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, 2024

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

Commission file number: 001-39717

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**20-2903526**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

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

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

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

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

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

Yes ☒ No □

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No □

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

Large accelerated filer □	Accelerated filer □
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company □

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes □ No ☒

As of November 1, 2024, the Company had 2,249,290 shares of common stock 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, 2024 (Unaudited)	December 31, 2023
ASSETS		
Current assets:		
Cash	$ 1,637,627	$ 4,203,488
Advances on research and development contract services	—	78,016
Prepaid insurance	17,081	17,116
Other prepaid expenses	34,256	10,000
Total current assets	1,688,964	4,308,620
Deferred offering costs	6,928	—
Total assets	$ 1,695,892	$ 4,308,620
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses, including $0 and $36,250 to related parties at September 30, 2024 and December 31, 2023, respectively	$ 72,859	$ 156,758
Research and development contract liabilities, including $0 and $120,768 to related parties at September 30, 2024 and December 31, 2023, respectively	256,097	157,100
Total current liabilities	328,956	313,858
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 at September 30, 2024 and December 31, 2023	3,500,000	3,500,000
Common stock, $0.0001 par value; authorized – 100,000,000 shares; issued and outstanding – 2,249,290 shares at September 30, 2024 and December 31, 2023	225	225
Additional paid-in capital	49,316,710	48,976,265
Accumulated deficit	(51,449,999)	(48,481,728)
Total stockholders' equity	1,366,936	3,994,762
Total liabilities and stockholders' equity	$ 1,695,892	$ 4,308,620

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,	
	2024	**2023**	**2024**	**2023**
Revenues	$ —	$ —	$ —	$ —
Costs and expenses:				
General and administrative costs:				
Compensation to related parties, including stock-based compensation expense of $106,827 and $112,106 for the three months ended September 30, 2024 and 2023, respectively, and $340,445 and $669,146 for the nine months ended September 30, 2024 and 2023, respectively	283,053	356,001	907,069	1,398,042
Patent and licensing legal and filing fees and costs	45,416	178,012	192,239	835,362
Other costs and expenses	293,158	357,681	1,168,582	1,081,893
Research and development costs, including $76,278 and $51,568 for the three months ended September 30, 2024 and 2023, respectively, and $210,362 and $156,950 for the nine months ended September 30, 2024 and 2023, respectively, to a related party	361,630	132,487	691,402	749,029
Total costs and expenses	983,257	1,024,181	2,959,292	4,064,326
Loss from operations	(983,257)	(1,024,181)	(2,959,292)	(4,064,326)
Interest income	1,437	5,809	6,529	13,538
Interest expense	(1,049)	(279)	(12,389)	(6,088)
Foreign currency gain (loss)	(3,161)	(109)	(3,119)	2,102
Net loss	$ (986,030)	$ (1,018,760)	$ (2,968,271)	$ (4,054,774)
Net loss per common share – basic and diluted	$ (0.44)	$ (0.49)	$ (1.32)	$ (2.25)
Weighted average common shares outstanding – basic and diluted	2,249,290	2,074,938	2,249,290	1,803,466

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, 2024 and 2023

	Convertible Series A Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Par Value	Capital	Deficit	Equity
Three months ended September 30, 2024:							
Balance, June 30, 2024	350,000	$ 3,500,000	2,249,290	$ 225	$ 49,209,883	$ (50,463,969)	$ 2,246,139
Stock-based compensation expense	—	—	—	—	106,827	—	106,827
Net loss	—	—	—	—	—	(986,030)	(986,030)
Balance, September 30, 2024	350,000	$ 3,500,000	2,249,290	$ 225	$ 49,316,710	$ (51,449,999)	$ 1,366,936
Nine months ended September 30, 2024:							
Balance, December 31, 2023	350,000	$ 3,500,000	2,249,290	$ 225	$ 48,976,265	$ (48,481,728)	$ 3,994,762
Stock-based compensation expense	—	—	—	—	340,445	—	340,445
Net loss	—	—	—	—	—	(2,968,271)	(2,968,271)
Balance, September 30, 2024	350,000	$ 3,500,000	2,249,290	$ 225	$ 49,316,710	$ (51,449,999)	$ 1,366,936

(continued)

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

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

Three Months and Nine Months Ended September 30, 2024 and 2023

	Convertible Series A Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Par Value	Capital	Deficit	Equity
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	350,000	$ 3,500,000	2,249,290	$ 225	$ 48,872,208	$ (47,449,473)	$ 4,922,960
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	350,000	$ 3,500,000	2,249,290	$ 225	$ 48,872,208	$ (47,449,473)	$ 4,922,960

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,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (2,968,271)	$ (4,054,774)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense included in -		
General and administrative costs	340,445	669,146
Research and development costs	—	—
Changes in operating assets and liabilities:		
(Increase) decrease in -		
Advances on research and development contract services	78,016	69,002
Prepaid insurance	35	25,994
Other prepaid expenses	(24,256)	(17,460)
Increase (decrease) in -		
Accounts payable and accrued expenses	(90,827)	(8,593)
Research and development contract liabilities	98,997	(74,457)
Net cash used in operating activities	(2,565,861)	(3,391,142)
Cash flows from financing activities:		
Proceeds from sale of securities in registered direct offering, net of offering costs	—	3,137,039
Exercise of pre-funded common stock warrants	—	41
Exercise of common stock options	—	6,281
Net cash provided by financing activities	—	3,143,361
Cash:		
Net decrease	(2,565,861)	(247,781)
Balance at beginning of period	4,203,488	5,353,392
Balance at end of period	$ 1,637,627	$ 5,105,611
Non-cash investing and financing activities:		
Deferred offering costs accrued	$ 6,928	$ —
Supplemental disclosures of cash flow information:		
Cash paid for -		
Interest	$ 12,389	$ 6,088
Income taxes	$ —	$ —

See accompanying notes to condensed consolidated financial statements.

1. Organization and Basis of Presentation

The condensed consolidated financial statements of Lixte Biotechnology Holdings, Inc., a Delaware corporation), including its wholly-owned Delaware subsidiary, Lixte Biotechnology, Inc. (collectively, the "Company"), at September 30, 2024, and for the three months and nine months ended September 30, 2024 and 2023, 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, 2024, and the results of its operations for the three months and nine months ended September 30, 2024 and 2023, and its cash flows for the nine months ended September 30, 2024 and 2023. Operating results for the interim periods presented are not necessarily indicative of the results to be expected for a full fiscal year. The condensed consolidated balance sheet at December 31, 2023 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, 2023, as filed with the SEC.

Business

The Company is a clinical-stage biopharmaceutical company focused on identifying new targets for cancer drug development and developing and commercializing cancer therapies. The Company's corporate office is located in Pasadena, California.

The Company's product pipeline is primarily focused on inhibitors of Protein Phosphatase 2A, which is used to enhance cytotoxic agents, radiation, immune checkpoint blockers and other cancer therapies. The Company believes that inhibitors of protein phosphatases have significant therapeutic potential for a broad range of cancers. The Company is focusing on the 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.

Nasdaq Compliance

The Company's common stock and the warrants are traded on the Nasdaq Capital Market ("Nasdaq") under the symbols "LIXT" and "LIXTW", respectively. On June 2, 2023, the Company effected a 1-for-10 reverse split of its outstanding shares of common stock in order to remain in compliance with the $1.00 minimum closing bid price requirement of Nasdaq. However, there can be no assurances that the Company will be able to remain in compliance with the $1.00 minimum closing bid price requirement of Nasdaq over time. In addition, Nasdaq has other continued listing requirements, one of which is maintaining a minimum net stockholders' equity of $2,500,000.

On August 19, 2024, the Company received a deficiency letter from the Listing Qualifications Department of Nasdaq indicating that it was not in compliance with Nasdaq Listing Rule 5550(b)(1) (the "Stockholders' Equity Rule"), which requires the Company to maintain a minimum stockholders' equity of $2,500,000. This notice of non-compliance has no immediate impact on the continued listing or trading of the Company's securities on Nasdaq, which will continue to be listed and traded on Nasdaq, subject to the Company's compliance with the other Nasdaq continued listing requirements.

On October 3, 2024, the Company submitted a letter to Nasdaq with its plan to regain compliance with the Stockholders' Equity Rule, which outlined the Company's proposed initiatives to regain compliance by raising equity capital through various registered equity offerings.

On October 21, 2024, Nasdaq provided the Company notice that it had granted an extension through February 18, 2025 for the Company to regain compliance with the Stockholders' Equity Rule. The Company must complete its capital raising initiatives and evidence compliance with the Stockholders' Equity Rule through filing a Current Report on Form 8-K with the SEC providing certain required information by February 18, 2025.

If the Company fails to evidence compliance with the Stockholders' Equity Rule upon filing its periodic report for the quarter ending March 31, 2025 with the SEC, the Company may be subject to delisting. If Nasdaq determines to delist the Company's common stock, the Company will have the right to appeal to a Nasdaq hearings panel. The hearing request would stay any suspension or delisting action pending the conclusion of the hearing process.

The Company intends to take reasonable measures available to regain compliance under Nasdaq's listing rules and to remain listed on Nasdaq. However, there can be no assurances that the Company will ultimately regain compliance with the Stockholders' Equity Rule, or be able to maintain compliance with all other applicable requirements for continued listing on Nasdaq. If the Company does not regain compliance with Nasdaq's listing rules within the time period permitted by Nasdaq, then the Company's securities will be delisted from Nasdaq.

Going Concern

For the nine months ended September 30, 2024, the Company recorded a net loss of $2,968,271 and used cash in operations of $2,565,861. At September 30, 2024, the Company had cash of $1,637,627 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, 2024, the Company's remaining financial contractual commitments pursuant to clinical trial agreements and clinical trial monitoring agreements not yet incurred aggregated approximately $3,918,000 (see Note 8), 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 consolidated financial statements also do not reflect any adjustments relating to the recoverability of assets and liabilities that might be necessary if the Company is unable to continue as a going concern. The Company has no recurring source of revenues 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 consolidated financial statements are being issued. In addition, our independent registered public accounting firm has included an explanatory paragraph in their report with respect to this uncertainty that accompanies our audited consolidated financial statements as of and for the year ended December 31, 2023. The Company's consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company's ability to continue as a going concern is dependent upon its ability to raise additional equity capital to fund its research and development activities and to ultimately achieve sustainable operating revenues and profitability. The amount and timing of future cash requirements depends on the pace, 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, 2024 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 the first quarter of 2025. As existing cash resources will not be sufficient to complete the clinical development of, and obtain regulatory approval for, the Company's product candidate, the Company will need to raise additional capital in one or more tranches to fund its operations during the next few months in order to be able to effectively manage its current business plan during 2025 and thereafter, as well as to maintain its listing on Nasdaq. Furthermore, the Company's operating plans and capital requirements may change as a result of many factors that are currently unknown and/or outside of the control of the Company. The Company is considering various strategies and alternatives to obtain the required additional capital.

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, 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.

2. 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.

Segment Information

The Company operates and reports in one segment, which consists of the development of a drug class called Protein Phosphatase 2A inhibitors. 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, and valuing equity instruments issued for services.

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, conduct 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 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.

Deferred Offering Costs

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

Patent and Licensing Legal and Filing Fees and Costs

Due to the significant uncertainty associated with the successful development of 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 $45,416 and $178,012 for the three months ended September 30, 2024 and 2023, respectively, and $192,239 and $835,362 for the nine months ended September 30, 2024 and 2023, respectively. Patent and licensing legal and filing fees and costs are included in general and administrative costs in the Company's consolidated statement 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 period (typically one year) or for a specific project or task. Costs and expenses incurred that represented 10% or more of general and administrative costs or research and development costs for the three months ended September 30, 2024 and 2023 are described below.

General and administrative costs for the three months ended September 30, 2024 and 2023 include charges from legal firms and other vendors for general licensing and patent prosecution costs relating to the Company's intellectual properties representing 7.3% and 20.0% of total general and administrative costs, respectively. General and administrative costs for the three months ended September 30, 2024 and 2023 also included charges for the cost of directors and officer's insurance of 18.4% and 11.9%, respectively, corporate legal fees of 9.8% and 10.6%, respectively, and for the fair value of stock options granted to directors and corporate officers representing 17.2% and 12.6%, respectively, of total general and administrative costs.

Research and development costs for the three months ended September 30, 2024 include charges from three vendors and consultants representing 57.2%, 21.1% and 15.1%, respectively, of total research and development costs. Research and development costs for the three months ended September 30, 2023 include charges from four vendors and consultants representing 38.9%, 24.9%, 15.9% and 14.9%, respectively, of total research and development costs.

Costs and expenses incurred that represented 10% or more of general and administrative costs or research and development costs for the nine months ended September 30, 2024 and 2023 are described below.

General and administrative costs for the nine months ended September 30, 2024 and 2023 include charges from legal firms and other vendors for general licensing and patent prosecution costs relating to the Company's intellectual properties representing 8.5% and 25.2% of total general and administrative costs, respectively. General and administrative costs for the nine months ended September 30, 2024 and 2023 also included charges for the cost of directors and officer's insurance of 16.0% and 9.3%, respectively, corporate legal fees of 11.5% and 7.5%, respectively, and for the fair value of stock options granted to directors and corporate officers representing 15.0% and 20.2%, respectively, of total general and administrative costs.

Research and development costs for the nine months ended September 30, 2024 include charges from three vendors and consultants representing 41.2%, 30.4% and 12.6%, respectively, of total research and development 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.

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. Due to the uncertainty of the Company's ability to realize the benefit of the deferred tax assets, the net deferred tax assets are fully offset by a valuation allowance at September 30, 2024 and December 31, 2023. 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, 2024 or December 31, 2023 and does not anticipate any material amount of unrecognized tax benefits through December 31, 2024.

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, 2024 or December 31, 2023. Subsequent to September 30, 2024, 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. The Company has determined that the warrants issued in the July 20, 2023 equity financing (see Note 4) meet the requirements 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 of 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 that are liability classified are recognized as a non-cash gain or loss in the statement of operations.

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, 2024 and 2023, 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,	
	2024	**2023**
Series A Convertible Preferred Stock	72,917	72,917
Common stock warrants	808,365	808,365
Common stock options, including options issued in the form of warrants	623,232	674,896
Total	1,504,514	1,556,178

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 in a foreign jurisdiction denominated in a local currency. The Company purchases the required foreign currency to pay such cost or expense on an as-needed basis. 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.

During the three months ended September 30, 2024 and 2023, the Company incurred various costs and expenses denominated in Euros, which were converted into United States dollars at the average rate of 1.0991 and 1.0885, respectively. During the nine months ended September 30, 2024 and 2023, the Company incurred various costs and expenses denominated in Euros, which were converted into United States dollars at the average rate of 1.0991 and 1.0839, respectively. As of September 30, 2024 and December 31, 2023, the Company did not hold any currencies other than the United States dollar in its bank accounts, and was not a party to any foreign currency forward or exchange contracts.

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, which consists 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 July 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 in July 2023. The adoption of ASU 2023-03 did not have any impact on the Company's consolidated financial statements, including their presentation and 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 statements, including their presentation and related disclosures.

3. Research and Development Costs

A summary of research and development costs for the three months and nine months ended September 30, 2024 and 2023, 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,	
	2024	2023	2024	2023
United States	$ 278,808	$ 68,315	$ 427,736	$ 291,846
Spain	6,544	9,496	51,022	283,035
China	—	3,108	2,282	17,198
Netherlands	76,278	51,568	210,362	156,950
Total	$ 361,630	$ 132,487	$ 691,402	$ 749,029

4. Stockholders' Equity

Preferred Stock

The Company is authorized to issue a total of 10,000,000 shares of preferred stock, par value $0.0001 per share. On March 17, 2015, the Company filed a Certificate of Designations, Preferences, Rights and Limitations of its Series A Convertible Preferred Stock with the Delaware Secretary of State to amend the Company's certificate of incorporation. The Company has designated a total of 350,000 shares as Series A Convertible Preferred Stock, which are non-voting and are not subject to increase without the written consent of a majority of the holders of the Series A Convertible Preferred Stock or as otherwise set forth in the Preferences, Rights and Limitations. The holders of each tranche of 175,000 shares of the Series A Convertible Preferred Stock are entitled to receive a per share dividend equal to 1% of the annual net revenue of the Company divided by 175,000, until converted or redeemed. As of September 30, 2024 and December 31, 2023, 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. The 350,000 outstanding shares of Series A Convertible Preferred Stock were convertible into a total of 72,917 shares of common stock at September 30, 2024 and December 31, 2023.

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, 2024 and December 31, 2023, the Company had 2,249,290 shares 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.

The authorized number of shares of common stock and the par value per share were not affected by the reverse stock split. No fractional shares were issued in connection with the reverse stock split, with all fractional shares being rounded up to the next 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.

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.

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 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 registered for resale on a registration statement on Form S-3 declared effective by the SEC on May 2, 2024.

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.

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 which provides that if any defined fundamental transactions are within the Company's control and are consummated, the holder of the unexercised common stock warrants would be entitled to receive, at its option, in exchange for extinguishment of such warrants, cash consideration equal to a Black-Scholes valuation amount, as defined in the warrant agreement. The fundamental transaction provision includes (i) a sale, lease, assignment, transfer, conveyance or other disposition of all or substantially all of the assets of the Company in one or a series of related transactions, or (ii) a change in control of the Company by which it, directly or indirectly, in one or more related transactions, consummates a stock or share purchase agreement or other business combination with another person or group, whereby such other person or group acquires more than 50% of the voting power of the common equity of the Company.

If such fundamental transaction is not within the Company's control, including not being approved by the Company's Board of Directors, the warrant holder would only be entitled to receive the same type or form of consideration (and in the same proportion) equal to the Black-Scholes valuation amount of the remaining unexercised portion of the warrant on the date of consummation of such fundamental transaction as the holders of the Company's common stock receive. Accordingly, these warrants are classified as a component of permanent stockholders' equity. The Company will account for any cash payment for a warrant redemption as a distribution from stockholders' equity, as and when a fundamental transaction is consummated and such cash payment is required to be made.

Common Stock Warrants

A summary of common stock warrant activity, including warrants to purchase common stock that were issued in conjunction with the Company's public offering, during the nine months ended September 30, 2024 is presented below.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Warrants outstanding at December 31, 2023	808,365	$ 16.407	
Issued	—	—	
Exercised	—	—	
Expired	—	—	
Warrants outstanding at September 30, 2024	808,365	$ 16.407	3.24
Warrants exercisable at December 31, 2023	808,365	$ 16.407	
Warrants exercisable at September 30, 2024	808,365	$ 16.407	3.24

At September 30, 2024, 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
$ 57.000	149,700
	808,365

The warrants exercisable at $57.00 per share at September 30, 2024 consist of 1,497,000 publicly-traded warrants, described herein on a pre-split 1-for-10 basis, 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 now represents the right to purchase 1/10th of a share of common stock at the original exercise price of $5.70 per share. Accordingly, the exercise of 10 warrants, each exercisable at $5.70, are required to acquire one share of post-split common stock, which is equivalent to a purchase price of $57.00 per share.

Based on the closing fair market value of $1.87 per share on September 30, 2024, there was no intrinsic value attributed to exercisable but unexercised common stock warrants at September 30, 2024.

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

5. Related Party Transactions

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

Employment Agreements with Officers

During July and August 2020, the Company entered into one-year employment agreements with 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. Except as noted below, these employment agreements were automatically renewed for additional one-year periods in July and August 2021, 2022, 2023 and 2024.

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. The employment agreement with Dr. Kovach terminated upon his death on October 5, 2023. During the three months and nine months ended September 30, 2023, the Company paid $62,500 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 statement of operations for such periods.

The Company entered into an employment agreement with Dr. James S. Miser, M.D., effective August 1, 2020, to act as the Company's Chief Medical Officer, with an annual salary of $150,000. Effective May 1, 2021, Dr. Miser's annual salary was increased to $175,000. Dr. Miser was required to devote at least 50% of his business time to the Company's activities. During the three months ended September 30, 2024 and 2023, the Company paid $14,583 and $43,750, 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. During the nine months ended September 30, 2024 and 2023, the Company paid $102,083 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 statement of operations for such periods. On May 29, 2024, the Company elected not to renew its employment agreement with Dr. Miser, as a result of which such employment agreement expired on July 31, 2024.

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 for the three months ended September 30, 2024 and 2023, the Company paid $3,218 and $7,323 respectively, on Mr. Forman's behalf. For the nine months ended September 30, 2024 and 2023, Mr. Forman has been provided a monthly office rent allowance, pursuant to which the Company paid $13,099 and $11,436 respectively, on Mr. Forman's behalf. During the three months ended September 30, 2024 and 2023, the Company paid $50,000 and $50,000, 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. During the nine months ended September 30, 2024 and 2023, the Company paid $150,000 and $150,000, respectively, to Mr. Forman under this employment agreement, which costs are included in general and administrative costs in the Company's consolidated statement 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, 2024 and 2023, the Company paid $43,750 and $43,750, 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. During the nine months ended September 30, 2024 and 2023, 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 statement 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. Effective October 6, 2023, Mr. van der Baan was appointed as Chairman of the Board of Directors upon the death of Dr. Kovach on October 5, 2023. 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 is eligible to receive an annual bonus as determined at the sole discretion of the Board of Directors. 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 provisions as described in the employment agreement. During the three months ended September 30, 2024 and 2023, the Company paid $39,175 and $1,667, respectively, to Mr. van der Baan under this employment agreement, which costs are included in general and administrative costs in the Company's consolidated statement of operations for such periods. During the nine months ended September 30, 2024 and 2023, the Company paid $115,754 and $1,667, respectively, to Mr. van der Baan under this employment agreement, which costs are included in general and administrative costs in the Company's consolidated statement of operations for such periods.

On May 31, 2024, the Company entered into a consulting agreement with Dr. Jan H.M. Schellens, M.D., Ph.D., Pursuant to the agreement, effective July 1, 2024, the Company engaged Dr. Schellens as a consultant, and, effective August 1, 2024, as the Company's Chief Medical Officer. The term of the agreement are in effect from July 1, 2024 until the earliest of (i) termination by either party upon sixty days' notice, (ii) Dr. Schellens' death or disability, or (iii) termination by the Company for breach as provided in the agreement. Under the agreement, Dr. Schellens provides his services for two days per week with the specific days in each week based on arrangements agreed to from time to time between Dr. Schellens and the Company's Chief Executive Officer. The Company pays Dr. Schellens an annual compensation of 104,000 Euros (approximately $116,000 as of September 30, 2024), payable on a monthly basis. During the three months and nine months ended September 30, 2024, the Company paid $28,718 and $28,718, respectively, to Dr. Schellens under this consulting agreement, which costs are included in general and administrative costs in the Company's consolidated statement of operations for such periods.

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. Upon his appointment, it was agreed that Dr. Bernards would receive annual compensation for his services on the Board only in the form of cash, in lieu of the annual June 30 grant of stock options as provided to the Company's other non-officer directors. During the three months ended September 30, 2024 and 2023, the Company recorded charges to general and administrative costs in the consolidated statement of operations of $0 and $10,000, respectively, with respect to his annual cash board compensation. During the nine months ended September 30, 2024 and 2023, the Company recorded charges to general and administrative costs in the consolidated statement of operations of $10,000 and $30,000, respectively, with respect to his annual cash board compensation.

In conjunction with the Company's efforts to preserve cash, effective with the quarter ended June 30, 2024, Dr. Bernards agreed to receive equity-based compensation for his services on the Board, for the quarters ended June 30, 2024, September 30, 2024 and December 31, 2024. In order to reconcile his Board compensation with that of the other non-officer directors, Dr. Bernards has agreed to receive the same Board compensation, both in form and amount, as the other non-officer directors.

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 8).

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 non-officer directors for their services on the Board of Directors (the "Board Plan"), which was subsequently amended effective May 25, 2022 and July 9, 2024. Officers who also serve on the Board of Directors are not compensated separately for their service on the Board of Directors.

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

Base director compensation - $20,000 per year (except for Dr. Bernards, who was paid an additional annual cash fee of $40,000, in lieu of the annual June 30 grant of stock option as described below, through March 31, 2024)
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

In conjunction with the Company's efforts to preserve cash, the Board approved an amendment to the Board Plan, such that for the quarters ended June 30, 2024, September 30, 2024 and December 31, 2024, the non-officer directors (including Dr. Bernards) will receive, in lieu of cash compensation, stock options exercisable for a period of five years, vesting immediately, to purchase common stock at an exercise price based on the closing market price at the end of each of the applicable quarters, with the amount of such stock options equal to the cash payment such director would otherwise have been entitled to receive for such quarter, divided by their quarter-end value as determined pursuant to the Black-Scholes option-pricing model. The Board may extend this amendment to the Board Plan for additional quarterly periods subsequent to December 31, 2024.

Equity compensation for directors is as follows:

Appointment of new 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 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 is 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 non-officer directors was $0 and $42,228, respectively, for the three months ended September 30, 2024 and 2023. Total cash compensation paid to non-officer directors was $38,819 and $127,229, respectively, for the nine months ended September 30, 2024 and 2023.

Stock-based compensation granted to members of the Company's Board of Directors, officers and affiliates is described at Note 6.

A summary of related party costs, including compensation under employment and consulting agreements and fees paid to non-officer directors for their services on the Board of Directors, for the three months and nine months ended September 30, 2024 and 2023, is presented below.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Related party costs:				
Cash-based	$ 176,226	$ 243,895	$ 566,624	$ 728,896
Stock-based	106,827	112,106	340,445	669,146
Total	$ 283,053	$ 356,001	$ 907,069	$ 1,398,042

6. 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. On November 27, 2023, the stockholders of the Company approved an amendment to the 2020 Plan to increase the number of common shares issuable thereunder by 336,667 shares, to a total of 750,000 shares.

As of September 30, 2024, unexpired stock options for 623,232 shares were issued and outstanding under the 2020 Plan and 126,768 shares were 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, 2024, 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	3.550% to 4.290%
Expected dividend yield	0%
Expected volatility	125.59% to 126.45%
Expected life	2.5 to 3.5 years

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	4.565% to 4.843%
Expected dividend yield	0%
Expected volatility	138.05%
Expected life	4.0 years

On July 15, 2020, as amended on August 12, 2020, in connection with the employment agreement 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. 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 a charge to general and administrative costs in the consolidated statement of operations for the three months and nine months ended September 30, 2023 of $11,806 and $61,501, respectively, with respect to these stock options.

On August 1, 2020, in connection with an employment agreement 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. 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 a charge to general and administrative costs in the consolidated statement of operations for the three months and nine months ended September 30, 2023 of $12,551 and $83,544, respectively, with respect to these stock options.

On August 12, 2020, in connection with the employment agreement 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. 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 a charge to general and administrative costs in the consolidated statement of operations for the three months and nine months ended September 30, 2023 of $11,806 and $61,501, 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. 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 a charge to general and administrative costs in the consolidated statement of operations for the three months and nine months ended September 30, 2023 of $0 and $76,388, 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. 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 a charge to general and administrative costs in the consolidated statement of operations for the three months and nine months ended September 30, 2023 of $0 and $211,413, 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 was charged to operations ratably from June 17, 2022 through June 30, 2024. During the three months ended September 30, 2024 and 2023, the Company recorded charges to general and administrative costs in the consolidated statement of operations of $0 and $9,801, respectively, with respect to these stock options. During the nine months ended September 30, 2024 and 2023, the Company recorded charges to general and administrative costs in the consolidated statement of operations of $19,390 and $29,084, 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 was charged to operations ratably from July 1, 2022 through June 30, 2024. During the three months ended September 30, 2024 and 2023, the Company recorded charges to general and administrative costs in the consolidated statement of operations of $0 and $23,916, respectively, with respect to these stock options. During the nine months ended September 30, 2024 and 2023, the Company recorded charges to general and administrative costs in the consolidated statement of operations of $47,310 and $70,964, 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. During the three months ended September 30, 2024 and 2023, the Company recorded charges to general and administrative costs in the consolidated statement of operations of $9,641 and $16,528, respectively, with respect to these stock options. During the nine months ended September 30, 2024 and 2023, the Company recorded charges to general and administrative costs in the consolidated statement of operations of $34,301 and $49,053, respectively, with respect to these stock options.

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. During the three months ended September 30, 2024 and 2023, the Company recorded charges to general and administrative costs in the consolidated statement of operations of $24,232 and $24,232, respectively, with respect to these stock options. During the nine months ended September 30, 2024 and 2023, the Company recorded charges to general and administrative costs in the consolidated statement of operations of $72,300 and $24,232, respectively, with respect to these stock options.

On September 26, 2023, in connection with the employment agreement entered into with Bas 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. During the three months ended September 30, 2024 and 2023, the Company recorded charges to general and administrative costs in the consolidated statement of operations of $33,712 and $1,466, respectively, with respect to these stock options. During the nine months ended September 30, 2024 and 2023, the Company recorded charges to general and administrative costs in the consolidated statement of operations of $100,402 and $1,466, respectively, with respect to these stock options.

On June 30, 2024, 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 $2.37 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 $73,976 ($1.8494 per share), which is being charged to operations ratably from July 1, 2024 through June 30, 2026. During the three months and nine months ended September 30, 2024, the Company record a charge general and administrative costs in the consolidated statement of operations of $9,324 and $9,324, respectively, with respect to these stock options.

On June 30, 2024, the Board of Directors, in conjunction with the Company's efforts to preserve cash, granted to the four non-officer directors of the Company a total of 16,598 stock options to purchase shares of the Company's common stock, exercisable for a period of five years at an exercise price of $2.37 per share (the closing market price on the grant date) The stock options were granted in lieu of cash compensation, are exercisable for a period of five years and were immediately vested. The number of stock options granted to each of the four non-officer directors of the Company was determined to be equal to the cash payment such director would otherwise have been entitled to receive for such quarter, divided by their quarter-end value as determined pursuant to the Black-Scholes option-pricing model and was determined to be $27,500 ($1.6570 per share), which was charged to operations on June 30, 2024, the date on which they became fully vested.

On July 1, 2024, in connection with the consulting agreement with Dr. Jan H.M. Schellens, M.D., Ph.D., Dr. Schellens was granted stock options to purchase 15,000 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 e price of $2.39 per share, which was equal to the closing market price of the Company's common stock on the grant date. The options vest quarterly over a three-year period commencing on the last day of each calendar quarter commencing September 30, 2024. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $29,074 ($1.9382 per share), which is being charged to operations ratably from July 1, 2024 through June 30, 2027. During the three months and nine months ended September 30, 2024, the Company record a charge general and administrative costs in the consolidated statement of operations of $2,418 and $2,418, respectively, with respect to these stock options.

On September 30, 2024, the Board of Directors, in conjunction with the Company's efforts to preserve cash, granted to the four non-officer directors of the Company a total of 21,217 stock options to purchase shares of the Company's common stock, exercisable for a period of five years at an exercise price of $1.87 per share (the closing market price on the grant date) The stock options were granted in lieu of cash compensation, are exercisable for a period of five years and were immediately vested. The number of stock options granted to each of the four non-officer directors of the Company was determined to be equal to the cash payment such director would otherwise have been entitled to receive for such quarter, divided by their quarter-end value as determined pursuant to the Black-Scholes option-pricing model and was determined to be $27,500 ($1.2961 per share), which was charged to operations on September 30, 2024, the date on which they became fully vested.

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 former 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, and the employment agreement of the Company's Chief Medical Officer, Dr. James S. Miser expired on July 31, 2024. Accordingly, the unvested stock options for each such person ceased vesting effective as of the respective dates that their services to the Company terminated. Furthermore, the expiration date of all vested stock options owned by each such person contractually expired one year from the respective dates that their services to the Company terminated.

A summary of stock-based compensation costs for the three months and nine months ended September 30, 2024 and 2023 is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Related parties	$ 106,827	$ 112,106	$ 340,445	$ 669,146
Non-related parties	—	—	—	—
Total stock-based compensation costs	$ 106,827	$ 112,106	$ 340,445	$ 669,146

A summary of stock option activity, including options issued in the form of warrants, during the nine months ended September 30, 2024 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Stock options outstanding at December 31, 2023	552,083	$ 15.330	
Granted	92,815	2.259	
Exercised	—	—	
Expired	(21,666)	42.461	
Stock options outstanding at September 30, 2024	623,232	$ 12.441	3.36
Stock options exercisable at December 31, 2023	252,292	$ 28.387	
Stock options exercisable at September 30, 2024	372,815	$ 18.305	2.87

Total deferred compensation expense for the outstanding value of unvested stock options was approximately $467,000 at September 30, 2024, which will be recognized subsequent to September 30, 2024 over a weighted-average period of approximately 21 months.

At September 30, 2024, the outstanding common stock options, including options issued in the form of warrants, are exercisable at the following prices per common share:

Exercise Prices	Options Outstanding (Shares)	Options Exercisable (Shares)
$ 1.870	21,217	21,217
$ 1.950	250,000	83,333
$ 2.370	56,598	21,598
$ 2.390	15,000	1,250
$ 5.025	8,750	8,750
$ 5.880	40,000	25,000
$ 7.400	55,000	55,000
$ 20.000	55,000	35,000
$ 20.600	20,000	20,000
$ 28.000	25,000	25,000
$ 30.300	30,000	30,000
$ 32.100	10,000	10,000
$ 60.000	8,333	8,333
$ 71.400	20,000	20,000
$ 120.000	8,334	8,334
	623,232	372,815

Based on the closing fair market value of $1.87 per share on September 30, 2024, there was no intrinsic value attributed to exercisable but unexercised common stock options at September 30, 2024.

Outstanding stock options to acquire 250,417 shares of the Company's common stock had not vested at September 30, 2024.

Upon the exercise of such stock options, the Company expects to satisfy the related stock obligations through the issuance of authorized but unissued shares of common stock.

7. Income Taxes

During the three months and nine months ended September 30, 2024 and 2023, the Company did not record any provision for income taxes, as the Company incurred losses during such 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.

8. Commitments and Contingencies

Legal Claims

The Company may be subject to legal claims and actions from time to time as part of its business activities. As of September 30, 2024 and December 31, 2023, the Company was not subject to any threatened or pending lawsuits, legal claims or legal proceedings.

Principal Commitments

Clinical Trial Agreements

At September 30, 2024, the Company's remaining financial contractual commitments pursuant to clinical trial agreements and clinical trial monitoring agreements not yet incurred, as described below, aggregated $3,918,000, including clinical trial agreements of $3,616,000 and clinical trial monitoring agreements of $302,000, 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 is obtained and analyzed, and is frequently modified, suspended or terminated, in part based on receipt or lack of receipt of an indication of clinical benefit or activity, 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 Company's ongoing contractual clinical trials described below as of September 30, 2024:

Description of Clinical Trial	Institution	Start Date	Projected End Date	Number of Patients in Trial	Study Objective	Clinical Update	Expected Date of Preliminary Efficacy Signal	NCT No.	Remaining Financial Contractual Commitment	
LB-100 combined with atezolizumab in microsatellite stable metastatic colon cancer (Phase 1b)	Netherlands Cancer Institute (NKI)	August 2024	December 2026	37	Determine RP2D with atezolizumab	First patient entered August 2024	June 2026	NCT06012734		(1)
LB-100 combined with doxorubicin in advanced soft tissue sarcoma (Phase 1b)	GEIS	June 2023	Recruitment completed September 2024	9 to 18	Determine MTD and RP2D	Fourteen patients entered	March 2025	NCT05809830	$ 284,000	
Doxorubicin with or without LB-100 in advanced soft tissue sarcoma (Randomized Phase 2)	GEIS	TBD	TBD	150	Determine efficacy: PFS	Clinical trial not yet begun (subject to completion of Phase 1b GEIS clinical trial)	December 2026	NCT05809830	$ 3,332,000	
LB-100 combined with dostarlimab in ovarian clear cell carcinoma (Phase 1b/2)	MD Anderson	January 2024	December 2027	21	Determine the OS of patients with recurrent ovarian clear cell carcinoma	Seven patients entered	December 2026	NCT06065462		(1)
Total									$ 3,616,000	

(1) The Company has no financial contractual commitment associated with this clinical trial at September 30, 2024.

Netherlands Cancer Institute. Effective June 10, 2024, the Company entered into a Clinical Trial Agreement with the Netherlands Cancer Institute ("NKI") (see Note 5) to conduct a Phase 1b clinical trial of the Company's protein phosphatase inhibitor, LB-100, combined with atezolizumab, a PD-L1 inhibitor, the proprietary molecule of F. Hoffman-La Roche Ltd. ("Roche"), for patients with microsatellite stable metastatic colon cancer. Under the agreement, the Company will provide its lead compound, LB-100, and under a separate agreement between NKI and Roche, Roche will provide atezolizumab and financial support for the clinical trial. The Company has no obligation to and will not provide any reimbursement of clinical trial costs. Pursuant to the agreement and the protocol set forth in the agreement, the clinical trial will be conducted by NKI at NKI's site in Amsterdam by principal investigator Neeltje Steeghs, MD, PhD, and NKI will be responsible for the recruitment of patients. The agreement provides for the protection of the respective intellectual property rights of each of the Company, NKI and Roche.

This Phase 1b clinical trial will evaluate safety, optimal dose and preliminary efficacy of LB-100 combined with atezolizumab for the treatment of patients with metastatic microsatellite stable colorectal cancer. Immunotherapy using monoclonal antibodies like atezolizumab can enhance the body's immune response against cancer and hinder tumor growth and spread. LB-100 has been found to improve the effectiveness of anticancer drugs in killing cancer cells by inhibiting a protein called PP2A on cell surfaces. Blocking PP2A increases stress signals in tumor cells expressing the PP2A protein. Accordingly, combining atezolizumab with LB-100 may enhance treatment efficacy for metastatic colorectal cancer, as cancer cells with heightened stress signals are more vulnerable to immunotherapy.

This study comprises a dose escalation phase and a dose expansion phase. The objective of the dose escalation phase is to determine the recommended Phase 2 dose (RP2D) of LB-100 when combined with the standard dosage of atezolizumab. The dose expansion phase will further investigate the preliminary efficacy, safety, tolerability, and pharmacokinetics/dynamics of the LB-100 and atezolizumab combination. The clinical trial opened in August 2024 with the enrollment of the first patient. Patient accrual is expected to take up to 24 months, with a maximum of 37 patients with advanced colorectal cancer to be enrolled in this study.

The principal investigator of the colorectal study testing LB-100 in combination with atezolizumab is currently investigating two Serious Adverse Events ("SAEs") observed in the clinical trial. Evaluation is underway to determine next steps (see "Serious Adverse Events" below for additional information).

The Company has no financial contractual commitment associated with this clinical trial.

City of Hope. Effective January 18, 2021, the Company executed a Clinical Research Support Agreement (the "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 was given in combination with carboplatin, etoposide and atezolizumab, an FDA-approved standard of care regimen, to previously untreated ED-SCLC patients. The LB-100 dose was to be escalated with the standard fixed doses of the 3-drug regimen to reach a recommended Phase 2 dose ("RP2D"). Patient entry was to be expanded so that a total of 12 patients would 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. Because patient accrual was slower than expected, effective March 6, 2023, the Company and City of Hope added the Sarah Cannon Research Institute ("SCRI"), Nashville, Tennessee, to the ongoing Phase 1b clinical trial. The Company and City of Hope continued efforts to increase patient accrual by adding additional sites and by modifying the protocol to increase the number of patients eligible for the clinical trial. The impact of these efforts to increase patient accrual and to decrease time to completion was evaluated in subsequent quarters.

After evaluating patient accrual through June 30, 2024, the Company and City of Hope agreed to close the clinical trial. Pursuant to the terms of the Agreement, the Company provided notice to City of Hope of the Company's intent to terminate the Agreement effective as of July 8, 2024. Upon closure, the Company incurred a prorated charge of $207,004 for the cost of patients enrolled to date. The Company is exploring alternative sites, including international locations, for the conduct of a small cell lung cancer clinical trial.

During the three months ended September 30, 2024 and 2023, the Company incurred costs of $207,004 and $0, respectively, pursuant to this Agreement. During the nine months ended September 30, 2024 and 2023, the Company incurred costs of $285,019 and $69,001, respectively, pursuant to this Agreement. As of September 30, 2024, total costs of $732,532 had been incurred pursuant to this Agreement.

GEIS. Effective July 31, 2019, the Company entered into a Collaboration Agreement for an Investigator-Initiated Clinical Trial with the Spanish Sarcoma Group (Grupo Español de Investigación en Sarcomas or "GEIS"), Madrid, Spain, to carry out a study entitled "Randomized phase I/II trial of LB-100 plus doxorubicin vs. doxorubicin alone in first line of advanced soft tissue sarcoma". The purpose of this clinical trial is to obtain information 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 improvement in survival 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 to four years. The Phase 1 portion of the study began in the quarter ended June 30, 2023 to determine the recommended Phase 2 dose of the combination of doxorubicin and LB-100. As advanced sarcoma is a very aggressive disease, the design of the Phase 2 portion 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 practice (GMP) of the active pharmaceutical 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 December 31, 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.

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 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 patents will be entered into the clinical trial. The recruitment for the Phase 1b portion of the protocol was extended with two patients and was completed during the quarter ended September 30, 2024. The Company expects to have data on toxicity and preliminary efficacy from this portion of the clinical trial by December 31, 2024, and a full report by June 30, 2025. Subject to clinical results and the availability of sufficient working capital resources, the Company anticipates that it will then be in a position to decide whether to proceed to the related Phase 2 portion of the study.

The interim analysis of the Phase 2 portion 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, 2024 and 2023, the Company did not incur any costs pursuant to this agreement. During the nine months ended September 30, 2024 and 2023, the Company incurred costs of $0 and $268,829, respectively, pursuant to this agreement. Through September 30, 2024, the Company has incurred charges 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 $3,616,000 (consisting of $284,000 for the Phase 1b portion and $3,332,000 for the Phase 2 portion) as of September 30, 2024, which is scheduled 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, and have not been significant.

MD Anderson Cancer Center Clinical Trial. On September 20, 2023, the Company announced an investigator-initiated Phase 1b/2 collaborative clinical trial to assess whether adding LB-100 to a human programmed death receptor-1 ("PD-1") blocking antibody of GSK plc ("GSK"), dostarlimab-gxly, may enhance the effectiveness of immunotherapy in the treatment of ovarian clear cell carcinoma ("OCCC"). The study objective is to determine the overall survival ("OS") of patients with OCCC. The clinical trial is being sponsored by The University of Texas MD Anderson Cancer Center ("MD Anderson") and is being conducted at The University of Texas - MD Anderson Cancer Center. The Company is providing LB-100 and GSK is providing dostarlimab-gxly and financial support for the clinical trial. On January 29, 2024, the Company announced the entry of the first patient into this clinical trial. The Company currently expects that this clinical trial will be completed by December 31, 2027.

Moffitt. Effective August 20, 2018, the Company entered into a Clinical Trial Research Agreement with the Moffitt Cancer Center and Research Institute Hospital Inc., Tampa, Florida ("Moffitt"), effective for a term of five years. 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 ("IND") 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 had failed or were intolerant of standard treatment. 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.

The clinical trial began at a single site in April 2019 and the first patient was entered into the clinical trial in July 2019. During the year ended December 31, 2023, the clinical trial was closed. Although the maximum tolerated dose ("MTD") was not achieved, there was no dose-limiting toxicity noted.

During the three months and nine months ended September 30, 2024 and 2023, the Company did not incur any costs pursuant to this agreement. As of September 30, 2024, total costs of $147,239 had been incurred pursuant to this agreement.

During September 2023, the Company decided not to pursue further studies in MDS, as other, more promising, opportunities had become available (see "Patent and License Agreements - Moffitt" below).

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. 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. Blood and brain tumor tissue were analyzed from seven patients after intravenous infusion of a single dose of LB-100. Results of the investigation demonstrated that there was virtually no entry of LB-100 into the brain tumor tissue. Accordingly, alternative methods of drug delivery will be required to determine if LB-100 has meaningful clinical anti-cancer activity against glioblastoma multiforme and other aggressive brain tumors. The Company is considering an additional clinical study to address the delivery of LB-100 to the brain.

Clinical Trial Monitoring Agreements

MD Anderson Cancer Center Clinical Trial. On May 15, 2024, the Company signed a letter of intent with Theradex to monitor the MD Andersen investigator-initiated Phase 1b/2 collaborative clinical trial to assess whether adding LB-100 to a human programmed death receptor-1 ("PD-1") blocking antibody of GSK plc ("GSK"), dostarlimab-gxly, may enhance the effectiveness of immunotherapy in the treatment of ovarian clear cell carcinoma ("OCCC"). On August 19, 2024, the Company signed a work order agreement with Theradex to monitor the MD Anderson clinical trial. The study oversight is expected to be completed by January 31, 2027.

Costs under this letter of intent and related work order agreement are estimated to be approximately $95,000. During the three months and nine months ended September 30, 2024, the Company incurred costs of $12,610 and $20,838 pursuant to this letter of intent and subsequent work order. As of September 30, 2024, total costs of $20,838 have been incurred pursuant to this letter of intent and subsequent work order.

The Company's aggregate commitment pursuant to this letter of intent, less amounts previously paid to date, totaled approximately $78,000 as of September 30, 2024, which is expected to be incurred through December 31, 2027.

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 were estimated to be approximately $335,000. During the three months ended September 30, 2024 and 2023, the Company incurred costs of $1,603 and $4,500, respectively, pursuant to this work order. During the nine months ended September 30, 2024 and 2023, the Company incurred costs of $10,603 and $15,740, respectively, pursuant to this work order. As of September 30, 2024, total costs of $89,284 had been incurred pursuant to this work order agreement.

As a result of the closure of the Agreement with City of Hope effective July 8, 2024 (see "Clinical Trial Agreements – City of Hope" above), the work order agreement with Theradex to monitor this clinical trial was concurrently terminated, although nominal oversight trailing costs subsequent to July 8, 2024 are expected to be incurred relating to the closure of this study.

GEIS. On June 22, 2023, the Company finalized a work order agreement with Theradex, to monitor the GEIS investigator-initiated clinical Phase I/II randomized trial of LB-100 plus doxorubicin vs. doxorubicin alone in first line of advanced soft tissue sarcoma. The study oversight is expected to be completed by December 31, 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 ended September 30, 2024 and 2023, the Company incurred costs of $13,475 and $3,750, respectively, pursuant to this work order. During the nine months ended September 30, 2024 and 2023, the Company incurred costs of $26,208 and $10,000, respectively, pursuant to this work order. As of September 30, 2024, total costs of $41,070 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 $118,000 as of September 30, 2024, which is expected to be incurred through December 31, 2026.

Netherlands Cancer Institute. On August 27, 2023, the Company finalized a work order agreement with Theradex, to monitor the NKI Phase 1b clinical trial of LB-100 combined with atezolizumab, a PD-L1 inhibitor, for patients with microsatellite stable metastatic colon cancer. The study oversight is expected to be completed by May 31, 2027.

Costs under this work order agreement are estimated to be approximately $106,380, with such payments expected to be allocated approximately 47% to Theradex for services and approximately 53% for payments for pass-through software costs. During the three months and nine months ended September 30, 2024, the Company incurred costs of $14,900 pursuant to this work order. As of September 30, 2024, total costs of $14,900 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 $106,380 as of September 30, 2024, which is expected to be incurred through May 31, 2027.

Patent and License Agreements

National Institute of Health. Effective February 23, 2024, the Company entered into a Patent License Agreement (the "License Agreement") with the National Institute of Neurological Disorders and Stroke ("NINDS") and the National Cancer Institute ("NCI"), each an institute or center of the National Institute of Health ("NIH"). Pursuant to the License Agreement, the Company has licensed on an exclusive basis the NIH's intellectual property rights claimed for a Cooperative Research and Development Agreement ("CRADA") subject invention co-developed with the Company, and the licensed field of use, which focuses on promoting anti-cancer activity alone, or in combination with standard anti-cancer drugs. The scope of this clinical research extends to checkpoint inhibitors, immunotherapy, and radiation for the treatment of cancer. The License Agreement is effective, and shall extend, on a licensed product, licensed process, and country basis, until the expiration of the last-to-expire valid claim of the jointly owned licensed patent rights in each such country in the licensed territory, estimated at twenty years, unless sooner terminated.

The License Agreement contemplates that the Company will seek to work with pharmaceutical companies and clinical trial sites (including comprehensive cancer centers) to initiate clinical trials within timeframes that will meet certain benchmarks. Data from the clinical trials will be the subject of various regulatory filings for marketing approval in applicable countries in the licensed territories. Subject to the receipt of marketing approval, the Company would be expected to commercialize the licensed products in markets where regulatory approval has been obtained.

The Company is obligated to pay the NIH a non-creditable, non-refundable license issue royalty of $50,000 and a first minimum annual royalty within sixty days from the effective date of the Agreement. The first minimum annual royalty of $25,643 was prorated from the effective date of the License Agreement to the next subsequent January 1. Thereafter, the minimum annual royalty of $30,000 is due each January 1 and may be credited against any earned royalties due for sales made in that year. The license issue royalty of $50,000 and the first minimum annual royalty of $25,643, were paid in April 2024.

The Company is obligated to pay the NIH, on a country-by-country basis, earned royalties of 2% on net sales of each royalty-bearing product and process, subject to reduction by 50% under certain circumstances relating to royalties paid by the Company to third parties, but not less than 1%. The Company's obligation to pay earned royalties under the License Agreement commences on the date of the first commercial sale of a royalty-bearing product or process and expires on the date on which the last valid claim of the licensed product or licensed process expires in such country.

The Company is obligated to pay the NIH benchmark royalties, on a one-time basis, within sixty days from the first achievement of each such benchmark. The License Agreement defines four such benchmarks, which the Company is required to pursue based on "commercially reasonable efforts" as defined in the License Agreement, with deadlines of October 1, 2024, 2027, 2029 and 2031, respectively, each with a different specified benchmark payment amount payable within thirty days of achieving such benchmark. The October 1, 2024 benchmark of $100,000 was defined as the dosing of the first patient with a licensed product in a Phase 2 clinical study of such licensed product in the licensed fields of use. The Company had not commenced a Phase 2 clinical study as of September 30, 2024. The total of all such benchmark payments is $1,225,000.

The Company is obligated to provide annual reports to the NIH on its progress toward the development and commercialization of products under the licensed patents. These reports, due within sixty days following the end of each calendar year, must include updates on research and development activities, regulatory submissions, manufacturing efforts, sublicensing, and sales initiatives. If any deviations from the established commercial development plan or agreed-upon benchmarks occur, the Company is obligated to provide explanation and may amend the commercial development plan and the benchmarks, which, subject to certain conditions, the NIH shall not unreasonably withhold, condition, or delay approval of any request of the Company to amend the commercial development plan and/or the benchmarks and to extend the time periods of the benchmarks.

The Company is obligated to pay the NIH sublicensing royalties of 5% on sublicensing revenue received for granting each sublicense within sixty days of receipt of such sublicensing revenue.

During the three months ended September 30, 2024, the Company incurred costs of $7,537 in connection with its obligations under the License Agreement. During the nine months ended September 30, 2024, the Company incurred costs of $68,106 in connection with its obligations under the License Agreement. Such costs when incurred have been included in general and administrative costs in the Company's consolidated statement of operations. As of September 30, 2024, total costs of $68,106 have been incurred pursuant to this agreement. The Company's aggregate commitment pursuant to this agreement, less amounts previously paid to date, totaled approximately $1,795,000 as of September 30, 2024, which is expected to be incurred over approximately the next twenty years.

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.

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 was 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.

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, 2024 and 2023, respectively. Consulting and advisory fees charged to operations pursuant to this agreement were $12,000 and $12,000 for the nine months ended September 30, 2024 and 2023, respectively. This agreement was terminated effective July 3, 2024.

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 fee. Effective March 1, 2024, the compensation payable under the Collaboration Agreement was converted to an hourly rate structure.

The Company recorded charges to operations pursuant to this Collaboration Agreement of $8,000 and $30,000 during the three months ended September 30, 2024 and 2023, respectively, which were included in research and development costs in the consolidated statements of operations. The Company recorded charges to operations pursuant to this Collaboration Agreement of $35,200 and $90,000 during the nine months ended September 30, 2024 and 2023, 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 5), 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 a preclinical study 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 preclinical study, at an approximate cost of 391,000 Euros and provide a sufficient supply of LB-100 to conduct the preclinical 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 added 500,000 Euros to the operating budget being funded by the Company.

During the three months ended September 30, 2024 and 2023, the Company incurred charges in the amount of $76,278 and $51,568, 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, 2024 and 2023, the Company incurred charges in the amount of $210,362 and $156,950, 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, 2024, total costs of $695,918 have been incurred pursuant to this agreement. The Company's aggregate commitment pursuant to this agreement, less amounts previously paid to date, totaled approximately $279,000 as of September 30, 2024, 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. As amended, the Company has contracted with MRI Global for stability analysis, storage and distribution of LB-100 for clinical trials in the United States. During the three months ended September 30, 2024 and 2023, the Company incurred costs of $9,062 and $21,045, respectively, pursuant to this contract. During the nine months ended September 30, 2024 and 2023, the Company incurred costs of $18,932 and $30,628, respectively, pursuant to this contract. As of September 30, 2024, total costs of $334,147 have been incurred pursuant to this contract.

The Company's aggregate commitment pursuant to this contract, less amounts previously paid to date, totaled approximately $124,000 as of September 30, 2024.

Specific Risks Associated with the Company's Business Activities

Serious Adverse Events

The Company's lead drug candidate, LB-100, is currently undergoing various clinical trials, and there is a risk that one or more of these trials could be placed on hold by regulatory authorities due to serious adverse events (SAEs) related to our drug candidate or to another company's drug used in combination in one of our clinical trials. It is possible that the SAEs could be attributable to our drug candidate and could include, but not be limited to, unexpected severe side effects, treatment-related deaths, or long-term health complications. A dose given could result in non-tolerable adverse events defined as dose-limiting toxicity (DLT). When two DLTs occur at the same dose-level that dose-level is considered too high and unsafe. Further treatment is only allowed at lower dose-levels that have previously been found safe.

If an SAE or a pattern of SAEs is observed during the course of a clinical trial involving our drug candidate, the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), or other regulatory authorities may issue a clinical hold, requiring us to pause or discontinue further enrollment and dosing in our clinical trial. It is also possible that the clinical trial could be terminated. Any of these actions could delay or halt the development of our drug candidate, increase development costs, and negatively impact our ability to ultimately achieve regulatory approval. Additionally, if an SAE is confirmed to be drug-related, we may be required to conduct additional studies, modify the study design, or abandon further development of the drug candidate altogether, which could materially impact our business, financial condition, and prospects.

The occurrence of an SAE and any resulting clinical hold could also harm our reputation with patients, physicians, health institutions, and investors, diminish our ability to attract clinical trial participants, and damage our ability to interest investors and obtain financing in the future. There can be no assurance that we will not experience such SAEs in the future or that any related clinical hold will be lifted in a timely manner, or at all.

The principal investigator of the colorectal study testing LB-100 in combination with atezolizumab (Roche PD-L1 inhibitor) is currently investigating two SAEs observed in the clinical trial that was launched in August 2024. Evaluation is underway to determine next steps.

Other Business 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. Although the Covid-19 outbreak has subsided, the extent to which the coronavirus or any other pandemics may reappear and impact the Company's clinical trial programs and capital raising efforts in the future is uncertain and cannot be predicted.

Inflation and Interest Rate Risk. The Company does not believe that inflation or increasing interest rates 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 some indications that the United States economy may be at risk of 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.

Geopolitical Risk. The geopolitical landscape poses inherent risks that could significantly impact the operations and financial performance of the Company. In the event of a military conflict, supply chain disruptions, geopolitical uncertainties, and economic repercussions may adversely affect the Company's ability to conduct research, develop, test and manufacture products, and distribute them globally. This could lead to delays in product development, interruptions in the supply of critical materials, and delays in clinical trials, thereby impeding the Company's clinical development and commercialization plans. Furthermore, the impact of a conflict on global financial markets may result in increased volatility and uncertainty in the capital markets, thereby affecting the valuation of the Company's publicly-traded shares. Investor confidence, market sentiment, and access to capital may all be negatively influenced. Such geopolitical risks are outside the control of the Company, and the actual effects on the Company's business, financial condition and results of operations may differ from current estimates.

Cybersecurity Risks. The Company has established policies and processes for assessing, identifying and managing material risk from cybersecurity threats, and has integrated these processes into its overall risk management systems and processes. The Company routinely assesses material risks from cybersecurity threats, including any potential unauthorized occurrence on or conducted through its information and email systems that may result in adverse effects on the confidentiality, integrity, or availability of the Company's information and email systems or any information residing therein. The Company conducts periodic risk assessments to identify cybersecurity threats, as well as assessments in the event of a material change in the Company's business practices that may affect information systems that are vulnerable to such cybersecurity threats. These risk assessments include identification of reasonably foreseeable internal and external risks, the likelihood and potential damage that could result from such risks, and the sufficiency of existing policies, procedures, systems and safeguards in place to manage such risks. The Company has not encountered any cybersecurity challenges that have materially impaired its operations or financial condition. Additional information regarding risks from cybersecurity threats is provided in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

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

9. Subsequent Events

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

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

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, 2023, 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 clinical-stage biopharmaceutical company focused on identifying new targets for cancer drug development and developing and commercializing cancer therapies. The Company's corporate office is located in Pasadena, California.

The Company's product pipeline is primarily focused on inhibitors of Protein Phosphatase 2A, which is used to enhance cytotoxic agents, radiation, immune checkpoint blockers and other cancer therapies. The Company believes that inhibitors of protein phosphatases have significant therapeutic potential for a broad range of cancers. The Company is focusing on the 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.

Recent Developments

On September 4, 2024, the Company announced it had received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for U.S. Patent application number 16/467,721, titled, "Oxabicycloheptanes for Modulation of Immune Response," for combining the Company's lead compound, LB-100, with various innovative cancer immunotherapies.

Going Concern

For the nine months ended September 30, 2024, the Company recorded a net loss of $2,968,271 and used cash in operations of $2,565,861. At September 30, 2024, the Company had cash of $1,637,627 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, 2024, the Company's remaining financial contractual commitments pursuant to clinical trial agreements and clinical trial monitoring agreements not yet incurred aggregated approximately $3,918,000, 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 consolidated financial statements also do not reflect any adjustments relating to the recoverability of assets and liabilities that might be necessary if the Company is unable to continue as a going concern. The Company has no recurring source of revenues 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 consolidated financial statements are being issued. In addition, our independent registered public accounting firm has included an explanatory paragraph in their report with respect to this uncertainty that accompanies our audited consolidated financial statements as of and for the year ended December 31, 2023. The Company's consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company's ability to continue as a going concern is dependent upon its ability to raise additional equity capital to fund its research and development activities and to ultimately achieve sustainable operating revenues and profitability. The amount and timing of future cash requirements depends on the pace, 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, 2024 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 the first quarter of 2025. As existing cash resources will not be sufficient to complete the clinical development of, and obtain regulatory approval for, the Company's product candidate, the Company will need to raise additional capital in one or more tranches to fund its operations during the next few months in order to be able to effectively manage its current business plan during 2025 and thereafter, as well as to maintain its listing on Nasdaq. Furthermore, the Company's operating plans and capital requirements may change as a result of many factors that are currently unknown and/or outside of the control of the Company. The Company is considering various strategies and alternatives to obtain the required additional capital.

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, 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.

Nasdaq Compliance

The Company's common stock and the warrants are traded on the Nasdaq Capital Market ("Nasdaq") under the symbols "LIXT" and "LIXTW", respectively. On June 2, 2023, the Company effected a 1-for-10 reverse split of its outstanding shares of common stock in order to remain in compliance with the $1.00 minimum closing bid price requirement of Nasdaq. However, there can be no assurances that the Company will be able to remain in compliance with the $1.00 minimum closing bid price requirement of Nasdaq over time. In addition, Nasdaq has other continued listing requirements, one of which is maintaining a minimum net stockholders' equity of $2,500,000.

On August 19, 2024, the Company received a deficiency letter from the Listing Qualifications Department of Nasdaq indicating that it was not in compliance with Nasdaq Listing Rule 5550(b)(1) (the "Stockholders' Equity Rule"), which requires the Company to maintain a minimum stockholders' equity of $2,500,000. This notice of non-compliance has no immediate impact on the continued listing or trading of the Company's securities on Nasdaq, which will continue to be listed and traded on Nasdaq, subject to the Company's compliance with the other Nasdaq continued listing requirements.

On October 3, 2024, the Company submitted a letter to Nasdaq with its plan to regain compliance with the Stockholders' Equity Rule, which outlined the Company's proposed initiatives to regain compliance by raising equity capital through various registered equity offerings.

On October 21, 2024, Nasdaq provided the Company notice that it had granted an extension through February 18, 2025 for the Company to regain compliance with the Stockholders' Equity Rule. The Company must complete its capital raising initiatives and evidence compliance with the Stockholders' Equity Rule through filing a Current Report on Form 8-K with the SEC providing certain required information by February 18, 2025.

If the Company fails to evidence compliance with the Stockholders' Equity Rule upon filing its periodic report for the quarter ending March 31, 2025 with the SEC, the Company may be subject to delisting. If Nasdaq determines to delist the Company's common stock, the Company will have the right to appeal to a Nasdaq hearings panel. The hearing request would stay any suspension or delisting action pending the conclusion of the hearing process.

The Company intends to take reasonable measures available to regain compliance under Nasdaq's listing rules and to remain listed on Nasdaq. However, there can be no assurances that the Company will ultimately regain compliance with the Stockholders' Equity Rule, or be able to maintain compliance with all other applicable requirements for continued listing on Nasdaq. If the Company does not regain compliance with Nasdaq's listing rules within the time period permitted by Nasdaq, then the Company's securities will be delisted from Nasdaq.

Recent Accounting Pronouncements

Information with respect to recent accounting pronouncements is provided at Note 2 to the condensed consolidated financial statements for the three months and nine months ended September 30, 2024 and 2023 included elsewhere in this document.

Concentration of Risk

Information with respect to concentration of risk is provided at Note 2 to the condensed consolidated financial statements for the three months and nine months ended September 30, 2024 and 2023 included elsewhere in this document.

Critical Accounting Policies and 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, and valuing equity instruments issued for services.

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 consisted of the development of a drug class called Protein Phosphatase 2A inhibitors. 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, conduct 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 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, 2024 and 2023, patent and licensing legal and filing fees and costs related to the development and protection of its intellectual property were $45,416 and $178,012, respectively, a decrease of $132,596, or 74.5%, in 2024 as compared to 2023.

During the nine months ended September 30, 2024 and 2023, patent and licensing legal and filing fees and costs related to the development and protection of its intellectual property were $192,239 and $835,362, respectively, a decrease of $643,123, or 77.0%, in 2024 as compared to 2023.

In September 2023, the Company appointed a new President and Chief Executive Officer, who, with the assistance of the Company's management, Board of Directors and patent legal counsel, conducted a comprehensive analysis of the Company's extensive patent portfolio in order to implement a program to balance patent prosecution costs with intellectual property protection benefits. As a result, the Company identified certain patent filings that it does not intend to continue to support in 2024 and thereafter. In addition, effective July 1, 2024, the Company changed its intellectual property law firm. The Company expects that patent and licensing legal and filing fees and costs will continue to be a significant continuing cost in 2024 and thereafter as the Company continues 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, 2023.

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. The Company has determined that the warrants issued in the July 20, 2023 equity financing meet the requirements 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 of 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 that are liability classified are recognized as a non-cash gain or loss in the statement of operations.

Summary of Business Activities and Plans

Company Overview

The Company is focusing its development activities on its lead compound LB-100. The Company believes that the mechanism by which LB-100 affects cancer cell growth is different from cancer agents currently approved for clinical use. LB-100 is currently being tested in clinical trials in Ovarian Clear Cell Carcinoma, Metastatic Micro Satellite Stable (MSS) Colon Cancer and Advanced Soft Tissue Sarcoma. LB-100 has shown anti-cancer activity in animal models of glioblastoma multiforme, neuroblastoma, and medulloblastoma, all cancers of neural tissue. LB-100 enhances the effectiveness of commonly used anti-cancer drugs in melanoma, breast cancer and sarcoma 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, LB-100 will improve therapeutic benefit.

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.

Intellectual Property

The Company's intellectual property includes proprietary know-how, proprietary methodologies and extensive clinical validation data and publications. To provide legal protection of the Company's intellectual property, the Company relies on a combination of patents, licenses, trade secrets, trademarks, confidentiality and non-disclosure clauses and agreements, and other forms of intellectual property protection to define and protect our rights to the Company's product candidates.

The Company's product candidates are expected to be covered by its patents. These patents now cover sole rights to the composition and synthesis of the Company's LB-100 series of drugs, which is the Company's lead clinical compound in development. The Company has filed patent applications covering the treatment of cancer with LB-100. The Company has also filed joint patent applications with the NIH and the Netherlands Cancer Institute for the treatment of cancer using LB-100 in combination with other drugs such as an immune checkpoint inhibitor and a WEE1 inhibitor.

Patent applications for the LB-100 series (oxabicycloheptanes and oxabicycloheptenes) have been filed in the United States and internationally under the Patent Cooperation Treaty. Patents for composition of matter and for several uses of the LB-100 series have been issued in the United States, Mexico, Australia, Japan, China, Hong Kong, Canada, and by the European Patent Office

The Company strives to protect and enhance the proprietary technology, inventions, and improvements that are commercially important to the development of its business, including seeking, maintaining, and defending its patent rights, which are owned solely by the Company's wholly-owned Delaware subsidiary, Lixte Biotechnology, Inc., except in several instances jointly with one of the Company's many collaborators. The Company also relies on trade secrets relating to its proprietary pipeline of product candidates and on know-how and continuing technological innovation to develop and strengthen its pipeline. The Company intend to rely on regulatory protection afforded by regulatory agencies through data exclusivity, market exclusivity, and patent term extensions, where available.

The Company's success will depend in large part on its ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to its business; defend and enforce its patents; preserve the confidentiality of its trade secrets; and operate without infringing valid and enforceable patents or proprietary rights of third parties. The Company's ability to stop third parties from making, using, selling, offering to sell, or importing its technology may depend on the extent to which the Company has rights under valid and enforceable licenses, patents, or trade secrets that cover these activities. In some cases, enforcement of these rights may depend on cooperation of the joint owners of the Company's jointly owned patents and patent applications.

With respect to both the Company's solely and jointly owned intellectual property, the Company cannot be sure that patents will be granted on any of its pending patent applications or on any patent applications filed solely or jointly by the Company in the future; the Company cannot be sure that any of its existing patents or any patents that may be granted to the Company in the future will be commercially useful in protecting the Company's intended commercial products or therapeutic methods; and the Company cannot be sure that an agency or court would determine that its solely or jointly owned patents are valid and enforceable.

Specific Risks Associated with the Company's Business Activities

Serious Adverse Events

The Company's lead drug candidate, LB-100, is currently undergoing various clinical trials, and there is a risk that one or more of these trials could be placed on hold by regulatory authorities due to serious adverse events (SAEs) related to our drug candidate or to another company's drug used in combination in one of our clinical trials. It is possible that the SAEs could be attributable to our drug candidate and could include, but not be limited to, unexpected severe side effects, treatment-related deaths, or long-term health complications. A dose given could result in non-tolerable adverse events defined as dose-limiting toxicity (DLT). When two DLTs occur at the same dose-level that dose-level is considered too high and unsafe. Further treatment is only allowed at lower dose-levels that have previously been found safe.

If an SAE or a pattern of SAEs is observed during the course of a clinical trial involving our drug candidate, the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), or other regulatory authorities may issue a clinical hold, requiring us to pause or discontinue further enrollment and dosing in our clinical trial. It is also possible that the clinical trial could be terminated. Any of these actions could delay or halt the development of our drug candidate, increase development costs, and negatively impact our ability to ultimately achieve regulatory approval. Additionally, if an SAE is confirmed to be drug-related, we may be required to conduct additional studies, modify the study design, or abandon further development of the drug candidate altogether, which could materially impact our business, financial condition, and prospects.

The occurrence of an SAE and any resulting clinical hold could also harm our reputation with patients, physicians, health institutions, and investors, diminish our ability to attract clinical trial participants, and damage our ability to interest investors and obtain financing in the future. There can be no assurance that we will not experience such SAEs in the future or that any related clinical hold will be lifted in a timely manner, or at all.

The principal investigator of the colorectal study testing LB-100 in combination with atezolizumab (Roche PD-L1 inhibitor) is currently investigating two SAEs observed in the clinical trial that was launched in August 2024. Evaluation is underway to determine next steps.

Other Business 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. Although Covid-19 outbreak has subsided, the extent to which the coronavirus or any other pandemics may reappear and impact the Company's clinical trial programs and capital raising efforts in the future is uncertain and cannot be predicted.

Inflation and Interest Rate Risk. The Company does not believe that inflation or increasing interest rates 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 some indications that the United States economy may be at risk of 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.

Geopolitical Risk. The geopolitical landscape poses inherent risks that could significantly impact the operations and financial performance of the Company. In the event of a military conflict, supply chain disruptions, geopolitical uncertainties, and economic repercussions may adversely affect the Company's ability to conduct research, develop, test and manufacture products, and distribute them globally. This could lead to delays in product development, interruptions in the supply of critical materials, and delays in clinical trials, thereby impeding the Company's clinical development and commercialization plans. Furthermore, the impact of a conflict on global financial markets may result in increased volatility and uncertainty in the capital markets, thereby affecting the valuation of the Company's publicly-traded shares. Investor confidence, market sentiment, and access to capital may all be negatively influenced. Such geopolitical risks are outside the control of the Company, and the actual effects on the Company's business, financial condition and results of operations may differ from current estimates.

Cybersecurity Risks. The Company has established policies and processes for assessing, identifying and managing material risk from cybersecurity threats, and has integrated these processes into its overall risk management systems and processes. The Company routinely assesses material risks from cybersecurity threats, including any potential unauthorized occurrence on or conducted through its information and email systems that may result in adverse effects on the confidentiality, integrity, or availability of the Company's information and email systems or any information residing therein. The Company conducts periodic risk assessments to identify cybersecurity threats, as well as assessments in the event of a material change in the Company's business practices that may affect information systems that are vulnerable to such cybersecurity threats. These risk assessments include identification of reasonably foreseeable internal and external risks, the likelihood and potential damage that could result from such risks, and the sufficiency of existing policies, procedures, systems and safeguards in place to manage such risks. The Company has not encountered any cybersecurity challenges that have materially impaired its operations or financial condition. Additional information regarding risks from cybersecurity threats is provided in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

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, 2024, 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,	
	2024	2023	2024	2023
Revenues	$ —	$ —	$ —	$ —
Costs and expenses:				
General and administrative costs:				
Compensation to related parties	283,053	356,001	907,069	1,398,042
Patent and licensing legal and filing fees and costs	45,416	178,012	192,239	835,362
Other costs and expenses	293,158	357,681	1,168,582	1,081,893
Research and development costs	361,630	132,487	691,402	749,029
Total costs and expenses	983,257	1,024,181	2,959,292	4,064,326
Loss from operations	(983,257)	(1,024,181)	(2,959,292)	(4,064,326)
Interest income	1,437	5,809	6,529	13,538
Interest expense	(1,049)	(279)	(12,389)	(6,088)
Foreign currency gain (loss)	(3,161)	(109)	(3,119)	2,102
Net loss	$ (986,030)	$ (1,018,760)	$ (2,968,271)	$ (4,054,774)
Net loss per common share – basic and diluted	$ (0.44)	$ (0.49)	$ (1.32)	$ (2.25)
Weighted average common shares outstanding – basic and diluted	2,249,290	2,074,938	2,249,290	1,803,466

Three Months Ended September 30, 2024 and 2023

Revenues. The Company did not have any revenues for the three months ended September 30, 2024 and 2023.

General and Administrative Costs. For the three months ended September 30, 2024, general and administrative costs were $621,627, which consisted of the fair value of vested stock options issued to directors and officers of $106,827 (including quarterly director and board committee fees of $27,500), patent and licensing legal and filing fees and costs of $45,416, other consulting and professional fees of $146,610, insurance expense of $116,440, officer salaries and related costs of $161,728, cash-based director and board committee fees of $0, licensing and royalties of $7,537, shareholder reporting costs of $2,941, listing fees of $12,375, filing fees of $2,864, taxes and licenses of $56, investor relations of $13,397, rent of $3,218, and other operating costs of $2,218.

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 (including quarterly director and board committee fees of $0), 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 and royalties of $21,507 relating to the termination of the Moffitt agreement.

General and administrative costs decreased by $270,067, or 30.3%, in 2024 as compared to 2023, primarily as a result of a decrease in the fair value of vested stock options issued to directors and officers of $5,279, a decrease in patent and licensing legal and filing fees and costs of $132,596, a decrease in officer salaries and related costs of $55,152, a decrease in cash-based director and board committee fees of $42,228, and a decrease in other consulting and professional fees of $53,274, offset by an increase in licensing and royalties of $29,044.

Research and Development Costs. For the three months ended September 30, 2024, research and development costs were $361,630, which consisted of clinical and related oversight costs of $250,342, regulatory service costs of $11,405, and preclinical research focused on development of additional novel anti-cancer compounds to add to the Company's clinical pipeline of $99,883.

Included in clinical and related oversight costs for the three months ended September 30, 2024 is $207,004 for the cost of patients enrolled in the City of Hope clinical trial prior to its termination on July 8, 2024.

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.

Effective June 10, 2024, the Company entered into a Clinical Trial Agreement with the Netherlands Cancer Institute ("NKI") to conduct a Phase 1b/2 clinical trial of the Company's protein phosphatase inhibitor, LB-100, combined with atezolizumab, a PD-L1 inhibitor, the proprietary molecule of F. Hoffman-La Roche Ltd. ("Roche"), for patients with metastatic colon cancer. NKI employs Dr. René Bernards, a director of the Company since June 15, 2022. The Company has no financial contractual commitment associated with this clinical trial.

Included in preclinical research costs for the three months ended September 30, 2024 and 2023 were $76,278 and $51,568, respectively, of costs paid to the Netherlands Cancer Institute, 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 potential 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 added 500,000 Euros 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 increased by $229,143, or 173.0%, in 2024 as compared to 2023, primarily as a result of a charge of $207,004 for the cost of patients enrolled in the City of Hope clinical trial prior to its termination on July 8, 2024.

Interest Income. For the three months ended September 30, 2024, the Company had interest income of $1,437, as compared to interest income of $5,809 for the three months ended September 30, 2023, related to the investment of the Company's cash resources.

Interest Expense. For the three months ended September 30, 2024, the Company had interest expense of $1,049, as compared to interest expense of $279 for the three months ended September 30, 2023, 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, 2024, the Company had a foreign currency loss of $3,161, as compared to a foreign currency loss of $109 for the three months ended September 30, 2023, from foreign currency transactions.

Net Loss. For the three months ended September 30, 2024, the Company incurred a net loss of $986,030, as compared to a net loss of $1,018,760 for the three months ended September 30, 2023.

Nine Months Ended September 30, 2024 and 2023

Revenues. The Company did not have any revenues for the nine months ended September 30, 2024 and 2023.

General and Administrative Costs. For the nine months ended September 30, 2024, general and administrative costs were $2,267,890, which consisted of the fair value of vested stock options issued to directors and officers of $340,445 (including quarterly director and board committee fees of $55,000), patent and licensing legal and filing fees and costs of $192,239, other consulting and professional fees of $510,582, insurance expense of $370,167, officer salaries and related costs of $549,317, cash-based director and board committee fees of $38,819, licensing and royalties of $68,106, shareholder reporting costs of $15,690, listing fees of $37,125, filing fees of $21,917, taxes and licenses of $30,869, investor relations of $48,191, rent of $13,099, conference fees of $14,475 and other operating costs of $16,849.

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, conference fees of $0 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.

General and administrative costs decreased by $1,047,407, or 31.6%, in 2024 as compared to 2023, primarily as a result of a decrease in the fair value of vested stock options issued to directors and officers of $328,701, a decrease in patent and licensing legal and filing fees and costs of $643,123, a decrease in shareholder reporting costs of $49,093, a decrease in officer salaries and related costs of $100,166, and a decrease in cash-based director and board committee fees of $88,410, offset by increases in licensing and royalties of $77,215, taxes and licenses of $19,386, and in insurance expense of $53,953.

Research and Development Costs. For the nine months ended September 30, 2024, research and development costs were $691,402, which consisted of clinical and related oversight costs of $358,318, regulatory service costs of $14,021, and preclinical research focused on development of additional novel anti-cancer compounds to add to the Company's clinical pipeline of $319,063.

Included in clinical and related oversight costs for the nine months ended September 30, 2024 is $207,004 for the cost of patients enrolled in the City of Hope clinical trial prior to its termination on July 8, 2024.

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 preclinical research focused on development of additional novel anti-cancer compounds to add to the Company's clinical pipeline of $339,583.

Effective June 10, 2024, the Company entered into a Clinical Trial Agreement with the Netherlands Cancer Institute ("NKI") to conduct a Phase 1b/2 clinical trial of the Company's protein phosphatase inhibitor, LB-100, combined with atezolizumab, a PD-L1 inhibitor, the proprietary molecule of F. Hoffman-La Roche Ltd. ("Roche"), for patients with metastatic colon cancer. NKI employs Dr. René Bernards, a director of the Company since June 15, 2022. The Company has no financial contractual commitment associated with this clinical trial.

Included in preclinical research costs for the nine months ended September 30, 2024 and 2023 were $210,362 and $156,950, respectively, of costs paid to the Netherlands Cancer Institute, 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 potential 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 added 500,000 Euros 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 $57,627, or 7.7%, in 2024 as compared to 2023, primarily as a result of a decrease in clinical and related oversight costs of $32,390.

Interest Income. For the nine months ended September 30, 2024, the Company had interest income of $6,529, as compared to interest income of $13,538 for the nine months ended September 30, 2023, related to the investment of the Company's cash resources.

Interest Expense. For the nine months ended September 30, 2024, the Company had interest expense of $12,389, as compared to interest expense of $6,088 for the nine months ended September 30, 2023, 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, 2024, the Company had a foreign currency loss of $3,119, as compared to a foreign currency gain of $2,102 for the nine months ended September 30, 2023, from foreign currency transactions.

Net Loss. For the nine months ended September 30, 2024, the Company incurred a net loss of $2,968,271, as compared to a net loss of $4,054,774 for the nine months ended September 30, 2023.

Liquidity and Capital Resources – September 30, 2024

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

	Nine Months Ended September 30,	
	2024	**2023**
Net cash used in operating activities	$ (2,565,861)	$ (3,391,142)
Net cash provided by (used in) investing activities	—	—
Net cash provided by financing activities	—	3,143,361
Net decrease in cash	$ (2,565,861)	$ (247,781)

At September 30, 2024, the Company had working capital of $1,360,008, as compared to working capital of $3,994,762 at December 31, 2023, reflecting a decrease in working capital of $2,634,754 for the nine months ended September 30, 2024. The decrease in working capital during the nine months ended September 30, 2024 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 the Company's patent portfolio. At September 30, 2024, the Company had cash of $1,637,627 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, 2024 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 the first quarter of 2025. As existing cash resources will not be sufficient to complete the clinical development of, and obtain regulatory approval for, the Company's product candidate, the Company will need to raise additional capital in one or more tranches to fund its operations during the next few months in order to be able to effectively manage its current business plan during 2025 and thereafter, as well as to maintain its listing on Nasdaq. Furthermore, the Company's operating plans and capital requirements may change as a result of many factors that are currently unknown and/or outside of the control of the Company. The Company is considering various strategies and alternatives to obtain the required additional capital.

At September 30, 2024, the Company's remaining financial contractual commitments pursuant to clinical trial agreements and clinical trial monitoring agreements not yet incurred aggregated $3,918,000, which are currently scheduled to be incurred through approximately December 31, 2027.

At September 30, 2024, 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, 2024, operating activities utilized cash of $2,565,861, as compared to utilizing cash of $3,391,142 for the nine months ended September 30, 2023, 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, 2024 and 2023, the Company had no investing activities.

Financing Activities. For the nine months ended September 30, 2024, the Company had no 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.

Principal Commitments

Clinical Trial Agreements

At September 30, 2024, the Company's remaining financial contractual commitments pursuant to clinical trial agreements and clinical trial monitoring agreements not yet incurred, as described below, aggregated $3,918,000, including clinical trial agreements of $3,616,000 and clinical trial monitoring agreements of $302,000, 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 is obtained and analyzed, and is frequently modified, suspended or terminated, in part based on receipt or lack of receipt of an indication of clinical benefit or activity, 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 Company's ongoing contractual clinical trials described below as of September 30, 2024:

Description of Clinical Trial	Institution	Start Date	Projected End Date	Number of Patients in Trial	Study Objective	Clinical Update	Expected Date of Preliminary Efficacy Signal	NCT No.	Remaining Financial Contractual Commitment
LB-100 combined with atezolizumab in microsatellite stable metastatic colon cancer (Phase 1b)	Netherlands Cancer Institute (NKI)	August 2024	December 2026	37	Determine RP2D with atezolizumab	First patient entered August 2024	June 2026	NCT06012734	(1)
LB-100 combined with doxorubicin in advanced soft tissue sarcoma (Phase 1b)	GEIS	June 2023	Recruitment completed September 2024	9 to 18	Determine MTD and RP2D	Fourteen patients entered	March 2025	NCT05809830	$ 284,000
Doxorubicin with or without LB-100 in advanced soft tissue sarcoma (Randomized Phase 2)	GEIS	TBD	TBD	150	Determine efficacy: PFS	Clinical trial not yet begun (subject to completion of Phase 1b GEIS clinical trial)	December 2026	NCT05809830	$ 3,332,000
LB-100 combined with dostarlimab in ovarian clear cell carcinoma (Phase 1b/2)	MD Anderson	January 2024	December 2027	21	Determine the OS of patients with recurrent ovarian clear cell carcinoma	Seven patients entered	December 2026	NCT06065462	(1)
Total									$ 3,616,000

(1) The Company has no financial contractual commitment associated with this clinical trial at September 30, 2024.

Netherlands Cancer Institute. Effective June 10, 2024, the Company entered into a Clinical Trial Agreement with the Netherlands Cancer Institute ("NKI") to conduct a Phase 1b clinical trial of the Company's protein phosphatase inhibitor, LB-100, combined with atezolizumab, a PD-L1 inhibitor, the proprietary molecule of F. Hoffman-La Roche Ltd. ("Roche"), for patients with microsatellite stable metastatic colon cancer. Under the agreement, the Company will provide its lead compound, LB-100, and under a separate agreement between NKI and Roche, Roche will provide atezolizumab and financial support for the clinical trial. The Company has no obligation to and will not provide any reimbursement of clinical trial costs. Pursuant to the agreement and the protocol set forth in the agreement, the clinical trial will be conducted by NKI at NKI's site in Amsterdam by principal investigator Neeltje Steeghs, MD, PhD, and NKI will be responsible for the recruitment of patients. The agreement provides for the protection of the respective intellectual property rights of each of the Company, NKI and Roche.

This Phase 1b clinical trial will evaluate safety, optimal dose and preliminary efficacy of LB-100 combined with atezolizumab for the treatment of patients with metastatic microsatellite stable colorectal cancer. Immunotherapy using monoclonal antibodies like atezolizumab can enhance the body's immune response against cancer and hinder tumor growth and spread. LB-100 has been found to improve the effectiveness of anticancer drugs in killing cancer cells by inhibiting a protein called PP2A on cell surfaces. Blocking PP2A increases stress signals in tumor cells expressing the PP2A protein. Accordingly, combining atezolizumab with LB-100 may enhance treatment efficacy for metastatic colorectal cancer, as cancer cells with heightened stress signals are more vulnerable to immunotherapy.

This study comprises a dose escalation phase and a dose expansion phase. The objective of the dose escalation phase is to determine the recommended Phase 2 dose (RP2D) of LB-100 when combined with the standard dosage of atezolizumab. The dose expansion phase will further investigate the preliminary efficacy, safety, tolerability, and pharmacokinetics/dynamics of the LB-100 and atezolizumab combination. The clinical trial opened in August 2024 with the enrollment of the first patient. Patient accrual is expected to take up to 24 months, with a maximum of 37 patients with advanced colorectal cancer to be enrolled in this study.

The principal investigator of the colorectal study testing LB-100 in combination with atezolizumab is currently investigating two Serious Adverse Events ("SAEs") observed in the clinical trial. Evaluation is underway to determine next steps (see "Serious Adverse Events" below for additional information).

The Company has no financial contractual commitment associated with this clinical trial.

City of Hope. Effective January 18, 2021, the Company executed a Clinical Research Support Agreement (the "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 was given in combination with carboplatin, etoposide and atezolizumab, an FDA-approved standard of care regimen, to previously untreated ED-SCLC patients. The LB-100 dose was to be escalated with the standard fixed doses of the 3-drug regimen to reach a recommended Phase 2 dose ("RP2D"). Patient entry was to be expanded so that a total of 12 patients would 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. Because patient accrual was slower than expected, effective March 6, 2023, the Company and City of Hope added the Sarah Cannon Research Institute ("SCRI"), Nashville, Tennessee, to the ongoing Phase 1b clinical trial. The Company and City of Hope continued efforts to increase patient accrual by adding additional sites and by modifying the protocol to increase the number of patients eligible for the clinical trial. The impact of these efforts to increase patient accrual and to decrease time to completion was evaluated in subsequent quarters.

After evaluating patient accrual through June 30, 2024, the Company and City of Hope agreed to close the clinical trial. Pursuant to the terms of the Agreement, the Company provided notice to City of Hope of the Company's intent to terminate the Agreement effective as of July 8, 2024. Upon closure, the Company incurred a prorated charge of $207,004 for the cost of patients enrolled to date. The Company is exploring alternative sites, including international locations, for the conduct of a small cell lung cancer clinical trial.

During the three months ended September 30, 2024 and 2023, the Company incurred costs of $207,004 and $0, respectively, pursuant to this Agreement. During the nine months ended September 30, 2024 and 2023, the Company incurred costs of $285,019 and $69,001, respectively, pursuant to this Agreement. As of September 30, 2024, total costs of $732,532 had been incurred pursuant to this Agreement.

GEIS. Effective July 31, 2019, the Company entered into a Collaboration Agreement for an Investigator-Initiated Clinical Trial with the Spanish Sarcoma Group (Grupo Español de Investigación en Sarcomas or "GEIS"), Madrid, Spain, to carry out a study entitled "Randomized phase I/II trial of LB-100 plus doxorubicin vs. doxorubicin alone in first line of advanced soft tissue sarcoma". The purpose of this clinical trial is to obtain information 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 improvement in survival 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 to four years. The Phase 1 portion of the study began in the quarter ended June 30, 2023 to determine the recommended Phase 2 dose of the combination of doxorubicin and LB-100. As advanced sarcoma is a very aggressive disease, the design of the Phase 2 portion 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 practice (GMP) of the active pharmaceutical 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 December 31, 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.

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 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 patents will be entered into the clinical trial. The recruitment for the Phase 1b portion of the protocol was extended with two patients and was completed during the quarter ended September 30, 2024. The Company expects to have data on toxicity and preliminary efficacy from this portion of the clinical trial by December 31, 2024, and a full report by June 30, 2025. Subject to clinical results and the availability of sufficient working capital resources, the Company anticipates that it will then be in a position to decide whether to proceed to the related Phase 2 portion of the study.

The interim analysis of the Phase 2 portion 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, 2024 and 2023, the Company did not incur any costs pursuant to this agreement. During the nine months ended September 30, 2024 and 2023, the Company incurred costs of $0 and $268,829, respectively, pursuant to this agreement. Through September 30, 2024, the Company has incurred charges 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 $3,616,000 (consisting of $284,000 for the Phase 1b portion and $3,332,000 for the Phase 2 portion) as of September 30, 2024, which is scheduled 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, and have not been significant.

MD Anderson Cancer Center Clinical Trial. On September 20, 2023, the Company announced an investigator-initiated Phase 1b/2 collaborative clinical trial to assess whether adding LB-100 to a human programmed death receptor-1 ("PD-1") blocking antibody of GSK plc ("GSK"), dostarlimab-gxly, may enhance the effectiveness of immunotherapy in the treatment of ovarian clear cell carcinoma ("OCCC"). The study objective is to determine the overall survival ("OS") of patients with OCCC. The clinical trial is being sponsored by The University of Texas MD Anderson Cancer Center ("MD Anderson") and is being conducted at The University of Texas - MD Anderson Cancer Center. The Company is providing LB-100 and GSK is providing dostarlimab-gxly and financial support for the clinical trial. On January 29, 2024, the Company announced the entry of the first patient into this clinical trial. The Company currently expects that this clinical trial will be completed by December 31, 2027.

Moffitt. Effective August 20, 2018, the Company entered into a Clinical Trial Research Agreement with the Moffitt Cancer Center and Research Institute Hospital Inc., Tampa, Florida ("Moffitt"), effective for a term of five years. 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 ("IND") 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 had failed or were intolerant of standard treatment. 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.

The clinical trial began at a single site in April 2019 and the first patient was entered into the clinical trial in July 2019. During the year ended December 31, 2023, the clinical trial was closed. Although the maximum tolerated dose ("MTD") was not achieved, there was no dose-limiting toxicity noted.

During the three months and nine months ended September 30, 2024 and 2023, the Company did not incur any costs pursuant to this agreement. As of September 30, 2024, total costs of $147,239 had been incurred pursuant to this agreement.

During September 2023, the Company decided not to pursue further studies in MDS, as other, more promising, opportunities had become available (see "Patent and License Agreements - Moffitt" below).

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. 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. Blood and brain tumor tissue were analyzed from seven patients after intravenous infusion of a single dose of LB-100. Results of the investigation demonstrated that there was virtually no entry of LB-100 into the brain tumor tissue. Accordingly, alternative methods of drug delivery will be required to determine if LB-100 has meaningful clinical anti-cancer activity against glioblastoma multiforme and other aggressive brain tumors. The Company is considering an additional clinical study to address the delivery of LB-100 to the brain.

Clinical Trial Monitoring Agreements

MD Anderson Cancer Center Clinical Trial. On May 15, 2024, the Company signed a letter of intent with Theradex to monitor the MD Andersen investigator-initiated Phase 1b/2 collaborative clinical trial to assess whether adding LB-100 to a human programmed death receptor-1 ("PD-1") blocking antibody of GSK plc ("GSK"), dostarlimab-gxly, may enhance the effectiveness of immunotherapy in the treatment of ovarian clear cell carcinoma ("OCCC"). On August 19, 2024, the Company signed a work order agreement with Theradex to monitor the MD Anderson clinical trial. The study oversight is expected to be completed by January 31, 2027.

Costs under this letter of intent and related work order agreement are estimated to be approximately $95,000. During the three months and nine months ended September 30, 2024, the Company incurred costs of $12,610 and $20,838 pursuant to this letter of intent and subsequent work order. As of September 30, 2024, total costs of $20,838 have been incurred pursuant to this letter of intent and subsequent work order.

The Company's aggregate commitment pursuant to this letter of intent, less amounts previously paid to date, totaled approximately $78,000 as of September 30, 2024, which is expected to be incurred through December 31, 2027.

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 were estimated to be approximately $335,000. During the three months ended September 30, 2024 and 2023, the Company incurred costs of $1,603 and $4,500, respectively, pursuant to this work order. During the nine months ended September 30, 2024 and 2023, the Company incurred costs of $10,603 and $15,740, respectively, pursuant to this work order. As of September 30, 2024, total costs of $89,284 had been incurred pursuant to this work order agreement.

As a result of the closure of the Agreement with City of Hope effective July 8, 2024 (see "Clinical Trial Agreements – City of Hope" above), the work order agreement with Theradex to monitor this clinical trial was concurrently terminated, although nominal oversight trailing costs subsequent to July 8, 2024 are expected to be incurred relating to the closure of this study.

GEIS. On June 22, 2023, the Company finalized a work order agreement with Theradex, to monitor the GEIS investigator-initiated clinical Phase I/II randomized trial of LB-100 plus doxorubicin vs. doxorubicin alone in first line of advanced soft tissue sarcoma. The study oversight is expected to be completed by December 31, 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 ended September 30, 2024 and 2023, the Company incurred costs of $13,475 and $3,750, respectively, pursuant to this work order. During the nine months ended September 30, 2024 and 2023, the Company incurred costs of $26,208 and $10,000, respectively, pursuant to this work order. As of September 30, 2024, total costs of $41,070 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 $118,000 as of September 30, 2024, which is expected to be incurred through December 31, 2026.

Netherlands Cancer Institute. On August 27, 2023, the Company finalized a work order agreement with Theradex, to monitor the NKI Phase 1b clinical trial of LB-100 combined with atezolizumab, a PD-L1 inhibitor, for patients with microsatellite stable metastatic colon cancer. The study oversight is expected to be completed by May 31, 2027.

Costs under this work order agreement are estimated to be approximately $106,380, with such payments expected to be allocated approximately 47% to Theradex for services and approximately 53% for payments for pass-through software costs. During the three months and nine months ended September 30, 2024, the Company incurred costs of $14,900 pursuant to this work order. As of September 30, 2024, total costs of $14,900 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 $106,380 as of September 30, 2024, which is expected to be incurred through May 31, 2027.

Patent and License Agreements

National Institute of Health. Effective February 23, 2024, the Company entered into a Patent License Agreement (the "License Agreement") with the National Institute of Neurological Disorders and Stroke ("NINDS") and the National Cancer Institute ("NCI"), each an institute or center of the National Institute of Health ("NIH"). Pursuant to the License Agreement, the Company has licensed on an exclusive basis the NIH's intellectual property rights claimed for a Cooperative Research and Development Agreement ("CRADA") subject invention co-developed with the Company, and the licensed field of use, which focuses on promoting anti-cancer activity alone, or in combination with standard anti-cancer drugs. The scope of this clinical research extends to checkpoint inhibitors, immunotherapy, and radiation for the treatment of cancer. The License Agreement is effective, and shall extend, on a licensed product, licensed process, and country basis, until the expiration of the last-to-expire valid claim of the jointly owned licensed patent rights in each such country in the licensed territory, estimated at twenty years, unless sooner terminated.

The License Agreement contemplates that the Company will seek to work with pharmaceutical companies and clinical trial sites (including comprehensive cancer centers) to initiate clinical trials within timeframes that will meet certain benchmarks. Data from the clinical trials will be the subject of various regulatory filings for marketing approval in applicable countries in the licensed territories. Subject to the receipt of marketing approval, the Company would be expected to commercialize the licensed products in markets where regulatory approval has been obtained.

The Company is obligated to pay the NIH a non-creditable, non-refundable license issue royalty of $50,000 and a first minimum annual royalty within sixty days from the effective date of the Agreement. The first minimum annual royalty of $25,643 was prorated from the effective date of the License Agreement to the next subsequent January 1. Thereafter, the minimum annual royalty of $30,000 is due each January 1 and may be credited against any earned royalties due for sales made in that year. The license issue royalty of $50,000 and the first minimum annual royalty of $25,643, were paid in April 2024.

The Company is obligated to pay the NIH, on a country-by-country basis, earned royalties of 2% on net sales of each royalty-bearing product and process, subject to reduction by 50% under certain circumstances relating to royalties paid by the Company to third parties, but not less than 1%. The Company's obligation to pay earned royalties under the License Agreement commences on the date of the first commercial sale of a royalty-bearing product or process and expires on the date on which the last valid claim of the licensed product or licensed process expires in such country.

The Company is obligated to pay the NIH benchmark royalties, on a one-time basis, within sixty days from the first achievement of each such benchmark. The License Agreement defines four such benchmarks, which the Company is required to pursue based on "commercially reasonable efforts" as defined in the License Agreement, with deadlines of October 1, 2024, 2027, 2029 and 2031, respectively, each with a different specified benchmark payment amount payable within thirty days of achieving such benchmark. The October 1, 2024 benchmark of $100,000 was defined as the dosing of the first patient with a licensed product in a Phase 2 clinical study of such licensed product in the licensed fields of use. The Company had not commenced a Phase 2 clinical study as of September 30, 2024. The total of all such benchmark payments is $1,225,000.

The Company is obligated to provide annual reports to the NIH on its progress toward the development and commercialization of products under the licensed patents. These reports, due within sixty days following the end of each calendar year, must include updates on research and development activities, regulatory submissions, manufacturing efforts, sublicensing, and sales initiatives. If any deviations from the established commercial development plan or agreed-upon benchmarks occur, the Company is obligated to provide explanation and may amend the commercial development plan and the benchmarks, which, subject to certain conditions, the NIH shall not unreasonably withhold, condition, or delay approval of any request of the Company to amend the commercial development plan and/or the benchmarks and to extend the time periods of the benchmarks.

The Company is obligated to pay the NIH sublicensing royalties of 5% on sublicensing revenue received for granting each sublicense within sixty days of receipt of such sublicensing revenue.

During the three months ended September 30, 2024, the Company incurred costs of $7,537 in connection with its obligations under the License Agreement. During the nine months ended September 30, 2024, the Company incurred costs of $68,106 in connection with its obligations under the License Agreement. Such costs when incurred have been included in general and administrative costs in the Company's consolidated statement of operations. As of September 30, 2024, total costs of $68,106 have been incurred pursuant to this agreement. The Company's aggregate commitment pursuant to this agreement, less amounts previously paid to date, totaled approximately $1,795,000 as of September 30, 2024, which is expected to be incurred over approximately the next twenty years.

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.

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 was 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.

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, 2024 and 2023, respectively. Consulting and advisory fees charged to operations pursuant to this agreement were $12,000 and $12,000 for the nine months ended September 30, 2024 and 2023, respectively. This agreement was terminated effective July 3, 2024.

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 fee. Effective March 1, 2024, the compensation payable under the Collaboration Agreement was converted to an hourly rate structure.

The Company recorded charges to operations pursuant to this Collaboration Agreement of $8,000 and $30,000 during the three months ended September 30, 2024 and 2023, respectively, which were included in research and development costs in the consolidated statements of operations. The Company recorded charges to operations pursuant to this Collaboration Agreement of $35,200 and $90,000 during the nine months ended September 30, 2024 and 2023, 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 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 a preclinical study 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 preclinical study, at an approximate cost of 391,000 Euros and provide a sufficient supply of LB-100 to conduct the preclinical 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 added 500,000 Euros to the operating budget being funded by the Company.

During the three months ended September 30, 2024 and 2023, the Company incurred charges in the amount of $76,278 and $51,568, 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, 2024 and 2023, the Company incurred charges in the amount of $210,362 and $156,950, 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, 2024, total costs of $695,918 have been incurred pursuant to this agreement. The Company's aggregate commitment pursuant to this agreement, less amounts previously paid to date, totaled approximately $279,000 as of September 30, 2024, 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. As amended, the Company has contracted with MRI Global for stability analysis, storage and distribution of LB-100 for clinical trials in the United States. During the three months ended September 30, 2024 and 2023, the Company incurred costs of $9,062 and $21,045, respectively, pursuant to this contract. During the nine months ended September 30, 2024 and 2023, the Company incurred costs of $18,932 and $30,628, respectively, pursuant to this contract. As of September 30, 2024, total costs of $334,147 have been incurred pursuant to this contract.

The Company's aggregate commitment pursuant to this contract, less amounts previously paid to date, totaled approximately $124,000 as of September 30, 2024.

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 herein, 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, 2024, 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, 2024 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, 2023, as filed with the Securities and Exchange Commission on March 19, 2024 (the "2023 Form 10-K").

The Risk Factors set forth in the 2023 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 2023 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 the filing of this document, except as disclosed herein, there have been no material changes to the Risk Factors previously disclosed in the Company's 2023 Form 10-K.

Serious Adverse Events

The Company's lead drug candidate, LB-100, is currently undergoing various clinical trials, and there is a risk that one or more of these trials could be placed on hold by regulatory authorities due to serious adverse events (SAEs) related to our drug candidate or to another company's drug used in combination in one of our clinical trials. It is possible that the SAEs could be attributable to our drug candidate and could include, but not be limited to, unexpected severe side effects, treatment-related deaths, or long-term health complications. A dose given could result in non-tolerable adverse events defined as dose-limiting toxicity (DLT). When two DLTs occur at the same dose-level that dose-level is considered too high and unsafe. Further treatment is only allowed at lower dose-levels that have previously been found safe.

If an SAE or a pattern of SAEs is observed during the course of a clinical trial involving our drug candidate, the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), or other regulatory authorities may issue a clinical hold, requiring us to pause or discontinue further enrollment and dosing in our clinical trial. It is also possible that the clinical trial could be terminated. Any of these actions could delay or halt the development of our drug candidate, increase development costs, and negatively impact our ability to ultimately achieve regulatory approval. Additionally, if an SAE is confirmed to be drug-related, we may be required to conduct additional studies, modify the study design, or abandon further development of the drug candidate altogether, which could materially impact our business, financial condition, and prospects.

The occurrence of an SAE and any resulting clinical hold could also harm our reputation with patients, physicians, health institutions, and investors, diminish our ability to attract clinical trial participants, and damage our ability to interest investors and obtain financing in the future. There can be no assurance that we will not experience such SAEs in the future or that any related clinical hold will be lifted in a timely manner, or at all.

The principal investigator of the colorectal study testing LB-100 in combination with atezolizumab (Roche PD-L1 inhibitor) is currently investigating two SAEs observed in the clinical trial that was launched in August 2024. Evaluation is underway to determine next steps.

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, 2024, 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
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 12, 2024

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

Date: November 12, 2024

By: */s/ ROBERT N. WEINGARTEN*
Robert N. Weingarten
Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

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 12, 2024

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

Exhibit 31.2

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

I, Robert N. Weingarten, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Lixte Biotechnology Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's Board of Directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2024

By: */s/ ROBERT N. WEINGARTEN*
Robert N. Weingarten
Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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, 2024 (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 12, 2024

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

Exhibit 32.2

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

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

(i) The Quarterly Report on Form 10-Q of the Company for the quarterly period ended September 30, 2024 (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 12, 2024

By: */s/ ROBERT N. WEINGARTEN*
Robert N. Weingarten
Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)