

**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, 2021

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

Commission file number: 001-39717

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.**

(Exact name of registrant as specified in its charter)

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

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

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	LIXT	The Nasdaq Stock Market LLC
Warrants to Purchase Common Stock, par value \$0.0001 per share	LIXTW	The Nasdaq Stock Market LLC

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).  
Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐  
Non-accelerated filer ☐

Accelerated filer ☐  
Smaller reporting company ☒  
Emerging growth company ☐

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

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

As of November 1, 2021, the Company had 13,746,593 shares of common stock, \$0.0001 par value, issued and outstanding.

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

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**PART I - FINANCIAL INFORMATION**

**ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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

**CONDENSED CONSOLIDATED BALANCE SHEETS**

	<b>September 30, 2021</b>	<b>December 31, 2020</b>
	<u>(Unaudited)</u>	
<b>ASSETS</b>		
Current assets:		
Cash	\$ 5,960,594	\$ 5,069,266
Advances on research and development contract services	216,018	76,898
Prepaid insurance	98,323	67,311
Other prepaid expenses and current assets	32,224	15,000
Total current assets	<u>6,307,159</u>	<u>5,228,475</u>
Deferred offering costs	26,376	—
Total assets	<u>\$ 6,333,535</u>	<u>\$ 5,228,475</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses, including \$60,333 and \$0 to related parties at September 30, 2021 and December 31, 2020, respectively	\$ 232,016	\$ 190,292
Accrued offering costs	—	10,467
Research and development contract liabilities	26,683	15,765
Total current liabilities	<u>258,699</u>	<u>216,524</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 – 729,167 shares	3,500,000	3,500,000
Common stock, \$0.0001 par value; authorized – 100,000,000 shares; issued and outstanding – 13,746,593 shares and 12,402,157 shares at September 30, 2021 and December 31, 2020, respectively	1,374	1,240
Additional paid-in capital	37,626,264	31,864,479
Accumulated deficit	(35,052,802)	(30,353,768)
Total stockholders' equity	<u>6,074,836</u>	<u>5,011,951</u>
Total liabilities and stockholders' equity	<u>\$ 6,333,535</u>	<u>\$ 5,228,475</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,	
	2021	2020	2021	2020
Revenues	\$ —	\$ —	\$ —	\$ —
Costs and expenses:				
General and administrative costs, including compensation to related parties of \$540,972 and \$464,483 for the three months ended September 30, 2021 and 2020, respectively, and \$2,390,308 and \$518,483 to related parties for the nine months ended September 30, 2021 and 2020, respectively	1,010,539	802,273	3,762,373	1,350,201
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	227,181	799,420	933,122	1,012,038
Total costs and expenses	1,237,720	1,601,693	4,695,495	2,362,239
Loss from operations	(1,237,720)	(1,601,693)	(4,695,495)	(2,362,239)
Interest income	161	38	487	4,284
Interest expense	—	—	(2,944)	—
Foreign currency loss	(1,165)	—	(1,082)	—
Net loss	\$ (1,238,724)	\$ (1,601,655)	\$ (4,699,034)	\$ (2,357,955)
Net loss per common share – basic and diluted	\$ (0.09)	\$ (0.14)	\$ (0.35)	\$ (0.21)
Weighted average common shares outstanding – basic and diluted	13,733,912	11,174,302	13,381,922	11,174,302

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, 2021 and 2020**

	<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>			
<b>Three months ended September 30, 2021:</b>							
Balance, June 30, 2021	350,000	\$ 3,500,000	13,663,260	\$ 1,366	\$ 37,179,050	\$ (33,814,078)	\$ 6,866,338
Exercise of options	—	—	83,333	8	99,992	—	100,000
Stock-based compensation expense	—	—	—	—	347,222	—	347,222
Net loss for the period	—	—	—	—	—	(1,238,724)	(1,238,724)
Balance, September 30, 2021	<u>350,000</u>	<u>\$ 3,500,000</u>	<u>13,746,593</u>	<u>\$ 1,374</u>	<u>\$ 37,626,264</u>	<u>\$ (35,052,802)</u>	<u>\$ 6,074,836</u>
<b>Nine months ended September 30, 2021:</b>							
Balance, December 31, 2020	350,000	\$ 3,500,000	12,402,157	\$ 1,240	\$ 31,864,479	\$ (30,353,768)	\$ 5,011,951
Proceeds from sale of common stock in direct equity offering, net of offering costs	—	—	1,133,102	113	3,689,648	—	3,689,761
Exercise of warrants	—	—	3,000	1	17,099	—	17,100
Exercise of options	—	—	208,334	20	200,980	—	201,000
Stock-based compensation expense	—	—	—	—	1,854,058	—	1,854,058
Net loss for the period	—	—	—	—	—	(4,699,034)	(4,699,034)
Balance, September 30, 2021	<u>350,000</u>	<u>\$ 3,500,000</u>	<u>13,746,593</u>	<u>\$ 1,374</u>	<u>\$ 37,626,264</u>	<u>\$ (35,052,802)</u>	<u>\$ 6,074,836</u>

(Continued)

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

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

**Three Months and Nine Months Ended September 30, 2021 and 2020**

	<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>			
<b>Three months ended September 30, 2020:</b>							
Balance, June 30, 2020	350,000	\$ 3,500,000	11,174,302	\$ 1,117	\$ 26,021,904	\$ (27,845,186)	\$ 1,677,835
Stock-based compensation expense	—	—	—	—	1,064,746	—	1,064,746
Net loss for the period	—	—	—	—	—	(1,601,655)	(1,601,655)
Balance, September 30, 2020	<u>350,000</u>	<u>\$ 3,500,000</u>	<u>11,174,302</u>	<u>\$ 1,117</u>	<u>\$ 27,086,650</u>	<u>\$ (29,446,841)</u>	<u>\$ 1,140,926</u>
<b>Nine months ended September 30, 2020:</b>							
Balance, December 31, 2019	350,000	\$ 3,500,000	11,174,302	\$ 1,117	\$ 26,021,904	\$ (27,088,886)	\$ 2,434,135
Stock-based compensation expense	—	—	—	—	1,064,746	—	1,064,746
Net loss for the period	—	—	—	—	—	(2,357,955)	(2,357,955)
Balance, September 30, 2020	<u>350,000</u>	<u>\$ 3,500,000</u>	<u>11,174,302</u>	<u>\$ 1,117</u>	<u>\$ 27,086,650</u>	<u>\$ (29,446,841)</u>	<u>\$ 1,140,926</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,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (4,699,034)	\$ (2,357,955)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense included in -		
General and administrative costs	1,854,058	394,031
Research and development costs	—	670,715
Changes in operating assets and liabilities:		
(Increase) decrease in -		
Advances on research and development contract services	(139,120)	(29,792)
Accrued interest receivable	—	14,367
Prepaid insurance	(31,012)	(34,583)
Other prepaid expenses and current assets	(17,224)	11,294
Increase (decrease) in -		
Accounts payable and accrued expenses	25,348	(28,031)
Research and development contract liabilities	10,918	(32,418)
Net cash used in operating activities	<u>(2,996,066)</u>	<u>(1,392,372)</u>
Cash flows from financing activities:		
Proceeds from sale of common stock in direct equity offering, net of offering costs	3,689,761	—
Payment of deferred offering costs	(10,000)	(130,244)
Exercise of common stock warrants	17,100	—
Exercise of common stock options	201,000	—
Payment of public offering costs	(10,467)	—
Net cash provided by (used in) financing activities	<u>3,887,394</u>	<u>(130,244)</u>
Cash:		
Net increase (decrease)	891,328	(1,522,616)
Balance at beginning of period	5,069,266	2,598,864
Balance at end of period	<u>\$ 5,960,594</u>	<u>\$ 1,076,248</u>
Supplemental disclosures of cash flow information:		
Cash paid for -		
Interest	\$ 2,944	\$ —
Income taxes	\$ —	\$ —
Noncash investing and financing activities:		
Accrual of deferred offering costs	<u>\$ 16,376</u>	<u>\$ 44,009</u>

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, 2021 and 2020**

**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, 2021, and for the three months and nine months ended September 30, 2021 and 2020, 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, 2021, and the results of its operations for the three months and nine months ended September 30, 2021 and 2020, and its cash flows for the nine months ended September 30, 2021 and 2020. 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, 2020 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, 2020, 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, 2021, the Company had cash of \$5,960,594 available to fund its operations. Because the Company is currently engaged in Phase 2 clinical trials, it is expected that it will take a significant amount of time and resources to develop any product or intellectual property capable of generating sustainable revenues. Accordingly, the Company’s business is unlikely to generate any sustainable operating revenues in the next several years and may never do so. Even if the Company is able to generate revenues through licensing its technologies or through product sales, there can be no assurance that the Company will be able to achieve positive earnings and operating cash flows.

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



As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern. The Company's independent registered public accounting firm, in its report on the Company's consolidated financial statements for the year ended December 31, 2020, has also expressed substantial doubt about the Company's ability to continue as a going concern. The Company's consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company's ability to continue as a going concern is dependent upon its ability to raise additional equity capital to fund its research and development activities and to ultimately achieve sustainable operating revenues and profitability. The amount and timing of future cash requirements depends on the pace and design of the Company's clinical trial program, which, in turn, depends on the availability of operating capital to fund such activities.

Effective November 30, 2020, the Company listed on The Nasdaq Capital Market in conjunction with the completion of its public offering of units of common stock and warrants that generated net cash proceeds of \$4,591,349. Subsequently, on January 18, 2021, the Company entered into a clinical trial agreement to carry out a Phase 1b clinical trial of LB-100, combined with a standard regimen for untreated, extensive-stage disease small cell lung cancer. This clinical trial is being conducted through City of Hope and is estimated to cost from \$2,500,000 to \$2,900,000 and take approximately 24 to 30 months. Combined with the Company's existing clinical trial commitments, this clinical trial commitment represents an additional demand on the Company's working capital resources. Although the Company completed a sale of common stock under a registered direct equity offering on March 2, 2021 that generated net cash proceeds of \$3,689,761, the Company estimates that it will need to raise additional capital to fund its operations, including its various clinical trial commitments, by the middle of 2022. In addition, the Company's operating plan may change as a result of many factors which are currently unknown to the Company, including possible additional clinical trials, and the Company may need additional funds sooner than currently planned.

As market conditions present uncertainty as to the Company's ability to secure additional funds, there can be no assurances that the Company will be able to secure additional financing on acceptable terms, as and when necessary, to continue to conduct operations. There is also significant uncertainty as to the effect that the coronavirus pandemic may have on the Company's clinical trial schedule and the amount and type of financing available to the Company in the future.

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

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

On November 18, 2020, the Company effected a 1-for-6 reverse split of its outstanding shares of common stock. No fractional shares were issued in connection with the reverse split, with any fractional shares resulting from the reverse split being rounded up to the nearest whole share.

All share and per share amounts and information presented herein has been retroactively adjusted to reflect the reverse stock split for all periods presented.

### **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*

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

## *Research and Development*

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

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

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

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

### ***Prepaid Insurance***

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

### ***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 \$137,114 and \$163,987 for the three months ended September 30, 2021 and 2020, and \$365,466 and \$440,899 for the nine months ended September 30, 2021 and 2020, 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, 2021 and 2020 are described as follows.

General and administrative costs for the three months ended September 30, 2021 and 2020 include charges from a legal firm for general licensing and patent prosecution costs relating to the Company's intellectual properties representing 13.6% and 20.4%, respectively, of total general and administrative costs. General and administrative costs for the three months ended September 30, 2020 also included 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, 2021 and 2020 include charges from a legal firm for general licensing and patent prosecution costs relating to the Company's intellectual properties representing 9.7% and 32.7%, respectively, of total general and administrative costs. General and administrative costs for the nine months ended September 30, 2020 also included 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, 2021 include charges from four vendors and consultants representing 49.1%, 13.5%, 13.2%, and 12.7%, respectively, of total research and development costs for that period. Research and development costs for the three months ended September 30, 2020 included 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 nine months ended September 30, 2021 include charges from three vendors and consultants representing 33.2%, 26.9%, and 10.5%, respectively, of total research and development costs for that period. Research and development costs for the nine months ended September 30, 2020 included charges from a consultant, and the value associated with extending stock options previously granted to that consultant, representing 75.2% of total research and development costs for that period.

## ***Income Taxes***

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

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

The Company is subject to U.S. federal income taxes and income taxes of various state tax jurisdictions. As the Company's net operating losses have yet to be utilized, all previous tax years remain open to examination by Federal authorities and other jurisdictions in which the Company currently operates or has operated in the past. The Company had no unrecognized tax benefits as of September 30, 2021 or December 31, 2020 and does not anticipate any material amount of unrecognized tax benefits within the 12 months subsequent to September 30, 2021.

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, 2021 or December 31, 2020. Subsequent to September 30, 2021, any interest and penalties related to uncertain tax positions will be recognized as a component of income tax expense.

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

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

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

The fair value of stock options granted as stock-based compensation is determined utilizing the Black-Scholes option-pricing model, and is affected by several variables, the most significant of which are the expected life of the stock option, the exercise price of the stock option as compared to the fair market value of the common stock on the grant date, and the estimated volatility of the common stock. Unless sufficient historical exercise data is available, the expected life of the stock option is calculated as the mid-point between the vesting period and the contractual term (the "simplified method"). The estimated volatility is based on the historical volatility of the Company's common stock, calculated utilizing a look-back period approximately equal to the contractual life of the stock option being granted. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. The fair market value of the common stock is determined by reference to the quoted market price of the Company's common stock on the grant date. The expected dividend yield is based on the Company's expectation of dividend payouts and is assumed to be zero.

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

### ***Earnings (Loss) Per Share***

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

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

At September 30, 2021 and 2020, 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.

	September 30,	
	2021	2020
Series A Convertible Preferred Stock	729,167	729,167
Common stock warrants	3,110,310	1,500,000
Common stock options, including options issued in the form of warrants	2,466,667	1,508,333
Total	6,306,144	3,737,500

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

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

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

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

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

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

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

## ***Recent Accounting Pronouncements***

In December 2019, the Financial Accounting Standards Board (the “FASB”) issued Accounting Standards Update (“ASU”) 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes (“ASU 2019-12”). ASU 2019-12 simplifies the accounting for income taxes by removing certain exceptions and enhances and simplifies various aspects of the income tax accounting guidance in ASC 740. ASU 2019-12 was effective January 1, 2021. The adoption of ASU 2019-12 did not have any impact on the Company’s consolidated financial statement presentation or disclosures.

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

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

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

## **4. Stockholders’ Equity**

### ***Preferred Stock***

The Company is authorized to issue a total of 10,000,000 shares of preferred stock, par value \$0.0001 per share. On March 17, 2015, the Company filed a Certificate of Designations, Preferences, Rights and Limitations of its Series A Convertible Preferred Stock with the Delaware Secretary of State to amend the Company’s certificate of incorporation. The Company has designated a total of 350,000 shares as Series A Convertible Preferred Stock, which are non-voting and are not subject to increase without the written consent of a majority of the holders of the Series A Convertible Preferred Stock or as otherwise set forth in the Preferences, Rights and Limitations. The holders of each tranche of 175,000 shares of the Series A Convertible Preferred Stock are entitled to receive a per share dividend equal to 1% of the annual net revenue of the Company divided by 175,000, until converted or redeemed. As of September 30, 2021 and December 31, 2020, 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 2.0833 shares of common stock (subject to customary anti-dilution provisions) and the Series A Convertible Preferred Stock is subject to mandatory conversion at the conversion rate in the event of a merger or sale transaction resulting in gross proceeds to the Company of at least \$21,875,000. The Series A Convertible Preferred Stock has a liquidation preference based on its assumed conversion into shares of common stock. The Series A Convertible Preferred Stock does not have a cash liquidation preference.

If fully converted, the 350,000 outstanding shares of Series A Convertible Preferred Stock would convert into 729,167 shares of common stock at September 30, 2021 and December 31, 2020. The Company had 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 December 31, 2020, the Company had the right to redeem the 175,000 shares of Series A Convertible Preferred Stock that were issued on January 21, 2016; however, that right expired on January 21, 2021. The Series A Convertible Preferred Stock has no right to cash, except with respect to the payment of the aforementioned dividend based on the generation of revenues by the Company. The shares of Series A Convertible Preferred Stock do not have any registration rights.

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

### ***Common Stock***

The Company is authorized to issue a total of 100,000,000 shares of common stock, par value \$0.0001 per share. As of September 30, 2021 and December 31, 2020, the Company had 13,746,593 shares and 12,402,157 shares, respectively, of common stock issued, issuable and outstanding.

Effective November 30, 2020, the Company raised gross proceeds \$5,700,000 through a public offering of 1,200,000 units at a sale price of \$4.75 per unit. Each unit consisted of one share of common stock and one warrant to purchase one share of common stock exercisable for five years at an exercise price of \$5.70 per share. Additionally, on December 7, 2020, the Company received an additional \$1,800 from the sale of 180,000 warrants as part of the overallotment option granted to the underwriters in the public offering. The warrants sold are exercisable for five years and represent the right to purchase one share of common stock at an exercise price of \$5.70 per share. The total cash costs of the public offering were \$1,110,451, resulting in net cash proceeds of \$4,591,349. Pursuant to the underwriting agreement, the Company also granted to the underwriters warrants to purchase up to 120,000 shares of common stock commencing on May 24, 2021 and expiring on November 24, 2025, at an exercise price of \$5.70 per share.

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

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

Effective April 22, 2021, stock options held by an officer and two of the Company's directors for 125,001 shares of common stock were exercised. Such stock options consisted of 75,000 options at \$0.72 per share, 16,667 options at \$0.90 per share, and 33,334 options at \$0.96 per share. The exercise of these stock options generated total cash proceeds of \$101,000 and resulted in the issuance of 125,001 shares of common stock.

Effective July 14, 2021, a stock option held by a consultant of the Company for 83,333 shares of common stock were exercised at \$1.20 per share. The exercise of this stock option generated total cash proceeds of \$100,000 and resulted in the issuance of 83,333 shares of common stock.

### Common Stock Warrants

A summary of common stock warrant activity during the nine months ended September 30, 2021 is presented below.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Warrants outstanding at December 31, 2020	3,000,000	\$ 5.850	
Issued	113,310	3.700	
Exercised	(3,000)	5.700	
Expired	—	—	
Warrants outstanding at September 30, 2021	3,110,310	\$ 5.772	2.73

At September 30, 2021, the outstanding warrants are exercisable at the following prices per common share:

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

Based on a fair market value of \$2.08 per share on September 30, 2021, there was no intrinsic value attributed to exercisable but unexercised common stock warrants at September 30, 2021.

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

### 5. Related Party Transactions

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

#### *Gil N Schwartzberg*

In September 2007, the Company entered into a consulting agreement with Gil N 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. Consideration under this consulting agreement, including amendments, has been paid exclusively in the form of stock options. In January 2014 and August 2018, the Company entered into respective amendments to this consulting agreement, which have resulted in the extension of the consulting agreement, as well as stock options for 666,667 shares of common stock exercisable at \$3.00 per share, through January 28, 2024. Effective April 9, 2021, Mr. Schwartzberg was appointed to the Company's Board of Directors. Mr. Schwartzberg is currently a significant stockholder of the Company and continues to be a consultant to the Company.

#### *Employment Agreements with Officers*

The Company entered into an employment agreement with Dr. Kovach dated July 15, 2020, effective October 1, 2020, for Dr. Kovach to continue to act as the Company's President, Chief Executive Officer and Chief Scientific Officer with an annual salary of \$250,000. During the three months and nine months ended September 30, 2020, and for services rendered prior to the above-described employment agreement, the Company paid Dr. Kovach a salary of \$15,000 and \$45,000, respectively, which amount is included in general and administrative costs in the Company's consolidated statements of operations.

The Company entered into an employment agreement with Dr. James S. Miser, M.D., effective August 1, 2020 to act as the Company's Chief Medical Officer with an annual salary of \$150,000. Effective May 1, 2021, Dr. Miser's annual salary was increased to \$175,000. Dr. Miser is required to devote at least 50% of his business time to the Company's activities.



The Company entered into an employment agreement with Eric J. Forman effective July 15, 2020, as amended on August 12, 2020, to act as the Company's Chief Administrative Officer with an annual salary of \$120,000. Eric Forman is the son-in-law of Gil Schwartzberg, a member of the Company's Board of Directors, and a significant stockholder of and consultant to the Company, and is the son of Dr. Stephen Forman, a member of the Company's Board of Directors. Julie Forman, the wife of Eric Forman and the daughter of Gil Schwartzberg, is Vice President of Morgan Stanley Wealth Management, at which firm the Company's cash is on deposit and the Company maintains a continuing banking relationship. Effective May 1, 2021, Mr. Forman's annual salary was increased to \$175,000. During the three months and nine months ended September 30, 2020, and for services rendered prior to his appointment as Chief Administrative Officer, the Company paid legal and consulting fees to the Eric Forman Law Office of \$14,000 and \$38,000, respectively, which amount is included in general and administrative costs in the Company's consolidated statements of operations.

The Company entered into an employment agreement with Robert N. Weingarten effective August 12, 2020 to act as the Company's Vice President and Chief Financial Officer with an annual salary of \$120,000. Effective May 1, 2021, Mr. Weingarten's annual salary was increased to \$175,000. During the three months and nine months ended September 30, 2020, and for services rendered prior to his appointment as Vice President and Chief Financial Officer, the Company paid Mr. Weingarten a total of \$32,620 and \$79,995, respectively, for accounting and financial consulting services rendered with respect to the preparation of the Company's consolidated financial statements and certain other financial and compliance matters.

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

#### ***Compensatory Arrangements for Board of Directors***

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

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

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

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

A summary of related party costs, including compensation under employment and consulting agreements and fees paid to non-officer directors for their service on the Board of Directors, for the three months and nine months ended September 30, 2021 and 2020 is presented below. This summary includes the above-described payments to Mr. Forman in 2020 prior to his appointment as Chief Administrative Officer and excludes the payments to Mr. Weingarten in 2020 prior to his appointment as Vice President and Chief Financial Officer.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Related party costs:				
Cash-based	\$ 193,750	\$ 70,452	\$ 536,250	\$ 124,452
Stock-based	347,222	394,031	1,854,058	394,031
Total	<u>\$ 540,972</u>	<u>\$ 464,483</u>	<u>\$ 2,390,308</u>	<u>\$ 518,483</u>

6. Stock-Based Compensation

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

On July 14, 2020, the Board of Directors of the Company adopted the 2020 Stock Incentive Plan (the “2020 Plan”), which provides for the granting of equity-based awards, consisting of stock options, restricted stock, restricted stock units, stock appreciation rights, and other stock-based awards to employees, officers, directors and consultants of the Company and its affiliates for up to 2,333,333 shares of the Company’s common stock, under terms and conditions as determined by the Company’s Board of Directors. Stockholders holding a majority of the voting power of the common stock of the Company approved the 2020 Plan pursuant to an action by written consent dated July 31, 2020. Stockholders of the Company were notified of such action by written consent pursuant to an Information Statement dated August 31, 2020 and mailed to stockholders on or about September 3, 2020. As of September 30, 2021, unexpired stock options for 1,400,000 shares were issued and outstanding under the 2020 Plan.

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

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

Cash-based features of the compensation package are described at Note 8.

The fair value of a stock option award is calculated on the grant date using the Black-Scholes option-pricing model. The risk-free interest rate is based on the U.S. Treasury yield curve in effect as of the grant date. The expected dividend yield assumption is based on the Company’s expectation of dividend payouts and is assumed to be zero. The estimated volatility is based on the historical volatility of the Company’s common stock, calculated utilizing a look-back period approximately equal to the contractual life of the stock option being granted. Unless sufficient historical exercise data is available, the expected life of the stock option is calculated as the mid-point between the vesting period and the contractual term (the “simplified method”). The fair market value of the common stock is determined by reference to the quoted market price of the common stock on the grant date.

For stock options requiring an assessment of value during the nine months ended September 30, 2021, the fair value of each stock option award was estimated using the Black-Scholes option-pricing model with the following assumptions:

Risk-free interest rate	0.89%
Expected dividend yield	0%
Expected volatility	198.79%
Expected life	3.5 to 3.6 years

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

Effective September 14, 2015, in connection with the Collaboration Agreement with BioPharmaWorks LLC ("BioPharmaWorks") as described at Note 8, the Company issued to BioPharmaWorks two stock options, in the form of warrants, to purchase 166,667 shares (83,333.5 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 grant date at \$6.00 per share. The second warrant vested on September 14, 2017 and was exercisable for a period of five years from the grant date at \$12.00 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 166,667 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 \$5.40 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 (\$4.0242 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 J. Forman, Mr. Forman was granted options for 58,333 shares of the Company's common stock. The options can be exercised on a cashless basis. The options have a term of five years and an exercise price of \$7.14 per share, which was equal to the closing market price of the Company's common stock on the grant date. The options vested as to 25% on August 12, 2020 and August 12, 2021, and will vest 25% on each of the second and third anniversaries of the grant date. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$400,855 (\$6.8718 per share), of which \$100,214 was attributable to the stock options fully-vested on August 12, 2020 and was therefore charged to operations on that date. The remaining unvested portion of the fair value of the stock options is being charged to operations ratably from August 12, 2020 through August 12, 2023. During the three months ended September 30, 2021 and 2020, the Company recorded charges to general and administrative costs in the consolidated statement of operations of \$25,259 and \$113,667, respectively, with respect to these stock options. During the nine months ended September 30, 2021 and 2020, the Company recorded charges to general and administrative costs in the consolidated statement of operations of \$74,954 and \$113,667, respectively, with respect to these stock options.

On August 1, 2020, in connection with an employment agreement entered into with Dr. James S. Miser, M.D., Dr. Miser was granted options for 83,334 shares of the Company's common stock. The options can be exercised on a cashless basis. The options have a term of five years and an exercise price of \$7.14 per share, which was equal to the closing market price of the Company's common stock on the effective date of the employment agreement. The options vested as to 25% on August 1, 2020 and August 1, 2021, and will vest 25% on each of the second and third anniversaries of the effective date. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$572,650 (\$6.8718 per share), of which \$143,163 was attributable to the stock options fully-vested on August 1, 2020 and was therefore charged to operations on that date. The remaining unvested portion of the fair value of the stock options is being charged to operations ratably from August 1, 2020 through August 1, 2023. During the three months ended September 30, 2021 and 2020, the Company recorded charges to general and administrative costs in the consolidated statement of operations of \$36,085 and \$166,697, respectively, with respect to these stock options. During the nine months ended September 30, 2021 and 2020, the Company recorded charges to general and administrative costs in the consolidated statement of operations of \$107,078 and \$166,697, respectively, with respect to these stock options.

On August 12, 2020, in connection with the employment agreement entered into with Robert N. Weingarten, Mr. Weingarten was granted options for 58,333 shares of the Company's common stock. The options can be exercised on a cashless basis. The options have a term of five years and an exercise price of \$7.14 per share, which was equal to the closing market price of the Company's common stock on the grant date. The options vested as to 25% on August 12, 2020 and August 12, 2021, and will vest 25% on each of the second and third anniversaries of the grant date. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$400,855 (\$6.8718 per share), of which \$100,214 was attributable to the stock options fully-vested on August 12, 2020 and was therefore charged to operations on that date. The remaining unvested portion of the fair value of the stock options is being charged to operations ratably from August 12, 2020 through August 12, 2023. During the three months ended September 30, 2021 and 2020, the Company recorded charges to general and administrative costs in the consolidated statement of operations of \$25,259 and \$113,667, respectively, with respect to these stock options. During the nine months ended September 30, 2021 and 2020, the Company recorded charges to general and administrative costs in the consolidated statement of operations of \$74,954 and \$113,667, respectively, with respect to these stock options.

Effective January 6, 2021, in recognition with their service as directors of the Company over the past year, the Company granted fully-vested stock options to purchase 50,000 shares of common stock to each of Dr. Winson Sze Chun Ho, Dr. Yun Yen, Dr. Stephen Forman, and Dr. Philip Palmedo (an aggregate of 200,000 shares), exercisable for a period of five years from the grant date at \$3.21 per share, which was the approximate fair market value of the Company's common stock on such date. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$571,312 (\$2.8566 per share) and was recorded as a charge to general and administrative costs in the consolidated statement of operations on the grant date.

On April 9, 2021, Winson Sze Chun Ho resigned from the Company's Board of Directors to focus on clinical and pre-clinical cancer research in academic medicine. Concurrent with his resignation, the Board of Directors appointed Gil Schwartzberg to fill the vacancy created by Dr. Ho's resignation. In connection with his appointment to the Board of Directors, and in accordance with the recently adopted cash and equity compensation package for the members of the Board of Directors, Mr. Schwartzberg was granted options exercisable for a period of five years to purchase 250,000 shares of the Company's common stock at an exercise price of \$3.20 per share (the closing market price on the grant date), vesting 50% on the grant date and the remainder vesting 12.5% on the last day of each subsequent calendar quarter-end until fully vested. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$753,611 (\$3.0144 per share), of which \$376,800 was attributable to the stock options fully-vested on April 9, 2021 and was therefore charged to operations on that date. The remaining unvested portion of the fair value of the stock options are being charged to operations ratably from April 9, 2021 through June 30, 2023. During the three months and nine months ended September 30, 2021, the Company recorded charges to general and administrative costs in the consolidated statement of operations of \$42,692 and \$457,543, respectively, with respect to these stock options.

On May 11, 2021, the Board of Directors appointed Regina Brown to the Board of Directors. In connection with her appointment to the Board of Directors, and in accordance with the recently adopted cash and equity compensation package for the members of the Board of Directors, Ms. Brown was granted options exercisable for a period of five years to purchase 250,000 shares of the Company's common stock at an exercise price of \$2.80 per share (the closing market price on the grant date), vesting 50% on the grant date and the remainder vesting 12.5% on the last day of each subsequent calendar quarter-end until fully vested. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$658,363 (\$2.6335 per share), of which \$329,188 was attributable to the stock options fully-vested on May 11, 2021 and was therefore charged to operations on that date. The remaining unvested portion of the fair value of the stock options are being charged to operations ratably from May 11, 2021 through June 30, 2023. During the three months and nine months ended September 30, 2021, the Company recorded charges to general and administrative costs in the consolidated statement of operations of \$38,827 and \$389,117, respectively, with respect to these stock options.

On June 30, 2021, the Board of Directors, in accordance with the recently adopted cash and equity compensation package for the members of the Board of Directors, granted to each of the five non-officer directors of the Company stock options exercisable for a period of five years to purchase 100,000 shares (a total of 500,000 shares) of the Company's common stock at an exercise price of \$3.03 per share (the closing market price on the grant date), vesting 12.5% on the last day of each subsequent calendar quarter-end until fully vested. The total fair value of the 500,000 stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$1,421,095 (\$2.84225 per share), which is being charged to operations ratably from July 1, 2021 through June 30, 2023. During the three months and nine months ended September 30, 2021, the Company recorded charges to general and administrative costs in the consolidated statement of operations of \$179,100 and \$179,100, respectively, with respect to these stock options.

A summary of stock-based compensation costs for the three months and nine months ended September 30, 2021 and 2020 is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Related parties	\$ 347,222	\$ 394,031	\$ 1,854,058	\$ 394,031
Non-related parties	—	670,715	—	670,715
Total stock-based compensation costs	<u>\$ 347,222</u>	<u>\$ 1,064,746</u>	<u>\$ 1,854,058</u>	<u>\$ 1,064,746</u>

A summary of stock option activity, including options issued in the form of warrants, during the nine months ended September 30, 2021 is presented below.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Stock options outstanding at December 31, 2020	1,475,000	\$ 4.136	
Granted	1,200,000	3.048	
Exercised	(208,334)	0.965	
Expired	—	—	
Rounding adjustment attributable to reverse stock split	1	—	
Stock options outstanding at September 30, 2021	<u>2,466,667</u>	<u>\$ 3.032</u>	<u>3.66</u>
Stock options exercisable at September 30, 2021	<u>1,710,417</u>	<u>\$ 3.971</u>	<u>1.83</u>

Total deferred compensation expense for the outstanding value of unvested stock options was approximately \$2,444,000 at September 30, 2021, which will be recognized subsequent to September 30, 2021 over a weighted-average period of approximately 21 months.

The exercise prices of common stock options outstanding and exercisable, including options issued in the form of warrants, at September 30, 2021 are as follows:

Exercise Prices	Options Outstanding (Shares)	Options Exercisable (Shares)
\$ 0.900	33,333	33,333
\$ 1.680	66,667	66,667
\$ 2.800	250,000	140,625
\$ 3.000	666,667	666,667
\$ 3.030	500,000	62,500
\$ 3.200	250,000	140,625
\$ 3.210	200,000	200,000
\$ 6.000	166,667	166,667
\$ 6.600	50,000	50,000
\$ 7.140	200,000	100,000
\$ 12.000	83,333	83,333
	<u>2,466,667</u>	<u>1,710,417</u>

The intrinsic value of exercisable but unexercised in-the-money stock options at September 30, 2021 was approximately \$66,000, based on a fair market value of \$2.08 per share on September 30, 2021.

Outstanding stock options to acquire 756,250 shares of the Company's common stock had not vested at September 30, 2021.

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

## **7. Income Taxes**

During the three months and nine months ended September 30, 2021 and 2020, the Company had not recorded any provision for income taxes as the Company incurred losses during those periods. Deferred tax assets and liabilities reflect the net tax effect of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company has recorded a full valuation allowance against its deferred tax assets for all periods presented as the Company believes it is more likely than not the deferred tax assets will not be realized.

## **8. Commitments and Contingencies**

### ***Legal Claims***

The Company may be subject to legal claims and actions from time to time as part of its business activities. As of September 30, 2021, 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 clinical trial is expected to be completed over a period of approximately four years from its initiation. However, with additional funds, the Company would consider adding two additional MDS centers to the Phase 2 portion of the study to accelerate patient accrual.

During the three months ended September 30, 2021 and 2020, the Company incurred costs of \$0 and \$10,643, respectively, pursuant to this agreement. During the nine months ended September 30, 2021 and 2020, the Company incurred costs of \$17,693 and \$36,008, respectively, pursuant to this agreement. As of September 30, 2021, total costs of \$103,927 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 in this clinical trial during the quarter ended December 31, 2020, with approximately 150 patients to be enrolled over two years. As advanced sarcoma is a very aggressive disease, the design of the study assumes a median progression free survival (PFS, no evidence of disease progression or death from any cause) of 4.5 months in the doxorubicin arm and an alternative median PFS of 7.5 months in the doxorubicin plus LB-100 arm to demonstrate a statistically significant decrease in relative risk of progression or death by adding LB-100. There is a planned interim analysis of the primary endpoint when 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 authority advised the Company that although it had approved the scientific and ethical basis of the protocol, it required that the Company manufacture new inventory of LB-100 under current Spanish pharmaceutical manufacturing standards. These regulations were adopted subsequent to the production of the Company’s existing LB-100 inventory.

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

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

The Company’s agreement with GEIS provides for various payments based on achieving specific milestones over the term of the agreement. Through September 30, 2021, the Company has paid GEIS an aggregate of \$67,582 towards the second milestone payment for current work being done under this agreement.

Accordingly, during the three months ended September 30, 2021 and 2020, the Company incurred costs of \$0 and \$0, respectively, pursuant to this agreement. During the nine months ended September 30, 2021 and 2020, the Company incurred costs of \$24,171 and \$43,411 respectively, pursuant to this agreement. As of September 30, 2021, total costs of \$155,053 have been incurred pursuant to this agreement.

The Company’s aggregate commitments pursuant to the aforementioned clinical trial agreements, less amounts previously paid to date under these agreements, totaled approximately \$4,950,000 as of September 30, 2021, consisting of approximately \$4,348,000 relating to the GEIS clinical trial and approximately \$602,000 relating to the Moffit clinical trial, which are expected to be incurred through December 31, 2025.

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

As of September 30, 2021, the Company estimates that this program to provide new inventory of the DP for the Spanish sarcoma study, and potentially for subsequent multiple trials within the European Union, will cost approximately \$977,000. The Company's remaining aggregate commitments under this program, less amounts previously paid to date, totaled approximately \$394,000 as of September 30, 2021. As the production of the new inventory is being conducted in Europe and is paid for in Euros, final costs are subject to foreign currency fluctuations between the United States Dollar and the Euro.

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

The clinical trial was initiated on March 9, 2021, with patient accrual expected to take approximately 18 to 24 months to complete. If LB-100 does potentiate the benefit of the standard regimen, some evidence could be noted at 12 months into the clinical trial, but an assessment of potential increased activity is likely to require at least 24 months. The Company is currently seeking to add two additional centers to increase the rate of accrual.

During the three months and nine months ended September 30, 2021, the Company incurred costs of \$0 and \$309,509, respectively, pursuant to this agreement. As of September 30, 2021, total costs of \$309,509 have been incurred pursuant to this agreement.

The Company's aggregate commitments pursuant to this clinical trial agreement, less amounts previously paid to date under this agreement, totaled approximately \$2,433,000 as of September 30, 2021, which are expected to be incurred over the next three years based upon a target of 42 enrollees. If a significant number of patients fail during the dose-escalation process, an increase of up to 12 patients would likely be necessary, at an estimated additional cost of approximately \$800,000. Alternatively, should fewer than 42 enrollees be required, the Company has agreed to compensate City of Hope on a per enrollee basis. The Company currently expects that enrollment in this clinical trial will range from approximately 18 to 30 enrollees, with 24 enrollees as the most likely number.

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

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



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

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

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

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

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, 2021 and 2020, the Company incurred costs of \$869 and \$917, respectively, pursuant to this work order. During the nine months ended September 30, 2021 and 2020, the Company incurred costs of \$9,350 and \$12,393, respectively, pursuant to this work order. As of September 30, 2021, total costs of \$91,505 have been incurred pursuant to this work order agreement.

The Company’s aggregate commitment pursuant to this clinical trial monitoring agreement, less amounts previously paid to date under this agreement, totaled approximately \$868,000 as of September 30, 2021, which are expected to be incurred through June 30, 2025.

**City of Hope.** On February 5, 2021, the Company signed a new work order agreement with Theradex to monitor the City of Hope investigator-initiated clinical trial in small cell lung cancer in accordance with FDA requirements for oversight by the sponsoring party. During the three months and nine months ended September 30, 2021, the Company incurred costs of \$6,857 and \$21,170, respectively, pursuant to this work order. As of September 30, 2021, total costs of \$21,170 have been incurred pursuant to this work order agreement.

The Company’s aggregate commitment pursuant to this clinical trial monitoring agreement, less amounts previously paid to date under this agreement, totaled approximately \$319,000 as of September 30, 2021, which are expected to be incurred through June 30, 2024.

## ***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 initial plan was to complete the validation process to evaluate LB-100 for the treatment of depressive or stress disorders in humans within three years; however, the exploitation of this patent for the treatment of depressive and stress disorders in humans will require substantial additional capital and/or a joint venture or other type of business arrangement with a pharmaceutical company with substantially greater capital and business resources than those available to the Company. As there can be no assurances that the Company will be able to obtain the capital or business resources necessary to focus on the exploitation of this patent, it is uncertain as to when, if at all, the Company may reach any of the development or commercialization milestones under the Agreement. As of September 30, 2021 and 2020, no amounts were due under this agreement.

Effective August 20, 2018, the Company entered into an Exclusive License Agreement with Moffitt. Pursuant to the License Agreement, Moffitt granted the Company an exclusive license under certain patents owned by Moffitt (the "Licensed Patents") relating to the treatment of MDS and a non-exclusive license under inventions, concepts, processes, information, data, know-how, research results, clinical data, and the like (other than the Licensed Patents) necessary or useful for the practice of any claim under the Licensed Patents or the use, development, manufacture or sale of any product for the treatment of MDS which would otherwise infringe a valid claim under the Licensed Patents. The Company was obligated to pay Moffitt a non-refundable license issue fee of \$25,000 after the first patient is entered into a Phase 1b/2 clinical trial to be managed and conducted by Moffitt. The clinical trial began at a single site in April 2019 and the first patient was entered into the clinical trial in July 2019. The Company is also obligated to pay Moffitt an annual license maintenance fee of \$25,000 commencing on the first anniversary of the Effective Date and every anniversary thereafter until the Company commences payment of minimum royalty payments. The Company has also agreed to pay non-refundable milestone payments to Moffitt, which cannot be credited against earned royalties payable by the Company, based on reaching various clinical and commercial milestones aggregating \$1,897,000, subject to reduction by 40% under certain circumstances relating to the status of Valid Claims, as such term is defined in the License Agreement. During the three months ended September 30, 2021 and 2020, the Company recorded charges to operations of \$6,301 and \$6,301, respectively, in connection with its obligations under the License Agreement. During the nine months ended September 30, 2021 and 2020, the Company recorded charges to operations of \$18,698 and \$18,699, respectively, in connection with its obligations under the License Agreement. As of September 30, 2021, no milestones had yet been attained.

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

## ***Employment Agreements with Officers***

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

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

### ***Other Significant Agreements and Contracts***

On December 24, 2013, the Company entered into an agreement with NDA Consulting Corp. for consultation and advice in the field of oncology research and drug development. As part of the agreement, NDA also agreed to cause its president, Dr. Daniel D. Von Hoff, M.D., to become a member of the Company's Scientific Advisory Committee. The term of the agreement was for one year and provided for a quarterly cash fee of \$4,000. The agreement has been automatically renewed for additional one-year terms on its anniversary date since 2014. Consulting and advisory fees charged to operations pursuant to this agreement were \$4,000 and \$4,000 for the three months ended September 30, 2021 and 2020, respectively, and \$12,000 and \$12,000 for the nine months ended September 30, 2021 and 2020, 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, 2021 and 2020, respectively, and \$90,000 and \$90,000 for the nine months ended September 30, 2021 and 2020, respectively, which were included in research and development costs in the consolidated statements of operations.

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

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

Effective December 21, 2020, the Company entered into a services agreement with IRTH Communications, LLC for investor/public relations, financial communications, and strategic consulting services, effective for an initial term of twelve months and renewable annually thereafter. The services agreement provided for a monthly cash fee of \$7,500, including during any renewal term, and the issuance of restricted shares of common stock, fully vested upon issuance, with a grant date fair value of \$100,000 (see Note 4). Upon the commencement of any renewal term, the Company will be obligated to issue additional restricted shares of common stock, fully vested upon issuance, with a grant date fair value of \$100,000. During the three months and nine months ended September 30, 2021, the Company incurred charges in the amount of \$22,500 and \$67,500, respectively, with respect to this agreement, which amount is included in general and administrative costs in the Company's consolidated statements of operations.

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

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

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

Over the near term, there is also significant and continuing uncertainty as to the effect that the coronavirus may have on the capital markets in general and on the amount and type of financing available to the Company in particular.

The Company intends to continue to monitor the situation and may adjust its current business and financing plans as more information and guidance become available.

#### **9. Subsequent Events**

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

On October 8, 2021, the Company entered into a Development Collaboration Agreement with the Netherlands Cancer Institute, Amsterdam (NKI), one of the world's leading comprehensive cancer centers, and Oncode Institute, Utrecht, a major independent cancer research center, to identify the most promising drugs to be combined with LB-100, and potentially LB-100 analogues, to be used to treat a range of cancers, as well as to identify the specific molecular mechanisms underlying the identified combinations. The Company has agreed to fund the study and provide a sufficient supply of LB-100 to conduct the study. The study is expected to take approximately two years to conduct.

On November 8, 2021, the Company granted BioPharmaWorks a fully-vested stock option (issued in the form of a warrant) to acquire 200,000 shares of the Company's common stock, exercisable for a period of five years from the grant date at \$2.06 per share, which was equal to the closing market price of the Company's common stock on the grant date. The fair value of the stock option will be calculated pursuant to the Black-Scholes option-pricing model and will be charged to operations upon issuance.

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

### Forward-Looking Statements

This Quarterly Report on Form 10-Q of Lixte Biotechnology Holdings, Inc. (the "Company") contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, and Section 21E of the Securities Exchange Act of 1934. These might include statements regarding the Company's financial position, business strategy and other plans and objectives for future operations, and assumptions and predictions about future clinical trials and their timing and costs, product demand, supply, manufacturing costs, marketing and pricing factors are all forward-looking statements. These statements are generally accompanied by words such as "intend", "anticipate", "believe", "estimate", "potential(ly)", "continue", "forecast", "predict", "plan", "may", "will", "could", "would", "should", "expect" or the negative of such terms or other comparable terminology. The Company believes that the assumptions and expectations reflected in such forward-looking statements are reasonable, based on information available to it on the date hereof, but the Company cannot provide assurances that these assumptions and expectations will prove to have been correct or that the Company will take any action that the Company may presently be planning. These forward-looking statements are inherently subject to known and unknown risks and uncertainties. Actual results or experience may differ materially from those expected, anticipated or implied in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, regulatory policies or changes thereto, available cash, research and development results, competition from other similar businesses, and market and general economic factors. This discussion should be read in conjunction with the condensed consolidated financial statements and notes thereto included in Item 1 of this Quarterly Report on Form 10-Q and the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020, including the section entitled "Item 1A. Risk Factors". The Company does not intend to update or revise any forward-looking statements to reflect new information, future events or otherwise.

### Overview

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

The Company'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.

### Recent Developments

The following are summaries of recent developments, including information contained in recent news releases issued by the Company:

#### ***Collaboration with Netherlands Cancer Institute (Amsterdam) and Oncode Institute (Utrecht) to Identify the Most Promising Drug Combinations for the Company's Lead Clinical Compound, LB-100, for Cancer Treatment***

On October 8, 2021, the Company entered into a Development Collaboration Agreement with the Netherlands Cancer Institute, Amsterdam (NKI), one of the world's leading comprehensive cancer centers, and Oncode Institute, Utrecht, a major independent cancer research center, to identify the most promising drugs to be combined with LB-100, and potentially LB-100 analogues, to be used to treat a range of cancers, as well as to identify the specific molecular mechanisms underlying the identified combinations. The Company has agreed to fund the study and provide a sufficient supply of LB-100 to conduct the study. The study is expected to take approximately two years to conduct.

The pre-clinical studies will be directed by Professor René Bernards (NKI), a leader in using genome wide functional genetic techniques to identify effective drug combinations, new drug targets, and mechanisms of resistance to cancer drugs. Using this technology, Prof. Bernards' group identified the now FDA-approved combination of BRAF and EGFR inhibitors for a group of colon cancer patients (Nature 483, 100-103, 2012), and more recently reported the identification of a new two drug regimen for liver cancer, which in preliminary Phase 1 clinical trials appears to be more active than standard therapy (Nature 595, 730–734, 2021).

There are many pre-clinical studies demonstrating the ability of the Company's lead clinical compound, LB-100, an inhibitor of protein phosphatase 2A, to potentiate the activity of different cytotoxic drugs. Although a targeted approach to cancer treatment has been a long-standing research goal of the Company, LB-100's ubiquitous activity and low toxicity have made it challenging to identify the most effective drug combinations and/or tumor targets. Prof. Bernards' approach makes it possible to select, from among a multitude of previously identified compounds, those most likely to be effective when combined with a second drug such as LB-100 and/or in cancers with a particular molecular abnormality. The ability to identify the most effective two drug combinations utilizing LB-100 and/or the molecular sub-types of cancers most vulnerable to treatment with LB-100 would be a significant milestone in the development of this novel compound.

#### ***LB-100 Elicits Anti-Tumor Activity in Small Lung Cancer Models by Unique Mechanism in an Important Pre-Clinical Study***

The Company's lead clinical compound, LB-100, a protein phosphatase 2A (PP2A) inhibitor, was reported to enhance the effectiveness of elements of standard therapy in models of small cell lung cancer (SCLC) (Mirzapourzadeh et al., Molecular Cancer Therapeutics, online July 12, 2021). This pre-clinical study reported that LB-100 potentiates standard therapy for SCLC, thus providing a strong rationale for a clinical trial of LB-100 in SCLC cancer recently initiated at City of Hope.

Dr. Ravi Salgia, MD, PhD, Professor and Chair of the Department of Medical Oncology and Therapeutics Research and Arthur & Rosalie Kaplan Chair in Medical Oncology, City of Hope, is the corresponding author of the paper. He is also the principal investigator for a recently opened Phase 1b clinical trial (NCT04560972) for patients with previously untreated advanced SCLC, in which LB-100 is added to a standard regimen of carboplatin, etoposide, and atezolizumab. Dr. Salgia and his scientific collaborators have carried out extensive pre-clinical studies of abnormal molecular features of SCLC and the effects of LB-100 on components of a standard regimen for the treatment of this disease.

They found multiple metabolic changes associated with cell death in these cancer cells when exposed to LB-100 alone and when combined with the drugs in this standard clinical regimen for this notoriously aggressive disease. LB-100 has been reported to increase the effectiveness of a number of anti-cancer drugs against several different types of human cancers without increasing toxicity in animal models. The recent pre-clinical study of SCLC cells noted that (1) LB-100 increases the amount of carboplatin that enters the tumor cells without increasing toxicity, and (2) LB-100 potentiates the action of the immune-blocker, atezolizumab.

These observations are important because, taken together, they not only constitute a strong rationale for the recently opened clinical trial of LB-100 plus chemo-immunotherapy in SCLC, but they complement earlier pre-clinical observations that LB-100 can (1) reverse resistance of cancer cells (ovarian) to cisplatin, another widely used chemotherapy drug (Chang et al., Molecular Cancer Therapeutics, Nov. 5, 2014), (2) increase the entry of another important anti-cancer agent, doxorubicin, into liver cancer cells associated with increased antitumor activity (Bai et al, Molecular Cancer Therapeutics, Aug. 14, 2014) , and (3) enhance the effectiveness of immune-blockers against several types of cancers (Ho et al. Nature Comm., May 29, 2018). These observations raise the possibility that the addition of LB-100 may be a general way to enhance standard therapies for cancers for which better treatments are urgently needed. The present trial in SCLC is an initial step in testing that hypothesis, as is the planned clinical trial in advanced soft tissue sarcoma in which LB-100 is combined with doxorubicin.

### ***National Cancer Institute Pharmacologic Clinical Trial***

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

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

### **Going Concern**

At September 30, 2021, the Company had cash of \$5,960,594 available to fund its operations. Because the Company is currently engaged in Phase 2 clinical trials, it is expected that it will take a significant amount of time and resources to develop any product or intellectual property capable of generating sustainable revenues. Accordingly, the Company's business is unlikely to generate any sustainable operating revenues in the next several years and may never do so. Even if the Company is able to generate revenues through licensing its technologies or through product sales, there can be no assurance that the Company will be able to achieve positive earnings and operating cash flows.

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

As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern. The Company's independent registered public accounting firm, in its report on the Company's consolidated financial statements for the year ended December 31, 2020, has also expressed substantial doubt about the Company's ability to continue as a going concern. The Company's consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### **Recent Accounting Pronouncements**

Information with respect to recent accounting pronouncements is provided at Note 3 to the condensed consolidated financial statements for the three months and nine months ended September 30, 2021 and 2020 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, 2021 and 2020 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 clinical trials with respect to the Company's compounds and product candidates. Research and development costs also include the costs to produce the compounds used in research and clinical trials, which are charged to operations as incurred.

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

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

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

### **Patent and Licensing 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”). The estimated volatility is based on the historical volatility of the Company’s common stock, calculated utilizing a look-back period approximately equal to the contractual life of the stock option being granted. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. The fair market value of the common stock is determined by reference to the quoted market price of the Company’s common stock on the grant date. The expected dividend yield is based on the Company’s expectation of dividend payouts and is assumed to be zero.

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

## **Summary of Business Activities and Plans**

### ***Company Overview***

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

The Company has developed two series of pharmacologically active drugs, the LB-100 series and the LB-200 series. The Company believes that the mechanism by which compounds of the LB-100 series affect cancer cell growth is different from cancer agents currently approved for clinical use. Lead compounds from each series have activity against a broad spectrum of common and rarer human cancers in cell culture systems. In addition, compounds from both series have anti-cancer activity in animal models of glioblastoma multiforme, neuroblastoma, and medulloblastoma, all cancers of neural tissue. Lead compounds of the LB-100 series also have activity against melanoma, breast cancer and sarcoma in animal models and enhance the effectiveness of commonly used anti-cancer drugs in these 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 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 the Company would require additional capital to fund further development. Accordingly, because of the Company’s focus on the clinical development of LB-100 and analogs for cancer therapy as described below in more detail, the Company has decided not to actively pursue the pre-clinical development of the LB-200 series of compounds at this time and intends 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 anti-tumor activity in humans at doses that are readily tolerable. Responses included objective regression (tumor shrinkage) lasting for 11 months of a pancreatic cancer and cessation of growth (stabilization of disease) for 4 months or more of 9 other progressive solid tumors out of 20 patients who had measurable disease. As Phase 1 clinical trials are fundamentally designed to determine safety of a new compound in humans, the Company was encouraged by these results. The next step is to demonstrate in Phase 2 clinical trials the efficacy of LB-100 in one or more specific tumor types, against which the compound has well documented activity in pre-clinical models.

As a compound moves through the FDA-approval process, it becomes an increasingly valuable property, but at a cost of additional investment at each stage. As the potential effectiveness of LB-100 has been documented at the clinical trial level, the Company has allocated resources to expand the breadth and depth of its patent portfolio. The Company's approach has been to operate with a minimum of overhead, moving compounds forward as efficiently and inexpensively as possible, and to raise funds to support each of these stages as certain milestones are reached. The Company's longer-term objective is to secure one or more strategic partnerships or licensing agreements with pharmaceutical companies with major programs in cancer.

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

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

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

Over the near term, there is also significant and continuing uncertainty as to the effect that the coronavirus may have on the capital markets in general and on the amount and type of financing available to the Company in particular.

The Company intends to continue to monitor the situation and may adjust its current business and financing plans as more information and guidance become available.

## Results of Operations

At September 30, 2021, 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,	
	2021	2020	2021	2020
Revenues	\$ —	\$ —	\$ —	\$ —
Costs and expenses:				
General and administrative costs	1,010,539	802,273	3,762,373	1,350,201
Research and development costs	227,181	799,420	933,122	1,012,038
Total costs and expenses	1,237,720	1,601,693	4,695,495	2,362,239
Loss from operations	(1,237,720)	(1,601,693)	(4,695,495)	(2,362,239)
Interest income	161	38	487	4,284
Interest expense	—	—	(2,944)	—
Foreign currency loss	(1,165)	—	(1,082)	—
Net loss	\$ (1,238,724)	\$ (1,601,655)	\$ (4,699,034)	\$ (2,357,955)
Net loss per common share – basic and diluted	\$ (0.09)	\$ (0.14)	\$ (0.35)	\$ (0.21)
Weighted average common shares outstanding – basic and diluted	13,733,912	11,174,302	13,381,922	11,174,302

## Three Months Ended September 30, 2021 and 2020

**Revenues.** The Company did not have any revenues for the three months ended September 30, 2021 and 2020.

**General and Administrative Costs.** For the three months ended September 30, 2021, general and administrative costs were \$1,010,539, which consisted of the fair value of vested stock options issued to directors of \$347,222, patent and licensing legal fees and costs of \$137,114, other consulting and professional fees of \$138,869, insurance expense of \$92,663, officer's salary and related costs of \$207,264, cash-based director and committee fees of \$32,500, licensing fees of \$6,301, shareholder reporting costs of \$21,000, listing fees of \$14,500, filing fees of \$4,653, taxes and licenses of \$3,481, and other operating costs of \$4,972.

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 directors 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, shareholder reporting costs of \$3,353, listing fees of \$3,000, filing fees of \$598, taxes and licenses of \$928, and other operating costs of \$2,460.

General and administrative costs increased by \$208,266, or 26.0%, in 2021 as compared to 2020, primarily as a result of an increase in insurance expense of \$66,260, and an increase in officer's salary and related costs of \$145,431.

Research and Development Costs. For the three months ended September 30, 2021, research and development costs were \$227,181, which consisted of contractor costs incurred in connection with the synthesis work done to develop a new supply of LB-100 of \$151,814, clinical and related oversight costs of \$7,726, and pre-clinical research focused on development of additional novel anti-cancer compounds to add to the Company's clinical pipeline of \$67,641.

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 a consultant of \$670,715, and contractor costs incurred in connection with the synthesis work done to develop a new supply of LB-100 of \$41,625, clinical and related oversight costs of \$16,686, and pre-clinical research focused on the development of additional novel anti-cancer compounds to add to the Company's clinical pipeline of \$70,394.

Research and development costs decreased by \$572,239, or 71.6% in 2021 as compared to 2020, primarily as a result of a decrease in the fair value of vested stock options issued to a consultant of \$670,715, offset by an increase in contractor costs incurred in connection with the synthesis work done to develop a new supply of LB-100 of \$110,189. The absence of costs associated with ongoing clinical trials during the three months ended September 30, 2021 and 2020 reflects the slow accrual of patients into such clinical trials.

Interest Income. For the three months ended September 30, 2021, the Company had interest income of \$161, as compared to interest income of \$38 for the three months ended September 30, 2020, as a result of an increase in the Company's cash resources invested in money market funds.

Interest Expense. The Company had no interest expense during the three months ended September 30, 2021 and 2020.

Foreign Currency Loss. For the three months ended September 30, 2021, the Company had a loss from foreign currency transactions of \$1,165. The Company had no foreign currency transactions during the three months ended September 30, 2020.

Net Loss. For the three months ended September 30, 2021, the Company incurred a net loss of \$1,238,724, as compared to a net loss of \$1,601,655 for the three months ended September 30, 2020.

#### **Nine Months Ended September 30, 2021 and 2020**

Revenues. The Company did not have any revenues for the nine months ended September 30, 2021 and 2020.

General and Administrative Costs. For the nine months ended September 30, 2021, general and administrative costs were \$3,762,373, which consisted of the fair value of vested stock options issued to directors of \$1,854,058, patent and licensing legal fees and costs of \$365,466, other consulting and professional fees of \$488,245, insurance expense of \$268,177, officer's salary and related costs of \$578,535, cash-based director and committee fees of \$60,333, licensing fees of \$18,698, shareholder reporting costs of \$40,760, listing fees of \$43,500, filing fees of \$17,217, taxes and licenses of \$10,594, and other operating costs of \$16,790.

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 directors 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, shareholder reporting costs of \$9,739, listing fees of \$9,000, filing fees of \$6,894, taxes and licenses of \$2,088, and other operating costs of \$7,011.

General and administrative costs increased by \$2,412,172, or 178.7%, in 2021 as compared to 2020, primarily as a result of an increase in the fair value of vested stock options issued to directors of \$1,460,027, an increase in other consulting and professional fees of \$176,947, an increase in insurance expense of \$213,359, and an increase in officer's salary and related costs of \$482,811.

**Research and Development Costs.** For the nine months ended September 30, 2021, research and development costs were \$933,122, which consisted of contractor costs incurred in connection with the synthesis work done to develop a new supply of LB-100 of \$424,141, clinical and related oversight costs of \$382,134, and pre-clinical research focused on development of additional novel anti-cancer compounds to add to the Company's clinical pipeline of \$156,639, offset by a refund of \$29,792 from a cancelled contract.

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 a consultant of \$670,715, and contractor costs incurred in connection with the synthesis work done to develop a new supply of LB-100 of \$41,625, clinical and related oversight costs of \$105,537, and pre-clinical research focused on development of additional novel anti-cancer compounds to add to the Company's clinical pipeline of \$194,161.

Research and development costs decreased by \$78,916, or 7.8% in 2021 as compared to 2020, primarily as a result of a decrease in the fair value of vested stock options issued to a consultant of \$670,715, offset by an increase in contractor costs incurred in connection with the synthesis work done to develop a new supply of LB-100 of \$382,516 and an increase in clinical and related oversight costs of \$276,597, which included an upfront payment to City of Hope of \$240,508 upon execution of the Clinical Research Support Agreement in January 2021. The absence of costs associated with ongoing clinical trials during the nine months ended September 30, 2021 and 2020 reflects the slow accrual of patients into such clinical trials.

**Interest Income.** For the nine months ended September 30, 2021, the Company had interest income of \$487, as compared to interest income of \$4,284 for the nine months ended September 30, 2020, as a result of a reduction in the Company's cash resources previously invested in short-term federally insured certificates of deposit.

**Interest Expense.** For the nine months ended September 30, 2021, the Company had interest expense of \$2,944 related to the financing of its directors and officers liability insurance premium. The Company had no interest expense during the nine months ended September 30, 2020.

**Foreign Currency Loss.** For the nine months ended September 30, 2021, the Company had a loss from foreign currency transactions of \$1,082. The Company had no foreign currency transactions during the nine months ended September 30, 2020.

**Net Loss.** For the nine months ended September 30, 2021, the Company incurred a net loss of \$4,699,034, as compared to a net loss of \$2,357,955 for the nine months ended September 30, 2020.

#### **Liquidity and Capital Resources – September 30, 2021**

At September 30, 2021, the Company had working capital of \$6,048,460, as compared to working capital of \$5,011,951 at December 31, 2020, reflecting an increase in working capital of \$1,036,509 for the nine months ended September 30, 2021. The increase in working capital during the nine months ended September 30, 2021 was the result of the net cash proceeds of \$3,689,761 from the Company's March 2021 direct equity offering, proceeds of \$17,100 from the exercise of warrants, and proceeds of \$201,000 from the exercise of stock options, that were utilized to pay offering costs of \$20,467 and to fund the Company's research and development activities and ongoing operating expenses, including the Company's clinical trial program and maintaining and developing the patent portfolio. At September 30, 2021, the Company had cash of \$5,960,594 available to fund its operations.

The Company's ability to continue as a going concern is dependent upon its ability to raise additional equity capital to fund its research and development activities and to ultimately achieve sustainable operating revenues and profitability. The amount and timing of future cash requirements depends on the pace and design of the Company's clinical trial program, which, in turn, depends on the availability of operating capital to fund such activities.

Effective November 30, 2020, the Company listed on The Nasdaq Capital Market in conjunction with the completion of its public offering of units of common stock and warrants that generated net cash proceeds of \$4,591,349. Subsequently, on January 18, 2021, the Company entered into a clinical trial agreement to carry out a Phase 1b clinical trial of LB-100, combined with a standard regimen for untreated, extensive-stage disease small cell lung cancer. This clinical trial is being conducted through City of Hope and is estimated to cost approximately \$2,900,000 and take approximately 24 to 30 months. Combined with the Company's existing clinical trial commitments, this clinical trial commitment represents an additional demand on the Company's working capital resources. Although the Company completed a sale of common stock under a registered direct equity offering on March 2, 2021 that generated net cash proceeds of \$3,689,761, the Company estimates that it will need to raise additional capital to fund its operations, including its various clinical trial commitments, by the middle of 2022. In addition, the Company's operating plan may change as a result of many factors which are currently unknown to the Company, including possible additional clinical trials, and the Company may need additional funds sooner than currently planned.

As market conditions present uncertainty as to the Company's ability to secure additional funds, there can be no assurances that the Company will be able to secure additional financing on acceptable terms, as and when necessary, to continue to conduct operations. There is also significant uncertainty as to the effect that the coronavirus pandemic may have on the Company's clinical trial schedule and the amount and type of financing available to the Company in the future.

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

Operating Activities. For the nine months ended September 30, 2021, operating activities utilized cash of \$2,996,066, as compared to utilizing cash of \$1,392,372 for the nine months ended September 30, 2020, 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, 2021 and 2020, the Company had no investing activities.

Financing Activities. For the nine months ended September 30, 2021, financing activities consisted of the gross proceeds from the sales of common stock in the Company's direct equity offering of \$4,192,478, reduced by offering costs of \$502,717, \$17,100 from the exercise of common stock warrants, and \$201,000 from the exercise of common stock options. The Company also paid offering costs of \$20,467 during the nine months ended September 30, 2021. For the nine months ended September 30, 2020, financing activities consisted of the payment of deferred offering costs of \$130,244.

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

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

During the three months ended September 30, 2021 and 2020, the Company incurred costs of \$0 and \$10,643, respectively, pursuant to this agreement. During the nine months ended September 30, 2021 and 2020, the Company incurred costs of \$17,693 and \$36,008, respectively, pursuant to this agreement. As of September 30, 2021, total costs of \$103,927 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 in this clinical trial during the quarter ended December 31, 2020, with approximately 150 patients to be enrolled over two years. As advanced sarcoma is a very aggressive disease, the design of the study assumes a median progression free survival (PFS, no evidence of disease progression or death from any cause) of 4.5 months in the doxorubicin arm and an alternative median PFS of 7.5 months in the doxorubicin plus LB-100 arm to demonstrate a statistically significant decrease in relative risk of progression or death by adding LB-100. There is a planned interim analysis of the primary endpoint when 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 authority advised the Company that although it had approved the scientific and ethical basis of the protocol, it required that the Company manufacture new inventory of LB-100 under current Spanish pharmaceutical manufacturing standards. These regulations were adopted subsequent to the production of the Company’s existing LB-100 inventory.

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

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

The Company's agreement with GEIS provides for various payments based on achieving specific milestones over the term of the agreement. Through September 30, 2021, the Company has paid GEIS an aggregate of \$67,582 towards the second milestone payment for current work being done under this agreement.

Accordingly, during the three months ended September 30, 2021 and 2020, the Company incurred costs of \$0 and \$0, respectively, pursuant to this agreement. During the nine months ended September 30, 2021 and 2020, the Company incurred costs of \$24,171 and \$43,411 respectively, pursuant to this agreement. As of September 30, 2021, total costs of \$155,053 have been incurred pursuant to this agreement.

The Company's aggregate commitments pursuant to the aforementioned clinical trial agreements, less amounts previously paid to date under these agreements, totaled approximately \$4,950,000 as of September 30, 2021, consisting of approximately \$4,348,000 relating to the GEIS clinical trial and approximately \$602,000 relating to the Moffit clinical trial, which are expected to be incurred through December 31, 2025.

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

As of September 30, 2021, the Company estimates that this program to provide new inventory of the DP for the Spanish sarcoma study, and potentially for subsequent multiple trials within the European Union, will cost approximately \$977,000. The Company's remaining aggregate commitments under this program, less amounts previously paid to date, totaled approximately \$394,000 as of September 30, 2021. As the production of the new inventory is being conducted in Europe and is paid for in Euros, final costs are subject to foreign currency fluctuations between the United States Dollar and the Euro.

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

The clinical trial was initiated on March 9, 2021, with patient accrual expected to take approximately 18 to 24 months to complete. If LB-100 does potentiate the benefit of the standard regimen, some evidence could be noted at 12 months into the clinical trial, but an assessment of potential increased activity is likely to require at least 24 months. The Company is currently seeking to add two additional centers to increase the rate of accrual.

During the three months and nine months ended September 30, 2021, the Company incurred costs of \$0 and \$309,509, respectively, pursuant to this agreement. As of September 30, 2021, total costs of \$309,509 have been incurred pursuant to this agreement.

The Company's aggregate commitments pursuant to this clinical trial agreement, less amounts previously paid to date under this agreement, totaled approximately \$2,433,000 as of September 30, 2021, which are expected to be incurred over the next three years based upon a target of 42 enrollees. If a significant number of patients fail during the dose-escalation process, an increase of up to 12 patients would likely be necessary, at an estimated additional cost of approximately \$800,000. Alternatively, should fewer than 42 enrollees be required, the Company has agreed to compensate City of Hope on a per enrollee basis. The Company currently expects that enrollment in this clinical trial will range from approximately 18 to 30 enrollees, with 24 enrollees as the most likely number.



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

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

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

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

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

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

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, 2021 and 2020, the Company incurred costs of \$869 and \$917, respectively, pursuant to this work order. During the nine months ended September 30, 2021 and 2020, the Company incurred costs of \$9,350 and \$12,393, respectively, pursuant to this work order. As of September 30, 2021, total costs of \$91,505 have been incurred pursuant to this work order agreement.

The Company's aggregate commitment pursuant to this clinical trial monitoring agreement, less amounts previously paid to date under this agreement, totaled approximately \$868,000 as of September 30, 2021, which are expected to be incurred through June 30, 2025.

**City of Hope.** On February 5, 2021, the Company signed a new work order agreement with Theradex to monitor the City of Hope investigator-initiated clinical trial in small cell lung cancer in accordance with FDA requirements for oversight by the sponsoring party. During the three months and nine months ended September 30, 2021, the Company incurred costs of \$6,857 and \$21,170, respectively, pursuant to this work order. As of September 30, 2021, total costs of \$21,170 have been incurred pursuant to this work order agreement.

The Company's aggregate commitment pursuant to this clinical trial monitoring agreement, less amounts previously paid to date under this agreement, totaled approximately \$318,000 as of September 30, 2021, which are expected to be incurred through June 30, 2024.

#### ***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 initial plan was to complete the validation process to evaluate LB-100 for the treatment of depressive or stress disorders in humans within three years; however, the exploitation of this patent for the treatment of depressive and stress disorders in humans will require substantial additional capital and/or a joint venture or other type of business arrangement with a pharmaceutical company with substantially greater capital and business resources than those available to the Company. As there can be no assurances that the Company will be able to obtain the capital or business resources necessary to focus on the exploitation of this patent, it is uncertain as to when, if at all, the Company may reach any of the development or commercialization milestones under the Agreement. As of September 30, 2021 and 2020, no amounts were due under this agreement.

Effective August 20, 2018, the Company entered into an Exclusive License Agreement with Moffitt. Pursuant to the License Agreement, Moffitt granted the Company an exclusive license under certain patents owned by Moffitt (the "Licensed Patents") relating to the treatment of MDS and a non-exclusive license under inventions, concepts, processes, information, data, know-how, research results, clinical data, and the like (other than the Licensed Patents) necessary or useful for the practice of any claim under the Licensed Patents or the use, development, manufacture or sale of any product for the treatment of MDS which would otherwise infringe a valid claim under the Licensed Patents. The Company was obligated to pay Moffitt a non-refundable license issue fee of \$25,000 after the first patient is entered into a Phase 1b/2 clinical trial to be managed and conducted by Moffitt. The clinical trial began at a single site in April 2019 and the first patient was entered into the clinical trial in July 2019. The Company is also obligated to pay Moffitt an annual license maintenance fee of \$25,000 commencing on the first anniversary of the Effective Date and every anniversary thereafter until the Company commences payment of minimum royalty payments. The Company has also agreed to pay non-refundable milestone payments to Moffitt, which cannot be credited against earned royalties payable by the Company, based on reaching various clinical and commercial milestones aggregating \$1,897,000, subject to reduction by 40% under certain circumstances relating to the status of Valid Claims, as such term is defined in the License Agreement. During the three months ended September 30, 2021 and 2020, the Company recorded charges to operations of \$6,301 and \$6,301, respectively, in connection with its obligations under the License Agreement. During the nine months ended September 30, 2021 and 2020, the Company recorded charges to operations of \$18,698 and \$18,699, respectively, in connection with its obligations under the License Agreement. As of September 30, 2021, no milestones had yet been attained.

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

#### ***Employment Agreements with Officers***

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

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

#### ***Other Significant Agreements and Contracts***

On December 24, 2013, the Company entered into an agreement with NDA Consulting Corp. for consultation and advice in the field of oncology research and drug development. As part of the agreement, NDA also agreed to cause its president, Dr. Daniel D. Von Hoff, M.D., to become a member of the Company's Scientific Advisory Committee. The term of the agreement was for one year and provided for a quarterly cash fee of \$4,000. The agreement has been automatically renewed for additional one-year terms on its anniversary date since 2014. Consulting and advisory fees charged to operations pursuant to this agreement were \$4,000 and \$4,000 for the three months ended September 30, 2021 and 2020, respectively, and \$12,000 and \$12,000 for the nine months ended September 30, 2021 and 2020, 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, 2021 and 2020, respectively, and \$90,000 and \$90,000 for the nine months ended September 30, 2021 and 2020, respectively, which were included in research and development costs in the consolidated statements of operations.

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

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

Effective December 21, 2020, the Company entered into a services agreement with IRTH Communications, LLC for investor/public relations, financial communications, and strategic consulting services, effective for an initial term of twelve months and renewable annually thereafter. The services agreement provided for a monthly cash fee of \$7,500, including during any renewal term, and the issuance of restricted shares of common stock, fully vested upon issuance, with a grant date fair value of \$100,000. Upon the commencement of any renewal term, the Company will be obligated to issue additional restricted shares of common stock, fully vested upon issuance, with a grant date fair value of \$100,000. During the three months and nine months ended September 30, 2021, the Company incurred charges in the amount of \$22,500 and \$67,500, respectively, with respect to this agreement, which amount is included in general and administrative costs in the Company's consolidated statements of operations.

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

At September 30, 2021, 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, 2021, 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 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 effective as of September 30, 2021 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.

However, if in future periods the Company develops material weaknesses in its internal control over financial reporting, the Company may not detect errors on a timely basis and its consolidated financial statements may be materially misstated. In addition, the Company may also engage in business activities or transactions in future periods that could negatively affect its internal control over financial reporting and result in additional material weaknesses.

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, 2021.

#### Changes in Internal Control 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, 2021 that has materially affected, or is reasonably likely to materially affect, the Company’s internal control over financial reporting.

## **PART II - OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

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

### **ITEM 1A. RISK FACTORS**

The Company's business, financial condition, results of operations and cash flows may be impacted by a number of factors, many of which are beyond the Company's control, including those set forth in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020, as filed with the Securities and Exchange Commission on March 26, 2021 (the "2020 Form 10-K").

The Risk Factors set forth in the 2020 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 2020 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 2020 Form 10-K.

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

Not applicable.

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

### **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

### **ITEM 5. OTHER INFORMATION**

Not applicable.

## ITEM 6. EXHIBITS

The following documents are filed as part of this report:

Exhibit Number	Description of Document
10.1*	<a href="#"><u>Development Collaboration Agreement by and between Lixte Biotechnology Holdings, Inc. and the Netherlands Cancer Institute, Amsterdam, and Oncode Institute, Utrecht, entered into on October 8, 2021 (certain portions of this Exhibit have been omitted based on a pending request for confidential treatment being filed with the Securities and Exchange Commission).</u></a>
31.1*	<a href="#"><u>Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u></a>
31.2*	<a href="#"><u>Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u></a>
32.1*	<a href="#"><u>Officer's Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u></a>
32.2*	<a href="#"><u>Officer's Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u></a>
101.INS	Inline XBRL Instance Document (does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL document and included in Exhibit 101.INS)

\* Filed herewith.

## SIGNATURES

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

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

(Registrant)

Date: November 10, 2021

By: /s/ JOHN S. KOVACH

John S. Kovach

Chief Executive Officer

Date: November 10, 2021

By: /s/ ROBERT N. WEINGARTEN

Robert N. Weingarten

Chief Financial Officer



CONFIDENTIAL TREATMENT REQUESTED

CONFIDENTIAL PORTIONS REDACTED

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## DEVELOPMENT COLLABORATION AGREEMENT

This DEVELOPMENT COLLABORATION Agreement (this “**Agreement**”) is entered into on October 8, 2021 (the “**Effective Date**”), by and between LIXTE BIOTECHNOLOGY HOLDINGS, INC. (“**Lixte**”), with its office and place of business at 680 E Colorado Blvd., Suite 180, Pasadena, CA 91101 and STICHTING HET NEDERLANDS KANKER INSTITUUT – ANTONI VAN LEEUWENHOEK ZIEKENHUIS, a foundation incorporated under the laws of The Netherlands, with its registered office at Plesmanlaan 121, 1066 CX Amsterdam (“**NKI-AVL**” or “**Institution**”) and STICHTING ONCODE INSTITUTE, a foundation incorporated under the laws of The Netherlands, with its registered office at Jaarbeursplein 6, 3521AL, Utrecht, and registered with the chamber of commerce with number 69303010 (“**Oncode**”). Each of Lixte, NKI-AVL and Oncode are referred to as a “**Party**” and together as, the “**Parties**.”

WHEREAS, Lixte owns and/or controls all rights in the Compound (defined below), including without limitation patents and other intellectual property covering and relating the composition of the Compound and use thereof; and

WHEREAS, NKI-AVL and Oncode have conducted certain preliminary research relating to which drug combinations with the Compound are most effective in treatment of cancer, and the Parties desire to collaborate to conduct additional research regarding the foregoing, on the terms and subject to the conditions set forth in this Agreement.

NOW THEREFORE, in consideration of the foregoing premises, the covenants, representations and warranties set forth in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which is acknowledged, the Parties agree as follows:

### 1. **Material and Information.**

1.1. “**Compound**” means the compound designated LB-100 and/or analogs, metabolites and/or active forms thereof; “**Material**” means any Compound provided by Lixte to Institution pursuant to this Agreement, together with any progeny, mutants, derivatives or parts thereof, and any materials that could not be made but for the use of the Material and/or Information. “**Information**” means data, research results, formulas, technical data, and any other information relating to the Material or the use thereof, which is disclosed to Institution by Lixte or its designees.

### 2. **Scope of Work.**

2.1. The Parties will collaborate in the performance of a preclinical research study in accordance with the terms of the Exhibit A (the “**Study**”), which is incorporated into this Agreement by reference. The terms of Exhibit A may not be modified except upon the mutual agreement of the Parties in an amendment executed by both Parties. From time to time, the Parties may agree to conduct additional studies, upon execution of a mutually agreed written scope of work executed by both Parties, annexed hereto and incorporated herein.

2.2. The Study will be conducted solely at facilities owned or controlled by Institution, and by personnel employed or retained by Institution. Institution certifies that, to its best knowledge, its facilities, resources and personnel are adequate to perform the Study contemplated by this Agreement. Institution agrees that all aspects of the Study will be conducted in conformity with all applicable laws. Institution further agrees not to conduct any research activities with the Compound which are contrary to the provisions of the Study or outside the scope of the Study.

2.3. It is anticipated that the Study shall commence following the Effective Date, and Institution shall use reasonable efforts to complete the Study within twenty-four (24) months of the Effective Date. The duration of the Study is as set forth in Exhibit A.

### **3. Collaboration With Lixte.**

3.1. Lixte will supply to Institution Information and quantities of the Compound reasonably necessary to conduct the Study. Lixte will provide the funding specified under "Budget" in Exhibit A.

3.2. Lixte will collaborate with Institution with respect to the design and implementation of the Study. Institution will provide regular reports to Lixte on the progress of the Study.

3.3. Except as specified in Exhibit A, each Party shall bear its own costs related to the conduct of the Study and the collaboration related thereto.

### **4. Ownership and Use of Compound, Material and Information.**

4.1. Lixte retains all right, title and interest in and to the Compound and all Material and Information. Except for the limited rights expressly granted herein with respect to the use of Material and Information, Recipient shall have no other rights in the Compound, or any Material or Information, and is granted no rights in any other Lixte intellectual property rights (including any patents, trade secret, trademarks or copyrights), whether expressly, by implication or estoppel. All rights not expressly granted herein are reserved to Lixte. Nothing herein shall restrict Lixte's right to use and distribute the Compound and Information, including without limitation to distribute same to commercial or non-commercial entities.

4.2. Lixte hereby grants to Institution, during the Study Term, a limited, non-exclusive, revocable, non-sublicenseable and non-transferable right to use the Material and Information, solely internally by Institution for the Study.

4.3. Institution acknowledges and agrees that:

(a) The Compound, Material and Information are subject to patent protection and reflect the confidential trade secrets of Lixte, and are made available for use by Institution solely for academic or scientific research, the results of which may not be disclosed or obligated in any way to any commercial third party;

(b) Principal Investigator shall not obtain Compound for the Study from any source other than Lixte or an authorized third party designated by Lixte;

(c) Except as expressly permitted hereunder, Institution shall not use any Material or Information, directly or indirectly, for any commercial purpose, including filing any patent application thereon or with respect thereto, or for any research sponsored by or in collaboration with any third party;

(d) Without limiting Institution's rights to publish research results in accordance with Section 7.2, Institution shall not disclose or transfer any Material or Information to any third party;

(e) Since not all of the Compound's characteristics are known, it should be used with caution and prudence; and

(f) The Material and Information may be used for investigational use in laboratory animals and/or in vitro studies, but not for any use in humans.

4.4. If this Agreement is terminated, if the Study is completed and Institution has unused Material, or at any time upon the request of Lixte, Institution shall promptly return the Material and any Information to Lixte or dispose of it in a lawful manner, at Lixte's discretion.

4.5. Institution shall restrict access to and use of the Material and Information to persons engaged in performing the Study as permitted hereunder. Institution shall supervise all persons engaged in performing the Study and/or who have access to the Material or Information, and shall ensure that such persons are informed of and abide by the applicable terms of this Agreement. Institution may not store or use the Material at any facility outside the control of Institution. Institution shall comply with all applicable laws and regulations, and all written instructions from Lixte, in the storage, handling, use, return, and disposal of the Material. Institution agrees not to transfer the Material to any third party without the prior written permission of Lixte. Institution shall at all times be responsible for the compliance with this Agreement by Institution's employees, representatives and/or any other person under its control and supervision who has access to the Material or Information. For the avoidance of doubt, no right is granted hereunder for any individual who leaves the employ of Institution to transfer or use any Material or Confidential to with any subsequent employer or institution.

## 5. Intellectual Property Rights.

5.1. Institution and Oncode acknowledge and agree that the Compound, Material, and Information are valuable business property of Lixte, subject to intellectual property rights owned by or licensed to Lixte. If the use of the Material or Information results in any Invention (defined below), Institution and Oncode agree to disclose promptly to Lixte any such Invention in confidence before otherwise disclosing the same publicly or to any third party, so that Lixte can determine whether such Invention should be the subject of a patent application. "**Invention**" means any invention, process, substance, or improvement, whether or not patentable, based on work conducted in the Study or otherwise invented through the use of, derived from, or which incorporates or comprises use of, any Material or Information, including without limitation any new use or improvement to any Material and/or any substance isolated, and all intellectual property rights therein and relating thereto.

5.2. Inventorship of an Invention shall be determined in accordance with U.S. patent law. Except as otherwise specified in this Section 5, an invention shall be solely owned by Institution if conceived, reduced to practice or otherwise invented ("**Invented**") solely by a representative of Institution, and jointly-owned by both Institution and Lixte if invented jointly by representatives of both Institution and Lixte, provided that any Invention that, in whole or part, comprises, or relates to or derives from the use of, the Compound (whether invented solely by Institution or jointly with Lixte or NCI) shall be jointly-owned by both Institution and Lixte.

5.3. With respect to any Invention owned in whole or part by Institution (a "**Institution Invention**"), Institution and Oncode hereby grant to Lixte: (i) a non-exclusive, royalty-free and fully paid up, worldwide, irrevocable, non-transferable (except to the successor to Lixte's business, whether by sale of all or substantially all of the equity or assets, by merger or otherwise) license under its rights in an Institution Invention to make, have made, use, import and otherwise practice such Institution Invention for any purpose relating to internal research or development activities and for any purpose related to the exploitation of the Compound and (ii) the exclusive option to obtain an exclusive license under Institution's rights in any such Institution Invention for all purposes (including without limitation the commercial manufacture and sale of products and services) on reasonable commercial terms (the "**Option**"). Upon Lixte's exercise of its Option, the Parties will promptly commence good faith negotiations in an attempt to reach an exclusive license agreement at a reasonable royalty rate satisfactory to both Parties (the approval of which is not to be unreasonably withheld, delayed or denied by Institution) and otherwise on other standard license terms. Should Lixte fail to exercise its Option within one (1) month, or the Parties negotiate in good faith but do not mutually agree and execute an exclusive license as set forth above within six (6) months from exercising the Option, Institution may grant a license under its rights in any such solely-owned Institution Invention to one or more third parties without Lixte's consent, provided that for a period of six (6) months after the expiration of the negotiation period with Lixte, Institution may not offer to license any solely owned or jointly-owned Institution Invention to any third party on materially better terms than those last offered to Lixte without first offering such terms to Lixte, in which case Lixte will have a period of thirty (30) days in which to accept or reject the offer and provide further that Lixte shall have no obligation to grant to such third party licensee any license under the Compound or any Lixte patents. For the avoidance of doubt, in the event Lixte elects not to exercise the Option, or if the parties enter into an exclusive license but such exclusive license expires or is terminated for any reason, Lixte shall retain the perpetual non-exclusive license specified in subsection (i) above. Notwithstanding anything to the contrary herein, and to the extent Institution is legally able to do so, Lixte shall solely own any Invention made through activities in breach of this Agreement, including without limitation any use of the Compound, Material or Information outside the scope of the license granted hereunder.

5.4. Institution shall not file any patent application for any Invention without giving adequate prior notice to Lixte of such Invention. If notwithstanding the foregoing, Institution files in its own name any application for patent for any Invention, it shall, and hereby does, assign to Lixte ownership or co-ownership, for as far as applicable, in accordance with this Section 5, more specifically Section 5.2.

5.5. Lixte shall control the prosecution of all patents for any Inventions, at Lixte's cost, with the cooperation of Institution, provided that Institution shall control the prosecution of any Invention that is solely owned by Institution and for which Lixte declines to exercise its licensing Option, in which case it is at the discretion of Institution whether or not to continue the prosecution or maintenance of such patents. Lixte shall keep Institution reasonable information of the progress of such patent prosecution.

5.6. Notwithstanding anything to the contrary herein, the Parties have agreed to collaborate with respect a patent application that will cover the research conducted by the research group of Prof. R. Bernards ("**Principal Investigator**") only prior to the Effective Date and directly relating to the subject matter of the Study, to include information and contributions by both Parties, and to file such application as a jointly-owned Invention. Such Invention and patent application shall be subject to the terms of this Agreement, including without limitation Section 5.3. Each Party shall execute and cause to be executed by its employees and agents all documents, and perform all acts, including providing reasonable assistance with the filing and prosecution of any patents, necessary to effect or evidence the ownership of any Invention as set forth in this Agreement, at the request and expense of the other Party.

## 6. Confidentiality.

6.1. Paragraphs 1 through 3 of the Reciprocal Non-Disclosure Agreement between the Parties dated • (attached hereto as Exhibit B) are incorporated herein by reference as if full stated herein, with the term "Lixte" substituted for "Provider" and "Institution" substituted for "Recipient." The Parties agree that the Compound, Material and Information (whether disclosed in writing, orally or through visual inspection) are the Confidential Information of Lixte, and the Study Results are the Confidential Information of both Parties, in each case including all copies of the foregoing and all summaries and notes thereof or derived therefrom whether created by Lixte or Institution.

6.2. A recipient of Confidential Information hereunder shall use such information solely for purposes of this Agreement, and hold in confidence and not disclose to any third party such Confidential Information during the term hereof and for a period of five (5) years from the termination of this Agreement.

## 7. Study Results and Publications.

7.1. Institution shall keep Lixte reasonably informed about the progress of the Study and the research results thereof. Within sixty (60) days of completing the Study, Institution shall provide Lixte with a copy of the data, materials and other research results obtained from the use of the Compound or Confidential Information ("**Study Data**").

7.2. In order to protect Lixte's proprietary and/or patent rights to the Compound and Information, Institution agrees to provide Lixte with an advance copy of any proposed publication or public disclosure (including abstracts, or presentation to a journal, editor, meeting, seminar or other third party) that makes reference to the Compound or Information, at least thirty (30) days prior to the proposed publication or public disclosure. If in the opinion of Lixte any such publication describes a patentable invention, Lixte shall have an opportunity to request that Institution delay the proposed publication or public disclosure until after a U.S. patent application has been filed. In no event shall the delay exceed sixty (60) days from the date that Institution provides Lixte with the advance copy of the proposed publication or public disclosure that makes reference to the Compound and Information. If Lixte determines such proposed publication or public disclosure contains any Confidential Information of Lixte, it shall notify Institution within such thirty (30) day review period and Institution shall delete such Lixte Confidential Information before proceeding with its planned publication. If a publication results from work using the Compound or Information, or based on any direct contribution made to the work by any Lixte scientists, Institution agrees to acknowledge Lixte and/or give credit to Lixte scientists as scientifically appropriate.

**8. Disclaimer of Warranties, Limitation of Liability and Indemnity.**

8.1. Institution acknowledges that the Compound is experimental in nature and that it is provided WITHOUT WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED. LIXTE MAKES NO REPRESENTATION THAT THE USE OF THE BIOLOGICAL MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK OR OTHER PROPRIETARY RIGHT. In no event shall Lixte be liable for any use of the Compound by Institution. To the extent permitted by Federal and State laws, Institution hereby agrees to defend, indemnify and hold Lixte harmless from any third-party claim arising out or loss, claim, damage or liability, of whatsoever kind or nature, which may arise from Institution's acts in connection with this Agreement or the Institution's use, handling or storage of the Compound, except to the extent such liability of claim arises from the gross negligence or willful misconduct of Lixte.

8.2. Institution and Oncode assume no responsibility or liability for the nature, conduct or results of any research, testing or other work performed hereunder. All information, results and reports are made available by Institution "as is" and Lixte understands and agrees that such information, results and reports are experimental in nature and are made available without any representation or warranty, express or implied, including any implied warranty of merchantability, satisfactory quality or fitness for any particular purpose or any warranty that the use of the information, results and reports will not infringe or violate any patent or other proprietary rights of any third party.

8.3. Lixte will indemnify NKI-AVL and Oncode, the Principal Investigator and every employee of NKI-AVL and Oncode (the Indemnified Parties) and keep them fully and effectively indemnified from any liability, loss or damage they may suffer as a result of claims against the Indemnified Parties arising out claims made by a third party against any of the Indemnified Parties to the extent arising as a result of Lixte's use of any of the results or any non-public materials, works or information received from the Indemnified Parties pursuant to the terms of this Agreement. The indemnity in this clause will not apply to the extent that the claim arises as a result of the Indemnified Party's act or omission, negligence, fraud, or willful misconduct.

8.4. Except under the indemnities in provided in this Section 8, the liability of either Party to the other for any damage arising out of a breach of this Agreement, the Study and the results, will not extend to any indirect damages or losses, or any loss of profits, loss of revenue, loss of data, loss of contracts or opportunity even if the Party bringing the claim has advised the other of the possibility of those losses, or if they were within the other Party's contemplation.

8.5. Except under the indemnities in this Section 8, the aggregate liability of any Party for damages as described in Section 8.4 will not exceed in total the Budget.

9. **Term and Termination.** This Agreement will commence on the Effective Date and terminate on its third anniversary, unless terminated earlier as permitted hereunder. Either Party may terminate this Agreement upon written notice in the event that the other Party is in material breach of this this Agreement and has failed to cure sure material breach within thirty (30) days of written notice of breach from the other Party. Lixte may terminate this Agreement immediately upon written notice in the event of a violation of law or Section 4.3 by Institution. Termination shall terminate all rights of Institution to use the Compound, Material and Information, but shall not relieve Institution of its obligations under this Agreement. Sections 1, 4, 5, 6, 7, 8, and 9 shall survive expiration or termination of this Agreement for any reason.

10. **Miscellaneous.**

10.1. Assignment. This Agreement, and the rights and obligations hereunder, may not be assigned, transferred, delegated or subcontracted, in whole or part, by Parties without the prior written consent of the other Parties, except that a Party may assign or transfer this agreement in its entirety to the successor to such Party's business, whether by sale of all or substantially all of the equity or assets, by merger (whether or not such Party is the surviving entity of such merger), by operation of law or otherwise. Any assignment or transfer in violation of this Section shall be null, void and without effect. This Agreement, including the indemnification provisions, shall be binding upon and inure to the benefit of the parties hereto, their respective permitted successors, assigns, legal representatives and heirs.

10.2. Governing Law and Dispute Resolution.

(a) In case of any dispute over the interpretation or the execution of this Agreement, the Parties undertake to make every effort to settle their dispute by amicable agreement. In the event of a dispute a party shall issue a notice describing the basis for the dispute, and senior representatives of the Parties shall promptly meet in good faith the attempt to resolve the dispute. If the Parties are unable to settle a dispute arising out of or in connection with this Agreement within sixty (60) days of issuance the dispute notice, then either party may commence an action. In the case of an action commenced by Lixte the governing law shall be Dutch law and the action shall be brought in the Netherlands courts, and in the event of an action commenced by NKI-AVL or Oncode, then the governing law shall be New York law and the action shall be brought in the state or federal courts located in New York, New York.

(b) In the event of any bona fide disagreement or disputed claim of any kind or nature between the Parties arising out of or relating to this Agreement or the breach, termination, enforcement, interpretation or validity thereof, the rights or obligations of the parties hereunder, or any payments due hereunder (each, a "**Dispute**"), the Parties shall attempt in good faith to resolve any Dispute promptly by negotiation between executives who have authority to settle the controversy and who are at a higher level of management than the persons with direct responsibility for administration of this Agreement. Upon the occurrence of a Dispute, a disputing Party shall notify the other Party in writing of such Dispute (a "**Dispute Notice**"). The Dispute Notice shall include a statement of the Party's position and a summary of arguments supporting that position, together with information reasonably necessary for the other Party to assess and respond to the subject of the Dispute, including copies of available supporting documents. Promptly following such Dispute Notice, the executives of both parties shall meet at a mutually acceptable time and place in good faith to attempt to resolve such Dispute by mutual agreement. If the Dispute has not been so resolved within thirty (30) days of the Dispute Notice, either Party may seek equitable and legal remedies under the court system.

10.3. Publicity. Neither party shall use the name of the other party (or the name of any of its divisions or affiliated companies) for promotional purposes without the prior written consent of the party whose name is proposed to be used, except as set forth in Section 7.2. No news release, publicity or other public announcement, either written or oral, regarding this Agreement or performance hereunder or regarding results arising from the Study, shall be made by Institution without the prior written approval of Lixte. Institution acknowledges that Lixte may make disclosures without prior consent to the extent required under applicable securities or other laws

10.4. Notices. All notices, consents or approvals required or permitted under this Agreement (each, a "**Notice**" or "**notice**") will be in writing and delivered by courier or overnight delivery service, or by certified mail, and in each instance will be deemed given upon receipt, to the addresses listed below:

If to Institution:

STICHTING HET NEDERLANDS KANKER INSTITUUT – ANTONI VAN LEEUWENHOEK ZIEKENHUIS  
Attn: Prof. Rene Bernards  
Plesmanlaan 121  
1066 CX Amsterdam, Netherlands  
[r.bernards@nki.nl](mailto:r.bernards@nki.nl)

with a copy to:

STICHTING ONCODE INSTITUTE  
Attn: Valorization Director  
Jaarbeursplein 6  
3521 AL, Utrecht, Netherlands  
[Chris.deJonghe@oncode.nl](mailto:Chris.deJonghe@oncode.nl)

If to Lixte:

LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
Attn: John Kovach, MD  
680 E Colorado Blvd., Suite 180  
Pasadena, CA 91101  
[jkovach@lixte.com](mailto:jkovach@lixte.com)

with copies to:

Joshua Rawson: [joshua.rawson@dechert.com](mailto:joshua.rawson@dechert.com)  
David Ficksman: [dlf@troygould.com](mailto:dlf@troygould.com)

10.5. Payments

(a) In consideration for the performance of the Study, Lixte agrees to pay Institution in accordance with the Budget set forth on Exhibit A. The parties acknowledge that the amounts to be paid by Lixte are reasonable compensation for the work performed and that neither Institution nor Principal Investigator has received any other compensation or other inducement in connection with this Agreement or its participation in the Study.

(b) Lixte will make all payments directly to Institution and not to Principal Investigator. Payments shall be made quarterly, within thirty (30) days of the issuance of a written invoice by Institution. Upon the request of Lixte, Institution will provide supporting documentation for the payments. Institution shall be responsible for any payments required to be made to Principal Investigator.

10.6. Modifications. This Agreement may not be altered, amended or modified except by written document signed by both parties.

10.7. Severability. If any term or condition of this Agreement, the deletion of which would not adversely affect the receipt of any material benefit by either party hereunder, shall be held illegal, invalid or unenforceable, the remaining terms and conditions of this Agreement shall not be affected thereby and such terms and conditions shall be valid and enforceable to the fullest extent permitted by law.

10.8. No Waiver. Failure on the part of Lixte or Institution to exercise or enforce any right conferred upon it hereunder shall not be deemed to be a waiver of any such right nor operate to bar the exercise or enforcement thereof at any time or times thereafter.



10.9. Entire Understanding. This Agreement, including the Exhibits hereto, set forth the entire understanding between the parties and any oral or written covenants, representations or warranties made by a Party in connection with the negotiations or otherwise with respect to this Agreement are not binding unless expressly stated herein.

10.10. Execution and Counterpart. The Parties agree that this Agreement may be executed and delivered by facsimile, electronic mail, internet, or any other suitable electronic means, this Agreement may be executed in counterparts, and the Parties agree that signatures delivered by any of the aforementioned means shall be deemed to be original, valid, and binding upon the Parties.

[REMAINDER OF PAGE BLANK; SIGNATURE PAGE IMMEDIATELY FOLLOWS]

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed, by duly authorized representatives, as of the last date written below.

STICHTING HET NEDERLANDS KANKER INSTITUUT – ANTONI VAN  
LEEUVENHOEK ZIEKENHUIS (“**NKI-AVL**”)

LIXTE BIOTECHNOLOGY HOLDINGS, INC. (“**Lixte**”).

BY: /s/ Henri van Luenen

BY: /s/ John S. Kovach

NAME: Henri van Leunen

NAME: John Kovach, MD

TITLE : Director of Operations

TITLE: CEO & President

DATE: 11 October 2021

DATE: 10/8/21

STICHTING ONCODE INSTITUTE (“**Oncode**”).

BY: /s/ Chris de Jonghe

NAME: Chris de Jonghe

TITLE: Valorization Director

DATE: 11 October 2021

**EXHIBIT A**

**THE STUDY**

**Research Collaboration Proposal.**

*Rene Bernards, The Netherlands Cancer Institute, Amsterdam, The Netherlands*

**Budget:**

Duration of Study: two (2) years. Any extension of the Study beyond two (2) years is subject to the written approval of Lixte.

Annual project cost

- a) Salary Cost. An annual payment of Euro €75,000 towards the salary cost of a post-doc.
- b) Consumable Costs. An annual payment of Euro €40,000 for bench fees and consumables (including mouse work).
- c) Infrastructure support. An annual payment of Euro €80,500 as overheads charged at 70% of the total project costs (salary cost + consumables).

**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, 2021

By: /s/ JOHN S. KOVACH

John S. Kovach  
Chief Executive Officer

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**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, 2021

By: /s/ ROBERT N. WEINGARTEN

Robert N. Weingarten  
Chief Financial Officer

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**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, 2021 (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, 2021

By: /s/ JOHN S. KOVACH

John S. Kovach  
Chief Executive Officer

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**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, 2021 (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, 2021

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

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