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

FORM 10-Q

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

For the quarterly period ended March 31, 2025

☐ 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 April 30, 2025, the Company had 2,684,074 shares of common stock issued and outstanding.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

TABLE OF CONTENTS

PART I - FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2025 (Unaudited)	December 31, 2024
ASSETS		
Current assets:		
Cash	$ 1,384,697	$ 1,038,952
Prepaid insurance	17,085	20,898
Other prepaid expenses	112,446	85,653
Total assets	$ 1,514,228	$ 1,145,503
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses, including $0 and $27,500 to related parties at March 31, 2025 and December 31, 2024, respectively	$ 112,476	$ 83,206
Research and development contract liabilities	242,622	235,078
Total current liabilities	355,098	318,284
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 March 31, 2025 and December 31, 2024	3,500,000	3,500,000
Common stock, $0.0001 par value; authorized – 100,000,000 shares; issued and outstanding – 2,684,074 sharers and 2,249,290 shares at March 31, 2025 and December 31, 2024, respectively	268	225
Additional paid-in capital	50,436,110	49,394,687
Accumulated deficit	(52,777,248)	(52,067,693)
Total stockholders' equity	1,159,130	827,219
Total liabilities and stockholders' equity	$ 1,514,228	$ 1,145,503

See accompanying notes to condensed consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,	
	2025	**2024**
Revenues	$ —	$ —
Costs and expenses:		
Research and development costs	91,457	119,064
General and administrative costs	615,483	847,815
Total costs and expenses	706,940	966,879
Loss from operations	(706,940)	(966,879)
Interest income	441	2,859
Interest expense	(3,135)	(7,186)
Foreign currency gain (loss)	79	(116)
Net loss	$ (709,555)	$ (971,322)
Net loss per common share – basic and diluted	$ (0.29)	$ (0.43)
Weighted average common shares outstanding – basic and diluted	2,471,513	2,249,290

See accompanying notes to condensed consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)

Three Months Ended March 31, 2025 and 2024

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Par Value	Capital	Deficit	Equity
Balance, December 31, 2024	350,000	$ 3,500,000	2,249,290	$ 225	$ 49,394,687	$ (52,067,693)	$ 827,219
Proceeds from sale of securities in registered direct offering, net of offering costs	—	—	434,784	43	914,185	—	914,228
Stock-based compensation expense	—	—	—	—	99,738	—	99,738
Stock options issued to settle accrued payable	—	—	—	—	27,500	—	27,500
Net loss	—	—	—	—	—	(709,555)	(709,555)
Balance, March 31, 2025	350,000	$ 3,500,000	2,684,074	$ 268	$ 50,436,110	$ (52,777,248)	$ 1,159,130
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	—	—	—	—	102,927	—	102,927
Net loss	—	—	—	—	—	(971,322)	(971,322)
Balance, March 31, 2024	350,000	$ 3,500,000	2,249,290	$ 225	$ 49,079,192	$ (49,453,050)	$ 3,126,367

See accompanying notes to condensed consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Three Months Ended March 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (709,555)	$ (971,322)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense included in -		
Research and development costs	—	—
General and administrative costs	99,738	102,927
Changes in operating assets and liabilities:		
(Increase) decrease in -		
Prepaid insurance	3,813	(5,678)
Other prepaid expenses	(26,793)	(64,130)
Increase in -		
Accounts payable and accrued expenses	56,770	89,929
Research and development contract liabilities	7,544	59,049
Net cash used in operating activities	(568,483)	(789,225)
Cash flows from financing activities:		
Proceeds from sale of securities in registered direct offering, net of offering costs	914,228	—
Net cash provided by financing activities	914,228	—
Cash:		
Net increase (decrease)	345,745	(789,225)
Balance at beginning of period	1,038,952	4,203,488
Balance at end of period	$ 1,384,697	$ 3,414,263
Supplemental disclosures of cash flow information:		
Cash paid for -		
Interest	$ 3,135	$ 7,186
Income taxes	$ —	$ —
Settlement of accrued compensation to Board of Directors by issuance of stock options	$ 27,500	—

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 March 31, 2025, and for the three months ended March 31, 2025 and 2024, are unaudited. In the opinion of management of the Company, all adjustments, including normal recurring accruals, have been made that are necessary to present fairly the financial position of the Company as of March 31, 2025, and the results of its operations for the three months ended March 31, 2025 and 2024, and its cash flows for the three months ended March 31, 2025 and 2024. 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, 2024 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, 2024, 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 warrants are traded on the Nasdaq Capital Market 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 letter from the Listing Qualifications Department (the "Staff") of the Nasdaq Stock Market LLC ("Nasdaq") indicating that the Company was not in compliance with the minimum stockholders' equity requirement of $2,500,000 for continued listing on the Nasdaq Capital Market under Listing Rule 5550(b)(1) (the "Stockholders' Equity Requirement").

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

On October 21, 2024, the Staff provided notice (the "Notice") to the Company that it had granted an extension through February 18, 2025 to regain compliance with the Stockholders' Equity Requirement, which required that the Company complete its capital raising initiatives and evidence compliance with the Stockholders' Equity Requirement through filing a Current Report on Form 8-K with the SEC providing certain required information.

As of February 18, 2025, the Company had not gained compliance with the Stockholders' Equity Requirement. On February 19, 2025, the Company received a Staff determination letter stating that the Company did not meet the terms of the extension because it did not complete its proposed financing initiatives to regain compliance. The Company timely requested a Hearing before a Nasdaq Hearings Panel (the "Panel").

On April 17, 2025, the Company received notice that the Panel had granted the Company an extension in which to regain compliance with all continued listing rules of the Nasdaq Capital Market. The Panel's determination followed a hearing on April 3, 2025, at which the Panel considered the Company's plan to regain compliance with the Stockholders' Equity Requirement. As a result of the extension, the Panel granted the Company's request for continued listing on the Nasdaq Capital Market, provided that the Company demonstrates compliance with the Stockholders' Equity Requirement and all other continued listing requirements for the Nasdaq Capital Market by July 3, 2025.

During the extension period, the Company's common stock and warrants will continue to trade on The Nasdaq Capital Market under the symbols "LIXT" and "LIXTW", respectively.

The Company is undertaking measures to regain compliance under Nasdaq's continued listing requirements within the extension period and to remain listed on the Nasdaq Capital Market. However, there can be no assurances that the Company will ultimately be able to regain compliance with the Stockholders' Equity Requirement, or be able to maintain compliance with all other applicable requirements for continued listing on the Nasdaq Capital Market. The Company's failure to meet these requirements would result in the Company's securities being delisted from the Nasdaq Capital Market.

Going Concern

For the three months ended March 31, 2025, the Company recorded a net loss of $709,555 and used cash in operations of $568,483. At March 31, 2025, the Company had cash of $1,384,697 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 March 31, 2025, the Company's remaining financial contractual commitments pursuant to clinical trial agreements and clinical trial monitoring agreements not yet incurred aggregated approximately $514,000 (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, the Company's independent registered public accounting firm included an explanatory paragraph in their report with respect to this uncertainty that accompanied the Company's audited consolidated financial statements as of and for the year ended December 31, 2024, in which they expressed substantial doubt about the Company's ability to continue as a going concern. The Company's consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company's ability to continue as a going concern is dependent upon its ability to raise additional equity capital to fund its research and development activities , including its ongoing clinical trials. The amount and timing of future cash requirements depends in substantial part 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 March 31, 2025 will provide sufficient working capital to fund the Company's operations, including its current clinical trial program with respect to the development of the Company's lead anti-cancer clinical compound LB-100, through no later than September 30, 2025. Existing cash resources will not be sufficient to complete the development of and to obtain regulatory approval for the Company's product candidate, which will require that the Company raise significant additional capital. The Company estimates that it will need to raise additional capital to fund its operations by mid-2025 to be able to proactively manage its current business plan during the remainder of 2025 and during 2026. In addition, the Company's operating plans may change as a result of many factors that are currently unknown and/or outside of the control of the Company, and additional funds may be needed sooner than planned. The Company is considering various strategies and alternatives to obtain the required additional capital. However, as market conditions present uncertainty as to the Company's ability to secure additional funds, there can be no assurances that the Company will be able to secure additional financing on acceptable terms, as and when necessary, to continue to conduct operations.

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

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying 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's President and Chief Executive Officer is the Company's Chief Operating Decision Maker ("CODM") and evaluates performance and makes operating decisions about allocating resources based on internal financial data presented on a consolidated basis. Because the CODM evaluates financial performance on a consolidated basis, the Company has determined that it operates in a single reportable segment, which consists of the development of a drug class called Protein Phosphatase 2A inhibitors, and is comprised of the consolidated financial results of the Company. The CODM uses consolidated net income (loss) as the sole measure of segment profit or loss. The required segment information, including significant segment expenses, is presented at Note 3.

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.

Offering Costs

Offering costs consist of costs incurred with respect to 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 $56,084 and $83,211 for the three months ended March 31, 2025 and 2024, 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 March 31, 2025 and 2024 are described below.

General and administrative costs for the three months ended March 31, 2025 and 2024 include charges from legal firms and other vendors for general licensing and patent prosecution costs relating to the Company's intellectual properties representing 9.1% and 9.8% of total general and administrative costs, respectively. General and administrative costs for the three months ended March 31, 2025 also include charges from two vendors and consultants representing 13.1% and 10.1% of total general and administrative costs. General and administrative costs for the three months ended March 31, 2024 also include charges from a vendor and consultant representing 14.7% of total general and administrative costs. General and administrative costs for the three months ended March 31, 2025 and 2024 also included charges for the fair value of stock options granted to directors and corporate officers representing 16.2% and 12.1%, respectively, of total general and administrative costs.

Research and development costs for the three months ended March 31, 2025 include charges from five vendors and consultants representing 30.7%, 17.1%, 15.3%, 15.1% and 14.7% of total research and development costs. Research and development costs for the three months ended March 31, 2024 include charges from three vendors and consultants representing 56.2%, 19.1% and 12.8% 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 March 31, 2025 and December 31, 2024. In the event the Company was to determine that it would be able to realize its deferred tax assets in the future in excess of its recorded amount, an adjustment to the deferred tax assets would be credited to operations in the period such determination was made. Should the Company determine that it would not be able to realize all or part of its deferred tax assets in the future, an adjustment to the deferred tax assets would be charged to operations in the period such determination was made.

The Company is subject to U.S. federal income taxes and income taxes of various state tax jurisdictions. As the Company's net operating losses have yet to be utilized, all previous tax years remain open to examination by Federal authorities and other jurisdictions in which the Company currently operates or has operated in the past. The Company had no unrecognized tax benefits as of March 31, 2025 and December 31, 2024 and does not anticipate any material amount of unrecognized tax benefits through December 31, 2025.

The Company accounts for uncertainties in income tax law under a comprehensive model for the financial statement recognition, measurement, presentation, and disclosure of uncertain tax positions taken or expected to be taken in income tax returns as prescribed by GAAP. The tax effects of a position are recognized only if it is "more-likely-than-not" to be sustained by the taxing authority as of the reporting date. If the tax position is not considered "more-likely-than-not" to be sustained, then no benefits of the position are recognized. The Company had not recorded any liability for uncertain tax positions as of March 31, 2025 or December 31, 2024. Subsequent to March 31, 2025, 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, 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, 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 and the February 2025 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 at each balance sheet date. At March 31, 2025 and December 31, 2024, the Company did not have any liability-classified warrants.

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 March 31, 2025 and 2024, the Company excluded the outstanding securities summarized below, which entitle the holders thereof to acquire shares of common stock, from its calculation of earnings per share, as their effect would have been anti-dilutive.

	March 31,	
	2025	**2024**
Series A Convertible Preferred Stock	72,917	72,917
Common stock warrants	1,275,758	808,365
Common stock options	662,078	552,083
Total	2,010,753	1,433,365

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 March 31, 2025 and 2024, the Company incurred various costs and expenses denominated in Euros, which were converted into United States dollars at the average rate of 1.0516 and 1.0848 Euros per United States dollar, respectively. As of March 31, 2025 and December 31, 2024, 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 November 2024, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2024-03, Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40). ASU 2024-03 amends the FASB Accounting Standards Codification to require specified information about certain costs and expenses in the notes to the financial statements at each interim and annual reporting period, including disclosure of the amounts of purchases of inventory; employee compensation; depreciation; intangible asset amortization; and depreciation, depletion, and amortization included in each relevant expense caption on the face of the income statement within continuing operations that contains any of the expense categories previously listed. Disclosure will also be required of the total amount of selling expenses and an entity's definition of selling expenses in annual reporting periods. ASU 2024-03 does not change or remove current expense disclosure requirements, but does affect where and how this information is presented in the notes to the financial statements. ASU 2024-03 is effective for annual reporting periods beginning January 1, 2027, and interim periods within annual reporting periods beginning January 1, 2028. Early adoption is permitted. The Company is in the process of evaluating ASU 2024-03 to determine its impact on the Company's consolidated financial statement presentation and related disclosures.

In January 2025, the FASB issued ASU 2025-01, Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40), Clarifying the Effective Date. ASU 2025-01 clarifies the effective date of ASU 2024-03 for all public business entities that do not have an annual reporting period that ends on December 31 (referred to as non-calendar year-end entities). All public business entities are required to adopt the disclosure requirements in the first annual reporting period beginning after December 15, 2026, and interim reporting periods within annual reporting periods beginning after December 15, 2027. As the Company's annual reporting period ends on December 31, ASU-2025-01 did not have any impact on the Company's process of evaluating ASU-2024-03 to determine its impact on the Company's consolidated financial statement 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.

Reclassifications

As a result of the adoption of ASU 2023-07 effective January 1, 2024, certain reclassifications have been made to the prior year statement of operations to conform it to the current year presentation. In presenting general and administrative costs on the Company's consolidated statement of operations for the three months ended March 31, 2024, $317,662 of compensation to related parties, $83,211 of patent and licensing legal and filing fees and costs, and $446,942 of other costs and expenses were shown separately. In presenting the Company's consolidated statement of operations for the three months ended March 31, 2024, the Company has combined these categories into general and administrative costs in the accompanying consolidated statement of operations for the three months ended March 31, 2024. These reclassifications had no effect on the reported results of operations, including loss from operations and net loss.

3. Segment Information

The Company's chief operating decision maker ("CODM") has been identified as the Company's President and Chief Executive Officer ("CEO"). The Company's CODM evaluates performance and makes operating decisions about allocating resources based on financial data presented on a consolidated basis. Because the CODM evaluates financial performance on a consolidated basis, the Company has determined that it has a single operating segment composed of the consolidated financial results of the Company.

The following table presents the significant segment expenses (10% or greater) and other segment items regularly reviewed by the Company's CODM and included in general and administrative costs.

	Three Months Ended March 31,	
	2025	**2024**
Compensation to related parties:		
Cash-based	$ 108,731	$ 214,735
Stock-based	99,738	102,927
Patent and licensing legal and filing fees and costs	56,084	83,211
Other consulting and professional fees	205,315	172,443
Insurance expense	64,277	126,854
Other costs and expenses, net	81,338	147,645
Total general and administrative costs	$ 615,483	$ 847,815

The following table presents the significant segment expenses (10% or greater) and other segment items regularly reviewed by the Company's CODM and included in research and development costs.

	Three Months Ended March 31,	
	2025	**2024**
Clinical and related oversight costs	$ 15,868	$ 10,030
Preclinical research focused on development of additional novel anti-cancer compounds	42,770	104,480
Compound Maintenance	32,819	3,894
Regulatory service costs	—	660
Total research and development costs	$ 91,457	$ 119,064

The following table presents a summary of research and development costs for the three months ended March 31, 2025 and 2024 based on the respective geographical regions where such costs were incurred.

	Three Months Ended March 31,	
	2025	2024
United States	$ 58,571	$ 34,583
Spain	32,886	15,234
China	—	2,282
Netherlands	—	66,965
Total	$ 91,457	$ 119,064

The following table presents the Company's total assets by segment at March 31, 2025 and December 31, 2024.

	March 31, 2025	December 31, 2024
Research and development assets	$ 29,669	$ 39,298
Corporate assets	1,484,559	1,106,205
Total assets	$ 1,514,228	$ 1,145,503

4. Stockholders' Equity

Preferred Stock

The Company is authorized to issue a total of 10,000,000 shares of preferred stock, par value $0.0001 per share. On March 17, 2015, the Company filed a Certificate of Designations, Preferences, Rights and Limitations of its Series A Convertible Preferred Stock with the Delaware Secretary of State to amend the Company's certificate of incorporation. The Company has designated a total of 350,000 shares as Series A Convertible Preferred Stock, which are non-voting and are not subject to increase without the written consent of a majority of the holders of the Series A Convertible Preferred Stock or as otherwise set forth in the Preferences, Rights and Limitations. The holders of each tranche of 175,000 shares of the Series A Convertible Preferred Stock are entitled to receive a per share dividend equal to 1% of the annual net revenue of the Company divided by 175,000, until converted or redeemed. As of March 31, 2025 and December 31, 2024, 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 March 31, 2025 and December 31, 2024.

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

Common Stock

The Company is authorized to issue a total of 100,000,000 shares of common stock, par value $0.0001 per share. As of March 31, 2025 and December 31, 2024, the Company had 2,684,074 shares and 2,249,290 shares, respectively, of common stock issued and outstanding.

July 2023 equity offering

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.

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 in 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 net proceeds from the registered direct offering and the concurrent private placement were used for general working capital purposes.

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.

February 2025 equity offering

Effective February 13, 2025, the Company sold, in a registered direct offering, an aggregate of 434,784 shares of the Company's common stock at an offering price of $2.415 per share, and in a concurrent private placement, warrants to purchase an aggregate of 434,784 shares of common stock. The common stock warrants were immediately exercisable for a term of five years from issuance at an exercise price of $2.29 per share.

The common stock warrants and the shares of common stock underlying the common stock warrants were not registered under the Securities Act, and were issued in reliance on an exemption from the registration requirements of the Securities Act afforded by Section 4(a)(2) thereof. The shares of common stock issuable upon exercise of the common stock warrants were registered for resale in a registration statement on Form S-1 declared effective by the SEC on April 10, 2025.

The registered direct offering and the concurrent private placement generated gross proceeds of $1,050,003 before deducing the placement agent's fee and related offering costs of $135,775, resulting in net proceeds of $914,228. Pursuant to the placement agent agreement, the Company granted the placement agent warrants to purchase 32,609 shares of common stock at an exercise price of $3.0188 per share and expiring on February 11, 2030. The net proceeds from the registered direct offering and the concurrent private placement will be used for general working capital purposes.

The exercise prices of the warrants issued to the institutional investors (exercisable at $2.29 per share) and to the placement agent (exercisable at $3.0188 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 and to the placement agent 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 offerings, is presented below.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Warrants outstanding at December 31, 2024	808,365	$ 16.407	
Issued	467,393	2,341	
Exercised	—	—	
Expired	—	—	
Warrants outstanding at March 31, 2025	1,275,758	$ 11.254	3.52
Warrants exercisable at December 31, 2024	808,365	$ 16.407	
Warrants exercisable at March 31, 2025	1,275,758	$ 11.254	3.52

At March 31, 2025, the outstanding warrants are exercisable at the following prices per common share:

Exercise Prices	Warrants Outstanding (Shares)
$ 2.2900	434,784
$ 3.0188	32,609
$ 6.0000	583,334
$ 6.6000	35,000
$ 20.0000	29,000
$ 37.0000	11,331
$ 57.0000	149,700
	1,275,758

The warrants exercisable at $57.00 per share at March 31, 2025 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 $1.21 per share on March 31, 2025, there was no intrinsic value attributed to exercisable but unexercised common stock warrants at March 31, 2025.

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.

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. 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. During the three months ended March 31, 2024 the Company paid $43,750 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 period.

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. The employment agreement with Mr. Forman terminated upon his resignation as an officer of the Company effective December 31, 2024. During the three months ended March 31, 2024, the Company paid $50,000 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. Additionally, Mr. Forman was provided a monthly office rent allowance, pursuant to which the Company paid $5,318 during the three months ended March 31, 2024.

The Company entered into an employment agreement with Robert N. Weingarten effective August 12, 2020 to act as the Company's Vice President and Chief Financial Officer, with an annual salary of $120,000. Effective May 1, 2021, Mr. Weingarten's annual salary was increased to $175,000. During the three months ended March 31, 2025 and 2024, 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.

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 March 31, 2025 and 2024, the Company paid $37,477 and $38,416, 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 is 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 $112,000 as of March 31, 2025), payable on a monthly basis. During the three months ended March 31, 2025, the Company paid $27,504 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.

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 of Directors 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 March 31, 2025 and 2024, 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.

In conjunction with the Company's efforts to preserve cash during 2024, effective with the quarter ended June 30, 2024, Dr. Bernards agreed to receive equity-based compensation for his services on the Board of Directors, for the quarters ended June 30, 2024 through December 31, 2024. In order to reconcile his Board of Directors compensation with that of the other non-officer directors, Dr. Bernards has agreed to receive the same Board of Directors compensation, both in form and amount, as the other non-officer directors for the year ending December 31, 2025.

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, July 9, 2024 and March 21, 2025. 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 of Directors have approved amendments to the Board Plan, such that for the quarters ended June 30, 2024 through December 31, 2025, the non-officer directors (including Dr. Bernards) have received or 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 upon issuance, 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 quarterly value as determined pursuant to the Black-Scholes option-pricing model. The Board of Directors may further extend this amendment to the Board Plan for additional quarterly periods subsequent to December 31, 2025.

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 $38,819 for the three months ended March 31, 2025 and 2024, respectively.

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 ended March 31, 2025 and 2024, is presented below.

	Three Months Ended March 31,	
	2025	**2024**
Related party costs:		
Cash-based	$ 108,731	$ 214,735
Stock-based	99,738	102,927
Total	$ 208,469	$ 317,662

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 March 31, 2025, unexpired stock options for 616,661 shares were issued and outstanding under the 2020 Plan and 133,339 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 three months ended March 31, 2025, 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	3.950%
Expected dividend yield	0%
Expected volatility	128.78%
Expected life	2.5 years

There were no stock options requiring an assessment of value issued during the three months ended March 31, 2024.

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. van der 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 March 31, 2024, the Company recorded a charge to general and administrative costs in the consolidated statement of operations of $9,695 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 March 31, 2024, the Company recorded a charge to general and administrative costs in the consolidated statement of operations of $23,655 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 March 31, 2025 and 2024, the Company recorded charges to general and administrative costs in the consolidated statements of operations of $4,043 and $12,264, 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 March 31, 2025 and 2024, the Company recorded charges to general and administrative costs in the consolidated statements of operations of $23,704 and $23,968, 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 March 31, 2025 and 2024, the Company recorded charges to general and administrative costs in the consolidated statements of operations of $32,979 and $33,345, 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 ended March 31, 2025, the Company record a charge general and administrative costs in the consolidated statements of operations of $9,120 with respect to these stock options.

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 ended March 31, 2025, the Company record a charge general and administrative costs in the consolidated statement of operations of $2,392 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 equal to the cash payment such director would otherwise have been entitled to receive for the quarter ended September 30, 2024, divided by their quarterly 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 the stock options were fully vested.

On January 20, 2025, 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 16,665 stock options to purchase shares of the Company's common stock, exercisable for a period of five years at an exercise price of $2.33 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 equal to the cash payment such director would otherwise have been entitled to receive for the quarter ended December 31, 2024, divided by their grant date value as determined pursuant to the Black-Scholes option-pricing model, and was determined to be $27,500 ($1.65002 per share). The grant date value of the stock options of $27,500 was accrued at December 31, 2024 and charged to operations at that date. During the three months ended March 31, 2025, there was no expense charged to operations with respect to these stock options.

On March 31, 2025, 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 32,181 stock options to purchase shares of the Company's common stock, exercisable for a period of five years at an exercise price of $1.21 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 equal to the cash payment such director would otherwise have been entitled to receive for the quarter ended March 31, 2025, divided by their grant date value as determined pursuant to the Black-Scholes option-pricing model, and was determined to be $27,500 ($0.8546 per share), which was charged to operations on March 31, 2025, the date on which the stock options were fully vested.

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, the employment agreement of the Company's Chief Medical Officer, Dr. James S. Miser expired on July 31, 2024, and the employment agreement of the Company's Vice President and Chief Operating Officer, Eric J. Forman, terminated upon his resignation from the Company on December 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 expire one year from the respective dates that their services to the Company terminated.

A summary of stock-based compensation costs for the three months ended March 31, 2025 and 2024 is as follows:

	Three Months Ended March 31,	
	2025	2024
Related parties	$ 99,738	$ 102,927
Non-related parties	—	—
Total stock-based compensation costs	$ 99,738	$ 102,927

A summary of stock option activity, including options issued in the form of warrants, during the three months ended March 31, 2025 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Stock options outstanding at December 31, 2024	613,232	$ 12.317	
Granted	48,846	1.592	
Exercised	—	—	
Expired	—	—	
Stock options outstanding at March 31, 2025	662,078	$ 11.526	2.99
Stock options exercisable at December 31, 2024	409,897	$ 17.100	
Stock options exercisable at March 31, 2025	490,826	$ 14.612	2.33

Total deferred compensation expense for the outstanding value of unvested stock options was approximately $303,000 at March 31, 2025, which will be recognized subsequent to March 31, 2025 over a weighted-average period of approximately 17 months.

At March 31, 2025, 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)
$ 1.210	32,181	32,181
$ 1.870	21,217	21,217
$ 1.950	250,000	124,998
$ 2.330	16,665	16,665
$ 2.370	56,598	31,598
$ 2.390	15,000	3,750
$ 5.025	8,750	8,750
$ 5.880	40,000	35,000
$ 7.400	55,000	55,000
$ 20.000	45,000	40,000
$ 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
	662,078	490,826

Based on the closing fair market value of $1.21 per share on March 31, 2025, there was no intrinsic value attributed to exercisable but unexercised common stock options at March 31, 2025.

Outstanding stock options to acquire 171,252 shares of the Company's common stock had not vested at March 31, 2025.

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 ended March 31, 2025 and 2024, 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 March 31, 2025 and December 31, 2024, the Company was not subject to any threatened or pending lawsuits, legal claims or legal proceedings.

Principal Commitments

Clinical Trial Agreements

At March 31, 2025, the Company's remaining financial contractual commitments pursuant to clinical trial agreements and clinical trial monitoring agreements not yet incurred, as described below, aggregated $514,000, including clinical trial agreements of $269,000 and clinical trial monitoring agreements of $245,000, 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 March 31, 2025:

Description of Clinical Trial	Institution	Start Date	Projected End Date	Planned 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 colorectal cancer (Phase 1b)	Netherlands Cancer Institute (NKI)	August 2024	December 2026	37	Determine RP2D with atezolizumab	First patient entered August 2024, in total two patients entered	June 2026	NCT06012734	(1)
LB-100 combined with doxorubicin in advanced soft tissue sarcoma (Phase 1b)	GEIS	June 2023	Recruitment completed September 2024	14	Determine MTD and RP2D	Fourteen patients entered	December 2025	NCT05809830	$ 269,000
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)	TBD	NCT05809830	$ (1)
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	16 patients entered	December 2026	NCT06065462	(1)
Total									$ 269,000

(1) The Company has no financial contractual commitment associated with this clinical trial at March 31, 2025.

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 colorectal 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. A total of two patients have been enrolled to date. 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. The Investigational Review Board (IRB) of the Netherlands Cancer Institute has requested additional information with respect to these SAEs and the study has been paused for enrollment until the IRB's questions have been satisfactorily addressed (see "Specific Risks Associated with the Company's Business Activities - 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, which is included in accounts payable and accrued expenses at March 31, 2025 and December 31, 2024.

During the three months ended March 31, 2025 and 2024, the Company incurred costs of $0 and $69,001, respectively, pursuant to this Agreement. As of March 31, 2025, 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 March 31, 2025, 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 during the quarter ending December 31, 2025.

Given the focus on the combination of LB-100 with immunotherapy in ovarian clear cell carcinoma and colorectal cancer and the availability of capital resources, the Company entered into Amendment No. 1 to the Collaboration Agreement effective March 11, 2025 that relieved the Company of the financial obligation to support the randomized Phase 2 portion of the clinical trial contemplated in the Collaboration Agreement of approximately $3,095,000. As a result, it is uncertain as to whether the Phase 2 portion of this clinical trial will proceed.

The Company's agreement with GEIS provided for various payments based on achieving specific milestones over the term of the agreement. During the three months ended March 31, 2025 and 2024, the Company did not incur any costs pursuant to this agreement. Through March 31, 2025, 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 $269,000 for the Phase 1b portion of this clinical trial as of March 31, 2025, which is scheduled to be incurred through December 31, 2025. 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.

On February 25, 2025, the Company announced that it has added the Robert H. Lurie Comprehensive Cancer Center (Lurie Cancer Center) of Northwestern University as a second site in a clinical trial combining the Company's proprietary compound LB-100 with GSK's dostarlimab to treat ovarian clear cell cancer. Patient recruitment is underway, and the first patient has been dosed.

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 ended March 31, 2025, the Company incurred costs of $7,279 pursuant to this letter of intent and subsequent work order. As of March 31, 2025, total costs of $34,041 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 $63,000 as of March 31, 2025, 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 March 31, 2025 and 2024, the Company incurred costs of $0 and $4,500, respectively, pursuant to this work order. As of March 31, 2025, total costs of $89,323 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 March 31, 2025 and 2024, the Company incurred costs of $3,872 and $5,529, respectively, pursuant to this work order. As of March 31, 2025, total costs of $53,327 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 $98,000 as of March 31, 2025, which is expected to be incurred through December 31, 2026.

Netherlands Cancer Institute. On August 27, 2024, 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 colorectal 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 three months ended March 31, 2025, the Company incurred costs of $4,500 pursuant to this work order. As of March 31, 2025, total costs of $24,691 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 $83,000 as of March 31, 2025, 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 second minimum annual royalty for 2025 of $30,000 was paid in December 2024 and was included in other prepaid expenses in the consolidated balance sheet at December 31, 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, 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 March 31, 2025. 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 March 31, 2025 and 2024, the Company incurred costs of $7,397 and $53,113, respectively, 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 March 31, 2025, total costs of $83,040 have been incurred pursuant to this agreement. The Company's aggregate commitment pursuant to this agreement, less amounts previously paid to date, totaled approximately $1,765,000 as of March 31, 2025, which is expected to be incurred over approximately the next twenty years.

Other Significant Agreements and Contracts

NDA Consulting Corp. On December 24, 2013, the Company entered into a consulting agreement with NDA Consulting Corp. for consultation and advice in the field of oncology research and drug development. As part of the consulting agreement, NDA also agreed to have its president, Dr. Daniel D. Von Hoff, M.D., serve on the Company's Scientific Advisory Committee during the term of such consulting agreement. The term of the consulting agreement was for one year and provided for a quarterly cash fee of $4,000. The consulting agreement had been automatically renewed for additional one-year terms on its anniversary date, most recently on December 24, 2023, but was subsequently terminated by mutual agreement effective September 30, 2024. Consulting and advisory fees charged to operations pursuant to this consulting agreement were $4,000 for the three months ended March 31, 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 $14,000 and $20,000 during the three months ended March 31, 2025 and 2024, 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.

On October 4, 2024, the Company entered into Amendment No. 3 to the Development Collaboration Agreement with NKI, which suspended Amendment No. 2 and provided for a new study term of one year and starts upon the dosing of the first patient in the trial at a project cost of 100,000 Euros.

During the three months ended March 31, 2025 and 2024, the Company incurred charges of $0 and $67,119, 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 March 31, 2025, 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 100,000 Euros (approximately $108,000 as of March 31, 2025), as of March 31, 2025, 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 March 31, 2025 and 2024, the Company incurred costs of $28,092 and $3,894, respectively, pursuant to this contract. As of March 31, 2025, total costs of $368,614 have been incurred pursuant to this contract.

The Company's aggregate commitment pursuant to this contract, less amounts previously paid to date, totaled approximately $102,000 as of March 31, 2025.

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

The occurrence of an SAE and any resulting clinical hold could also harm the Company's reputation with patients, physicians, health institutions, and investors, diminish its ability to attract clinical trial participants, and damage its ability to interest investors and obtain financing in the future. There can be no assurance that the Company 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. The Netherlands Cancer Institute ("NKI") Institutional Review Board (the "IRB") has put the colorectal cancer study on hold. The adverse reactions that developed in the two patients were dyspnea (shortness of breath) due to lung toxicity possibly or probably related to the combination of LB-100 and atezolizumab in one patient and fever and aphasia possibly or probably related to the combination of LB-100 and atezolizumab in the second patient. The patient who developed lung toxicity deceased due to the combination of lung metastases of colorectal cancer and dyspnea. The patient with fever and aphasia fully recovered from the adverse events with supportive medication.

Given the identified adverse events in the two patients in the clinical trial, the IRB requested from the principal investigator of the study at the NKI information as to whether the adverse events could have been caused by the combination of LB-100 and atezolizumab and information about the mode of action of the combination of LB-100 and atezolizumab. The principal investigator is preparing a response to the IRB detailing the safety experience with LB-100 given alone and in combination with other cancer drugs, especially doxorubicin and dostarlimab. Doxorubicin is a well-known chemotherapy, and dostarlimab is a well-known immunotherapy of which the mode of action is closely related to that of atezolizumab.

The reported adverse events in the colorectal cancer study have not been seen in any other patients thus far treated with LB-100 alone or in combination with other cancer drugs. Through March 2025, a total of 78 patients have received or are receiving experimental treatment with LB-100. It is expected that it will take at least two months to prepare a detailed response to the IRB, during which time the Company intends to update the safety overview of LB-100.

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 have had a material effect on its operations to date, other than their 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, 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 could 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 to date that have materially impaired its operations or financial condition.

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

9. Subsequent Events

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

On April 17, 2025, the Company received notice that a Nasdaq Hearings Panel (the "Panel") had granted the Company an extension in which to regain compliance with all continued listing rules of the Nasdaq Capital Market. The Panel's determination followed a hearing on April 3, 2025, at which the Panel considered the Company's plan to regain compliance with the minimum stockholders' equity requirement of $2,500,000 for continued listing on the Nasdaq Capital Market (the Stockholders' Equity Requirement"). As a result of the extension, the Panel granted the Company's request for continued listing on the Nasdaq Capital Market, provided that the Company demonstrates compliance with the Stockholders' Equity Requirement and all other continued listing requirements for the Nasdaq Capital Market by July 3, 2025. Additional information with regard to Nasdaq compliance is provided at "Note 1. Organization and Basis of Presentation – Nasdaq Compliance".

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, 2024, 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.

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 access to equity capital to fund its operating requirements.

Recent Significant Developments

Summaries of News Releases

March 10, 2025 –

The Company announced online publication of new preclinical data in BioXriv and International Journal of Pharmaceutics demonstrating how the Company's lead clinical compound, LB-100, is converted into its active form, endothall, a protein phosphatase (PP2A) inhibitor that has been found to be effective in cancer treatment in combination with immunotherapy.

As published in BioXriv, scientists at the Netherlands Cancer Institute have discovered an enzyme that mediates the conversion of LB-100 into the active metabolite endothall. Accordingly, this protein represents a potential biomarker to identify patients who are most likely to respond to LB100. The biomarker discovery study was performed in the laboratories of Dr. René Bernards, Ph.D., group leader at the Netherlands Cancer Institute and a member of the Company's Board of Directors.

As published in the International Journal of Pharmaceutics, Dr. Hans Rollema and colleagues, medicinal chemists and biochemists at BioPharmaWorks LLC, a consultant to the Company, studied how LB-100 can spontaneously convert into the active metabolite endothall by hydrolysis. Their data indicate that this conversion is slow under physiological conditions. The enzymatic conversion of LB-100 identified by the Bernards laboratory expedites the activation of LB-100 inside the cell.

March 31, 2025 -

The Company announced it will conduct a new preclinical study in collaboration with the Netherlands Cancer Institute to test whether "initiated" cells that carry mutations found in cancer cells can be eliminated by treatment with the Company's proprietary compound LB-100.

Increasing evidence indicates that as individuals age, certain mutations accumulate that are found in cancer cells. While these "initiated" cells behave essentially normally, they can propagate to form reservoirs of pre-malignant cells from which malignant cells may eventually emerge. Recent data from the Company's ongoing clinical collaboration with the Netherlands Cancer Institute shows that LB-100 activates oncogenic signaling and that this is detrimental to cancer cells.

The new study in animal models will investigate whether "initiated" cells, harboring a mutant RAS oncogene, can be eliminated with LB-100. If successful, LB-100 could have a significant role in the elimination of initiated cells in aged individuals and could reduce the risk of developing a wide range of cancers as a person ages.

The study will be led by Dr. René Bernards, Ph.D., a global leader in the field of molecular carcinogenesis and group leader at the Netherlands Cancer Institute, one of the world's leading comprehensive cancer centers. Dr. Bernards also is a member of the Company's Board of Directors. This study will not require any additional funding commitment from the Company and is expected to be completed by June 30, 2025.

Going Concern

For the three months ended March 31, 2025, the Company recorded a net loss of $709,555 and used cash in operations of $568,483. At March 31, 2025, the Company had cash of $1,384,697 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 March 31, 2025, the Company's remaining financial contractual commitments pursuant to clinical trial agreements and clinical trial monitoring agreements not yet incurred aggregated approximately $514,000, 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, the Company's independent registered public accounting firm included an explanatory paragraph in their report with respect to this uncertainty that accompanied the Company's audited consolidated financial statements as of and for the year ended December 31, 2024, in which they expressed substantial doubt about the Company's ability to continue as a going concern. The Company's consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company's ability to continue as a going concern is dependent upon its ability to raise additional equity capital to fund its research and development activities , including its ongoing clinical trials. The amount and timing of future cash requirements depends in substantial part 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 March 31, 2025 will provide sufficient working capital to fund the Company's operations, including its current clinical trial program with respect to the development of the Company's lead anti-cancer clinical compound LB-100, through no later than September 30, 2025. Existing cash resources will not be sufficient to complete the development of and to obtain regulatory approval for the Company's product candidate, which will require that the Company raise significant additional capital. The Company estimates that it will need to raise additional capital to fund its operations by mid-2025 to be able to proactively manage its current business plan during the remainder of 2025 and during 2026. In addition, the Company's operating plans may change as a result of many factors that are currently unknown and/or outside of the control of the Company, and additional funds may be needed sooner than planned. The Company is considering various strategies and alternatives to obtain the required additional capital. However, as market conditions present uncertainty as to the Company's ability to secure additional funds, there can be no assurances that the Company will be able to secure additional financing on acceptable terms, as and when necessary, to continue to conduct operations.

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

Nasdaq Compliance

The Company's common stock and warrants are traded on the Nasdaq Capital Market 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 letter from the Listing Qualifications Department (the "Staff") of the Nasdaq Stock Market LLC ("Nasdaq") indicating that the Company was not in compliance with the minimum stockholders' equity requirement of $2,500,000 for continued listing on the Nasdaq Capital Market under Listing Rule 5550(b)(1) (the "Stockholders' Equity Requirement").

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

On October 21, 2024, the Staff provided notice (the "Notice") to the Company that it had granted an extension through February 18, 2025 to regain compliance with the Stockholders' Equity Requirement, which required that the Company complete its capital raising initiatives and evidence compliance with the Stockholders' Equity Requirement through filing a Current Report on Form 8-K with the SEC providing certain required information.

As of February 18, 2025, the Company had not gained compliance with the Stockholders' Equity Requirement. On February 19, 2025, the Company received a Staff determination letter stating that the Company did not meet the terms of the extension because it did not complete its proposed financing initiatives to regain compliance. The Company timely requested a Hearing before a Nasdaq Hearings Panel (the "Panel").

On April 17, 2025, the Company received notice that the Panel had granted the Company an extension in which to regain compliance with all continued listing rules of the Nasdaq Capital Market. The Panel's determination followed a hearing on April 3, 2025, at which the Panel considered the Company's plan to regain compliance with the Stockholders' Equity Requirement. As a result of the extension, the Panel granted the Company's request for continued listing on the Nasdaq Capital Market, provided that the Company demonstrates compliance with the Stockholders' Equity Requirement and all other continued listing requirements for the Nasdaq Capital Market by July 3, 2025.

During the extension period, the Company's common stock and warrants will continue to trade on The Nasdaq Capital Market under the symbols "LIXT" and "LIXTW", respectively.

The Company is undertaking measures to regain compliance under Nasdaq's continued listing requirements within the extension period and to remain listed on the Nasdaq Capital Market. However, there can be no assurances that the Company will ultimately be able to regain compliance with the Stockholders' Equity Requirement, or be able to maintain compliance with all other applicable requirements for continued listing on the Nasdaq Capital Market. The Company's failure to meet these requirements would result in the Company's securities being delisted from the Nasdaq Capital Market.

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 ended March 31, 2025 and 2024 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 ended March 31, 2025 and 2024 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's President and Chief Executive Officer is the Company's Chief Operating Decision Maker ("CODM") and evaluates performance and makes operating decisions about allocating resources based on internal financial data presented on a consolidated basis. Because the CODM evaluates financial performance on a consolidated basis, the Company has determined that it operates in a single reportable segment, which consists of the development of a drug class called Protein Phosphatase 2A inhibitors, and is comprised of the consolidated financial results of the Company. The CODM uses consolidated net income (loss) as the sole measure of segment profit or loss.

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosure. ASU 2023-07 amends the FASB Accounting Standards Codification to require additional reportable segment disclosures of a public entity by requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker, requiring other new disclosures, and requiring enhanced interim disclosures. ASU 2023-07 requires public entities with a single reportable segment to provide all the disclosures required by ASU 2023-07 and all existing segment disclosures in Topic 280 on an interim and annual basis. The Company adopted ASU 2023-07 effective January 1, 2024 for the 2024 annual period, including quarterly periods, on a retrospective basis.

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 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 are included in general and administrative costs in the Company's consolidated statement of operations.

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 review and analysis of the Company's patent portfolio in order to implement a program to balance patent prosecution costs with intellectual property protection benefits. As a result of such review and analysis, the Company identified certain patent filings that it decided not to continue to support in 2024 and thereafter. In addition, the Company changed patent legal counsel in mid-2024. The Company expects that patent and licensing legal and filing fees and costs will continue to be a significant continuing cost in 2025 and thereafter as the Company continues to manage its patent portfolio related to the clinical development of LB-100.

As a result of such review and analysis, patent and licensing legal and filing fees and costs related to the development and protection of the Company's intellectual property, primarily related to LB-100, decreased to $56,084 for the three months ended March 31, 2025, as compared to $83,211 for the three months ended March 31, 2024, a decrease of $27,127, or 32.6%.

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, 2024.

Stock-Based Compensation

The Company periodically issues common stock and stock options to officers, directors, employees, 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, 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 and in the February 2025 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 at each balance sheet date. At March 31, 2025 and December 31, 2024, the Company did not have any liability-classified warrants.

Summary of Business Activities and Plans

Company 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 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.

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 has also been shown to enhance the effectiveness of commonly used anti-cancer drugs in animal models of melanoma, breast cancer and sarcoma. 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 manage 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.

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

The occurrence of an SAE and any resulting clinical hold could also harm the Company's reputation with patients, physicians, health institutions, and investors, diminish its ability to attract clinical trial participants, and damage its ability to interest investors and obtain financing in the future. There can be no assurance that the Company 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. The Institutional Review Board (the "IRB") of the Netherlands Cancer Institute ("NKI") has put the colorectal cancer study on hold. The adverse reactions that developed in the two patients were dyspnea (shortness of breath) due to lung toxicity possibly or probably related to the combination of LB-100 and atezolizumab in one patient and fever and aphasia possibly or probably related to the combination of LB-100 and atezolizumab in the second patient. The patient who developed lung toxicity deceased due to the combination of lung metastases of colorectal cancer and dyspnea. The patient with fever and aphasia fully recovered from the adverse events with supportive medication.

Given the identified adverse events in the two patients in the clinical trial, the IRB requested from the principal investigator of the study at the NKI information as to whether the adverse events could have been caused by the combination of LB-100 and atezolizumab and information about the mode of action of the combination of LB-100 and atezolizumab. The principal investigator is preparing a response to the IRB detailing the safety experience with LB-100 given alone and in combination with other cancer drugs, especially doxorubicin and dostarlimab. Doxorubicin is a well-known chemotherapy, and dostarlimab is a well-known immunotherapy of which the mode of action is closely related to that of atezolizumab.

The reported adverse events in the colorectal cancer study have not been seen in any other patients thus far treated with LB-100 alone or in combination with other cancer drugs. Through March 2025, a total of 78 patients have received or are receiving experimental treatment with LB-100. It is expected that it will take at least two months to prepare a detailed response to the IRB, during which time the Company intends to update the safety overview of LB-100.

External Risks Associated with the Company's Business Activities

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 pandemic may reappear and impact the Company's clinical trial programs and capital raising efforts in the future is uncertain and cannot be predicted.

Inflation and Interest Rate Risk. The Company does not believe that inflation or increasing interest rates have had a material effect on its operations to date, other than their 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, 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 could 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 to date that have materially impaired its operations or financial condition.

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

Results of Operations

At March 31, 2025, 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 March 31,	
	2025	**2024**
Revenues	$ —	$ —
Costs and expenses:		
Research and development costs	91,457	119,064
General and administrative costs	615,483	847,815
Total costs and expenses	706,940	966,879
Loss from operations	(706,940)	(966,879)
Interest income	441	2,859
Interest expense	(3,135)	(7,186)
Foreign currency gain (loss)	79	(116)
Net loss	$ (709,555)	$ (971,322)
Net loss per common share – basic and diluted	$ (0.29)	$ (0.43)
Weighted average common shares outstanding – basic and diluted	2,471,513	2,249,290

Three Months Ended March 31, 2025 and 2024

Revenues. The Company did not have any revenues for the three months ended March 31, 2025 and 2024.

Research and Development Costs. For the three months ended March 31, 2025, research and development costs were $91,457, which consisted of clinical and related oversight costs of $15,868, compound maintenance costs of $32,819, and preclinical research focused on development of additional novel anti-cancer compounds to add to the Company's clinical pipeline of $42,770.

For the year three months ended March 31, 2024, research and development costs were $119,064, which consisted of clinical and related oversight costs of $10,030, compound maintenance costs of $3,894, regulatory service costs of $660, and preclinical research focused on development of additional novel anti-cancer compounds to add to the Company's clinical pipeline of $104,480.

Included in preclinical research costs for the three months ended March 31, 2025 and 2024 were $0 and $66,965, 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 provided for additional research activities, extended 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.

On October 4, 2024, the Company entered into Amendment No. 3 to the Development Collaboration Agreement with NKI, which suspended Amendment No. 2 and provided for a new study term of one year commencing upon the dosing of the first patient in the clinical trial at a project cost of 100,000 Euros (see "Principal Commitments – Other Significant Agreements and Contracts – Netherlands Cancer Institute" below).

Research and development costs decreased by $27,607, or 23.2%, in 2025 as compared to 2024, primarily as a result of a decrease in preclinical research focused on development of additional novel anti-cancer compounds to add to the Company's clinical pipeline of $61,710, offset by an increase in compound maintenance costs of $28,925.

General and Administrative Costs. For the three months ended March 31, 2025, general and administrative costs were $615,483, which consisted of the fair value of vested stock options issued to directors and officers of $99,738 (including quarterly director and board committee fees of $27,500), patent and licensing legal and filing fees and costs of $56,084, other consulting and professional fees of $205,315, insurance expense of $64,277, officer compensation and related costs of $118,268, cash-based director and board committee fees of $0, licensing and royalties of $7,397, shareholder reporting costs of $4,811, listing fees of $33,250, filing fees of $9,750, investor relations of $11,397, taxes and licenses of $5,056, and other operating costs of $2,998, offset by a rent refund of $2,858.

For the three months ended March 31, 2024, general and administrative costs were $847,815, which consisted of the fair value of vested stock options issued to directors and officers of $102,927, patent and licensing legal and filing fees and costs of $83,211, other consulting and professional fees of $172,443, insurance expense of $126,854, officer compensation and related costs of $195,618, cash-based director and board committee fees of $38,819, licensing and royalties of $53,113, shareholder reporting costs of $8,938, listing fees of $12,375, filing fees of $7,734, investor relations of $17,397, taxes and licenses of $15,406, rent of $5,651, and other operating costs of $7,329.

General and administrative costs decreased by $232,332, or 27.4%, in 2025 as compared to 2024, primarily as a result of decreases in patent and licensing legal and filing fees and costs of $27,127, insurance expense of $62,577, officer compensation and related costs of $77,350, cash-based director and board committee fees of $38,819, licensing and royalties of $45,716, investor relations of $6,000, taxes and licenses of $10,350, and rent of $8,509, offset by increases in other consulting and professional fees of $32,872 and listing fees of $20,875.

Interest Income. For the three months ended March 31, 2025, the Company had interest income of $441, as compared to interest income of $2,859 for the three months ended March 31, 2024, related to the investment of the Company's cash resources.

Interest Expense. For the three months ended March 31, 2025, the Company had interest expense of $3,135, as compared to interest expense of $7,186 for the three months ended March 31, 2024, related to the financing of the premium for the Company's directors and officers liability insurance policy.

Foreign Currency Gain (Loss). For the three months ended March 31, 2025, the Company had a foreign currency gain of $79, as compared to a foreign currency loss of $116 for the three months ended March 31, 2024, from foreign currency transactions.

Net Loss. For the three months ended March 31, 2025, the Company incurred a net loss of $709,555, as compared to a net loss of $971,322 for the three months ended March 31, 2024.

Liquidity and Capital Resources – March 31, 2025

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

	Three Months Ended March 31,	
	2025	**2024**
Net cash used in operating activities	$ (568,483)	$ (789,225)
Net cash provided by (used in) investing activities	—	—
Net cash provided by financing activities	914,228	—
Net increase (decrease) in cash	$ 345,745	$ (789,225)

At March 31, 2025, the Company had working capital of $1,159,130, as compared to working capital of $827,219 at December 31, 2024, reflecting a net increase in working capital of $331,911 for the three months ended March 31, 2025. The increase in working capital during the three months ended March 31, 2025 was primarily the result of the net proceeds of $914,228 from the sale of securities in a registered direct offering and concurrent private placement that closed on February 13, 2025, the proceeds from which are being used to fund the Company's ongoing research and development activities and other operating expenses. At March 31, 2025, the Company had cash of $1,384,697 available to fund its operations.

Going Concern

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, the Company's independent registered public accounting firm included an explanatory paragraph in their report with respect to this uncertainty that accompanied the Company's audited consolidated financial statements as of and for the year ended December 31, 2024, in which they expressed substantial doubt about the Company's ability to continue as a going concern. The Company's consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company's ability to continue as a going concern is dependent upon its ability to raise additional equity capital to fund its research and development activities and to ultimately achieve sustainable operating revenues and profitability. The amount and timing of future cash requirements depends on the pace, 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 March 31, 2025 will provide sufficient working capital to fund the Company's operations, including its current clinical trial program with respect to the development of the Company's lead anti-cancer clinical compound LB-100, through no later than September 30, 2025. Existing cash resources will not be sufficient to complete the development of and obtain regulatory approval for the Company's product candidate, which will require that the Company raise significant additional capital. The Company estimates that it will need to raise additional capital to fund its operations by mid-2025 to be able to proactively manage its current business plan during the remainder of 2025 and during 2026. In addition, the Company's operating plans may change as a result of many factors that are currently unknown and/or outside of the control of the Company, and additional funds may be needed sooner than planned. The Company is considering various strategies and alternatives to obtain the required additional capital. However, as market conditions present uncertainty as to the Company's ability to secure additional funds, there can be no assurance that the Company will be able to secure additional financing on acceptable terms, as and when necessary, to continue to conduct operations.

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

At March 31, 2025, the Company's remaining financial contractual commitments pursuant to clinical trial agreements and clinical trial monitoring agreements not yet incurred aggregated $514,000, which are currently scheduled to be incurred through approximately December 31, 2027.

At March 31, 2025, the Company did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

Operating Activities. For the three months ended March 31, 2025, operating activities utilized cash of $568,483, as compared to utilizing cash of $789,225 for the three months ended March 31, 2024, to fund the Company's ongoing research and development activities and other operating expenses.

Investing Activities. For the three months ended March 31, 2025 and 2024, the Company did not have any investing activities.

Financing Activities. For the three months ended March 31, 2025, financing activities consisted of the gross proceeds from the sale of securities in the Company's registered direct offering of $1,050,003, reduced by offering costs of $135,775. For the three months ended March 31, 2024, the Company had no financing activities.

Principal Commitments

Clinical Trial Agreements

At March 31, 2025, the Company's remaining financial contractual commitments pursuant to clinical trial agreements and clinical trial monitoring agreements not yet incurred, as described below, aggregated $514,000, including clinical trial agreements of $269,000 and clinical trial monitoring agreements of $245,000, 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 March 31, 2025:

Description of Clinical Trial	Institution	Start Date	Projected End Date	Planned 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 colorectal cancer (Phase 1b)	Netherlands Cancer Institute (NKI)	August 2024	December 2026	37	Determine RP2D with atezolizumab	First patient entered August 2024, in total two patients entered	June 2026	NCT06012734	(1)
LB-100 combined with doxorubicin in advanced soft tissue sarcoma (Phase 1b)	GEIS	June 2023	Recruitment completed September 2024	14	Determine MTD and RP2D	Fourteen patients entered	December 2025	NCT05809830	$ 269,000
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)	TBD	NCT05809830	$ (1)
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	16 patients entered	December 2026	NCT06065462	(1)
Total									$ 269,000

(1) The Company has no financial contractual commitment associated with this clinical trial at March 31, 2025.

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 colorectal 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. A total of two patients have been enrolled to date. 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. The Investigational Review Board (IRB) of the Netherlands Cancer Institute has requested additional information with respect to these SAEs and the study has been paused for enrollment until the IRB's questions have been satisfactorily addressed (see "Specific Risks Associated with the Company's Business Activities - 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, which is included in accounts payable and accrued expenses at March 31, 2025 and December 31, 2024.

During the three months ended March 31, 2025 and 2024, the Company incurred costs of $0 and $69,001, respectively, pursuant to this Agreement. As of March 31, 2025, 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 March 31, 2025, 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 during the quarter ending December 31, 2025.

Given the focus on the combination of LB-100 with immunotherapy in ovarian clear cell carcinoma and colorectal cancer and the availability of capital resources, the Company entered into Amendment No. 1 to the Collaboration Agreement effective March 11, 2025 that relieved the Company of the financial obligation to support the randomized Phase 2 portion of the clinical trial contemplated in the Collaboration Agreement of approximately $3,095,000. As a result, it is uncertain as to whether the Phase 2 portion of this clinical trial will proceed.

The Company's agreement with GEIS provided for various payments based on achieving specific milestones over the term of the agreement. During the three months ended March 31, 2025 and 2024, the Company did not incur any costs pursuant to this agreement. Through March 31, 2025, 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 $269,000 for the Phase 1b portion of this clinical trial as of March 31, 2025, which is scheduled to be incurred through December 31, 2025. 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.

On February 25, 2025, the Company announced that it has added the Robert H. Lurie Comprehensive Cancer Center (Lurie Cancer Center) of Northwestern University as a second site in a clinical trial combining the Company's proprietary compound LB-100 with GSK's dostarlimab to treat ovarian clear cell cancer. Patient recruitment is underway, and the first patient has been dosed.

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 ended March 31, 2025, the Company incurred costs of $7,279 pursuant to this letter of intent and subsequent work order. As of March 31, 2025, total costs of $34,041 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 $63,000 as of March 31, 2025, 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 March 31, 2025 and 2024, the Company incurred costs of $0 and $4,500, respectively, pursuant to this work order. As of March 31, 2025, total costs of $89,323 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 March 31, 2025 and 2024, the Company incurred costs of $3,872 and $5,529, respectively, pursuant to this work order. As of March 31, 2025, total costs of $53,327 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 $98,000 as of March 31, 2025, which is expected to be incurred through December 31, 2026.

Netherlands Cancer Institute. On August 27, 2024, 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 colorectal 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 three months ended March 31, 2025, the Company incurred costs of $4,500 pursuant to this work order. As of March 31, 2025, total costs of $24,691 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 $83,000 as of March 31, 2025, 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 second minimum annual royalty for 2025 of $30,000 was paid in December 2024 and was included in other prepaid expenses in the consolidated balance sheet at December 31, 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, 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 March 31, 2025. 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 March 31, 2025 and 2024, the Company incurred costs of $7,397 and $53,113, respectively, 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 March 31, 2025, total costs of $83,040 have been incurred pursuant to this agreement. The Company's aggregate commitment pursuant to this agreement, less amounts previously paid to date, totaled approximately $1,765,000 as of March 31, 2025, which is expected to be incurred over approximately the next twenty years.

Other Significant Agreements and Contracts

NDA Consulting Corp. On December 24, 2013, the Company entered into a consulting agreement with NDA Consulting Corp. for consultation and advice in the field of oncology research and drug development. As part of the consulting agreement, NDA also agreed to have its president, Dr. Daniel D. Von Hoff, M.D., serve on the Company's Scientific Advisory Committee during the term of such consulting agreement. The term of the consulting agreement was for one year and provided for a quarterly cash fee of $4,000. The consulting agreement had been automatically renewed for additional one-year terms on its anniversary date, most recently on December 24, 2023, but was subsequently terminated by mutual agreement effective September 30, 2024. Consulting and advisory fees charged to operations pursuant to this consulting agreement were $4,000 for the three months ended March 31, 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 $14,000 and $20,000 during the three months ended March 31, 2025 and 2024, 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.

On October 4, 2024, the Company entered into Amendment No. 3 to the Development Collaboration Agreement with NKI, which suspended Amendment No. 2 and provided for a new study term of one year and starts upon the dosing of the first patient in the trial at a project cost of 100,000 Euros.

During the three months ended March 31, 2025 and 2024, the Company incurred charges of $0 and $67,119, 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 March 31, 2025, 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 100,000 Euros (approximately $108,000 as of March 31, 2025), as of March 31, 2025, 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 March 31, 2025 and 2024, the Company incurred costs of $28,092 and $3,894, respectively, pursuant to this contract. As of March 31, 2025, total costs of $368,614 have been incurred pursuant to this contract.

The Company's aggregate commitment pursuant to this contract, less amounts previously paid to date, totaled approximately $102,000 as of March 31, 2025.

Trends, Events and Uncertainties

Research and development of new pharmaceutical compounds by its nature is 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 any pharmaceutical compound to the extent needed to create future sales to sustain operations as contemplated herein.

There can be no assurance that the Company's pharmaceutical compound will obtain the regulatory approvals and market acceptance to achieve sustainable revenues sufficient to support the Company's operations. Even if the Company is able to generate revenues, there can be no assurance that the Company will be able to achieve operating profitability or positive operating cash flows. There can be no assurance 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, through strategic alliances, joint ventures or other transaction structures that could require the Company to relinquish rights to and/or control of LB-100, or to discontinue operations entirely.

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

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

In accordance with Exchange Act Rules 13a-15 and 15d-15, an evaluation was completed under the supervision and with the participation of the Company's management, including its Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of March 31, 2025, 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 March 31, 2025 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, 2024, as filed with the Securities and Exchange Commission on March 24, 2025 (the "2024 Form 10-K").

The Risk Factors set forth in the 2024 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 2024 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 2024 Form 10-K.

Nasdaq Compliance

The Company's common stock and warrants are traded on the Nasdaq Capital Market 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 letter from the Listing Qualifications Department (the "Staff") of the Nasdaq Stock Market LLC ("Nasdaq") indicating that the Company was not in compliance with the minimum stockholders' equity requirement of $2,500,000 for continued listing on the Nasdaq Capital Market under Listing Rule 5550(b)(1) (the "Stockholders' Equity Requirement").

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

On October 21, 2024, the Staff provided notice (the "Notice") to the Company that it had granted an extension through February 18, 2025 to regain compliance with the Stockholders' Equity Requirement, which required that the Company complete its capital raising initiatives and evidence compliance with the Stockholders' Equity Requirement through filing a Current Report on Form 8-K with the SEC providing certain required information.

As of February 18, 2025, the Company had not gained compliance with the Stockholders' Equity Requirement. On February 19, 2025, the Company received a Staff determination letter stating that the Company did not meet the terms of the extension because it did not complete its proposed financing initiatives to regain compliance. The Company timely requested a Hearing before a Nasdaq Hearings Panel (the "Panel").

On April 17, 2025, the Company received notice that the Panel had granted the Company an extension in which to regain compliance with all continued listing rules of the Nasdaq Capital Market. The Panel's determination followed a hearing on April 3, 2025, at which the Panel considered the Company's plan to regain compliance with the Stockholders' Equity Requirement. As a result of the extension, the Panel granted the Company's request for continued listing on the Nasdaq Capital Market, provided that the Company demonstrates compliance with the Stockholders' Equity Requirement and all other continued listing requirements for the Nasdaq Capital Market by July 3, 2025.

During the extension period, the Company's common stock and warrants will continue to trade on The Nasdaq Capital Market under the symbols "LIXT" and "LIXTW", respectively.

The Company is undertaking measures to regain compliance under Nasdaq's continued listing requirements within the extension period and to remain listed on the Nasdaq Capital Market. However, there can be no assurances that the Company will ultimately be able to regain compliance with the Stockholders' Equity Requirement, or be able to maintain compliance with all other applicable requirements for continued listing on the Nasdaq Capital Market. The Company's failure to meet these requirements would result in the Company's securities being delisted from the Nasdaq Capital Market.

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

The occurrence of an SAE and any resulting clinical hold could also harm the Company's reputation with patients, physicians, health institutions, and investors, diminish its ability to attract clinical trial participants, and damage its ability to interest investors and obtain financing in the future. There can be no assurance that the Company 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. The Institutional Review Board (the "IRB") of the Netherlands Cancer Institute ("NKI") has put the colorectal cancer study on hold. The adverse reactions that developed in the two patients were dyspnea (shortness of breath) due to lung toxicity possibly or probably related to the combination of LB-100 and atezolizumab in one patient and fever and aphasia possibly or probably related to the combination of LB-100 and atezolizumab in the second patient. The patient who developed lung toxicity deceased due to the combination of lung metastases of colorectal cancer and dyspnea. The patient with fever and aphasia fully recovered from the adverse events with supportive medication.

Given the identified adverse events in the two patients in the clinical trial, the IRB requested from the principal investigator of the study at the NKI information as to whether the adverse events could have been caused by the combination of LB-100 and atezolizumab and information about the mode of action of the combination of LB-100 and atezolizumab. The principal investigator is preparing a response to the IRB detailing the safety experience with LB-100 given alone and in combination with other cancer drugs, especially doxorubicin and dostarlimab. Doxorubicin is a well-known chemotherapy, and dostarlimab is a well-known immunotherapy of which the mode of action is closely related to that of atezolizumab.

The reported adverse events in the colorectal cancer study have not been seen in any other patients thus far treated with LB-100 alone or in combination with other cancer drugs. Through March 2025, a total of 78 patients have received or are receiving experimental treatment with LB-100. It is expected that it will take at least two months to prepare a detailed response to the IRB, during which time the Company intends to update the safety overview of LB-100.

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

Effective February 13, 2025, the Company sold, in a registered direct offering, an aggregate of 434,784 shares of the Company's common stock at an offering price of $2.415 per share, and in a concurrent private placement, warrants to purchase an aggregate of 434,784 shares of common stock. The common stock warrants were immediately exercisable for a term of five years from issuance at an exercise price of $2.29 per share.

The common stock warrants and the shares of common stock underlying the common stock warrants were not registered under the Securities Act, and were issued in reliance on an exemption from the registration requirements of the Securities Act afforded by Section 4(a)(2) thereof. The shares of common stock issuable upon exercise of the common stock warrants were registered for resale in a registration statement on Form S-1 declared effective by the SEC on April 10, 2025.

The registered direct offering and the concurrent private placement generated gross proceeds of $1,050,003 before deducing the placement agent's fee and related offering costs of $135,775, resulting in net proceeds of $914,228. Pursuant to the placement agent agreement, the Company granted the placement agent warrants to purchase 32,609 shares of common stock at an exercise price of $3.0188 per share and expiring on February 11, 2030.

The net proceeds from the registered direct offering and the concurrent private placement will be used to fund the Company's operations.

Additional information with respect to this equity financing is provided at "Note 4. Stockholders' Equity – Common Stock – February 2025 Equity Offering".

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

During the three months ended March 31, 2025, 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: May 12, 2025

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

Date: May 12, 2025

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: May 12, 2025

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: May 12, 2025

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 March 31, 2025 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

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

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

Date: May 12, 2025

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 March 31, 2025 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

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

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

Date: May 12, 2025

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