

**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, 2023

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 6, 2023, the Company had 2,249,290 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

	September 30, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash	\$ 5,105,611	\$ 5,353,392
Advances on research and development contract services	78,015	147,017
Prepaid insurance	23,230	49,224
Other prepaid expenses and current assets	27,840	10,380
Total current assets	<u>5,234,696</u>	<u>5,560,013</u>
Total assets	<u>\$ 5,234,696</u>	<u>\$ 5,560,013</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses, including \$43,895 and \$46,982 to related parties at September 30, 2023 and December 31, 2022, respectively	\$ 221,171	\$ 229,764
Research and development contract liabilities	90,565	165,022
Total current liabilities	<u>311,736</u>	<u>394,786</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 – 72,917 shares	3,500,000	3,500,000
Common stock, \$0.0001 par value; authorized – 100,000,000 shares; issued and outstanding – 2,249,290 shares and 1,664,706 shares at September 30, 2023 and December 31, 2022, respectively	225	166
Additional paid-in capital	48,872,208	45,059,760
Accumulated deficit	(47,449,473)	(43,394,699)
Total stockholders' equity	<u>4,922,960</u>	<u>5,165,227</u>
Total liabilities and stockholders' equity	<u>\$ 5,234,696</u>	<u>\$ 5,560,013</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,	
	2023	2022	2023	2022
Revenues	\$ —	\$ —	\$ —	\$ —
Costs and expenses:				
General and administrative costs:				
Compensation to related parties, including stock-based compensation expense of \$112,106 and \$396,883 for the three months ended September 30, 2023 and 2022, respectively, and \$669,146 and \$1,160,649 for the nine months ended September 30, 2023 and 2022, respectively	356,001	643,957	1,398,042	1,963,409
Patent and licensing legal and filing fees and costs	178,012	271,163	835,362	944,789
Other costs and expenses	357,681	290,993	1,081,893	875,016
Research and development costs	132,487	272,388	749,029	895,649
Total costs and expenses	<u>1,024,181</u>	<u>1,478,501</u>	<u>4,064,326</u>	<u>4,678,863</u>
Loss from operations	(1,024,181)	(1,478,501)	(4,064,326)	(4,678,863)
Interest income	5,809	3,911	13,538	4,211
Interest expense	(279)	(2,119)	(6,088)	(5,240)
Foreign currency gain (loss)	(109)	(1,300)	2,102	(1,339)
Net loss	<u>\$ (1,018,760)</u>	<u>\$ (1,478,009)</u>	<u>\$ (4,054,774)</u>	<u>\$ (4,681,231)</u>
Net loss per common share – basic and diluted	<u>\$ (0.49)</u>	<u>\$ (0.89)</u>	<u>\$ (2.25)</u>	<u>\$ (3.01)</u>
Weighted average common shares outstanding – basic and diluted	<u>2,074,938</u>	<u>1,664,659</u>	<u>1,803,466</u>	<u>1,554,183</u>

See accompanying notes to condensed consolidated financial statements.

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

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

Three Months and Nine Months Ended September 30, 2023 and 2022

	Convertible Series A Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Par Value			
Three months ended September 30, 2023:							
Balance, June 30, 2023	350,000	\$ 3,500,000	1,665,956	\$ 166	\$ 45,623,081	\$ (46,430,713)	\$ 2,692,534
Proceeds from sale of securities in registered direct offering, net of offering costs	—	—	180,000	18	3,137,021	—	3,137,039
Exercise of pre-funded common stock warrants	—	—	403,334	41	—	—	41
Stock-based compensation expense	—	—	—	—	112,106	—	112,106
Net loss	—	—	—	—	—	(1,018,760)	(1,018,760)
Balance, September 30, 2023	<u>350,000</u>	<u>\$ 3,500,000</u>	<u>2,249,290</u>	<u>\$ 225</u>	<u>\$ 48,872,208</u>	<u>\$ (47,449,473)</u>	<u>\$ 4,922,960</u>
Nine months ended September 30, 2023:							
Balance, December 31, 2022	350,000	\$ 3,500,000	1,664,706	\$ 166	\$ 45,059,760	\$ (43,394,699)	\$ 5,165,227
Proceeds from sale of securities in registered direct offering, net of offering costs	—	—	180,000	18	3,137,021	—	3,137,039
Exercise of pre-funded common stock warrants	—	—	403,334	41	—	—	41
Exercise of common stock options	—	—	1,250	—	6,281	—	6,281
Stock-based compensation expense	—	—	—	—	669,146	—	669,146
Net loss	—	—	—	—	—	(4,054,774)	(4,054,774)
Balance, September 30, 2023	<u>350,000</u>	<u>\$ 3,500,000</u>	<u>2,249,290</u>	<u>\$ 225</u>	<u>\$ 48,872,208</u>	<u>\$ (47,449,473)</u>	<u>\$ 4,922,960</u>

(Continued)

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

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

Three Months and Nine Months Ended September 30, 2023 and 2022

	Convertible Series A Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Par Value			
Three months ended September 30, 2022:							
Balance, June 30, 2022	350,000	\$ 3,500,000	1,664,593	\$ 166	\$ 44,277,486	\$ (40,285,386)	\$ 7,492,266
Stock-based compensation expense	—	—	—	—	396,883	—	396,883
Net loss	—	—	—	—	—	(1,478,009)	(1,478,009)
Balance, September 30, 2022	<u>350,000</u>	<u>\$ 3,500,000</u>	<u>1,664,593</u>	<u>\$ 166</u>	<u>\$ 44,674,369</u>	<u>\$ (41,763,395)</u>	<u>\$ 6,411,140</u>
Nine months ended September 30, 2022:							
Balance, December 31, 2021	350,000	\$ 3,500,000	1,374,593	\$ 137	\$ 38,372,365	\$ (37,082,164)	\$ 4,790,338
Proceeds from sale of securities in registered direct offering, net of offering costs	—	—	290,000	29	5,141,355	—	5,141,384
Stock-based compensation expense	—	—	—	—	1,160,649	—	1,160,649
Net loss	—	—	—	—	—	(4,681,231)	(4,681,231)
Balance, September 30, 2022	<u>350,000</u>	<u>\$ 3,500,000</u>	<u>1,664,593</u>	<u>\$ 166</u>	<u>\$ 44,674,369</u>	<u>\$ (41,763,395)</u>	<u>\$ 6,411,140</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,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (4,054,774)	\$ (4,681,231)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense included in -		
General and administrative costs	669,146	1,160,649
Research and development costs	—	—
Changes in operating assets and liabilities:		
(Increase) decrease in -		
Advances on research and development contract services	69,002	3,224
Prepaid insurance	25,994	22,375
Other prepaid expenses and current assets	(17,460)	(13,708)
Increase (decrease) in -		
Accounts payable and accrued expenses	(8,593)	81,433
Research and development contract liabilities	(74,457)	23,969
Net cash used in operating activities	(3,391,142)	(3,403,289)
Cash flows from financing activities:		
Proceeds from sale of securities in registered direct offering, net of offering costs	3,137,039	5,141,384
Exercise of pre-funded common stock warrants	41	—
Exercise of common stock options	6,281	—
Net cash provided by financing activities	3,143,361	5,141,384
Cash:		
Net increase (decrease)	(247,781)	1,738,095
Balance at beginning of period	5,353,392	4,823,745
Balance at end of period	\$ 5,105,611	\$ 6,561,840
Supplemental disclosures of cash flow information:		
Cash paid for -		
Interest	\$ 6,088	\$ 5,240
Income taxes	\$ —	\$ —

See accompanying notes to condensed consolidated financial statements.

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

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

Three Months and Nine Months Ended September 30, 2023 and 2022

1. Organization and Basis of Presentation

The condensed consolidated financial statements of Lixte Biotechnology Holdings, Inc., a Delaware corporation), including its wholly-owned Delaware subsidiary, Lixte Biotechnology, Inc. (collectively, the “Company”), at September 30, 2023, and for the three months and nine months ended September 30, 2023 and 2022, 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, 2023, and the results of its operations for the three months and nine months ended September 30, 2023 and 2022, and its cash flows for the nine months ended September 30, 2023 and 2022. 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, 2022 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 (“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, 2022, as filed with the SEC.

President and Chief Executive Officer

Effective September 26, 2023, Bas van der Baan was appointed as the Company’s President and Chief Executive Officer, at which time he replaced Dr. John S. Kovach as the Company’s President and Chief Executive Officer. Dr. Kovach passed away on October 5, 2023.

Reverse Stock Split

On June 2, 2023, the Company effected a 1-for-10 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 have been retroactively adjusted to reflect the reverse stock split for all periods presented.

Nasdaq Listing

The Company’s common stock and the warrants are traded on The Nasdaq Capital Market under the symbols “LIXT” and “LIXTW”, respectively.

In order to achieve compliance with the \$1.00 minimum closing bid price requirement of the Nasdaq Capital Market, the Company held a special meeting of stockholders on May 26, 2023 to seek approval for an amendment to the Company’s Certificate of Incorporation to effect a reverse stock split of its issued and outstanding shares of common stock. As a result of the approval of this amendment, the Company effected a 1-for-10 reverse stock split of its issued and outstanding common stock effective on Friday, June 2, 2023. Commencing with the opening of trading on the Nasdaq Capital Market on Monday, June 5, 2023, the Company’s common stock began trading on a post-split basis under the same symbol LIXT. The Company subsequently received confirmation from Nasdaq that it had regained compliance with the minimum bid price requirement of \$1.00 per share under Nasdaq Listing Rule 5550(a)(2) and currently meets all other applicable criteria for continued listing.

However, there can be no assurances that the Company will be able to remain in compliance with the \$1.00 minimum bid price requirement over time, or that it will be successful in maintaining compliance with any of the other Nasdaq continued listing requirements.

2. Business

The Company is a drug research 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 corporate office is located in Pasadena, California.

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. The Company believes that inhibitors of protein phosphatases have broad therapeutic potential not only for cancer but also for other debilitating and life-threatening diseases. The Company is directing its efforts on clinical development of a specific protein phosphatase inhibitor, referred to as LB-100, which has been shown to have clinical anti-cancer activity at doses that produce little or no toxicity.

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, relies on stock-based compensation for a substantial portion of employee and consultant compensation, and is dependent on periodic infusions of equity capital to fund its operating requirements.

Going Concern

As reflected in the accompanying financial statements, for the nine months ended September 30, 2023, the Company recorded a net loss of \$4,054,774 and used cash in operations of \$3,391,142. At September 30, 2023, the Company had cash of \$5,105,611 available to fund its operations. Because the Company is currently engaged in various early-stage 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 technology, product sales or other commercial activities, there can be no assurance that the Company will be able to achieve and maintain positive earnings and operating cash flows. At September 30, 2023, the Company's remaining contractual commitments pursuant to clinical trial agreements and clinical trial monitoring agreements not yet incurred aggregated approximately \$6,262,000 (see Note 9), which are currently scheduled to be incurred through approximately December 31, 2027.

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 through the recurring sale of its equity securities.

Based on the foregoing, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern within one year after the date that the accompanying interim condensed consolidated financial statements are being issued. The Company's interim condensed 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, design and results of the Company's clinical trial program, which, in turn, depends on the availability of operating capital to fund such activities.

Based on current operating plans, the Company estimates that its existing cash resources at September 30, 2023 will provide sufficient working capital to fund the current clinical trial program with respect to the development of the Company's lead anti-cancer clinical compound LB-100 through at least September 30, 2024. However, existing cash resources will not be sufficient to complete the development of and obtain regulatory approval for the Company's product candidate, which will require that the Company raise significant additional capital. The Company estimates that it will need to raise additional capital to fund its operations by mid-2024 to be able to proactively manage its current business plan during the remainder of 2024 and during 2025. In addition, the Company's operating plans may change as a result of many factors that are currently unknown and/or outside of the control of the Company, and additional funds may be needed sooner than planned.

As market conditions present uncertainty as to the Company's ability to secure additional funds, there can be no assurance that the Company will be able to secure additional financing on acceptable terms, as and when necessary, to continue to conduct operations.

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

3. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying 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 Lixte Biotechnology Holdings, Inc. and its wholly-owned subsidiary, Lixte Biotechnology, Inc. Intercompany balances and transactions have been eliminated in consolidation.

Foreign Currency Translation

The consolidated financial statements are presented in the United States dollar, which is the functional and reporting currency of the Company.

The Company periodically incurs a cost or expense denominated in a foreign currency. Such cost or expense is converted into United States dollars for financial statement purposes based on the foreign currency conversion rate in effect on the transaction date. The Company purchases the requisite foreign currency to pay such cost or expense on an as-needed basis. Any gain or loss resulting from the purchase of the foreign currency is included as foreign currency gain (loss) in the consolidated statement of operations. As of September 30, 2023 and December 31, 2022, the Company did not hold any currencies other than the United States dollar in its bank account.

Segment Information

The Company operates and reports in one segment, which focuses on the utilization of biomarker technology to identify enzyme targets associated with serious common diseases and then designing novel compounds to attack those targets. The Company's operating segment is reported in a manner consistent with the internal reporting provided to the Company's Chief Operating Decision Maker, which is the Company's President and Chief Executive Officer.

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 the calculation of accruals for clinical trial costs and other potential liabilities, valuing equity instruments issued for services, and the realization of deferred tax assets.

Cash

Cash is held in a cash bank deposit program maintained by Morgan Stanley Wealth Management, a division of Morgan Stanley Smith Barney LLC (“Morgan Stanley”). Morgan Stanley is a FINRA-regulated broker-dealer. The Company’s policy is to maintain its cash balances with financial institutions in the United States 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 periodically has cash balances in financial institutions in excess of the FDIC and SIPC insurance limits of \$250,000 and \$500,000, respectively. Morgan Stanley Wealth Management also maintains supplemental insurance coverage for the cash balances of its customers. The Company has not experienced any losses to date resulting from this policy.

Research and Development

Research and development costs consist primarily of fees paid to consultants and contractors, and other expenses relating to the negotiation, design, development and management of clinical trials with respect to the Company’s clinical compound and product candidate. Research and development costs also include the costs to manufacture the compounds used in research and clinical trials, which are charged to operations as incurred. The Company’s inventory of LB-100 for clinical use has been manufactured separately in the United States and in the European Union in accordance with the laws and regulations of such jurisdictions.

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 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 respective agreement. Obligations incurred with respect to mandatory scheduled payments under agreements without milestone provisions are accounted for when due, are recognized ratably over the appropriate period, as specified in the respective 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 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 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 various clinical trial and research and development contracts on a quarterly basis.

Prepaid Insurance

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

Patent and Licensing Legal and Filing Fees and Costs

Due to the significant uncertainty associated with the successful development of one or more commercially viable products based on the Company's research efforts and related patent applications, all patent and licensing legal and filing fees and costs related to the development and protection of the Company's intellectual property are charged to operations as incurred. Patent and licensing legal and filing fees and costs were \$178,012 and \$271,163 for the three months ended September 30, 2023 and 2022, respectively, and \$835,362 and \$944,789 for the nine months ended September 30, 2023 and 2022, respectively. Patent and licensing legal and filing fees and costs are included in general and administrative costs in the Company's consolidated statements of operations.

Concentration of Risk

The Company periodically contracts with vendors and consultants to provide services related to the Company's operations. Charges incurred for these services can be for a specific time period (typically one year) or for a specific project or task. Costs and expenses incurred that represented 10% or more of general and administrative costs or research and development costs for the three months and nine months ended September 30, 2023 and 2022 are described as follows.

General and administrative costs for the three months ended September 30, 2023 and 2022 included charges from legal firms and other vendors for general licensing and patent prosecution costs relating to the Company's intellectual properties representing 20.0% and 22.5% of total general and administrative costs, respectively. General and administrative costs for the three months ended September 30, 2023 and 2022 also included charges for the fair value of stock options granted to directors and corporate officers representing 12.6% and 32.9%, respectively, of total general and administrative costs. General and administrative costs for the three months ended September 30, 2023 also included charges from two vendors representing 11.9% and 10.6%, respectively, of total general and administrative costs.

Research and development costs for the three months ended September 30, 2023 included charges from four vendors and consultants representing 38.9%, 24.9%, 15.9% and 14.9%, respectively, of total research and development costs. Research and development costs for the three months ended September 30, 2022 include charges from four vendors and consultants representing 32.0%, 23.2%, 16.9% and 11.0%, respectively, of total research and development costs.

General and administrative costs for the nine months ended September 30, 2023 and 2022 include charges from legal firms and other vendors for general licensing and patent prosecution costs relating to the Company's intellectual properties representing 25.2% and 25.0% of total general and administrative costs, respectively. General and administrative costs for the nine months ended September 30, 2023 and 2022 also included charges for the fair value of stock options granted to directors and corporate officers representing 20.2% and 30.7%, respectively, of total general and administrative costs.

Research and development costs for the nine months ended September 30, 2023 include charges from three vendors and consultants representing 35.9%, 21.0% and 12.4%, respectively, of total research and development costs. Research and development costs for the nine months ended September 30, 2022 include charges from three vendors and consultants representing 31.0%, 16.7% and 10.0%, respectively, of total research and development costs.

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, 2023 or December 31, 2022 and does not anticipate any material amount of unrecognized tax benefits through December 31, 2023.

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, 2023 or December 31, 2022. Subsequent to September 30, 2023, 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. Recognition of compensation expense for non-employees is in the same period and manner as if the Company had paid cash for the services.

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.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in Accounting Standards Codification ("ASC") 480, Distinguishing Liabilities from Equity ("ASC 480"), and ASC 815, Derivatives and Hedging ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted when the warrants are issued and at the end each subsequent quarterly period while the warrants are outstanding. For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be liability classified and recorded at their initial fair value on the date of issuance and remeasured at fair value at each balance sheet date thereafter. Changes in the estimated fair value of the warrants are recognized as a non-cash gain or loss on the statements of operations. The Company has determined that the warrants issued in the July 20, 2023 equity financing (see Note 5) meet the requirements for equity classification.

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 respective 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 common shares 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, 2023 and 2022, 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,	
	2023	2022
Series A Convertible Preferred Stock	72,917	72,917
Common stock warrants	808,365	340,031
Common stock options, including options issued in the form of warrants	674,896	332,500
Total	1,556,178	745,448

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 May 2021, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“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 was effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply the guidance provided in ASU 2021-04 prospectively to modifications or exchanges occurring on or after the effective date. The Company adopted ASU 2021-04 effective January 1, 2022. The adoption of ASU 2021-04 did not have any impact on the Company’s consolidated financial statement presentation or related disclosures.

In July 2023, the FASB issued ASU 2023-03, Presentation of Financial Statements (Topic 205), Income Statement — Reporting Comprehensive Income (Topic 220), Distinguishing Liabilities from Equity (Topic 480), Equity (Topic 505), and Compensation — Stock Compensation (Topic 718) Presentation of Financial Statements (“ASU 2023-03”). ASU 2023-03 amends the FASB Accounting Standards Codification to include Amendments to SEC Paragraphs pursuant to SEC Staff Accounting Bulletin No. 120, SEC Staff Announcement at the March 24, 2022 EITF Meeting, and SEC Staff Accounting Bulletin Topic 6.B, Accounting Series Release 280 — General Revision of Regulation S-X: Income or Loss Applicable to Common Stock. As ASU 2023-03 did not provide any new guidance, there was no transition or effective date associated with its adoption. Accordingly, the Company adopted ASU 2023-03 immediately upon its issuance. The adoption of ASU 2023-03 did not have any impact on the Company’s consolidated financial statement presentation or related 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. Research and Development Costs

A summary of research and development costs for the three months and nine months ended September 30, 2023 and 2022, including costs associated with clinical trials involving the Company’s lead clinical compound LB-100, are summarized below based on the respective geographical regions where such costs have been incurred.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
United States	\$ 68,315	\$ 161,744	\$ 291,846	\$ 316,565
Spain	9,496	1,246	283,035	348,850
China	3,108	63,330	17,198	81,050
Netherlands	51,568	46,068	156,950	149,184
Total	\$ 132,487	\$ 272,388	\$ 749,029	\$ 895,649

5. 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, 2023 and December 31, 2022, the Company had 9,650,000 shares of undesignated preferred stock which may be issued with such rights and powers as the Board of Directors may designate.

Each share of Series A Convertible Preferred Stock may be converted, at the option of the holder, into 0.20833 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 any cash liquidation preference rights or any registration rights. If fully converted, the 350,000 outstanding shares of Series A Convertible Preferred Stock would convert into 72,917 shares of common stock at September 30, 2023 and December 31, 2022.

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, 2023 and December 31, 2022, the Company had 2,249,290 shares and 1,664,706 shares, respectively, of common stock issued and outstanding.

On June 2, 2023, the Company effected a 1-for-10 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 have been retroactively adjusted to reflect the reverse stock split for all periods presented.

Effective March 10, 2023, the Company issued 1,250 shares of common stock upon the exercise of a stock option in the form of a warrant held by a consultant to the Company for 1,250 shares exercisable at \$5.025 per share for total cash proceeds of \$6,281.

April 12, 2022 Sale of Common Stock

Effective April 12, 2022, the Company completed the sale of 290,000 shares of common stock at a price of \$20.00 per share in a registered direct offering, generating gross proceeds of \$5,800,000. The total cash costs of this offering were \$658,616, resulting in net proceeds of \$5,141,384. Pursuant to the placement agents' agreement, the Company granted warrants to the placement agents to purchase 29,000 shares of common stock at an exercise price of \$20.00 per share exercisable through April 14, 2027.

July 20, 2023 Sale of Common Stock and Warrants

Effective July 20, 2023, the Company sold 180,000 shares of common stock at a price of \$6.00 per share and pre-funded warrants to purchase 403,334 shares of common stock at a price of \$5.9999 per pre-funded warrant to an institutional investor in a registered direct offering. The pre-funded warrants had an exercise price of \$0.0001 per share, were immediately exercisable upon issuance, and were valid and exercisable until all pre-funded warrants were exercised in full. As of August 7, 2023, all pre-funded warrants had been exercised in full. The pre-funded warrants were determined to be common stock equivalents.

In a concurrent private placement to the institutional investor, the Company also sold warrants to purchase 583,334 shares of common stock. Each common warrant had an initial exercise price of \$6.00 per share, was immediately exercisable upon issuance, and expires five years thereafter on July 20, 2028. The common warrants and the shares of common stock issuable upon exercise of the common warrants were not registered under the Securities Act of 1933, as amended (the "Securities Act") and were offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act and Rule 506(b) promulgated thereunder. The shares of common stock issuable upon exercise of the warrants were subsequently registered for resale on a registration statement on Form S-3 declared effective by the SEC on August 21, 2023.

The registered direct offering and the concurrent private placement generated gross proceeds of \$3,499,964. The total cash costs of the registered direct offering and the private placement were \$362,925, resulting in net proceeds of \$3,137,039. Pursuant to the placement agent agreement, the Company granted the placement agent warrants to purchase 35,000 shares of common stock at an exercise price of \$6.60 per share and expiring on July 20, 2028.

During the period from July 24, 2023 through August 7, 2023, the 403,334 pre-funded warrants, exercisable at \$0.0001 per common share, were exercised for total cash proceeds of \$41, resulting in the issuance of 403,334 shares of common stock.

The exercise prices of the warrants issued to the institutional investor (exercisable at \$6.00 per share) and to the placement agent (exercisable at \$6.60 per share) are subject to customary adjustments for stock splits, stock dividends, stock combinations, reclassifications, reorganizations or similar events affecting the Company's common stock. In addition, the warrants issued to the institutional investor contain a "fundamental transaction" provision whereby in the event of a fundamental transaction (a sale or transfer of assets or ownership of the Company as defined in the warrant agreement) within the Company's control, the holder of the unexercised common stock warrants will be entitled to receive cash consideration equal to a Black-Scholes valuation, as defined in the warrant agreement. If such fundamental transaction is not within the Company's control, the warrant holder would only be entitled to receive the same form of consideration (and in the same proportion) as the holders of the Company's common stock, hence these warrants are classified as a component of permanent equity. The Company will account for any such cash payment for a warrant redemption as a distribution from stockholders' equity, as and when such cash payment is made.

Common Stock Warrants

A summary of common stock warrant activity during the nine months ended September 30, 2023, excluding the 403,334 pre-funded warrants, exercisable at \$0.0001 per common share, to purchase 403,334 shares of common stock described above, is presented below.

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Life (in Years)</u>
Warrants outstanding at December 31, 2022	190,031	\$ 50.161	
Issued	618,334	6.034	
Exercised	—	—	
Expired	—	—	
Warrants outstanding at September 30, 2023	<u>808,365</u>	<u>\$ 16.407</u>	<u>4.24</u>
Warrants exercisable at December 31, 2022	<u>190,031</u>	<u>\$ 50.161</u>	
Warrants exercisable at September 30, 2023	<u>808,365</u>	<u>\$ 16.407</u>	<u>4.24</u>

At September 30, 2023, the outstanding warrants are exercisable at the following prices per common share:

Exercise Prices	Warrants Outstanding (Shares)
\$ 6.000	583,334
\$ 6.600	35,000
\$ 20.000	29,000
\$ 37.000	11,331
<u>\$ 57.000</u>	<u>149,700</u>
	<u>808,365</u>

The warrants exercisable at \$57.00 per share at September 30, 2023 consist of 1,497,000 publicly-traded warrants pre-split 1-for-10 that were issued as part of the Company's November 2020 public offering of units and are exercisable for a period of five years thereafter. As a result of the 1-for-10 reverse split of the Company's common stock effective June 2, 2023, each such publicly-traded warrant currently represents the right to purchase 1/10th of a share of common stock at the original exercise price of \$5.70 per share. Accordingly, upon exercise, 10 warrants, each exercisable at \$5.70, will be required to acquire one share of post-split common stock, which is equivalent to a purchase price of \$57.00.

Based on a fair market value of \$2.45 per share on September 30, 2023, there was no intrinsic value attributed to exercisable but unexercised common stock warrants at September 30, 2023.

Information with respect to the issuance of common stock in connection with various stock-based compensation arrangements is provided at Note 7.

6. Related Party Transactions

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

Employment Agreements with Officers

During July and August 2020, the Company entered into one-year employment agreements with each of its executive officers at that time, consisting of Dr. John S. Kovach, Eric J. Forman, Dr. James S. Miser, and Robert N. Weingarten, payable monthly, as described below. These employment agreements were 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 additional one-year periods in July and August 2021, 2022 and 2023.

The Company entered into an employment agreement with Dr. Kovach dated July 15, 2020, effective October 1, 2020, to provide for Dr. Kovach to continue to act as the Company's President, Chief Executive Officer and Chief Scientific Officer, with an annual salary of \$250,000. During the three months ended September 30, 2023 and 2022, the Company paid \$62,500 and \$62,500, respectively, to Dr. Kovach under this employment agreement, and during the nine months ended September 30, 2023 and 2022, the Company paid \$187,500 and \$187,500, respectively, to Dr. Kovach under this employment agreement, which costs are included in general and administrative costs in the Company's consolidated statements of operations for such periods. The employment agreement with Dr. Kovach terminated upon his death on October 5, 2023.

The Company entered into an employment agreement with Dr. James S. Miser, M.D., effective August 1, 2020 to act as the Company's Chief Medical Officer, with an annual salary of \$150,000. Effective May 1, 2021, Dr. Miser's annual salary was increased to \$175,000. Dr. Miser is required to devote at least 50% of his business time to the Company's activities. During the three months ended September 30, 2023 and 2022, the Company paid \$43,750 and \$43,750, respectively, to Dr. Miser under this employment agreement, and during the nine months ended September 30, 2023 and 2022, the Company paid \$131,250 and \$131,250, respectively, to Dr. Miser under this employment agreement, which costs are included in general and administrative costs in the Company's consolidated statements of operations for such periods.

The Company entered into an employment agreement with Eric J. Forman effective July 15, 2020, as amended on August 12, 2020, to act as the Company's Chief Administrative Officer, with an annual salary of \$120,000. Mr. Forman is the son-in-law of Gil Schwartzberg (deceased), a former member of the Company's Board of Directors who died on October 30, 2022 and was 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 Mr. 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 with which the Company maintains a continuing banking relationship. Effective May 1, 2021, Mr. Forman's annual salary was increased to \$175,000. Additionally, effective November 6, 2022, Mr. Forman was promoted to Vice President and Chief Operating Officer with an annual salary of \$200,000. Effective October 1, 2022, Mr. Forman has been provided a monthly office rent allowance, pursuant to which Mr. Forman was paid \$7,323 and \$11,436, respectively, for the three months and nine months ended September 30, 2023. During the three months ended September 30, 2023 and 2022, the Company paid \$50,000 and \$43,750, respectively, to Mr. Forman under this employment agreement, and during the nine months ended September 30, 2023 and 2022, the Company paid \$150,000 and \$131,250, respectively, to Mr. Forman under this employment agreement, which costs are included in general and administrative costs in the Company's consolidated statements of operations for such periods.

The Company entered into an employment agreement with Robert N. Weingarten effective August 12, 2020 to act as the Company's Vice President and Chief Financial Officer, with an annual salary of \$120,000. Effective May 1, 2021, Mr. Weingarten's annual salary was increased to \$175,000. During the three months ended September 30, 2023 and 2022, the Company paid \$43,750 and \$43,750, respectively, to Mr. Weingarten under this employment agreement, and during the nine months ended September 30, 2023 and 2022, the Company paid \$131,250 and \$131,250, respectively, to Mr. Weingarten under this employment agreement, which costs are included in general and administrative costs in the Company's consolidated statements of operations for such periods.

The Company entered into an employment agreement with Bastiaan van der Baan effective September 26, 2023, to act as the Company's President and Chief Executive Officer and as Vice Chairman of the Board of Directors with an annual salary of \$150,000. The term of the employment agreement is for three years and is automatically renewable for additional one-year periods unless terminated by either party, subject to early termination as described in the employment agreement. Under the employment agreement, Mr. van der Baan's annual salary may be increased from time to time at the sole discretion of the Board of Directors. In addition, Mr. van der Baan will be eligible to receive an annual bonus as determined in the sole discretion of the Board of Directors. During the three months and nine months ended September 30, 2023, the Company paid \$1,667 to Mr. van der Baan under this employment agreement, which costs are included in general and administrative costs in the Company's consolidated statements of operations for such periods. Mr. Van der Baan was appointed as Chairman of the Board of Directors upon the death of Dr. Kovach on October 5, 2023.

Appointment of Dr. René Bernards to the Board of Directors

Effective as of June 15, 2022, Dr. René Bernards was appointed to the Company's Board of Directors as an independent director. Dr. Bernards is a leader in the field of molecular carcinogenesis and is employed by the Netherlands Cancer Institute in Amsterdam. As a new director, in lieu of a grant of stock options, Dr. Bernards received a one-time cash board fee of \$100,000, which was paid upon his appointment to the Board of Directors, and an annual cash board fee of \$40,000, payable quarterly.

Previously, on October 8, 2021, the Company had entered into a Development Collaboration Agreement (subsequently amended and extended) with the Netherlands Cancer Institute, Amsterdam, 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 (see Note 9).

Compensatory Arrangements for Members of the Board of Directors

Effective April 9, 2021, the Board of Directors approved a comprehensive cash and equity compensation program for the independent members of the Board of Directors and committee members. Effective May 25, 2022, the Board of Directors approved an amendment to the program. Officers who also serve on the Board of Directors are not compensated separately for their service on the Board of Directors.

Cash compensation for independent directors, payable quarterly, is as follows:

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

Equity compensation for independent directors is as follows:

Appointment of new independent directors – The Company grants options to purchase 25,000 shares of common stock, exercisable for a period of five years, at the closing market price on the date of grant, vesting 50% on the grant date and the remaining 50% vesting 12.5% on the last day of each calendar quarter beginning in the quarter immediately subsequent to the date of the grant until fully vested, subject to continued service. At the discretion of the Board of Directors, for a nominee to the Board of Directors who is restricted by their respective institution or employer from receiving equity-based compensation, in lieu of the grant of such stock options, the Company may elect to pay a one-time cash fee of \$100,000 to such director, payable upfront.

Annual grant of options to independent directors – Effective on the last business day of the month of June, the Company grants options to purchase 10,000 shares of common stock, exercisable for a period of five years, at the closing market price on the date of grant, vesting 12.5% on the last day of each calendar quarter beginning in the quarter immediately subsequent to the date of grant until fully vested, subject to continued service. If any director has served for less than 12 full calendar months on the grant date, the amount of such stock option grant shall be prorated based on the length of service of such director. At the discretion of the Board of Directors, for a nominee to the Board of Directors who is restricted by their respective institution or employer from receiving equity-based compensation, in lieu of the grant of such stock options, the Company may elect to pay an annual cash fee of \$40,000 to such director, payable quarterly.

Total cash compensation paid to independent directors was \$42,228 and \$53,324, respectively, for the three months ended September 30, 2023 and 2022. Total cash compensation paid to independent directors was \$127,229 and \$221,510, respectively, for the nine months ended September 30, 2023 and 2022.

Stock-based compensation granted to members of the Company's Board of Directors, officers and affiliates is described at Note 7.

A summary of related party costs, including compensation under employment and consulting agreements and fees paid to non-officer directors for their services on the Board of Directors, for the three months and nine months ended September 30, 2023 and 2022, is presented below.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Related party costs:				
Cash-based	\$ 243,895	\$ 247,074	\$ 728,896	\$ 802,760
Stock-based	112,106	396,883	669,146	1,160,649
Total	<u>\$ 356,001</u>	<u>\$ 643,957</u>	<u>\$ 1,398,042</u>	<u>\$ 1,963,409</u>

7. Stock-Based Compensation

The Company periodically 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 was subsequently approved by the stockholders of the Company. The 2020 Plan 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, initially for a total of 233,333 shares of the Company’s common stock, under terms and conditions as determined by the Company’s Board of Directors. On October 7, 2022, the stockholders of the Company approved an amendment to the 2020 Plan to increase the number of common shares issuable thereunder by 180,000 shares, to a total of 413,333 shares. The Company has scheduled a meeting of stockholders for November 27, 2023 to consider and vote on, among other matters, a proposal to increase the number of common shares issuable under the 2020 Plan by 336,667 shares, to a total of 750,000 shares.

As of September 30, 2023, there was a deficiency of 136,980 shares with respect to stock options issuable under the 2020 Plan. However, subject to approval of the proposal to increase the number of common shares issuable under the 2020 Plan at the meeting of stockholders scheduled for November 27, 2023, there will be unexpired stock options for 550,313 shares issued and outstanding under the 2020 Plan and 199,687 shares available for issuance under the 2020 Plan.

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, 2023, 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	4.843%
Expected dividend yield	0%
Expected volatility	138.05%
Expected life	4.0 years

For stock options requiring an assessment of value during the nine months ended September 30, 2022, 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	3.03%
Expected dividend yield	0%
Expected volatility	198.79%
Expected life	3.6 years

On July 15, 2020, as amended on August 12, 2020, in connection with the employment agreement entered into with Eric J. Forman, Mr. Forman was granted stock options to purchase 5,833 shares of the Company's common stock. The options can be exercised on a cashless basis. The options are exercisable for a period of five years at an exercise price of \$71.40 per share, which was equal to the closing market price of the Company's common stock on the grant date. The options vested 25% on August 12, 2020, 2021 and 2022, respectively, with the final 25% vesting on August 12, 2023, subject to continued service. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$400,855 (\$68.718 per share), of which \$100,214 was attributable to the portion of 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 was charged to operations ratably from August 12, 2020 through August 12, 2023. The Company recorded charges to general and administrative costs in the consolidated statement of operations of \$11,806 and \$25,259 for the three months ended September 30, 2023 and 2022, respectively, and \$61,501 and \$74,954 for the nine months ended September 30, 2023 and 2022, 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 stock options to purchase 8,333 shares of the Company's common stock. The options can be exercised on a cashless basis. The options are exercisable for a period of five years at an exercise price of \$71.40 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 25% on August 1, 2020, 2021 and 2022, respectively, with the final 25% vesting on August 1, 2023, subject to continued service. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$572,650 (\$68.718 per share), of which \$143,163 was attributable to the portion of 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 was charged to operations ratably from August 1, 2020 through August 1, 2023. The Company recorded charges to general and administrative costs in the consolidated statement of operations of \$12,551 and \$36,085 for the three months ended September 30, 2023 and 2022, respectively, and \$83,544 and \$107,078 for the nine months ended September 30, 2023 and 2022, 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 stock options to purchase 5,833 shares of the Company's common stock. The options can be exercised on a cashless basis. The options are exercisable for a period of five years at an exercise price of \$71.40 per share, which was equal to the closing market price of the Company's common stock on the grant date. The options vested 25% on August 12, 2020, 2021 and 2022, respectively, with the final 25% vesting on August 12, 2023, subject to continued service. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$400,855 (\$68.718 per share), of which \$100,214 was attributable to the portion of 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 was charged to operations ratably from August 12, 2020 through August 12, 2023. The Company recorded charges to general and administrative costs in the consolidated statement of operations of \$11,806 and \$25,259 for the three months ended September 30, 2023 and 2022, respectively, and \$61,501 and \$74,954 for the nine months ended September 30, 2023 and 2022, respectively, with respect to these stock options.

On April 9, 2021, the Board of Directors appointed Gil Schwartzberg to fill the vacancy created by a former director's resignation. In connection with his appointment to the Board of Directors, and in accordance with the Company's cash and equity compensation package for members of the Board of Directors, Mr. Schwartzberg was granted stock options to purchase 25,000 shares of the Company's common stock, exercisable for a period of five years at an exercise price of \$32.00 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, subject to continued service. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$753,611 (\$30.144 per share), of which \$376,800 was attributable to the portion of the stock options fully vested on April 9, 2021 and was therefore charged to operations on that date. Although the remaining unvested portion of the fair value of the stock options was being charged to operations ratably from April 9, 2021 through June 30, 2023, the vesting of these stock options terminated on October 30, 2022 as a result of the death of Mr. Schwartzberg on that date. The Company recorded charges to general and administrative costs in the consolidated statement of operations of \$42,692 and \$126,684 for the three months and nine months ended September 30, 2022, 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 Company's cash and equity compensation package for members of the Board of Directors, Ms. Brown was granted stock options to purchase 25,000 shares of the Company's common stock, exercisable for a period of five years at an exercise price of \$28.00 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, subject to continued service. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$658,363 (\$26.335 per share), of which \$329,188 was attributable to the portion of 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 was charged to operations ratably from May 11, 2021 through June 30, 2023. The Company recorded charges to general and administrative costs in the consolidated statement of operations of \$0 and \$38,827 for the three months ended September 30, 2023 and 2022, respectively, and \$76,388 and \$115,215 for the nine months ended September 30, 2023 and 2022, respectively, with respect to these stock options.

On June 30, 2021, the Board of Directors, in accordance with the Company's cash and equity compensation package for members of the Board of Directors, granted to each of the five non-officer directors of the Company stock options to purchase 10,000 shares (a total of 50,000 shares) of the Company's common stock, exercisable for a period of five years at an exercise price of \$30.30 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, subject to continued service. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$1,421,095 (\$28.423 per share), which was charged to operations ratably from July 1, 2021 through June 30, 2023. The Company recorded charges to general and administrative costs in the consolidated statement of operations of \$0 and \$179,100 for the three months ended September 30, 2023 and 2022, respectively, and \$211,412 and \$531,455 for the nine months ended September 30, 2023 and 2022, respectively, with respect to these stock options.

On June 17, 2022, the Board of Directors appointed Bas van der Baan to the Board of Directors. In connection with his appointment to the Board of Directors, and in accordance with the Company's cash and equity compensation package for members of the Board of Directors, Mr. Baan was granted stock options to purchase 25,000 shares of the Company's common stock, exercisable for a period of five years at an exercise price of \$7.40 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, subject to continued service. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$158,525 (\$6.341 per share), of which \$79,263 was attributable to the portion of the stock options fully vested on June 17, 2022 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 June 17, 2022 through June 30, 2024. The Company recorded charges to general and administrative costs in the consolidated statement of operations of \$9,801 and \$9,801 for the three months ended September 30, 2023 and 2022, respectively, and \$29,084 and \$90,449 for the nine months ended September 30, 2023 and 2022, respectively, with respect to these stock options.

On June 30, 2022, the Board of Directors, in accordance with the Company's cash and equity compensation package for members of the Board of Directors, granted to each of the five non-officer directors of the Company stock options to purchase 10,000 shares (a total of 50,000 shares) of the Company's common stock, exercisable for a period of five years at an exercise price of \$7.40 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, subject to continued service. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$316,700 (\$6.334 per share), which is being charged to operations ratably from July 1, 2022 through June 30, 2024. The Company recorded charges to general and administrative costs in the consolidated statement of operations of \$23,916 and \$39,860 for the three months ended September 30, 2023 and 2022, respectively, and \$70,965 and \$39,860 for the nine months ended September 30, 2023 and 2022, respectively, with respect to these stock options.

On November 6, 2022, the Board of Directors granted to each of the four officers of the Company stock options to purchase 20,000 shares (a total of 80,000 shares) of the Company's common stock, exercisable for a period of five years at an exercise price of \$20.00 per share, vesting 25% on issuance and 25% on each anniversary date thereafter until fully vested, subject to continued service. The total fair value of the 80,000 stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$262,560 (\$3.282 per share), which is being charged to operations ratably from November 6, 2022 through November 6, 2025. The Company recorded a total charge to general and administrative costs in the consolidated statement of operations of \$16,528 and \$49,053 for the three months and nine months ended September 30, 2023, respectively, with respect to these stock options.

On November 6, 2022, the Company issued a stock option, in the form of a warrant, to BioPharmaWorks to purchase 10,000 shares of the Company's common stock, which was fully vested upon issuance and is exercisable for a period of five years at \$5.025 per share (the closing market price on the issue date). The fair value of the warrant, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$43,264 (\$4.326 per share) and was charged to general and administrative costs in the consolidated statement of operations on that date.

On June 30, 2023, the Board of Directors, in accordance with the Company's cash and equity compensation package for members of the Board of Directors, granted to each of the four non-officer directors of the Company stock options to purchase 10,000 shares (a total of 40,000 shares) of the Company's common stock, exercisable for a period of five years at an exercise price of \$5.88 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, subject to continued service. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$192,593 (\$4.8131 per share), which is being charged to operations ratably from July 1, 2023 through June 30, 2025. The Company recorded a total charge to general and administrative costs in the consolidated statement of operations of \$24,232 for the three months and nine months ended September 30, 2023 with respect to these stock options.

On September 26, 2023, in connection with the employment agreement entered into with Bastiaan van der Baan, Mr. van der Baan was granted stock options to purchase 250,000 shares of the Company's common stock. The options can be exercised on a cashless basis. The options are exercisable for a period of five years at an exercise price of \$1.95 per share, which was equal to the closing market price of the Company's common stock on the grant date. The options vest in equal increments quarterly over a three-year period commencing on the last day of each calendar quarter commencing October 1, 2023, subject to continued service. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$403,066 (\$1.612 per share), which is being charged to operations ratably from September 26, 2023 through September 30, 2026. The Company recorded a charge to general and administrative costs in the consolidated statement of operations of \$1,466 for the three months and nine months ended September 30, 2023 with respect to these stock options.

Dr. Philip Palmedo, a director of the Company since 2006, did not stand for re-election to the Company's Board of Directors at the Company's annual meeting of stockholders held on October 7, 2022. Gil Schwartzberg, a director of the Company, died on October 30, 2022. Dr. John S. Kovach, the Chairman of the Board of Directors and the Company's President and Chief Executive Officer, and Chief Scientific Officer, died on October 5, 2023. Accordingly, the unvested stock options for each of such persons ceased vesting effective as of the respective dates that their service to the Company terminated. Furthermore, the expiration date of all vested stock options owned by each of such persons are contractually scheduled to expire one year from the respective dates that their service to the Company terminated.

A summary of stock-based compensation costs for the three months and nine months ended September 30, 2023 and 2022 is as follows:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2023	2022	2023	2022
Related parties	\$ 112,106	\$ 396,883	\$ 669,146	\$ 1,160,649
Non-related parties	—	—	—	—
Total stock-based compensation costs	\$ 112,106	\$ 396,883	\$ 669,146	\$ 1,160,649

A summary of stock option activity, including options issued in the form of warrants, during the nine months ended September 30, 2023 is as follows:

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Life (in Years)</u>
Stock options outstanding at December 31, 2022	389,479	\$ 29.1826	
Granted	290,000	2.4920	
Exercised	(1,250)	5.0250	
Expired	(3,333)	16.800	
Stock options outstanding at September 30, 2023	<u>674,896</u>	<u>\$ 17.8197</u>	<u>4.96</u>
Stock options exercisable at December 31, 2022	281,979	\$ 32.8335	
Stock options exercisable at September 30, 2023	<u>313,959</u>	<u>\$ 31.8997</u>	<u>1.93</u>

Total deferred compensation expense for the outstanding value of unvested stock options was approximately \$808,000 at September 30, 2023, which will be recognized subsequent to September 30, 2023 over a weighted-average period of approximately 28 months.

The exercise prices of common stock options outstanding and exercisable, including options issued in the form of warrants, at September 30, 2023 are as follows:

<u>Exercise Prices</u>	<u>Options Outstanding (Shares)</u>	<u>Options Exercisable (Shares)</u>
\$ 1.950	250,000	—
\$ 5.025	8,750	8,750
\$ 5.880	40,000	5,000
\$ 7.400	57,500	41,563
\$ 20.000	80,000	20,000
\$ 20.600	20,000	20,000
\$ 28.000	25,000	25,000
\$ 30.000	66,667	66,667
\$ 30.300	42,500	42,500
\$ 32.000	20,313	20,313
\$ 32.100	15,000	15,000
\$ 60.000	16,667	16,667
\$ 66.000	4,167	4,167
\$ 71.400	20,000	20,000
\$ 120.000	8,332	8,332
	<u>674,896</u>	<u>313,959</u>

Based on a fair market value of \$2.45 per share on September 30, 2023, there was no intrinsic value attributed to exercisable but unexercised common stock options at September 30, 2023.

Outstanding stock options to acquire 360,938 shares of the Company's common stock had not vested at September 30, 2023.

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

8. Income Taxes

During the three months and nine months ended September 30, 2023 and 2022, the Company did not record any provision for income taxes, as the Company incurred losses during those periods. Deferred tax assets and liabilities reflect the net tax effect of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company has recorded a full valuation allowance against its deferred tax assets for all periods presented as the Company currently believes it is more likely than not that the deferred tax assets will not be realized.

9. 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, 2023 and December 31, 2022, the Company was not subject to any pending or threatened legal claims or actions.

Principal Commitments

Clinical Trial Agreements

At September 30, 2023, the Company's remaining contractual commitments pursuant to clinical trial agreements and clinical trial monitoring agreements not yet incurred, as described below, aggregated \$6,262,000, which, based on current estimates, are currently scheduled to be incurred through approximately December 31, 2027. The Company's ability to conduct and fund these contractual commitments is subject to the timely availability of sufficient capital to fund such expenditures, as well as any changes in the allocation or reallocation of such funds to the Company's current or future clinical trial programs. The Company expects that the full amount of these expenditures will be incurred only if such clinical trial programs are conducted as originally designed and their respective enrollments and duration are not modified or reduced. Clinical trial programs, such as the types that the Company is engaged in, can be highly variable and can frequently involve a series of changes and modifications over time as clinical data are obtained and analyzed, and are frequently modified, suspended or terminated before the clinical trial endpoint is reached. Accordingly, such contractual commitments as discussed herein should be considered as estimates only based on current clinical assumptions and conditions, and are typically subject to significant modifications and revisions over time.

The following is a summary of the contractual clinical trials discussed below as of September 30, 2023:

<u>Description of Clinical Trial</u>	<u>Type of Clinical Trial</u>	<u>Institution</u>	<u>Estimated Start Date</u>	<u>Estimated End Date</u>	<u>Number of Patients in Trial</u>	<u>Study Objective</u>	<u>Clinical Update</u>	<u>NCT No.</u>
LB-100 combined with carboplatin, etoposide and atezolizumab in small cell lung cancer	Phase 1b	City of Hope and Sarah Cannon	March 2021	March 2026	14 to 36	Determine RP2D	Three patients entered	NCT04560972
LB-100 combined with doxorubicin in sarcoma	Phase 1b	GEIS	June 2023	June 2024	9 to 18	Determine MTD and RP2D	One patient entered	NCT05809830
Doxorubicin with or without LB-100 in sarcoma	Randomized Phase 2	GEIS	July 2024	June 2026	150	Determine efficacy: PFS	Clinical trial not yet begun (subject to completion of Phase 1b GEIS clinical trial)	NCT05809830
LB-100 combined with dostarlimab in ovarian clear cell carcinoma	Phase 1b/2	MD Anderson	March 2024	December 2025	21	Determine the survival of patients with ovarian clear cell carcinoma	No patients entered at September 30, 2023	NCT06065462

Moffitt. Effective August 20, 2018, the Company entered into a five-year Clinical Trial Research Agreement with the Moffitt Cancer Center and Research Institute Hospital Inc., Tampa, Florida ("Moffitt"). Pursuant to the Clinical Trial Research Agreement, Moffitt agreed to conduct and manage a Phase 1b/2 clinical trial to evaluate the toxicity and 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 to conduct a Phase 1b/2 clinical trial to evaluate the toxicity and 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 utilized 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.

During the three months ended June 30, 2023, the Phase 1b/2 clinical trial at Moffitt evaluating LB-100 in patients with MDS was closed by the principal investigator. In this clinical trial, single agent LB-100 was used on a new schedule of days 1, 3, and 5 every 3 weeks. The Company is not employing this schedule in its other clinical trials. Although the Maximally Tolerated Dose (“MTD”) was not achieved, there was no dose-limiting toxicity on this schedule at doses that were greater than the MTD in the Phase 1 clinical trial of LB-100 on the Monday, Tuesday, Wednesday schedule.

During the three months ended September 30, 2023 and 2022, the Company incurred costs of \$0 and \$9,218, respectively, pursuant to this agreement, which have been included in research and development costs in the Company’s consolidated statements of operations. During the nine months ended September 30, 2023 and 2022, the Company incurred costs of \$0 and \$18,623, respectively, pursuant to this agreement, which have been included in research and development costs in the Company’s consolidated statements of operations. As of September 30, 2023, total costs of \$131,074 have been incurred pursuant to this agreement.

The Company has decided not to pursue further studies in MDS, as other opportunities have become available (see “Patent and License Agreements - Moffitt” below).

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

GEIS has a network of referral centers in Spain and across Europe that have an impressive track record of efficiently conducting innovative studies in ASTS. The Company agreed to provide GEIS with a supply of LB-100 to be utilized in the conduct of this clinical trial, as well as to provide funding for the clinical trial. The goal is to enter approximately 150 to 170 patients in this clinical trial over a period of two years. As advanced sarcoma is a very aggressive disease, the design of the study assumes a median progression free survival (“PFS”, no evidence of disease progression or death from any cause) of 4.5 months in the doxorubicin arm and an alternative median PFS of 7.5 months in the doxorubicin plus LB-100 arm to demonstrate a statistically significant decrease in relative risk of progression or death by adding LB-100. There is a planned interim analysis of the primary endpoint when approximately 50% of the 102 events required for final analysis is reached.

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

In order to manufacture a new inventory supply of LB-100 for the GEIS clinical trial, the Company 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 included 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 was then transferred to a vendor that prepares the clinical drug product, also under GMP conditions documented by an independent auditor. The clinical drug product was then sent to a vendor to test for purity and sterility, provide appropriate labels, store the drug, and distribute the drug to the clinical centers for use in the clinical trials. A formal application documenting all steps taken to prepare the clinical drug product for clinical use was submitted to the appropriate regulatory authorities for review and approval before being used in a clinical trial.

As of September 30, 2023, this program to provide new inventory of the clinical drug product for the Spanish Sarcoma Group study, and potentially for subsequent multiple trials within the European Union, had cost approximately \$1,144,000. Although the production of new inventory has been completed, nominal trailing costs subsequent to September 30, 2023 may be incurred.

On October 13, 2022, the Company announced that the Spanish Agency for Medicines and Health Products (Agencia Española de Medicamentos y Productos Sanitarios or “AEMPS”) had authorized a Phase 1b/randomized Phase 2 study of LB-100, the Company’s lead clinical compound, plus doxorubicin, versus doxorubicin alone, the global standard for initial treatment of advanced soft tissue sarcomas (ASTS). Consequently, this clinical trial commenced during the quarter ended June 30, 2023 and is expected to be completed and a report prepared by December 31, 2026. In April 2023, GEIS completed its first site initiation visit in preparation for the clinical trial at Fundación Jiménez Díaz University Hospital (Madrid). Up to 170 patients will be entered into the clinical trial. The Phase 1b section of the protocol is expected to be completed by June 30, 2024, at which time the Company expects to have data on both response and toxicity from this portion of the clinical trial, and subject to clinical results, anticipates that it will be able to proceed to a related Phase 2 study.

The interim analysis of this clinical trial will be done before full accrual of patients is completed to determine whether the study has the possibility of showing superiority of the combination of LB-100 plus doxorubicin 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. During the three months ended September 30, 2023 and 2022, the Company did not incur any costs pursuant to this agreement. During the nine months ended September 30, 2023 and 2022, the Company incurred costs of \$268,829 and \$0, respectively, pursuant to this agreement. Such costs, when incurred, are included in research and development costs in the Company’s consolidated statements of operations. Through September 30, 2023, the Company has paid GEIS an aggregate of \$684,652 for work done under this agreement through the fourth milestone.

The Company’s aggregate commitment pursuant to this agreement, less amounts previously paid to date, totaled approximately \$3,423,000 as of September 30, 2023, which is expected to be incurred through December 31, 2027. As the work 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. Such fluctuations are recorded in the consolidated statements of operations as foreign currency gain or loss, as appropriate.

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 an FDA-approved standard regimen for treatment of untreated extensive-stage disease small cell lung cancer (“ED-SCLC”). LB-100 will be given in combination with carboplatin, etoposide and atezolizumab, an FDA-approved but marginally effective regimen, to previously untreated ED-SCLC patients. The dose of LB-100 will be escalated with the standard fixed doses of the 3-drug regimen to reach a recommended Phase 2 dose (“RP2D”). Patient entry will be expanded so that a total of 12 patients will be evaluable at the RP2D to confirm the safety of the LB-100 combination and to look for potential therapeutic activity as assessed by objective response rate, duration of overall response, progression-free-survival and overall survival.

The clinical trial was initiated on March 9, 2021, with patient accrual expected to take approximately two years to complete. However, as patient accrual was slower than expected, the Company has been seeking to add additional sites to increase the rate of patient accrual. Effective March 6, 2023, the Sarah Cannon Research Institute (“SCRI”), Nashville, Tennessee, joined the City of Hope’s ongoing Phase 1b clinical trial. The Company is continuing its efforts to add additional sites. The addition of SCRI is expected to expedite and expand the accrual of patients to this clinical trial, thus reducing the time required to demonstrate the feasibility, tolerability and efficacy of adding LB-100 to the current standard treatment regimen. With the addition of SCRI, the Company currently expects that this clinical trial will be completed by March 31, 2026.

In early July 2023, the Company was notified that one of three centers accruing patients to its Phase 1b clinical trial in small cell lung cancer had a shortage of carboplatin and as a result the clinical trial was placed on a temporary enrollment hold. This matter was resolved and the temporary enrollment hold was lifted in late July 2023.

During the three months ended September 30, 2023 and 2022, the Company did not incur any costs pursuant to this agreement. During the nine months ended September 30, 2023 and 2022, the Company incurred costs of \$69,001 and \$0, respectively, pursuant to this agreement, which are included in research and development costs in the Company’s consolidated statements of operations. As of September 30, 2023, total costs of \$447,512 have been incurred pursuant to this agreement.

The Company’s aggregate commitment pursuant to this agreement, less amounts previously paid to date, totaled approximately \$2,433,000 as of September 30, 2023, which is expected to be incurred through March 31, 2026. If a significant number of patients fail during the dose-escalation process, an increase of up to 12 patients would likely be necessary, at an estimated additional cost of approximately \$800,000.

The Company currently expects that enrollment in this clinical trial will range from approximately 18 to 30 enrollees, with 24 enrollees as the most likely number. Should fewer than 42 enrollees be required, the Company has agreed to compensate City of Hope on a per enrollee basis. If a significant improvement in outcome is seen with the addition of LB-100, this would be an important advance in the treatment of a very aggressive disease.

Theradex. On June 22, 2023, the Company finalized a work order agreement with Theradex Systems, Inc. (“Theradex”), an international contract research organization (“CRO”), to conduct a Phase I/II randomized trial of LB-100 plus doxorubicin vs. doxorubicin alone in first line of advanced soft tissue sarcomas. The study is expected to be completed by June 30, 2026.

Costs under this work order agreement are estimated to be approximately \$153,000, with such payments expected to be allocated approximately 72% to Theradex for services and approximately 28% for payments for pass-through software costs. During the three months and nine months ended September 30, 2023, the Company incurred costs of \$3,750 and 10,000, respectively, pursuant to this work order. As of September 30, 2023, total costs of \$10,000 have been incurred pursuant to this work order agreement.

The Company’s aggregate commitment pursuant to this clinical trial monitoring agreement, less amounts previously paid to date, totaled approximately \$144,000 as of September 30, 2023, which is expected to be incurred through June 30, 2026.

National Cancer Institute Pharmacologic Clinical Trial. In May 2019, the National Cancer Institute (“NCI”) initiated a glioblastoma (“GBM”) pharmacologic clinical trial. This study was being conducted and funded by the NCI under a Cooperative Research and Development Agreement, with the Company responsible for 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 has not been determined. Many drugs potentially useful for GBM treatment do not enter the brain in amounts necessary for anti-cancer action.

The NCI study was designed to determine the extent to which LB-100 enters recurrent malignant gliomas. Patients having surgery to remove one or more tumors received one dose of LB-100 prior to surgery and had blood and tumor tissue analyzed to determine the amount of LB-100 present and to determine whether the cells in the tumors showed the biochemical changes expected to be present if LB-100 reached its molecular target. As a result of the innovative design of the NCI study, it was believed that data from a few patients would 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. Five patients were entered into this study and analysis of the blood and tissue has been conducted. If there is clinical evidence in at least two of the patients of penetration of LB 100 into tumor tissue, the study will be deemed as successful. Results of this study are currently being reviewed by the NCI and a report is pending.

MD Anderson Cancer Center Trial. On September 20, 2023, the Company announced a Phase 1b/2 collaborative clinical trial to assess whether adding LB-100 to the programmed death receptor-1 (“PD-1”)–blocking monoclonal antibody of GSK plc (“GSK”), dostarlimab, may enhance the effectiveness of immunotherapy in the treatment of ovarian clear cell carcinoma (“OCCC”). The clinical trial is sponsored by The University of Texas MD Anderson Cancer Center (“MD Anderson”) and will be conducted at MD Anderson, and will also be open at Northwestern University’s Robert H. Lurie Comprehensive Cancer Center. The Company will provide LB-100 and GSK will provide dostarlimab and financial support for the clinical trial.

Clinical Trial Monitoring Agreements

Moffitt. On September 12, 2018, the Company finalized a work order agreement with Theradex (“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.

The costs of the Phase 1b/2 clinical trial being paid to or through Theradex have been recorded and charged to operations based on periodic documentation provided by the CRO. During the three months ended September 30, 2023 and 2022, the Company incurred costs of \$566 and \$11,953, respectively, pursuant to this work order. During the nine months ended September 30, 2023 and 2022, the Company incurred costs of \$20,850 and \$19,792, respectively, pursuant to this work order. As of September 30, 2023, total costs of \$148,138 have been incurred pursuant to this work order agreement.

As a result of the closure of the Company’s Clinical Trial Research Agreement with Moffitt during the three months ended June 30, 2023 (see “Clinical Trial Agreements – Moffitt” above), this work order agreement with Theradex to monitor the Clinical Trial Research Agreement with Moffitt was similarly suspended, although nominal oversight trailing costs subsequent to September 30, 2023 are expected to be incurred relating to the closure of the Moffitt study.

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. Costs under this work order agreement are estimated to be approximately \$335,000. During the three months ended September 30, 2023 and 2022, the Company incurred costs of \$4,500 and \$7,731, respectively, pursuant to this work order. During the nine months ended September 30, 2023 and 2022, the Company incurred costs of \$15,740 and \$23,466, respectively, pursuant to this work order. As of September 30, 2023, total costs of \$74,181 have been incurred pursuant to this work order agreement.

The Company’s aggregate commitment pursuant to this clinical trial monitoring agreement, less amounts previously paid to date, totaled approximately \$262,000 as of September 30, 2023, which is expected to be incurred through March 31, 2026.

Patent and License Agreements

Moffitt. 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 was 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 was 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 had also agreed to pay non-refundable milestone payments to Moffitt, which could not 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.

On October 4, 2023, the Company received a counter-signed termination letter dated September 29, 2023 with respect to the Exclusive License Agreement dated August 20, 2018 between the Company and Moffitt, effective September 30, 2023. The Company and Moffitt agreed that no termination fee shall be due or payable by the Company, and Moffitt acknowledged that no payments are owed by the Company under the Agreement.

During the three months and nine months ended September 30, 2023, the Company recorded credits to operations of \$21,507 and \$9,109, respectively, representing the reversal of obligations previously recorded with respect to the Exclusive License Agreement. During the three months and nine months ended September 30, 2022, the Company recorded charges to operations of \$6,301 and \$18,699, respectively, in connection with its obligations under the Exclusive License Agreement.

Employment Agreements with Officers

During July and August 2020, the Company entered into one-year employment agreements with each of its executive officers at that time, consisting of Dr. John S. Kovach, Eric J. Forman, Dr. James S. Miser, and Robert N. Weingarten, which provided for aggregate annual cash compensation of \$640,000, payable monthly (see Note 6). These employment agreements were 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 additional one-year periods in July and August 2021, 2022 and 2023.

On April 9, 2021, the Board of Directors increased the annual cash compensation of Eric J. Forman, Dr. James S. Miser, and Robert N. Weingarten under the employment agreements, such that the aggregate annual compensation for all officers increased to \$775,000, effective May 1, 2021.

Effective November 6, 2022, Mr. Forman was promoted to Vice President and Chief Operating Officer, with an annual salary of \$200,000. In addition, Mr. Forman is being provided an office allowance of approximately \$1,500 per month through December 31, 2023.

On September 26, 2023, the Company entered into an employment agreement with Bastiaan van der Baan to act as the Company’s President and Chief Executive Officer and as Vice Chairman of the Board of Directors with an annual salary of \$150,000. The term of the employment agreement is for three years and is automatically renewable for additional one-year periods unless terminated by either party, subject to early termination as described in the employment agreement. Under the employment agreement, Mr. van der Baan’s annual may be increased from time to time at the sole discretion of the Board of Directors. In addition, Mr. van der Baan will be eligible to receive an annual bonus as determined in the sole discretion of the Board of Directors. Mr. Van der Baan was appointed as Chairman of the Board of Directors upon the death of Dr. Kovach on October 5, 2023.

The aggregate annual cash compensation for all officers increased to \$950,000, effective September 26, 2023, which has continued through September 30, 2023. As a result of Dr. Kovach’s death on October 5, 2023, aggregate annual compensation of all officers will decrease to \$700,000 from that date forward.

Other Significant Agreements and Contracts

NDA Consulting Corp. 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, 2023 and 2022, respectively, and \$12,000 and \$12,000 for the nine months ended September 30, 2023 and 2022, which were included in research and development costs in the consolidated statements of operations.

BioPharmaWorks. 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, assisting the Company to commercialize its products and strengthen its patent portfolio; identifying large pharmaceutical companies with a potential interest in the Company's product pipeline; assisting in preparing technical presentations concerning the Company's products; consultation in drug discovery and development; and identifying providers and overseeing tasks relating to clinical development 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 (see Note 7). The Company recorded charges to operations pursuant to this Collaboration Agreement of \$30,000 and \$30,000 for the three months ended September 30, 2023 and 2022, respectively, and \$90,000 and \$90,000 for the nine months ended September 30, 2023 and 2022, respectively, which were included in research and development costs in the consolidated statements of operations.

Netherlands Cancer Institute. On October 8, 2021, the Company entered into a Development Collaboration Agreement with the Netherlands Cancer Institute, Amsterdam ("NKI") (see Note 6), one of the world's leading comprehensive cancer centers, and Oncode Institute, Utrecht, a major independent cancer research center, for a term of three years. The Development Collaboration Agreement was subsequently modified by Amendment No. 1 thereto. The Development Collaboration Agreement is intended 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 agreed to fund the study, at an approximate cost of 391,000 Euros and provide a sufficient supply of LB-100 to conduct the study.

On October 3, 2023, the Company entered into Amendment No. 2 to the Development Collaboration Agreement with NKI, which provides for additional research activities, extends the termination date of the Development Collaboration Agreement by two years to October 8, 2026, and adds 250,000 Euros (approximately \$263,000 at October 3, 2023) to the operating budget being funded by the Company.

During the three months ended September 30, 2023 and 2022, the Company incurred charges in the amount of \$51,568 and \$46,068, respectively, with respect to this agreement, which amounts are included in research and development costs in the Company's consolidated statements of operations. During the nine months ended September 30, 2023 and 2022, the Company incurred charges in the amount of \$156,949 and \$149,184, respectively, with respect to this agreement, which amounts are included in research and development costs in the Company's consolidated statements of operations. As of September 30, 2023, total costs of \$416,356 have been incurred pursuant to this agreement. The Company's aggregate commitment pursuant to this agreement, as amended, less amounts previously paid to date, totaled approximately \$316,000 as of September 30, 2023, which is expected to be incurred through October 8, 2026. As the work 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.

MRI Global. The Company has contracted with MRI Global for stability analysis, storage and distribution of LB-100 for clinical trials in the United States. On June 10, 2022, the contract was amended to reflect a new total contract price of \$273,980 for services to be rendered through April 30, 2023. Effective April 17, 2023, the contract was further amended to reflect a new total contract price of \$326,274 for services to be rendered through April 30, 2024. During the three months ended September 30, 2023 and 2022, the Company incurred costs of \$19,845 and \$5,549, respectively, pursuant to this contract. During the nine months ended September 30, 2023 and 2022, the Company incurred costs of \$27,028 and \$25,902, respectively, pursuant to this work order. As of September 30, 2023, total costs of \$241,841 have been incurred pursuant to this contract.

The Company's aggregate commitment pursuant to this contract, less amounts previously paid to date, totaled approximately \$84,000 as of September 30, 2023.

External Risks

Covid-19 Virus. The global outbreak of the novel coronavirus (Covid-19) in early 2020 led to disruptions in general economic activities throughout the world as businesses and governments implemented broad actions to mitigate this public health crisis. The extent to which the coronavirus pandemic may reappear and impact the Company's clinical trial programs and capital raising efforts in the future is uncertain and cannot be predicted.

Inflation Risk. The Company does not believe that inflation has had a material effect on its operations to date, other than its impact on the general economy. However, there is a risk that the Company's operating costs could become subject to inflationary and interest rate pressures in the future, which would have the effect of increasing the Company's operating costs (including, specifically, clinical trial costs), and which would put additional stress on the Company's working capital resources.

Supply Chain Issues. The Company does not currently expect that supply chain issues will have a significant impact on its business activities, including its ongoing clinical trials.

Potential Recession. There are various indications that the United States economy may be entering a recessionary period. Although unclear at this time, an economic recession would likely impact the general business environment and the capital markets, which could, in turn, affect the Company.

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

10. Subsequent Events

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

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, 2022, 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 research 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 corporate office is located in Pasadena, California.

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. The Company believes that inhibitors of protein phosphatases have broad therapeutic potential not only for cancer but also for other debilitating and life-threatening diseases. The Company is directing its efforts on clinical development of a specific protein phosphatase inhibitor, referred to as LB-100, which has been shown to have clinical anti-cancer activity at doses that produce little or no toxicity.

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, relies on stock-based compensation for a substantial portion of employee and consultant compensation, and is dependent on periodic infusions of equity capital to fund its operating requirements.

Reverse Stock Split

On June 2, 2023, the Company effected a 1-for-10 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 have been retroactively adjusted to reflect the reverse stock split for all periods presented.

Recent Developments

President and Chief Executive Officer

Effective September 26, 2023, Bas van der Baan was appointed as the Company's President and Chief Executive Officer, at which time he replaced Dr. John S. Kovach as the Company's President and Chief Executive Officer. Dr. Kovach passed away on October 5, 2023.

News Release

On September 20, 2023, the Company announced a Phase 1b/2 collaborative clinical trial to assess whether adding LIXTE's LB-100 to GSK's programmed death receptor-1 (PD-1)-blocking monoclonal antibody, dostarlimab, may enhance the effectiveness of immunotherapy in the treatment of ovarian clear cell carcinoma (OCCC). The clinical trial is sponsored by The University of Texas - MD Anderson Cancer Center and will be conducted at MD Anderson, and will also be open at Northwestern University's Robert H. Lurie Comprehensive Cancer Center. LIXTE will provide LB-100 and GSK will provide dostarlimab and financial support for the clinical trial.

The clinical trial is based on the observation of longer survival of patients with OCCC treated with immunotherapy whose cancer cells have an acquired gene mutation resulting in a reduction in PP2A. This finding was reported by the lead clinical investigators of this new clinical trial: Amir Jazaeri MD, Professor of Gynecologic Oncology at MD Anderson, and Emily Hinchcliff, MD, MPH, Assistant Professor of Obstetrics and Gynecology at Northwestern University Feinberg School of Medicine. The observation by Drs. Jazaeri and Hinchcliff is that a genetically acquired reduction in PP2A enhances sensitivity to immunotherapy and raises the possibility that reducing PP2A pharmacologically with LB-100 will enhance the anti-tumor effect of the PD-1 blocking monoclonal antibody dostarlimab in patients with OCCC lacking the genetic reduction in PP2A.

Going Concern

As reflected in the accompanying financial statements, for the nine months ended September 30, 2023, the Company recorded a net loss of \$4,054,774 and used cash in operations of \$3,391,142. At September 30, 2023, the Company had cash of \$5,105,611 available to fund its operations. Because the Company is currently engaged in various early-stage 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 technology, product sales or other commercial activities, there can be no assurance that the Company will be able to achieve and maintain positive earnings and operating cash flows. At September 30, 2023, the Company's remaining contractual commitments pursuant to clinical trial agreements and clinical trial monitoring agreements not yet incurred aggregated approximately \$6,262,000, which are currently scheduled to be incurred through approximately December 31, 2027.

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 through the recurring sale of its equity securities.

Based on the foregoing, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern within one year after the date that the accompanying interim condensed consolidated financial statements are being issued. The Company's interim condensed 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, design and results of the Company's clinical trial program, which, in turn, depends on the availability of operating capital to fund such activities.

Based on current operating plans, the Company estimates that its existing cash resources at September 30, 2023 will provide sufficient working capital to fund the current clinical trial program with respect to the development of the Company's lead anti-cancer clinical compound LB-100 through at least September 30, 2024. However, existing cash resources will not be sufficient to complete the development of and obtain regulatory approval for the Company's product candidate, which will require that the Company raise significant additional capital. The Company estimates that it will need to raise additional capital to fund its operations by mid-2024 to be able to proactively manage its current business plan during the remainder of 2024 and during 2025. In addition, the Company's operating plans may change as a result of many factors that are currently unknown and/or outside of the control of the Company, and additional funds may be needed sooner than planned.

As market conditions present uncertainty as to the Company's ability to secure additional funds, there can be no assurance that the Company will be able to secure additional financing on acceptable terms, as and when necessary, to continue to conduct operations.

If cash resources are insufficient to satisfy the Company's ongoing cash requirements, the Company would be required to scale back or discontinue its 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.

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, 2023 and 2022 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, 2023 and 2022 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 the calculation of accruals for clinical trial costs and other 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.

Cash

Cash is held in a cash bank deposit program maintained by Morgan Stanley Wealth Management, a division of Morgan Stanley Smith Barney LLC ("Morgan Stanley"). Morgan Stanley is a FINRA-regulated broker-dealer. The Company's policy is to maintain its cash balances with financial institutions in the United States 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 periodically has cash balances in financial institutions in excess of the FDIC and SIPC insurance limits of \$250,000 and \$500,000, respectively. Morgan Stanley Wealth Management also maintains supplemental insurance coverage for the cash balances of its customers. The Company has not experienced any losses to date resulting from this policy.

Segment Information

The Company operates and reports in one segment, which focuses on the utilization of biomarker technology to identify enzyme targets associated with serious common diseases and then designing novel compounds to attack those targets. The Company's operating segment is reported in a manner consistent with the internal reporting provided to the Company's Chief Operating Decision Maker, which is the Company's President and Chief Executive Officer.

Research and Development

Research and development costs consist primarily of fees paid to consultants and contractors, and other expenses relating to the negotiation, design, development and management of clinical trials with respect to the Company's clinical compound and product candidate. Research and development costs also include the costs to manufacture the compounds used in research and clinical trials, which are charged to operations as incurred. The Company's inventory of LB-100 for clinical use has been manufactured separately in the United States and in the European Union in accordance with the laws and regulations of such jurisdictions.

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 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 respective agreement. Obligations incurred with respect to mandatory scheduled payments under agreements without milestone provisions are accounted for when due, are recognized ratably over the appropriate period, as specified in the respective 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 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 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 various clinical trial and research and development contracts on a quarterly basis.

Patent and Licensing Legal and Filing Fees and Costs

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

During the three months ended September 30, 2023 and 2022, patent and licensing legal and filing fees and costs related to the development and protection of its intellectual property were \$178,012 and \$271,163, respectively, a decrease of \$93,151, or 34.4% in 2023, as compared to 2022. During the nine months ended September 30, 2023 and 2022, patent and licensing legal and filing fees and costs related to the development and protection of its intellectual property were \$835,362 and \$944,789, respectively, a decrease of \$109,427, or 11.6% in 2023, as compared to 2022.

In late 2021, the Company engaged a new patent law firm that is highly regarded for its expertise in biotechnology. This firm conducted a comprehensive analysis of the Company's extensive patent portfolio in order to implement a program to maximize intellectual property protection, both domestically and internationally. As a result, several patents were filed in 2022, reflecting potential new uses of the Company's lead clinical compound LB-100 in cancer therapy. The Company expects that patent and licensing legal and filing fees and costs will remain relatively stable for the remainder of 2023 as compared to 2022, as the Company continues to focus on efforts to expand clinical programs to analyze various potential uses for LB-100 and to develop and expand its patent portfolio related to the clinical development of LB-100.

A descriptive summary of the patent portfolio for the Company's most important clinical programs involving the development of LB-100, as well as a detailed listing of each domestic and international patent that has been issued, is presented at "ITEM 1. BUSINESS – Intellectual Property" in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

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.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in Accounting Standards Codification ("ASC") 480, Distinguishing Liabilities from Equity ("ASC 480"), and ASC 815, Derivatives and Hedging ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted when the warrants are issued and at the end each subsequent quarterly period while the warrants are outstanding. For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be liability classified and recorded at their initial fair value on the date of issuance and remeasured at fair value at each balance sheet date thereafter. Changes in the estimated fair value of the warrants are recognized as a non-cash gain or loss on the statements of operations. The Company has determined that the warrants issued in the July 20, 2023 equity financing meet the requirements for equity classification.

Summary of Business Activities and Plans

Company Overview

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

Product Candidates

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

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

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

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

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

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

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

External Risks

Covid-19 Virus. The global outbreak of the novel coronavirus (Covid-19) in early 2020 led to disruptions in general economic activities throughout the world as businesses and governments implemented broad actions to mitigate this public health crisis. The extent to which the coronavirus pandemic may reappear and impact the Company's clinical trial programs and capital raising efforts in the future is uncertain and cannot be predicted.

Inflation Risk. The Company does not believe that inflation has had a material effect on its operations to date, other than its impact on the general economy. However, there is a risk that the Company's operating costs could become subject to inflationary and interest rate pressures in the future, which would have the effect of increasing the Company's operating costs (including, specifically, clinical trial costs), and which would put additional stress on the Company's working capital resources.

Supply Chain Issues. The Company does not currently expect that supply chain issues will have a significant impact on its business activities, including its ongoing clinical trials.

Potential Recession. There are various indications that the United States economy may be entering a recessionary period. Although unclear at this time, an economic recession would likely impact the general business environment and the capital markets, which could, in turn, affect the Company.

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

Results of Operations

At September 30, 2023, the Company had not yet commenced any revenue-generating operations, does not have any positive cash flows from operations, and is dependent on its ability to raise equity capital to fund its operating requirements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues	\$ —	\$ —	\$ —	\$ —
Costs and expenses:				
General and administrative costs:				
Compensation to related parties	356,001	643,957	1,398,042	1,963,409
Patent and licensing legal and filing fees and costs	178,012	271,163	835,362	944,789
Other costs and expenses	357,681	290,993	1,081,893	875,016
Research and development costs	132,487	272,388	749,029	895,649
Total costs and expenses	1,024,181	1,478,501	4,064,326	4,678,863
Loss from operations	(1,024,181)	(1,478,501)	(4,064,326)	(4,678,863)
Interest income	5,809	3,911	13,538	4,211
Interest expense	(279)	(2,119)	(6,088)	(5,240)
Foreign currency gain (loss)	(109)	(1,300)	2,102	(1,339)
Net loss	\$ (1,018,760)	\$ (1,478,009)	\$ (4,054,774)	\$ (4,681,231)
Net loss per common share – basic and diluted	\$ (0.49)	\$ (0.89)	\$ (2.25)	\$ (3.01)
Weighted average common shares outstanding – basic and diluted	2,074,938	1,664,659	1,803,466	1,554,183

Three Months Ended September 30, 2023 and 2022

Revenues. The Company did not have any revenues for the three months ended September 30, 2023 and 2022.

General and Administrative Costs. For the three months ended September 30, 2023, general and administrative costs were \$891,694, which consisted of the fair value of vested stock options issued to directors and officers of \$112,106, patent and licensing legal and filing fees and costs of \$178,012, other consulting and professional fees of \$199,884, insurance expense of \$107,910, officer salaries and related costs of \$216,880, cash-based director and board committee fees of \$42,228, shareholder reporting costs of \$3,887, listing fees of \$15,500, filing fees of \$4,439, taxes and licenses of \$3,946, investor relations of \$14,172, rent of \$7,323 and other operating costs of \$6,914, offset by a credit to licensing fees of \$21,507 relating to the termination of the Moffitt agreement.

For the three months ended September 30, 2022, general and administrative costs were \$1,206,113, which consisted of the fair value of vested stock options issued to directors and officers of \$396,883, patent and licensing legal and filing fees and costs of \$271,163, other consulting and professional fees of \$108,630, insurance expense of \$114,983, officer salaries and related costs of \$207,091, cash-based director and board committee fees of \$53,324, licensing fees of \$6,301, shareholder reporting costs of \$20,487, listing fees of \$14,875, filing fees of \$3,048, taxes and licenses of \$4,094, investor relations of \$2,397, and other operating costs of \$2,837.

General and administrative costs decreased by \$314,419, or 26.1%, in 2023 as compared to 2022, primarily as a result of a decrease in the fair value of vested stock options issued to directors and officers of \$284,777, a decrease in patent and licensing legal and filing fees and costs of \$93,151, a decrease in licensing fees of \$27,808 a decrease in shareholder reporting of \$16,600, offset by increases in investor relations of \$11,775 and an increase in consulting and professional fees of \$91,254.

Research and Development Costs. For the three months ended September 30, 2023, research and development costs were \$132,487, which consisted of clinical and related oversight costs of \$8,816, regulatory service costs of \$10,919, and pre-clinical research focused on development of additional novel anti-cancer compounds to add to the Company's clinical pipeline of \$124,752, offset by a credit of \$12,000 relating to the termination of the Moffitt agreement.

For the three months ended September 30, 2022, research and development costs were \$272,388, which consisted of contractor costs incurred in connection with the synthesis work done to develop a new supply of LB-100 for the Spanish clinical trial of \$1,246, clinical and related oversight costs of \$28,902, regulatory service costs of \$5,330, and pre-clinical research focused on development of additional novel anti-cancer compounds to add to the Company's clinical pipeline of \$236,910.

Included in pre-clinical research costs for the three months ended September 30, 2023 and 2022 were \$51,568 and \$46,068, respectively, of costs paid to the Netherlands Cancer Institute, which employs Dr. René Bernards, a director of the Company since June 15, 2022. On October 8, 2021, the Company entered into a Development Collaboration Agreement with the Netherlands Cancer Institute, Amsterdam, one of the world's leading comprehensive cancer centers, and Onco Institute, Utrecht, a major independent cancer research center, as amended by Amendment No. 1. The Development Collaboration Agreement is intended 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.

On October 3, 2023, the Company entered into Amendment No. 2 to the Development Collaboration Agreement with the Netherlands Cancer Institute, which provides for additional research activities, extends the termination date of the Development Collaboration Agreement by two years to October 8, 2026, and adds 250,000 Euros (approximately \$263,000 at October 3, 2023) to the operating budget being funded by the Company (see "Principal Commitments – Other Significant Agreements and Contracts – Netherlands Cancer Institute" below).

Research and development costs decreased by \$139,901, or 51.4%, in 2023 as compared to 2022, primarily as a result of a decrease in pre-clinical research focused on development of additional novel anti-cancer compounds to add to the Company's clinical pipeline of \$112,158 and a credit of \$12,000 relating to the termination of the Moffitt agreement.

Interest Income. For the three months ended September 30, 2023, the Company had interest income of \$5,809, as compared to interest income of \$3,911 for the three months ended September 30, 2022, related to the investment of funds generated by the Company's financing activities.

Interest Expense. For the three months ended September 30, 2023, the Company had interest expense of \$279, as compared to interest expense of \$2,119 for the three months ended September 30, 2022, related to the financing of the premium for the Company's directors and officers liability insurance policy.

Foreign Currency Loss. For the three months ended September 30, 2023, the Company had a foreign currency loss of \$109, as compared to a foreign currency loss of \$1,300 for the three months ended September 30, 2022, from foreign currency transactions.

Net Loss. For the three months ended September 30, 2023, the Company incurred a net loss of \$1,018,760, as compared to a net loss of \$1,478,009 for the three months ended September 30, 2022.

Nine Months Ended September 30, 2023 and 2022

Revenues. The Company did not have any revenues for the nine months ended September 30, 2023 and 2022.

General and Administrative Costs. For the nine months ended September 30, 2023, general and administrative costs were \$3,315,297, which consisted of the fair value of vested stock options issued to directors and officers of \$669,146, patent and licensing legal and filing fees and costs of \$835,362, other consulting and professional fees of \$529,830, insurance expense of \$316,214, officer salaries and related costs of \$649,483, cash-based director and board committee fees of \$127,229, shareholder reporting costs of \$64,783, listing fees of \$46,500, filing fees of \$14,634, taxes and licenses of \$11,483, investor relations of \$36,516, rent of \$11,436 and other operating costs of \$11,790, offset by a credit to licensing fees of \$9,109 relating to the termination of the Moffitt agreement.

For the nine months ended September 30, 2022, general and administrative costs were \$3,783,214, which consisted of the fair value of vested stock options issued to directors and officers of \$1,160,649, patent and licensing legal and filing fees and costs of \$944,789, other consulting and professional fees of \$344,085, insurance expense of \$349,254, officer salaries and related costs of \$627,579, cash-based director and board committee fees of \$221,510, licensing fees of \$18,699, shareholder reporting costs of \$26,811, listing fees of \$44,625, filing fees of \$11,460, taxes and licenses of \$12,231, investor relations of \$7,246, and other operating costs of \$14,276.

General and administrative costs decreased by \$467,917, or 12.4%, in 2023 as compared to 2022, primarily as a result of a decrease in the fair value of vested stock options issued to directors and officers of \$491,503, a decrease in patent and licensing legal and filing fees and costs of \$109,427, a decrease in licensing fees of \$27,808 a decrease in cash-based director and board committee fees of \$94,281, offset by an increase in shareholder reporting of \$37,972, an increase in investor relations of \$29,270, an increase in rent of \$11,436 and an increase in consulting and professional fees of \$185,745.

Research and Development Costs. For the nine months ended September 30, 2023, research and development costs were \$749,029, which consisted of clinical and related oversight costs of \$390,708, regulatory service costs of \$18,738, and pre-clinical research focused on development of additional novel anti-cancer compounds to add to the Company's clinical pipeline of \$339,583.

For the nine months ended September 30, 2022, research and development costs were \$895,649, which consisted of contractor costs incurred in connection with the synthesis work done to develop a new supply of LB-100 for the Spanish clinical trial of \$352,734, clinical and related oversight costs of \$61,880, regulatory service costs of \$5,690, and pre-clinical research focused on development of additional novel anti-cancer compounds to add to the Company's clinical pipeline of \$475,345.

Included in pre-clinical research costs for the nine months ended September 30, 2023 and 2022 were \$156,950 and \$149,184, respectively, of costs paid to the Netherlands Cancer Institute, which employs Dr. René Bernards, a director of the Company since June 15, 2022. On October 8, 2021, the Company entered into a Development Collaboration Agreement with the Netherlands Cancer Institute, Amsterdam, 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.

On October 3, 2023, the Company entered into Amendment No. 2 to the Development Collaboration Agreement with the Netherlands Cancer Institute, which provides for additional research activities, extends the termination date of the Development Collaboration Agreement by two years to October 8, 2026, and adds 250,000 Euros (approximately \$263,000 at October 3, 2023) to the operating budget being funded by the Company (see "Principal Commitments – Other Significant Agreements and Contracts – Netherlands Cancer Institute" below).

Research and development costs decreased by \$146,620, or 16.4%, in 2023 as compared to 2022, primarily as a result of a decrease in contractor costs incurred in connection with the synthesis work done to develop a new supply of LB-100 for the Spanish clinical trial of \$352,734 and a decrease in pre-clinical research focused on development of additional novel anti-cancer compounds to add to the Company's clinical pipeline of \$135,762, offset by an increase in clinical and related oversight costs of \$328,828.

Interest Income. For the nine months ended September 30, 2023, the Company had interest income of \$13,538, as compared to interest income of \$4,211 for the nine months ended September 30, 2022, related to the investment of funds generated by the Company's financing activities.

Interest Expense. For the nine months ended September 30, 2023, the Company had interest expense of \$6,088, as compared to interest expense of \$5,240 for the nine months ended September 30, 2022, related to the financing of the premium for the Company's directors and officers liability insurance policy.

Foreign Currency Gain (Loss). For the nine months ended September 30, 2023, the Company had a foreign currency gain of \$2,102, as compared to a foreign currency loss of \$1,339 for the nine months ended September 30, 2022, from foreign currency transactions.

Net Loss. For the nine months ended September 30, 2023, the Company incurred a net loss of \$4,054,774, as compared to a net loss of \$4,681,231 for the nine months ended September 30, 2022.

Liquidity and Capital Resources – September 30, 2023

The Company's consolidated statements of cash flows as discussed herein are as follows:

	Nine Months Ended September 30,	
	2023	2022
Net cash used in operating activities	\$ (3,391,142)	\$ (3,403,289)
Net cash provided by (used in) investing activities	—	—
Net cash provided by financing activities	3,143,361	5,141,384
Net increase (decrease) in cash	\$ (247,781)	\$ 1,738,095

At September 30, 2023, the Company had working capital of \$4,922,960, as compared to working capital of \$5,165,227 at December 31, 2022, reflecting a decrease in working capital of \$242,267 for the nine months ended September 30, 2023. The decrease in working capital during the nine months ended September 30, 2023 was primarily the result of the funding of the Company's ongoing research and development activities and other ongoing operating expenses, including maintaining and developing its patent portfolio, offset by proceeds from the sale of securities on July 20, 2023. At September 30, 2023, the Company had cash of \$5,105,611 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, design and results of the Company's clinical trial program, which, in turn, depends on the availability of operating capital to fund such activities.

Based on current operating plans, the Company estimates that its existing cash resources at September 30, 2023 will provide sufficient working capital to fund the current clinical trial program with respect to the development of the Company's lead anti-cancer clinical compound LB-100 through at least September 30, 2024. However, existing cash resources will not be sufficient to complete the development of and obtain regulatory approval for the Company's product candidate, which will require that the Company raise significant additional capital. The Company estimates that it will need to raise additional capital to fund its operations by mid-2024 to be able to proactively manage its current business plan during the remainder of 2024 and during 2025. In addition, the Company's operating plans may change as a result of many factors that are currently unknown and/or outside of the control of the Company, and additional funds may be needed sooner than planned.

At September 30, 2023, the Company's remaining contractual commitments pursuant to clinical trial agreements and clinical trial monitoring agreements not yet incurred aggregated \$6,262,000, which are currently scheduled to be incurred through approximately December 31, 2027.

At September 30, 2023, the Company did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

Operating Activities. For the nine months ended September 30, 2023, operating activities utilized cash of \$3,391,142, as compared to utilizing cash of \$3,403,289 for the nine months ended September 30, 2022, 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, 2023 and 2022, the Company had no investing activities.

Financing Activities. For the nine months ended September 30, 2023, financing activities consisted primarily of the gross proceeds from the sale of securities in the Company's registered direct offering of \$3,499,964, reduced by offering costs of \$362,925, and \$6,281 from the exercise of common stock options. For the nine months September 30, 2022, financing activities consisted of the gross proceeds from the sale of securities in the Company's registered direct offering of \$5,800,000, reduced by offering costs of \$658,616.

Principal Commitments

Clinical Trial Agreements

At September 30, 2023, the Company's remaining contractual commitments pursuant to clinical trial agreements and clinical trial monitoring agreements not yet incurred, as described below, aggregated \$6,262,000, which, based on current estimates, are currently scheduled to be incurred through approximately December 31, 2027. The Company's ability to conduct and fund these contractual commitments is subject to the timely availability of sufficient capital to fund such expenditures, as well as any changes in the allocation or reallocation of such funds to the Company's current or future clinical trial programs. The Company expects that the full amount of these expenditures will be incurred only if such clinical trial programs are conducted as originally designed and their respective enrollments and duration are not modified or reduced. Clinical trial programs, such as the types that the Company is engaged in, can be highly variable and can frequently involve a series of changes and modifications over time as clinical data are obtained and analyzed, and are frequently modified, suspended or terminated before the clinical trial endpoint is reached. Accordingly, such contractual commitments as discussed herein should be considered as estimates only based on current clinical assumptions and conditions, and are typically subject to significant modifications and revisions over time.

The following is a summary of the contractual clinical trials discussed below as of September 30, 2023:

<u>Description of Clinical Trial</u>	<u>Type of Clinical Trial</u>	<u>Institution</u>	<u>Estimated Start Date</u>	<u>Estimated End Date</u>	<u>Number of Patients in Trial</u>	<u>Study Objective</u>	<u>Clinical Update</u>	<u>NCT No.</u>
LB-100 combined with carboplatin, etoposide and atezolizumab in small cell lung cancer	Phase 1b	City of Hope and Sarah Cannon	March 2021	March 2026	14 to 36	Determine RP2D	Three patients entered	NCT04560972
LB-100 combined with doxorubicin in sarcoma	Phase 1b	GEIS	June 2023	June 2024	9 to 18	Determine MTD and RP2D	One patient entered	NCT05809830
Doxorubicin with or without LB-100 in sarcoma	Randomized Phase 2	GEIS	July 2024	June 2026	150	Determine efficacy: PFS	Clinical trial not yet begun (subject to completion of Phase 1b GEIS clinical trial)	NCT05809830
LB-100 combined with dostarlimab in ovarian clear cell carcinoma	Phase 1b/2	MD Anderson	March 2024	December 2025	21	Determine the survival of patients with ovarian clear cell carcinoma	No patients entered at September 30, 2023	NCT06065462

Moffitt. Effective August 20, 2018, the Company entered into a five-year Clinical Trial Research Agreement with the Moffitt Cancer Center and Research Institute Hospital Inc., Tampa, Florida ("Moffitt"). Pursuant to the Clinical Trial Research Agreement, Moffitt agreed to conduct and manage a Phase 1b/2 clinical trial to evaluate the toxicity and 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 to conduct a Phase 1b/2 clinical trial to evaluate the toxicity and 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 utilized 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.

During the three months ended June 30, 2023, the Phase 1b/2 clinical trial at Moffitt evaluating LB-100 in patients with MDS was closed by the principal investigator. In this clinical trial, single agent LB-100 was used on a new schedule of days 1, 3, and 5 every 3 weeks. The Company is not employing this schedule in its other clinical trials. Although the Maximally Tolerated Dose (“MTD”) was not achieved, there was no dose-limiting toxicity on this schedule at doses that were greater than the MTD in the Phase 1 clinical trial of LB-100 on the Monday, Tuesday, Wednesday schedule.

During the three months ended September 30, 2023 and 2022, the Company incurred costs of \$0 and \$9,218, respectively, pursuant to this agreement, which have been included in research and development costs in the Company’s consolidated statements of operations. During the nine months ended September 30, 2023 and 2022, the Company incurred costs of \$0 and \$18,623, respectively, pursuant to this agreement, which have been included in research and development costs in the Company’s consolidated statements of operations. As of September 30, 2023, total costs of \$131,074 have been incurred pursuant to this agreement.

The Company has decided not to pursue further studies in MDS, as other opportunities have become available (see “Patent and License Agreements - Moffitt” below).

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

GEIS has a network of referral centers in Spain and across Europe that have an impressive track record of efficiently conducting innovative studies in ASTS. The Company agreed to provide GEIS with a supply of LB-100 to be utilized in the conduct of this clinical trial, as well as to provide funding for the clinical trial. The goal is to enter approximately 150 to 170 patients in this clinical trial over a period of two years. As advanced sarcoma is a very aggressive disease, the design of the study assumes a median progression free survival (“PFS”, no evidence of disease progression or death from any cause) of 4.5 months in the doxorubicin arm and an alternative median PFS of 7.5 months in the doxorubicin plus LB-100 arm to demonstrate a statistically significant decrease in relative risk of progression or death by adding LB-100. There is a planned interim analysis of the primary endpoint when approximately 50% of the 102 events required for final analysis is reached.

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

In order to manufacture a new inventory supply of LB-100 for the GEIS clinical trial, the Company 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 included 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 was then transferred to a vendor that prepares the clinical drug product, also under GMP conditions documented by an independent auditor. The clinical drug product was then sent to a vendor to test for purity and sterility, provide appropriate labels, store the drug, and distribute the drug to the clinical centers for use in the clinical trials. A formal application documenting all steps taken to prepare the clinical drug product for clinical use was submitted to the appropriate regulatory authorities for review and approval before being used in a clinical trial.

As of September 30, 2023, this program to provide new inventory of the clinical drug product for the Spanish Sarcoma Group study, and potentially for subsequent multiple trials within the European Union, had cost approximately \$1,144,000. Although the production of new inventory has been completed, nominal trailing costs subsequent to September 30, 2023 may be incurred.

On October 13, 2022, the Company announced that the Spanish Agency for Medicines and Health Products (Agencia Española de Medicamentos y Productos Sanitarios or “AEMPS”) had authorized a Phase 1b/randomized Phase 2 study of LB-100, the Company’s lead clinical compound, plus doxorubicin, versus doxorubicin alone, the global standard for initial treatment of advanced soft tissue sarcomas (ASTS). Consequently, this clinical trial commenced during the quarter ended June 30, 2023 and is expected to be completed and a report prepared by December 31, 2026. In April 2023, GEIS completed its first site initiation visit in preparation for the clinical trial at Fundación Jiménez Díaz University Hospital (Madrid). Up to 170 patients will be entered into the clinical trial. The Phase 1b section of the protocol is expected to be completed by June 30, 2024, at which time the Company expects to have data on both response and toxicity from this portion of the clinical trial, and subject to clinical results, anticipates that it will be able to proceed to a related Phase 2 study.

The interim analysis of this clinical trial will be done before full accrual of patients is completed to determine whether the study has the possibility of showing superiority of the combination of LB-100 plus doxorubicin 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. During the three months ended September 30, 2023 and 2022, the Company did not incur any costs pursuant to this agreement. During the nine months ended September 30, 2023 and 2022, the Company incurred costs of \$268,829 and \$0, respectively, pursuant to this agreement. Such costs, when incurred, are included in research and development costs in the Company’s consolidated statements of operations. Through September 30, 2023, the Company has paid GEIS an aggregate of \$684,652 for work done under this agreement through the fourth milestone.

The Company’s aggregate commitment pursuant to this agreement, less amounts previously paid to date, totaled approximately \$3,423,000 as of September 30, 2023, which is expected to be incurred through December 31, 2027. As the work 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. Such fluctuations are recorded in the consolidated statements of operations as foreign currency gain or loss, as appropriate.

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 an FDA-approved standard regimen for treatment of untreated extensive-stage disease small cell lung cancer (“ED-SCLC”). LB-100 will be given in combination with carboplatin, etoposide and atezolizumab, an FDA-approved but marginally effective regimen, to previously untreated ED-SCLC patients. The dose of LB-100 will be escalated with the standard fixed doses of the 3-drug regimen to reach a recommended Phase 2 dose (“RP2D”). Patient entry will be expanded so that a total of 12 patients will be evaluable at the RP2D to confirm the safety of the LB-100 combination and to look for potential therapeutic activity as assessed by objective response rate, duration of overall response, progression-free-survival and overall survival.

The clinical trial was initiated on March 9, 2021, with patient accrual expected to take approximately two years to complete. However, as patient accrual was slower than expected, the Company has been seeking to add additional sites to increase the rate of patient accrual. Effective March 6, 2023, the Sarah Cannon Research Institute (“SCRI”), Nashville, Tennessee, joined the City of Hope’s ongoing Phase 1b clinical trial. The Company is continuing its efforts to add additional sites. The addition of SCRI is expected to expedite and expand the accrual of patients to this clinical trial, thus reducing the time required to demonstrate the feasibility, tolerability and efficacy of adding LB-100 to the current standard treatment regimen. With the addition of SCRI, the Company currently expects that this clinical trial will be completed by March 31, 2026.

In early July 2023, the Company was notified that one of three centers accruing patients to its Phase 1b clinical trial in small cell lung cancer had a shortage of carboplatin and as a result the clinical trial was placed on a temporary enrollment hold. This matter was resolved and the temporary enrollment hold was lifted in late July 2023.

During the three months ended September 30, 2023 and 2022, the Company did not incur any costs pursuant to this agreement. During the nine months ended September 30, 2023 and 2022, the Company incurred costs of \$69,001 and \$0, respectively, pursuant to this agreement, which are included in research and development costs in the Company's consolidated statements of operations. As of September 30, 2023, total costs of \$447,512 have been incurred pursuant to this agreement.

The Company's aggregate commitment pursuant to this agreement, less amounts previously paid to date, totaled approximately \$2,433,000 as of September 30, 2023, which is expected to be incurred through March 31, 2026. If a significant number of patients fail during the dose-escalation process, an increase of up to 12 patients would likely be necessary, at an estimated additional cost of approximately \$800,000.

The Company currently expects that enrollment in this clinical trial will range from approximately 18 to 30 enrollees, with 24 enrollees as the most likely number. Should fewer than 42 enrollees be required, the Company has agreed to compensate City of Hope on a per enrollee basis. If a significant improvement in outcome is seen with the addition of LB-100, this would be an important advance in the treatment of a very aggressive disease.

Theradex. On June 22, 2023, the Company finalized a work order agreement with Theradex Systems, Inc. ("Theradex"), an international contract research organization ("CRO"), to conduct a Phase I/II randomized trial of LB-100 plus doxorubicin vs. doxorubicin alone in first line of advanced soft tissue sarcomas. The study is expected to be completed by June 30, 2026.

Costs under this work order agreement are estimated to be approximately \$153,000, with such payments expected to be allocated approximately 72% to Theradex for services and approximately 28% for payments for pass-through software costs. During the three months and nine months ended September 30, 2023, the Company incurred costs of \$3,750 and 10,000, respectively, pursuant to this work order. As of September 30, 2023, total costs of \$10,000 have been incurred pursuant to this work order agreement.

The Company's aggregate commitment pursuant to this clinical trial monitoring agreement, less amounts previously paid to date, totaled approximately \$144,000 as of September 30, 2023, which is expected to be incurred through June 30, 2026.

National Cancer Institute Pharmacologic Clinical Trial. In May 2019, the National Cancer Institute ("NCI") initiated a glioblastoma ("GBM") pharmacologic clinical trial. This study was being conducted and funded by the NCI under a Cooperative Research and Development Agreement, with the Company responsible for 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 has not been determined. Many drugs potentially useful for GBM treatment do not enter the brain in amounts necessary for anti-cancer action.

The NCI study was designed to determine the extent to which LB-100 enters recurrent malignant gliomas. Patients having surgery to remove one or more tumors received one dose of LB-100 prior to surgery and had blood and tumor tissue analyzed to determine the amount of LB-100 present and to determine whether the cells in the tumors showed the biochemical changes expected to be present if LB-100 reached its molecular target. As a result of the innovative design of the NCI study, it was believed that data from a few patients would 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. Five patients were entered into this study and analysis of the blood and tissue has been conducted. If there is clinical evidence in at least two of the patients of penetration of LB 100 into tumor tissue, the study will be deemed as successful. Results of this study are currently being reviewed by the NCI and a report is pending.

MD Anderson Cancer Center Trial. On September 20, 2023, the Company announced a Phase 1b/2 collaborative clinical trial to assess whether adding LB-100 to the programmed death receptor-1 (“PD-1”)–blocking monoclonal antibody of GSK plc (“GSK”), dostarlimab, may enhance the effectiveness of immunotherapy in the treatment of ovarian clear cell carcinoma (“OCCC”). The clinical trial is sponsored by The University of Texas MD Anderson Cancer Center (“MD Anderson”) and will be conducted at MD Anderson, and will also be open at Northwestern University’s Robert H. Lurie Comprehensive Cancer Center. The Company will provide LB-100 and GSK will provide dostarlimab and financial support for the clinical trial.

Clinical Trial Monitoring Agreements

Moffitt. On September 12, 2018, the Company finalized a work order agreement with Theradex (“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.

The costs of the Phase 1b/2 clinical trial being paid to or through Theradex have been recorded and charged to operations based on periodic documentation provided by the CRO. During the three months ended September 30, 2023 and 2022, the Company incurred costs of \$566 and \$11,953, respectively, pursuant to this work order. During the nine months ended September 30, 2023 and 2022, the Company incurred costs of \$20,850 and \$19,792, respectively, pursuant to this work order. As of September 30, 2023, total costs of \$148,138 have been incurred pursuant to this work order agreement.

As a result of the closure of the Company’s Clinical Trial Research Agreement with Moffitt during the three months ended June 30, 2023 (see “Clinical Trial Agreements – Moffitt” above), this work order agreement with Theradex to monitor the Clinical Trial Research Agreement with Moffitt was similarly suspended, although nominal oversight trailing costs subsequent to September 30, 2023 are expected to be incurred relating to the closure of the Moffitt study.

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. Costs under this work order agreement are estimated to be approximately \$335,000. During the three months ended September 30, 2023 and 2022, the Company incurred costs of \$4,500 and \$7,731, respectively, pursuant to this work order. During the nine months ended September 30, 2023 and 2022, the Company incurred costs of \$15,740 and \$23,466, respectively, pursuant to this work order. As of September 30, 2023, total costs of \$74,181 have been incurred pursuant to this work order agreement.

The Company’s aggregate commitment pursuant to this clinical trial monitoring agreement, less amounts previously paid to date, totaled approximately \$262,000 as of September 30, 2023, which is expected to be incurred through March 31, 2026.

Patent and License Agreements

Moffitt. 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 was 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 was 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 had also agreed to pay non-refundable milestone payments to Moffitt, which could not 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.

On October 4, 2023, the Company received a counter-signed termination letter dated September 29, 2023 with respect to the Exclusive License Agreement dated August 20, 2018 between the Company and Moffitt, effective September 30, 2023. The Company and Moffitt agreed that no termination fee shall be due or payable by the Company, and Moffitt acknowledged that no payments are owed by the Company under the Agreement.

During the three months and nine months ended September 30, 2023, the Company recorded credits to operations of \$21,507 and \$9,109, respectively, representing the reversal of obligations previously recorded with respect to the Exclusive License Agreement. During the three months and nine months ended September 30, 2022, the Company recorded charges to operations of \$6,301 and \$18,699, respectively, in connection with its obligations under the Exclusive License Agreement.

Employment Agreements with Officers

During July and August 2020, the Company entered into one-year employment agreements with each of its executive officers at that time, consisting of Dr. John S. Kovach, Eric J. Forman, Dr. James S. Miser, and Robert N. Weingarten, which provided for aggregate annual cash compensation of \$640,000, payable monthly. These employment agreements were 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 additional one-year periods in July and August 2021, 2022 and 2023.

On April 9, 2021, the Board of Directors increased the annual cash compensation of Eric J. Forman, Dr. James S. Miser, and Robert N. Weingarten under the employment agreements, such that the aggregate annual compensation for all officers increased to \$775,000, effective May 1, 2021.

Effective November 6, 2022, Mr. Forman was promoted to Vice President and Chief Operating Officer, with an annual salary of \$200,000. In addition, Mr. Forman is being provided an office allowance of approximately \$1,500 per month through December 31, 2023.

On September 26, 2023, the Company entered into an employment agreement with Bastiaan van der Baan to act as the Company's President and Chief Executive Officer and as Vice Chairman of the Board of Directors with an annual salary of \$150,000. The term of the employment agreement is for three years and is automatically renewable for additional one-year periods unless terminated by either party, subject to early termination as described in the employment agreement. Under the employment agreement, Mr. van der Baan's annual may be increased from time to time at the sole discretion of the Board of Directors. In addition, Mr. van der Baan will be eligible to receive an annual bonus as determined in the sole discretion of the Board of Directors. Mr. Van der Baan was appointed as Chairman of the Board of Directors upon the death of Dr. Kovach on October 5, 2023.

The aggregate annual cash compensation for all officers increased to \$950,000, effective September 26, 2023, which has continued through September 30, 2023. As a result of Dr. Kovach's death on October 5, 2023, aggregate annual compensation of all officers will decrease to \$700,000 from that date forward.

Other Significant Agreements and Contracts

NDA Consulting Corp. 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, 2023 and 2022, respectively, and \$12,000 and \$12,000 for the nine months ended September 30, 2023 and 2022, which were included in research and development costs in the consolidated statements of operations.

BioPharmaWorks. 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, assisting the Company to commercialize its products and strengthen its patent portfolio; identifying large pharmaceutical companies with a potential interest in the Company's product pipeline; assisting in preparing technical presentations concerning the Company's products; consultation in drug discovery and development; and identifying providers and overseeing tasks relating to clinical development of new compounds.

BioPharmaWorks was founded in 2015 by former Pfizer scientists with extensive multi-disciplinary research and development and drug development experience. The Collaboration Agreement was for an initial term of two years and automatically renews for subsequent annual periods unless terminated by a party not less than 60 days prior to the expiration of the applicable period. In connection with the Collaboration Agreement, the Company agreed to pay BioPharmaWorks a monthly fee of \$10,000, subject to the right of the Company to pay a negotiated hourly rate in lieu of the monthly payment and agreed to issue to BioPharmaWorks certain equity-based compensation. The Company recorded charges to operations pursuant to this Collaboration Agreement of \$30,000 and \$30,000 for the three months ended September 30, 2023 and 2022, respectively, and \$90,000 and \$90,000 for the nine months ended September 30, 2023 and 2022, respectively, which were included in research and development costs in the consolidated statements of operations.

Netherlands Cancer Institute. 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 Onco Institute, Utrecht, a major independent cancer research center, for a term of three years. The Development Collaboration Agreement was subsequently modified by Amendment No. 1 thereto. The Development Collaboration Agreement is intended 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 agreed to fund the study, at an approximate cost of 391,000 Euros and provide a sufficient supply of LB-100 to conduct the study.

On October 3, 2023, the Company entered into Amendment No. 2 to the Development Collaboration Agreement with NKI, which provides for additional research activities, extends the termination date of the Development Collaboration Agreement by two years to October 8, 2026, and adds 250,000 Euros (approximately \$263,000 at October 3, 2023) to the operating budget being funded by the Company.

During the three months ended September 30, 2023 and 2022, the Company incurred charges in the amount of \$51,568 and \$46,068, respectively, with respect to this agreement, which amounts are included in research and development costs in the Company’s consolidated statements of operations. During the nine months ended September 30, 2023 and 2022, the Company incurred charges in the amount of \$156,949 and \$149,184, respectively, with respect to this agreement, which amounts are included in research and development costs in the Company’s consolidated statements of operations. As of September 30, 2023, total costs of \$416,356 have been incurred pursuant to this agreement. The Company’s aggregate commitment pursuant to this agreement, as amended, less amounts previously paid to date, totaled approximately \$316,000 as of September 30, 2023, which is expected to be incurred through October 8, 2026. As the work 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.

MRI Global. The Company has contracted with MRI Global for stability analysis, storage and distribution of LB-100 for clinical trials in the United States. On June 10, 2022, the contract was amended to reflect a new total contract price of \$273,980 for services to be rendered through April 30, 2023. Effective April 17, 2023, the contract was further amended to reflect a new total contract price of \$326,274 for services to be rendered through April 30, 2024. During the three months ended September 30, 2023 and 2022, the Company incurred costs of \$19,845 and \$5,549, respectively, pursuant to this contract. During the nine months ended September 30, 2023 and 2022, the Company incurred costs of \$27,028 and \$25,902, respectively, pursuant to this work order. As of September 30, 2023, total costs of \$241,841 have been incurred pursuant to this contract.

The Company’s aggregate commitment pursuant to this contract, less amounts previously paid to date, totaled approximately \$84,000 as of September 30, 2023.

Trends, Events and Uncertainties

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

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

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

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

In accordance with Exchange Act Rules 13a-15 and 15d-15, an evaluation was completed under the supervision and with the participation of the Company's management, including its Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of September 30, 2023, the end of the most recent fiscal period covered by this report. Based on that evaluation, the Company's management has concluded that the Company's disclosure controls and procedures were effective in providing reasonable assurance that information required to be disclosed in the Company's reports filed or submitted under the Exchange Act was recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission.

Limitations on Effectiveness of Disclosure Controls and Procedures

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

Changes in Internal Control Over Financial Reporting

The Company's management, including its Chief Executive Officer and Chief Financial Officer, has determined that no change in the Company's internal control over financial reporting (as that term is defined in Rules 13(a)-15(f) and 15(d)-15(f) of the Securities Exchange Act of 1934) occurred during the period ended September 30, 2023 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, 2022, as filed with the Securities and Exchange Commission on March 29, 2023 (the "2022 Form 10-K").

The Risk Factors set forth in the 2022 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 2022 Form 10-K could materially adversely affect the Company's business, financial condition or future results and the actual outcome of matters as to which forward-looking statements are made. These are not the only risks that the Company faces. Additional risks and uncertainties not currently known to the Company or that the Company currently deems to be immaterial also may materially adversely affect the Company's business, financial condition and/or operating results.

As of the date of this filing, except as disclosed in this document, there have been no material changes to the Risk Factors previously disclosed in the Company's 2022 Form 10-K.

Nasdaq Listing

The Company's common stock and the warrants are traded on The Nasdaq Capital Market under the symbols "LIXT" and "LIXTW", respectively.

In order to achieve compliance with the \$1.00 minimum closing bid price requirement of the Nasdaq Capital Market, the Company held a special meeting of stockholders on May 26, 2023 to seek approval for an amendment to the Company's Certificate of Incorporation to effect a reverse stock split of its issued and outstanding shares of common stock. As a result of the approval of this amendment, the Company effected a 1-for-10 reverse stock split of its issued and outstanding common stock effective on Friday, June 2, 2023. Commencing with the opening of trading on the Nasdaq Capital Market on Monday, June 5, 2023, the Company's common stock began trading on a post-split basis under the same symbol LIXT. The Company subsequently received confirmation from Nasdaq that it had regained compliance with the minimum bid price requirement of \$1.00 per share under Nasdaq Listing Rule 5550(a)(2) and currently meets all other applicable criteria for continued listing.

However, there can be no assurances that the Company will be able to remain in compliance with the \$1.00 minimum bid price requirement over time, or that it will be successful in maintaining compliance with any of the other Nasdaq continued listing requirements.

External Risks

Covid-19 Virus. The global outbreak of the novel coronavirus (Covid-19) in early 2020 led to disruptions in general economic activities throughout the world as businesses and governments implemented broad actions to mitigate this public health crisis. The extent to which the coronavirus pandemic may reappear and impact the Company's clinical trial programs and capital raising efforts in the future is uncertain and cannot be predicted.

Inflation Risk. The Company does not believe that inflation has had a material effect on its operations to date, other than its impact on the general economy. However, there is a risk that the Company's operating costs could become subject to inflationary and interest rate pressures in the future, which would have the effect of increasing the Company's operating costs (including, specifically, clinical trial costs), and which would put additional stress on the Company's working capital resources.

Supply Chain Issues. The Company does not currently expect that supply chain issues will have a significant impact on its business activities, including its ongoing clinical trials.

Potential Recession. There are various indications that the United States economy may be entering a recessionary period. Although unclear at this time, an economic recession would likely impact the general business environment and the capital markets, which could, in turn, affect the Company.

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

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

During the three months ended September 30, 2023, no director or officer (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated a “Rule 10b5-1 trading arrangement” as such term is defined in Item 408(a) of Regulation S-K.

ITEM 6. EXHIBITS

The following documents are filed as part of this report:

Exhibit Number	Description of Document
4.1	Form of Common Stock Purchase Warrant, filed as Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on July 20, 2023
4.2	Form of Pre-Funded Common Stock Purchase Warrant, filed as Exhibit 4.2 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on July 20, 2023
4.3	Form of Placement Agent Warrant, filed as Exhibit 4.3 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on July 20, 2023
10.1	Amendment to Contract between Lixte Biotechnology Holdings, Inc. and MRI Global effective April 17, 2023, filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2023, as filed with the Securities and Exchange Commission on May 10, 2023
10.2	Securities Purchase Agreement, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on July 20, 2023
10.3*	Amendment No. 1 to Development Collaboration Agreement by and between Lixte Biotechnology Holdings, Inc and the Netherlands Cancer Institute, Amsterdam, and the Onco Institute, Utrecht, entered into on October 8, 2021
10.4	Amendment No. 2 to Development Collaboration Agreement by and between Lixte Biotechnology Holdings, Inc and the Netherlands Cancer Institute, Amsterdam, and the Onco Institute, Utrecht, entered into on October 13, 2023, filed as Exhibit 10.2 to the Company Current Report on Form 8-K, as filed with the Securities and Exchange Commission on October 17, 2023 (certain portions of this Exhibit have been omitted)
10.5*	Termination letter between H. Lee Moffitt Cancer Center and Research Institute, Inc. and the Company dated October 4, 2023 and effective as of September 30, 2023
10.6	Employment Agreement between the Company and Bastiaan van der Baan effective as of September 26, 2023, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on September 27, 2023
31.1*	Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Officer's Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Officer's Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	Inline XBRL Instance Document (does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL document and included in Exhibit 101.INS)

* Filed herewith.

SIGNATURES

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

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

(Registrant)

Date: November 9, 2023

By: /s/ BASTIAAN VAN DER BAAN

Bastiaan van der Baan
Chief Executive Officer
(Principal Executive Officer)

Date: November 9, 2023

By: /s/ ROBERT N. WEINGARTEN

Robert N. Weingarten
Chief Financial Officer
(Principal Financial and Accounting Officer)

AMENDMENT NO. ONE TO DEVELOPMENT COLLABORATION AGREEMENT

Amendment No. One to the Development Collaboration Agreement, effective *nunc pro tunc* as of October 8, 2021 (the “**Amendment**”), by and between LIXTE BIOTECHNOLOGY HOLDINGS, INC., with its office and place of business at 680 E Colorado Blvd., Suite 180, Pasadena, CA 91101, 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**”); 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, a “**Party**” and together, the “**Parties**”).

WHEREAS, the Parties have entered into a Development Collaboration Agreement dated October 8, 2021 (the “**Existing Agreement**”);

WHEREAS, the Parties hereto desire to amend the Existing Agreement solely to substitute Party LIXTE BIOTECHNOLOGY HOLDINGS, INC. with its wholly-owned subsidiary LIXTE BIOTECHNOLOGY, INC. on the terms and subject to the conditions set forth herein;

WHEREAS, LIXTE BIOTECHNOLOGY HOLDINGS, INC. wishes to transfer by novation to LIXTE BIOTECHNOLOGY, INC., and LIXTE BIOTECHNOLOGY, INC. wishes to accept the transfer by novation of, all the rights, title, interest, liabilities, duties, and obligations of LIXTE BIOTECHNOLOGY HOLDINGS, INC. under and in respect of the Existing Agreement;

WHEREAS, each of NKI-AVL and Oncode wishes to release LIXTE BIOTECHNOLOGY HOLDINGS, INC. from its obligations under and in respect of the Existing Agreement in exchange, inter alia, for LIXTE BIOTECHNOLOGY, INC.’s assumption of the same obligations;

WHEREAS, each of LIXTE BIOTECHNOLOGY HOLDINGS, INC. and LIXTE BIOTECHNOLOGY, INC. shall sign this Amendment for avoidance of doubt with respect to the validity hereof; and

WHEREAS, pursuant to Section 10.6 of the Existing Agreement, the amendments contemplated by the Parties must be contained in a written agreement signed by the Parties.

NOW, THEREFORE, in consideration of the foregoing and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Definitions. Capitalized terms used and not defined in this Amendment have the respective meanings assigned to them in the Existing Agreement.
2. Amendments to the Existing Agreement. As of the Effective Date (defined below), the Existing Agreement is hereby amended or modified as follows:
 - (a) The introductory paragraph of the Existing Agreement is hereby deleted in its entirety and replaced with the following:

“This DEVELOPMENT COLLABORATION Agreement (this “Agreement”) is entered into on October 8, 2021 (the “Effective Date”), by and between LIXTE BIOTECHNOLOGY, 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.”

(b) The following language in Section 10.4 of the Existing Agreement is hereby deleted in its entirety:

“If to Lixte:

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

and is replaced with the following:

“If to Lixte:

LIXTE BIOTECHNOLOGY, INC.
Attn: John Kovach, MD
680 E Colorado Blvd., Suite 180
Pasadena, CA 91101
jkovach@lixte.com”

3. Date of Effectiveness: Limited Effect. This Amendment will be deemed effective as of October 8, 2021 (the “**Effective Date**”). Except as expressly provided in this Amendment, all of the terms and provisions of the Existing Agreement are and will remain in full force and effect and are hereby ratified and confirmed by the Parties. Without limiting the generality of the foregoing, the amendments contained herein will not be construed as an amendment to or waiver of any other provision of the Existing Agreement or as a waiver of or consent to any further or future action on the part of either Party that would require the waiver or consent of the other Party. On and after the Effective Date, each reference in the Existing Agreement to “this Agreement,” “the Agreement,” “hereunder,” “hereof,” “herein,” or words of like import, and each reference to the Existing Agreement in any other agreements, documents, or instruments

executed and delivered pursuant to, or in connection with, the Existing Agreement, will mean and be a reference to the Existing Agreement as amended by this Amendment.

4. In consideration of this novation, as of the Effective Date, LIXTE BIOTECHNOLOGY HOLDINGS, INC. shall (i) be relieved of all obligations to perform under the Existing Agreement; (ii) be fully relieved of liability to any other party to this Amendment arising out of the Existing Agreement; and (iii) waives all rights, title and interest under the Existing Agreement, as if it had not at any time been a party to such Existing Agreement.

5. Representations and Warranties.

(a) LIXTE BIOTECHNOLOGY, INC. hereby (i) agrees to be bound by the Existing Agreement in accordance with its terms as if it had at all times been a party to the Existing Agreement; (ii) assumes all obligations, duties, and liabilities and acquires all rights, title, and interest under the Existing Agreement as if the it had at all times been a party to the Existing Agreement; and (iii) warrants that it is ready, able, and willing to fully perform all obligations, duties, and liabilities under the Existing Agreement.

(b) Each Party hereby represents and warrants to the other Party that:

(i) It has the full right, power, and authority to enter into this Amendment and to perform its obligations hereunder.

(ii) The execution of this Amendment by the individual whose signature is set forth at the end of this Amendment on behalf of such Party, and the delivery of this Amendment by such Party, have been duly authorized by all necessary action on the part of such Party.

(iii) This Amendment has been executed and delivered by such Party and (assuming due authorization, execution, and delivery by the other Party hereto) constitutes the legal, valid, and binding obligation of such Party, enforceable against such Party in accordance with its terms.

EXCEPT FOR THE EXPRESS REPRESENTATIONS AND WARRANTIES SET FORTH IN THE EXISTING AGREEMENT AND IN THIS SECTION 4 OF THIS AMENDMENT, (A) NEITHER PARTY HERETO NOR ANY PERSON ON SUCH PARTY'S BEHALF HAS MADE OR MAKES ANY EXPRESS OR IMPLIED REPRESENTATION OR WARRANTY WHATSOEVER, EITHER ORAL OR WRITTEN, WHETHER ARISING BY LAW, COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE OF TRADE, OR OTHERWISE, ALL OF WHICH ARE EXPRESSLY DISCLAIMED, AND (B) EACH PARTY HERETO ACKNOWLEDGES THAT IT HAS NOT RELIED UPON ANY REPRESENTATION OR WARRANTY MADE BY THE OTHER PARTY, OR ANY OTHER PERSON ON SUCH OTHER PARTY'S BEHALF, EXCEPT AS SPECIFICALLY PROVIDED IN THIS SECTION 4.

6. Miscellaneous.

(a) In case of any dispute over the interpretation or the execution of this Amendment, 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 Amendment within sixty (60) days of issuance the dispute notice, then either party may commence an action. In the case 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, and in the case of an action commenced by another Party, the governing law shall be Dutch law and the action shall be brought in the Netherlands courts.

(b) This Amendment shall inure to the benefit of and be binding upon each of the Parties and each of their respective permitted successors and permitted assigns.

(c) The headings in this Amendment are for reference only and do not affect the interpretation of this Amendment.

(d) This Amendment may be executed in counterparts, each of which is deemed an original, but all of which constitute one and the same agreement. Delivery of an executed counterpart of this Amendment electronically or by facsimile shall be effective as delivery of an original executed counterpart of this Amendment.

(e) This Amendment constitutes the sole and entire agreement between the Parties with respect to the subject matter contained herein, and supersedes all prior and contemporaneous understandings, agreements, representations, and warranties, both written and oral, with respect to such subject matter.

(f) Each Party shall pay its own costs and expenses in connection with this Amendment (including the fees and expenses of its advisors, accountants, and legal counsel).

IN WITNESS WHEREOF, the Parties have executed this Amendment as of the Effective Date.

* * *

THE REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK

STICHTING HET NEDERLANDS KANKER
INSTITUUT – ANTONI VAN
LEEUVENHOEK ZIEKENHUIS

By _____

Name: Henri van Luenen

DocuSigned by:
Henri van Luenen
B5D5988930AA45A...

Title: Director of Operations

LIXTE BIOTECHNOLOGY, INC.

By John S. Kovach

Name: John S. Kovach, M.D.

Title: CEO and Founder

STICHTING ONCODE INSTITUTE

By Chris De Jonghe

Name: Chris De Jonghe

Title: Valorization Director

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

By John S. Kovach

Name: John S. Kovach

Title: CEO and Founder



September 29, 2023

Via FedEx

H. Lee Moffitt Cancer Center
12902 Magnolia Drive, MRC INNOV
Tampa, Florida 33612
Attn: Sr. Director
Office of Innovation and Industry Alliances

Re: Termination of Exclusive License Agreement

Dear Sir or Madam:

This letter is in reference to that certain Exclusive License Agreement dated August 20, 2018 between H. Lee Moffitt Cancer Center and Research Institute, Inc. ("Moffitt") and Lixte Biotechnology Holdings, Inc. ("Lixte") (the "Agreement"). Capitalized terms used but not defined in this letter have the meanings ascribed to them in the Agreement.

Lixte hereby gives notice of termination of the Agreement pursuant to Section 12.5(b) of the Agreement and gives notice that Lixte has discontinued development of all Royalty-Bearing Products. Lixte publicly announced discontinuance of its development programs for all Royalty-Bearing Products in its June 2023 10-Q filing (see pages 24 and 41, which state Lixte's decision to discontinue development of products for use in connection with the treatment of MDS).

Notwithstanding Section 12.5(b) of the Agreement, Lixte and Moffitt agree that termination of the Agreement will be effective on [September 30, 2023]. Further, Lixte and Moffitt agree that no termination fee shall be due or payable by Lixte, and Moffitt acknowledges that no payments are owed by Lixte under the Agreement.

We kindly ask that you acknowledge Moffitt's receipt and agreement with the foregoing by returning a countersigned copy of this letter to bvanderbaan@lixte.com.

[Signature Page Follows]

Sincerely,

Lixte Biotechnology Holdings, Inc.



By:
Name: Bastiaan van der Baan
Its: Chief Executive Officer

Acknowledged and Agreed:

H. Lee Moffitt Cancer Center and Research Institute, Inc.

By: 
Name: Xavier Avat
Its: Executive Vice President, Chief Business Officer
9/29/2023

With copies to:

H. Lee Moffitt Cancer Center and Research Institute, Inc.
Attention: Office of General Counsel
12902 Magnolia Drive, SRB-OGC
Tampa, Florida 33212-9497

and

Moffitt Cancer Center
Attention: Sayantan Purkayastha
Licensing Specialist II
Office of Innovation and Industry Alliances
email: sayantan.purkayastha@moffit.org

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

I, Bastiaan van der Baan, 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 9, 2023

By: /s/ BASTIAAN VAN DER BAAN

Bastiaan van der Baan
(Principal Executive Officer)

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

I, Robert N. Weingarten, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Lixte Biotechnology Holdings, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's Board of Directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2023

By: /s/ ROBERT N. WEINGARTEN

Robert N. Weingarten
Chief Financial Officer
(Principal Financial and Accounting Officer)

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

I, Bastiaan van der Baan, 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, 2023 (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 9, 2023

By: /s/ BASTIAAN VAN DER BAAN
Bastiaan van der Baan
Chief Executive Officer
(Principal Executive Officer)

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

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

(i) The Quarterly Report on Form 10-Q of the Company for the quarterly period ended September 30, 2023 (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 9, 2023

By: /s/ ROBERT N. WEINGARTEN

Robert N. Weingarten
Chief Financial Officer
(Principal Financial and Accounting Officer)
