agreement, Dr. Miser will play a leadership role in planning, implementation, and oversight of clinical trials. Dr. Miser will be responsible for assisting and developing strategic clinical goals and the implementation and safety monitoring of investigational studies. Dr. Miser will be the primary medical monitor for all clinical investigational studies and for the oversight of third party CRO monitors. Dr. Miser will work closely with the Company's Chief Executive Officer on the development of specific goals needed to ensure the timely implementation of appropriate clinical studies needed for successful registration of therapeutic products and new drug development. Dr. Miser will be required to devote at least 50% of his business time to the Company's activities. Dr. Miser will receive an annual salary of \$150,000. Dr. Miser was also granted options to acquire 500,000 shares of the Company's common stock. The effective date of the agreement is August 1, 2020. The agreement shall remain in effect until the earlier of (i) one year from the effective date, automatically renewable for additional one-year periods unless terminated by either party upon 60 days written notice prior to the end of the applicable one-year period, (ii) his death, or (iii) termination for cause. During the three months and nine months ended September 30, 2020, the Company incurred charges for salary in the amount of \$25,000, with respect to this agreement.

**Robert Weingarten.** On August 12, 2020, the Company entered into an employment agreement with Robert N. Weingarten pursuant to which Mr. Weingarten was appointed as the Company's Vice-President and Chief Financial Officer. Mr. Weingarten will receive an annual salary of \$120,000. Mr. Weingarten was also granted options to acquire 350,000 shares of the Company's common stock. The effective date of the agreement is August 12, 2020. The agreement shall remain in effect until the earlier of (i) one year from the effective date, automatically renewable for additional one-year periods unless terminated by either party upon 60 days written notice prior to the end of the applicable one-year period, (ii) his death, or (iii) termination for cause. During the three months and nine months ended September 30, 2020, the Company incurred charges for salary in the amount of \$16,452, with respect to this agreement.

### ***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 September 30, 2020 and 2019, respectively, and \$12,000 and \$12,000 for the nine months ended September 30, 2020 and 2019, respectively, which were included in research and development costs in the consolidated statements of operations.

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

BioPharmaWorks was founded in 2015 by former Pfizer scientists with extensive multi-disciplinary research and development and drug development experience. The Collaboration Agreement was for an initial term of two years and automatically renews for subsequent annual periods unless terminated by a party not less than 60 days prior to the expiration of the applicable period. In connection with the Collaboration Agreement, the Company agreed to pay BioPharmaWorks a monthly fee of \$10,000, subject to the right of the Company to pay a negotiated hourly rate in lieu of the monthly payment and agreed to issue to BioPharmaWorks certain equity-based compensation. In April 2018, it was mutually agreed to suspend services and payments under the Collaboration Agreement, without extending its term, for the period from February 1, 2018 through the September 13, 2019 anniversary date. In February 2019, the Company and BioPharmaWorks subsequently agreed to resume the Collaboration Agreement effective March 1, 2019, and the Collaboration Agreement is currently in effect. The Company recorded charges to operations pursuant to this Collaboration Agreement of \$30,000 and \$30,000 for the three months ended September 30, 2020 and 2019, respectively, and \$90,000 and \$70,000 for the nine months ended September 30, 2020 and 2019, 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 preclinical studies of the potential benefit of LB-100 in a mouse model of Angelman Syndrome (AS) as reported in The Proceedings of The National Academy of Science (Wang et al, June 3, 2019). The preclinical studies will take place at The University of California - Davis under the direction of Dr. David Segal, an internationally recognized leader in AS research. If the preclinical studies confirm that LB-100 reduces AS signs in rodent models, the Company has agreed to enter into discussions with FAST with respect to possible collaborations to most efficiently assess the benefit of LB-100 in patients with AS, which is a rare disease affecting an estimated one out of 12,000 to one out of 20,000 persons in the United States. The genetic cause of AS, reduced function of a specific maternal gene called Ube3, has been understood for some time, but the molecular abnormality resulting from the genetic lesion has now been shown to be increased concentrations of protein phosphatase 2A (PP2A), a molecular target of 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.

### **Off-Balance Sheet Arrangements**

At September 30, 2020, the Company did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Not applicable.

### ITEM 4. CONTROLS AND PROCEDURES

#### Evaluation of Disclosure Controls and Procedures

As required by Rule 15d-15(b) of the Securities and Exchange Commission (the “SEC”), the Company carried out an evaluation, under the supervision and with the participation of its management, consisting of the Company’s principal executive officer and principal financial officer, of the effectiveness of the design and operation of the Company’s disclosure controls and procedures as of September 30, 2020, the end of the most recent period covered by this report.

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

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

#### Management’s Report on Internal Control Over Financial Reporting

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

Based on the Company’s assessment, management has concluded that its internal control over financial reporting was not effective as of September 30, 2020 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. Generally Accepted Accounting Principles, as described below.

The Company’s management has concluded that the Company had a material weakness in its internal controls at September 30, 2020. Until recently, the Company’s Chief Executive Officer had almost complete responsibility for the processing of invoices and the preparation of checks, and the Company’s finance department did not have adequate internal staff and resources to process the accounting information and prepare periodic financial statements and footnotes. In order to mitigate these internal control weaknesses, the Company had designed and implemented measures and systems, including expanded bookkeeping and review procedures and the utilization of the services of qualified outside consultants with the expertise to perform specific accounting and finance functions, as well as the review of major transactions and agreements by the Board of Directors.

In order to address these internal controls weaknesses, effective August 12, 2020, the Company entered into an Employment Agreement with Robert N. Weingarten to serve as the Company’s Vice President and Chief Financial Officer. Mr. Weingarten is an experienced business consultant and advisor focusing on accounting and SEC compliance issues. Since 1979, Mr. Weingarten has provided such financial consulting and advisory services, has acted as chief financial officer, and has served on the boards of directors of numerous public companies in various stages of development, operation or reorganization. Mr. Weingarten has experience in a variety of industries, including the pharmaceutical industry. Mr. Weingarten is familiar with the financial and business operations of the Company, as he has provided accounting and financial consulting services to the Company for a number of years with respect to the preparation of the Company’s consolidated financial statements and certain other financial and compliance matters. During the next few months, Mr. Weingarten is expected to work with management to implement various policies and procedures that are expected to address and mitigate these internal control weaknesses.

However, these efforts may not be fully successful, which could undermine the Company's ability to provide accurate, timely and reliable reports on its financial and operating results. In addition, if the Company identifies additional material weaknesses in its internal control over financial reporting, the Company may not detect errors on a timely basis and its financial statements may be materially misstated. Moreover, in the future the Company may engage in business activities or transactions that could negatively affect its internal control over financial reporting and result in additional material weaknesses.

The Company's management, consisting of its Chief Executive Officer and its Chief Financial Officer, does not expect that its disclosure controls and procedures or its internal controls over financial reporting will prevent all error or fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Furthermore, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Due to the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and any instances of malfeasance or fraud have been detected.

Management believes that the consolidated financial statements included in this report fairly present, in all material respects, the Company's financial condition, results of operations and cash flows as of and for the period ended September 30, 2020.

#### **Changes in Internal Controls Over Financial Reporting**

The Company's management, consisting of its Chief Executive Officer and its 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 period ended September 30, 2020 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting, other than the material weaknesses as noted above.

## PART II - OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

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

### ITEM 1A. RISK FACTORS

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

The Risk Factors set forth in the 2019 Form 10-K should be read carefully in connection with evaluating the Company's business and in connection with the forward-looking statements contained in this Quarterly Report on Form 10-Q. Any of the risks described in the 2019 Form 10-K could materially adversely affect the Company's business, financial condition or future results and the actual outcome of matters as to which forward-looking statements are made. These are not the only risks that the Company faces. Additional risks and uncertainties not currently known to the Company or that the Company currently deems to be immaterial also may materially adversely affect the Company's business, financial condition and/or operating results.

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

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

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

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

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

### 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
3.1	<a href="#">Amended and Restated Bylaws.</a> <sup>1</sup>
10.1	<a href="#">Employment Agreement Between the Company and Dr. James Miser.</a> <sup>1+</sup>
10.2	<a href="#">Employment Agreement Between the Company and Robert N. Weingarten.</a> <sup>2+</sup>
10.3	<a href="#">Employment Agreement Between the Company and Dr. John Kovach.</a> <sup>1+</sup>
10.4	<a href="#">Employment Agreement Between the Company and Eric Forman.</a> <sup>1+</sup>
10.5	<a href="#">2020 Stock Incentive Plan.</a> <sup>1+</sup>
31.1*	<a href="#">Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
31.2*	<a href="#">Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
32.1*	<a href="#">Officer's Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
32.2*	<a href="#">Officer's Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document

\* Filed herewith.

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

+ Indicates a management contract or any compensatory plan, contract or arrangement.

1 Filed as an Exhibit to the Company's Current Reports on Form 8-K, as filed with the Securities and Exchange Commission on July 17, 2020 and incorporated herein by reference.

2 Filed as an Exhibit to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on August 18, 2020 and incorporated herein by reference.

**SIGNATURES**

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

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

(Registrant)

Date: November 10, 2020

By: /s/ JOHN S. KOVACH

John S. Kovach  
Chief Executive Officer

Date: November 10, 2020

By: /s/ ROBERT N. WEINGARTEN

Robert N. Weingarten  
Chief Financial Officer

**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: November 10, 2020

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

---

**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: November 10, 2020

By: /s/ ROBERT N. WEINGARTEN

Robert N. Weingarten  
Chief Financial Officer

---

**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 September 30, 2020 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

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

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

Date: November 10, 2020

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

---

**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 September 30, 2020 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

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

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

Date: November 10, 2020

By: /s/ ROBERT N. WEINGARTEN

Robert N. Weingarten  
Chief Financial Officer

---