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

OR

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

For the Transition Period from _____ to _____

Commission File Number 001-33650

LISATA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	22-2343568
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
110 Allen Road, 2nd Floor, Basking Ridge, New Jersey	07920
(Address of principal executive offices)	(zip code)

Registrant's telephone number, including area code: 908-842-0100

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 $0.001 per share	LSTA	The Nasdaq Capital Market

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 and post 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 definition 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 ☒

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	**Outstanding as of May 8, 2025**
Common stock, $0.001 par value per share	8,598,204 shares

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report (this "Quarterly Report") contains "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995, as well as historical information. When used in this Quarterly Report, statements that are not statements of current or historical fact may be deemed to be forward-looking statements, including, without limitation, all statements related to any expectations of revenues, expenses, cash flows, earnings or losses from operations, cash required to maintain current and planned operations, capital or other financial items; any statements of the plans, strategies and objectives of management for future operations; any plans or expectations with respect to product research, development and commercialization, including regulatory approvals; any other statements of expectations, plans, intentions or beliefs; and any statements of assumptions underlying any of the foregoing. Without limiting the foregoing, the words "plan," "project," "forecast," "outlook," "intend," "may," "will," "expect," "anticipate," "likely," "believe," "could," "anticipate," "estimate," "continue," "target" or similar expressions or other variations or comparable terminology are intended to identify such forward-looking statements, although some forward-looking statements are expressed differently. We remind readers that forward-looking statements are merely predictions and therefore inherently subject to uncertainties and other factors and involve known and unknown risks that could cause the actual results, performance, levels of activity or our achievements or industry results, to be materially different from any future results, performance, levels of activity or our achievements or industry results expressed or implied by such forward-looking statements. Factors that could cause our actual results to differ materially from anticipated results expressed or implied by forward-looking statements include, among others:

- our ability to obtain sufficient capital or strategic business arrangements to fund our operations and expansion plans, including collecting amounts owed to us under various licensing and other strategic arrangements, meeting our financial obligations under various licensing and other strategic arrangements, the funding of our clinical trials for product candidates, and the commercialization of the relevant technology;
- our ability to build and maintain the management and human resources infrastructure necessary to support the operation and/or growth of our business;
- whether a market is established for our products and our ability to capture a meaningful share of this market;
- scientific, regulatory and medical developments beyond our control;
- our ability to obtain and maintain, as applicable, appropriate governmental licenses, accreditations or certifications or to comply with healthcare laws and regulations or any other adverse effect or limitations caused by government regulation of our business;
- whether any of our current or future patent applications result in issued patents, the scope of those patents and our ability to obtain and maintain other rights to technology required or desirable for the conduct of our business, and our ability to commercialize products without infringing upon the claims of third-party patents;
- whether any potential strategic or financial benefits of various licensing agreements will be realized;
- our ability to diversify our pipeline of development product candidates, which could include an acquisition, merger, business combination, in-license or other strategic transaction, and whether any of such efforts will result in us entering into or completing any transaction or that any such transaction, if completed, will add to shareholder value;
- the results of our development activities;
- our ability to complete our other planned clinical trials (or initiate other trials) in accordance with our estimated timelines due to delays associated with enrolling patients due to the novelty of the treatment, the size of the patient population, competition with other clinical trials for similar subjects, patient and/or investigator site availability and accessibility due to external macroenvironmental factors and the need of patients to meet the inclusion criteria of the trial or otherwise;
- the extent to which any future public health crisis and their long-term effects may impact, directly or indirectly, our business, including our clinical trials and financial condition; and
- other factors discussed in "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on February 27, 2025 (our "2024 Form 10-K").

The factors discussed herein, including those risks described in "Item 1A. Risk Factors" and elsewhere in our 2024 Form 10-K and in our other periodic filings with the SEC, which are available for review at *www.sec.gov,* could cause actual results and developments to be materially different from those expressed or implied by such statements. All forward-looking statements attributable to us are expressly qualified in their entirety by these and other factors. Readers are cautioned not to place undue

reliance on these forward-looking statements, which speak only as of the date they were made. Except as required by law, we undertake no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

LISATA THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)

	March 31, 2025	December 31, 2024
ASSETS	**(Unaudited)**	
Cash and cash equivalents	$ 20,217	$ 16,209
Marketable securities	5,616	15,036
Accounts receivable	750	900
Prepaid and other current assets	2,034	2,433
Total current assets	28,617	34,578
Property and equipment, net	74	72
Acquired license - intangible, net	174	192
Other assets	116	160
Total assets	$ 28,981	$ 35,002
LIABILITIES, NON-CONTROLLING INTERESTS AND STOCKHOLDERS' EQUITY		
Liabilities		
Accounts payable	$ 602	$ 1,284
Accrued liabilities	3,205	4,329
Total current liabilities	3,807	5,613
Other long-term liabilities	72	72
Total liabilities	3,879	5,685
Commitments and Contingencies (Note 14)		
Stockholders' Equity		
Common stock, $0.001 par value, authorized 500,000,000 shares; issued 8,620,900 and 8,409,582 shares at March 31, 2025 and December 31, 2024, respectively; and outstanding, 8,620,162 and 8,408,844 shares at March 31, 2025 and December 31, 2024, respectively	9	8
Additional paid-in capital	578,923	578,418
Treasury stock, at cost; 738 shares at March 31, 2025 and December 31, 2024	(708)	(708)
Accumulated deficit	(552,790)	(548,066)
Accumulated other comprehensive loss	(78)	(81)
Total Lisata Therapeutics, Inc. stockholders' equity	25,356	29,571
Non-controlling interests	(254)	(254)
Total equity	25,102	29,317
Total liabilities, non-controlling interests and stockholders' equity	$ 28,981	$ 35,002

See accompanying notes to consolidated financial statements.

LISATA THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except per share data)

	Three Months Ended March 31,	
	2025	**2024**
Operating Expenses:		
Research and development	$ 2,602	$ 3,241
General and administrative	3,245	3,360
Total operating expenses	5,847	6,601
Operating loss	(5,847)	(6,601)
Other income (expense):		
Investment income, net	266	589
Other expense, net	(105)	(187)
Total other income	161	402
Net loss before benefit from income taxes and noncontrolling interests	(5,686)	(6,199)
Benefit from income taxes	(962)	(798)
Net loss	$ (4,724)	$ (5,401)
Less - net income (loss) attributable to noncontrolling interests	—	—
Net loss attributable to Lisata Therapeutics, Inc. common stockholders	$ (4,724)	$ (5,401)
Basic and diluted loss per share		
Lisata Therapeutics, Inc. common stockholders	$ (0.55)	$ (0.65)
Weighted average common shares outstanding		
Basic and diluted shares	8,602	8,294

See accompanying notes to consolidated financial statements.

LISATA THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited)
(In thousands)

	Three Months Ended March 31,	
	2025	**2024**
Net loss	$ (4,724)	$ (5,401)
Other comprehensive gain (loss):		
Available for sale securities - net unrealized loss	(2)	(13)
Cumulative translation adjustment arising during the period	5	(49)
Total other comprehensive gain (loss)	3	(62)
Comprehensive loss attributable to Lisata Therapeutics, Inc. common stockholders	$ (4,721)	$ (5,463)

See accompanying notes to consolidated financial statements.

LISATA THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EQUITY
(Unaudited)
(In thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Treasury Stock	Total Lisata Therapeutics, Inc. Stockholders' Equity	Non-Controlling Interest in Subsidiary	Total Equity
	Shares	Amount							
Balance at December 31, 2023	8,151	$ 8	$ 576,971	$ (42)	$ (528,081)	$ (708)	$ 48,148	$ (254)	$ 47,894
Net loss	—	—	—	—	(5,401)	—	(5,401)	—	(5,401)
Share-based compensation	157	—	312	—	—	—	312	—	312
Unrealized loss on marketable securities	—	—	—	(13)	—	—	(13)	—	(13)
Foreign currency translation adjustment	—	—	—	(49)	—	—	(49)	—	(49)
Balance at March 31, 2024	8,308	$ 8	$ 577,283	$ (104)	$ (533,482)	$ (708)	$ 42,997	$ (254)	$ 42,743

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Treasury Stock	Total Lisata Therapeutics, Inc. Stockholders' Equity	Non-Controlling Interest in Subsidiary	Total Equity
	Shares	Amount							
Balance at December 31, 2024	8,410	$ 8	$ 578,418	$ (81)	$ (548,066)	$ (708)	$ 29,571	$ (254)	$ 29,317
Net loss	—	—	—	—	(4,724)	—	(4,724)	—	(4,724)
Share-based compensation	151	—	286	—	—	—	286	—	286
Net proceeds from issuances of common stock	56	1	211	—	—	—	212	—	212
Proceeds from option exercise	4	—	8	—	—	—	8	—	8
Unrealized loss on marketable securities	—	—	—	(2)	—	—	(2)	—	(2)
Foreign currency translation adjustment	—	—	—	5	—	—	5	—	5
Balance at March 31, 2025	8,621	$ 9	$ 578,923	$ (78)	$ (552,790)	$ (708)	$ 25,356	$ (254)	$ 25,102

LISATA THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Three Months Ended March 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (4,724)	$ (5,401)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	530	454
Depreciation and amortization	43	46
Loss from equity method investment	—	100
Amortization/accretion on marketable securities	(41)	(152)
Changes in operating assets and liabilities:		
Accounts receivable	150	—
Prepaid and other current assets	405	(872)
Other assets	44	41
Accounts payable, accrued liabilities and other liabilities	(1,809)	(1,243)
Net cash used in operating activities	(5,402)	(7,027)
Cash flows from investing activities:		
Purchase of marketable securities	(5,055)	(18,824)
Sale of marketable securities	14,514	25,360
Purchase of property and equipment	(28)	—
Investment in Impilo Therapeutics	—	(100)
Net cash provided by investing activities	9,431	6,436
Cash flows from financing activities:		
Proceeds from exercise of options	8	—
Tax withholding payments on net share settlement equity awards	(243)	(142)
Net proceeds from issuance of common stock	212	—
Net cash used in financing activities	(23)	(142)
Effect of exchange rate changes on cash	2	(55)
Net increase (decrease) in cash and cash equivalents	4,008	(788)
Cash and cash equivalents at beginning of period	16,209	22,593
Cash and cash equivalents at end of period	$ 20,217	$ 21,805

See accompanying notes to consolidated financial statements.

LISATA THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

Note 1 – Description of Business

Overview

Lisata Therapeutics, Inc. (together with its subsidiaries, the "Company") is a clinical-stage pharmaceutical company dedicated to the discovery, development, and commercialization of innovative therapies for the treatment of solid tumors and other major diseases. The Company's investigational product, certepetide (formerly known as LSTA1 or CEND-1), is designed to activate a novel uptake pathway that allows co-administered or tethered (i.e., molecularly bound) anti-cancer drugs to target and penetrate solid tumors more effectively. Certepetide actuates this active transport system in a tumor-specific manner, resulting in systemically co-administered anti-cancer drugs more efficiently penetrating and accumulating in the tumor, while normal tissues are expected to remain unaffected. Certepetide has also been shown to modify the tumor microenvironment ("TME") by reducing T-regulatory cells and augmenting cytotoxic T cells, thereby making tumors more susceptible to immunotherapies while also inhibiting the metastatic cascade (i.e., the spread of cancer to other parts of the body). The Company, its collaborators and other researchers have amassed and continue to amass significant non-clinical data demonstrating enhanced delivery of a range of existing and emerging anti-cancer therapies, including chemotherapeutics, immunotherapies, and RNA-based therapeutics. To date, certepetide has also demonstrated favorable safety, tolerability and activity in completed and ongoing clinical trials designed to enhance delivery of standard-of-care chemotherapy for pancreatic cancer. The Company is exploring certepetide as a means to enable a variety of therapeutic modalities to treat a range of solid tumors more effectively. Currently, certepetide is the subject of several Phase 2 clinical studies being conducted globally in a variety of solid tumor types, including metastatic pancreatic ductal adenocarcinoma (mPDAC), cholangiocarcinoma, appendiceal cancer, colon cancer and glioblastoma multiforme in combination with a variety of anti-cancer regimens.

The Company's leadership team has decades of collective biopharmaceutical and pharmaceutical product development experience across a variety of therapeutic categories and at all stages of development from preclinical through to product registration and launch. The Company's goal is to develop and commercialize products that address important unmet medical needs.

The Company has a history of net operating losses and negative cash flows from operating activities, and has cash, cash equivalents and marketable securities of approximately $25.8 million as of March 31, 2025. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant revenues from its products currently in development. To manage capital for operating needs in the short-term, initiation of the FORTIFIDE study remains on hold as the Company is investigating a potentially faster and more cost-effective approach to achieving the study objective. The Company has similarly decided to delay commencement of certain phase 3 readiness activities for chemistry, manufacturing and controls ("CMC"). The Company believes that, as a result, it currently has sufficient cash to meet its funding requirements over the next year. To meet our long-term liquidity needs, the Company expects that it will need additional financing, which could result in additional potential issuances of debt or equity securities in public or private financings, partnerships and/or collaborations and/or sale of assets.

Basis of Presentation

The accompanying unaudited Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the SEC for interim financial information. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, the accompanying Consolidated Financial Statements of the Company and its subsidiaries, which are unaudited, include all normal and recurring adjustments considered necessary to present fairly the Company's financial position as of March 31, 2025, and the results of its operations and its cash flows for the periods presented. The unaudited consolidated financial statements herein should be read together with the historical consolidated financial statements of the Company for the years ended December 31, 2024 and 2023 included in our 2024 Form 10-K. Operating results for the three months ended March 31, 2025 are not necessarily indicative of the results that may be expected for the year ending December 31, 2025.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements. Estimates also affect the reported amounts of expenses during the reporting

period. The Company bases its estimates on historical experience and other assumptions believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. The Company makes critical estimates and assumptions in determining stock-based awards values. Accordingly, actual results could differ from those estimates and assumptions.

Segment Information

The Company operates as one operating segment, the research and development of its investigational drug product. The Company's Chief Operating Decision Maker ("CODM") is its Chief Executive Officer, who manages the business on a consolidated basis.

Principles of Consolidation

The Consolidated Financial Statements include the accounts of Lisata Therapeutics, Inc. and its wholly owned and majority owned subsidiaries and affiliates. All intercompany activities have been eliminated in consolidation.

Foreign Currency Remeasurement

The Company's reporting currency is the U.S. Dollar. The functional currency of Lisata Therapeutics Australia Pty Ltd., which is a foreign subsidiary of the Company, is the Australian Dollar. The assets and liabilities of Lisata Therapeutics Australia Pty Ltd. are translated into U.S. Dollars at the exchange rates in effect at each balance sheet date, and the results of operations are translated using the average exchange rates prevailing throughout the reporting period. Adjustments resulting from translating foreign functional currency financial statements into U.S. Dollars are included in the foreign currency translation adjustment, a component of accumulated other comprehensive income (loss) in stockholders' equity.

Note 2 – Summary of Significant Accounting Policies

Cash and Cash Equivalents

Cash and cash equivalents include short-term, highly liquid, investments with maturities of ninety days or less when purchased.

Concentration of Risks

The Company is subject to credit risk from its portfolio of cash, cash equivalents, accounts receivable and marketable securities. Under its investment policy, the Company limits amounts invested in such securities by credit rating, maturity, industry group, investment type and issuer, except for securities issued by the U.S. government, thereby reducing credit risk exposure. Cash is held at major banks in the United States and may exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. The goals of the Company's investment policy, in order of priority, are as follows: safety and preservation of principal and diversification of risk, liquidity of investments sufficient to meet cash flow requirements, and a competitive after-tax rate of return. The Company's accounts receivable balance as of March 31, 2025 and December 31, 2024 is derived from its license agreement dated November 30, 2024, more fully described in Note 17. The Company has no significant off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts, or other hedging arrangements.

Accounts Receivable

Accounts receivable is stated at historical cost, less allowance for credit losses. The Company records an expense based on a forward-looking current expected credit loss model to maintain its allowance for credit losses, which replaced the allowance for doubtful accounts. When determining its allowance for trade accounts receivable, the Company considers the probability of recoverability of accounts receivable based on experience, taking into account current collection trends and general economic factors, including bankruptcy rates. The Company also considers future economic trends to estimate expected credit losses over the lifetime of the asset. Credit risks are assessed based on historical write-offs, net of recoveries, as well as an analysis of the aged accounts receivable balances with allowances generally increasing as the receivable ages. Accounts receivable may be fully reserved for when specific collection issues are known to exist, such as pending bankruptcies. Account balances are written off against the allowance when it is determined that the receivable will not be recovered. As of March 31, 2025 and December 31, 2024, there was no allowance for credit losses.

Marketable Securities

The Company determines the appropriate classification of its marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. All of the Company's marketable securities are considered as available-for-sale and

carried at estimated fair values and reported in cash equivalents and marketable securities. Unrealized gains and losses on available-for-sale securities, that are not the result of credit losses, are excluded from net income and reported in accumulated other comprehensive income (loss) as a separate component of stockholders' equity. Other income (expense), net, includes interest, dividends, amortization of purchase premiums and discounts, realized gains and losses on sales of securities and credit losses recognized through an allowance for credit losses, if any. The cost of securities sold is based on the specific identification method. The Company regularly reviews all of its investments for other-than-temporary declines in fair value. The Company's review includes the consideration of the cause of the impairment, including the creditworthiness of the security issuers, the number of securities in an unrealized loss position, the severity and duration of the unrealized losses, whether the Company has the intent to sell the securities and whether it is more likely than not that it will be required to sell the securities before the recovery of their amortized cost basis. When the Company determines that the decline in fair value of an investment is below its accounting basis and this decline is other-than-temporary, it reduces the carrying value of the security it holds and records a loss for the amount of such decline.

Property and Equipment

The cost of property and equipment is depreciated over the estimated useful lives of the related assets. Depreciation is computed on the straight-line method. Repairs and maintenance expenditures that do not extend original asset lives are charged to expense as incurred. The estimated useful lives of property and equipment are as follows:

Furniture and fixtures	10 years
Computer equipment	3 years
Software	3 years
Leasehold improvements	Shorter of useful life or lease term

Long-lived Assets

Long-lived assets consist of property and equipment. The assets are amortized on a straight-line basis over their respective useful lives. The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset exceeds the fair value of the asset. If other events or changes in circumstances indicate that the carrying amount of an asset that the Company expects to hold and use may not be recoverable, the Company will estimate the undiscounted future cash flows expected to result from the use of the asset and/or its eventual disposition, and recognize an impairment loss, if any. The impairment loss, if determined to be necessary, would be measured as the amount by which the carrying amount of the assets exceeds the fair value of the assets.

Share-Based Compensation

The Company expenses all share-based payment awards to employees, directors, and consultants, including grants of stock options, warrants, and restricted stock, over the requisite service period based on the grant date fair value of the awards. For awards with performance-based vesting criteria, the Company estimates the probability of achievement of the performance criteria and recognizes compensation expense related to those awards expected to vest. The Company determines the fair value of option awards using the Black-Scholes option-pricing model which uses both historical and current market data to estimate the fair value. This method incorporates various assumptions such as the risk-free interest rate, expected volatility, expected dividend yield and expected life of the options or warrants. Share-based compensation expense also includes an estimate, which is made at the time of the grant, of the number of awards that are expected to be forfeited. The fair value of the Company’s restricted stock and restricted stock units is based on the closing market price of the Company’s common stock on the date of grant.

Loss Per Share

Basic loss per share is based on the weighted effect of all shares of common stock issued and outstanding and is calculated by dividing net loss attributable to common stockholders by the weighted average shares outstanding during the period. Diluted loss per share is calculated by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock used in the basic loss per share calculation plus the number of shares of common stock that would be issued assuming conversion of all potentially dilutive securities outstanding. Diluted loss per share is not presented as such potentially dilutive securities are anti-dilutive to losses incurred in all periods presented.

Treasury Stock

Treasury stock purchases are accounted for under the cost method whereby the entire cost of the acquired stock is recorded as treasury stock. Gains or losses on the subsequent reissuance of shares are credited or charged to additional paid in capital.

Research and Development Costs

Research and development ("R&D") expenses include salaries, benefits, and other headcount related costs, clinical trial and related clinical manufacturing costs, contract and other outside service fees including sponsored research agreements, and facilities and overhead costs. The Company expenses the costs associated with research and development activities when incurred.

To further drive the Company's initiatives, the Company will continue targeting key governmental agencies and not-for-profit organizations to contribute funds for the Company's research and development programs. The Company accounts for such grants as a deduction to the related expense in research and development operating expenses when earned.

In-process Research and Development Expense

Upfront payments that relate to the acquisition of a new drug compound, as well as pre-commercial milestone payments, are immediately expensed as IPR&D in the period in which they are incurred, provided that the new drug compound did not also include processes or activities that would constitute a "business" as defined under U.S. GAAP, the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no established alternative future use. The Company accounts for contingent consideration payable upon achievement of certain regulatory, development or sales milestones in such asset acquisitions when the underlying contingency is probable and estimable. Milestone payments made to third parties subsequent to regulatory approval will be capitalized as intangible assets and amortized over the estimated remaining useful life of the related product.

Intangible Asset

The Company's intangible asset consists of a single asset, a license agreement with Qilu Pharmaceutical, Co., Ltd. ("Qilu") acquired in the Company's acquisition of Cend Therapeutics, Inc (the "Cend Merger"), with a value of $0.4 million. The intangible asset is stated at fair value and is amortized using the straight-line method over its estimated useful life of 5.00 years. Amortization expense was $17 thousand for the three months ended March 31, 2025, and $17 thousand for the three months ended March 31, 2024, respectively. The intangible asset is reviewed for potential impairment when events or circumstances indicate that carrying amounts may not be recoverable. The projected amortization expense is $71 thousand per year for the next 2.50 years.

Revenue Recognition

The Company evaluates license and collaboration arrangements to determine whether units of account within the arrangement exhibit the characteristics of a vendor and customer relationship. For arrangements and units of account where a customer relationship exists, the Company applies the revenue recognition guidance. The Company recognizes revenue upon the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with customers the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies the performance obligations. At contract inception, the Company assesses the goods or services promised within each contract and assesses whether each promised good or service is distinct and determines those that are performance obligations. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Taxes imposed by governmental authorities on the Company's revenue, such as sales taxes and withholding taxes, are excluded from net revenue.

If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. If licenses are bundled with other performance obligations, the Company would utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company recognized no revenue for the three months ended March 31, 2025 and 2024.

Milestones

At the inception of each arrangement that includes milestone payments (variable consideration), the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company or the Company's collaboration partner's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjusts the Company's estimate of the overall transaction price. Any such adjustments are allocated on a cumulative catch-up basis to satisfied and partially satisfied performance obligations, with the consideration allocated to an ongoing performance obligation being recognized over the period of performance. For the three months ended March 31, 2025 and March 31, 2024, the Company has not recognized revenue related to milestones.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue from any collaborative arrangement.

Note 3 – Available-for-Sale Securities

The following table is a summary of available-for-sale securities recorded in cash and cash equivalents or marketable securities in the Company's Consolidated Balance Sheets (in thousands):

	March 31, 2025				December 31, 2024			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities	$ 10,301	$ —	$ (6)	$ 10,295	$ 16,025	$ —	$ (4)	$ 16,021
Money market funds	12,129	—	—	12,129	6,614	—	—	6,614
Agency bonds	—	—	—	—	613	—	—	613
Treasury bills	—	—	—	—	1,496	—	—	1,496
Municipal debt securities	560	—	—	560	905	—	—	905
Total	$ 22,990	$ —	$ (6)	$ 22,984	$ 25,653	$ —	$ (4)	$ 25,649

Estimated fair values of available-for-sale securities are generally based on prices obtained from commercial pricing services. The following table summarizes the classification of the available-for-sale securities in the Company's Consolidated Balance Sheets (in thousands):

	March 31, 2025	December 31, 2024
Cash equivalents	$ 17,368	$ 10,613
Marketable securities	5,616	15,036
Total	$ 22,984	$ 25,649

The following table summarizes the Company's portfolio of available-for-sale securities by contractual maturity (in thousands):

	March 31, 2025	
	Amortized Cost	Estimated Fair Value
Less than one year	$ 22,990	$ 22,984
Greater than one year	—	—
Total	$ 22,990	$ 22,984

Note 4 – Property and Equipment

Property and equipment consisted of the following (in thousands):

	March 31, 2025	December 31, 2024
Computer equipment	617	589
Leasehold improvements	72	72
Property and equipment, gross	689	661
Accumulated depreciation	(615)	(589)
Property and equipment, net	$ 74	$ 72

The Company’s results included depreciation expense of approximately $26 thousand and $29 thousand for the three months ended March 31, 2025 and 2024, respectively.

Note 5 – Income (Loss) Per Share

For the three months ended March 31, 2025 and 2024, the Company incurred net losses and therefore no common stock equivalents were utilized in the calculation of diluted loss per share as they are anti-dilutive in the periods presented. At March 31, 2025 and 2024, the Company excluded the following potentially dilutive securities (in thousands):

	March 31	
	2025	2024
Stock options	1,529	1,454
Warrants	1,497	1,422
Restricted stock units	325	354

Note 6 – Fair Value Measurements

Fair value of financial assets and liabilities that are being measured and reported are defined as the exchange price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the principal market at the measurement date (exit price). The Company is required to classify fair value measurements in one of the following categories:

Level 1 inputs are defined as quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2 inputs are defined as inputs other than quoted prices included within Level 1 that are observable for the assets or liabilities, either directly or indirectly.

Level 3 inputs are defined as unobservable inputs for the assets or liabilities.

Financial assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurement. The Company’s assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of the fair value of assets and liabilities and their placement within the fair value hierarchy levels.

The Company's financial assets and liabilities that were accounted for at fair value on a recurring basis as of March 31, 2025 and December 31, 2024 were as follows (in thousands):

	March 31, 2025				December 31, 2024			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Cash equivalents	$ 17,368	$ —	$ —	$ 17,368	$ 10,613	$ —	$ —	$ 10,613
Marketable securities - available-for-sale	—	5,616	—	5,616	—	15,036	—	15,036
	$ 17,368	$ 5,616	$ —	$ 22,984	$ 10,613	$ 15,036	$ —	$ 25,649

The carrying values of cash, cash equivalents, accounts receivable, accounts payable and accrued expenses approximate fair value as of March 31, 2025 and December 31, 2024, due to the short maturity nature of these items.

Note 7 – Accrued Liabilities

Accrued liabilities as of March 31, 2025 and December 31, 2024 were as follows (in thousands):

	March 31, 2025	December 31, 2024
Salaries, employee benefits and related taxes	$ 1,532	$ 2,640
Clinical and R&D related liabilities	1,166	1,333
Accounting & tax consulting liabilities	133	55
Operating lease liabilities — current	92	137
Other	282	164
Total	$ 3,205	$ 4,329

Note 8 – Operating Leases

The Company has an operating lease for one office which expires on September 30, 2025. The Company estimates its incremental borrowing rate at lease commencement to determine the present value of lease payments as the Company's lease does not provide an implicit rate of return. The Company recognizes lease expense on a straight-line basis over the lease term. For lease agreements entered into or reassessed after the adoption of ASU No. 2016-02, Leases (Topic 842), the Company elected to account for non-lease components associated with its leases and lease components as a single lease component. The Company's lease includes an option for the Company to extend the lease term and/or sub-lease space in whole or in part.

Operating lease liabilities and right-of-use assets were recorded in the following captions of the Company's balance sheet as follows (in thousands):

	March 31, 2025	December 31, 2024
Right-of-Use Assets:		
Other assets	$ 93	$ 138
Total Right-of-Use Asset	$ 93	$ 138
Operating Lease Liabilities:		
Accrued liabilities	$ 92	$ 137
Total Operating Lease Liabilities	$ 92	$ 137

As of March 31, 2025, the weighted average remaining lease term for the Company's operating lease was 0.50 years, and the weighted average discount rate for the Company's operating lease was 9.625%. As of December 31, 2024, the weighted average remaining lease term for the Company's operating lease was 0.75 years, and the weighted average discount rate for the Company's operating lease was 9.625%.

Future minimum lease payments under the lease agreement as of March 31, 2025 were as follows (in thousands):

Years ended	Operating Leases
2025	95
Total lease payments	95
Less: Amounts representing interest	(3)
Present value of lease liabilities	$ 92

Note 9 – Stockholders' Equity

Equity Issuances

At The Market Offering Agreement

On June 4, 2021, the Company entered into an At The Market Offering Agreement (the “ATM Agreement”) with H.C. Wainwright & Co., LLC, as sales agent, in connection with an “at the market offering” under which the Company from time to time may offer and sell shares of its common stock, having an aggregate offering price of up to $50.0 million. As of the date of this filing and so long as the Company’s public float remains below $75.0 million, the Company is subject to limitations pursuant to General Instruction I.B.6 of Form S-3 (the “Baby Shelf Limitation”), which limits the amount the Company can offer to up to one-third of its public float during any trailing 12-month period. Subsequent to the filing of a prospectus supplement to the Company's Registration Statement on Form S-3 (File No. 333-279034) relating to the at the market offering on August 21, 2024, the aggregate market value of its outstanding common stock held by non-affiliates was approximately $29.6 million. Pursuant to the Baby Shelf Limitation, since the aggregate market value of the Company's outstanding common stock held by non-affiliates was below $75.0 million at the time of such prospectus supplement filing, the aggregate amount of securities that the Company is permitted to offer and sell is now $9,855,890, which is equal to one-third of the aggregate market value of our common stock held by non-affiliates as of August 20, 2024. If the Company’s public float exceeds $75.0 million on a future measurement date, it will no longer be subject to the Baby Shelf Limitation. During the three months ended March 31, 2025, the Company issued 55,578 shares of common stock under the ATM Agreement for net proceeds of $211,369. Since inception, the Company has issued 123,751 shares of common stock under the ATM Agreement for net proceeds of $492,216.

Stock Options and Warrants

The following table summarizes the activity for stock options and warrants for the three months ended March 31, 2025:

	Stock Options				Warrants			
	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (In Thousands)	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (In Thousands)
Outstanding at December 31, 2024	1,440,535	$ 8.82	5.46	$ 157.0	1,496,744	$ 40.52	1.29	$ 7.5
Changes during the period:								
Granted	111,400	3.80			—	—		
Exercised	(4,329)	1.88			—	—		
Forfeited	—	—			—	—		
Expired	(18,215)	198.23			—	—		
Outstanding at March 31, 2025	1,529,391	$ 6.22	5.62	$ 79.0	1,496,744	$ 40.52	1.05	$ —
Vested at March 31, 2025 or expected to vest in the future	1,517,488	$ 6.24	5.59	$ 79.0	1,496,744	$ 40.52	1.05	$ —
Vested at March 31, 2025	1,344,298	$ 6.60	5.14	$ 78.0	1,496,744	$ 40.52	1.05	$ —

Restricted Stock

During the three months ended March 31, 2025 and 2024, the Company issued restricted stock for services as follows (in thousands, except share data):

	Three Months Ended March 31,	
	2025	**2024**
Number of restricted stock issued	215,550	203,800
Value of restricted stock issued	$ 819	$ 628

The weighted average estimated fair value of restricted stock issued for services in the three months ended March 31, 2025 and 2024 was $3.80 and $3.08 per share, respectively. The fair value of the restricted stock was determined using the Company's closing stock price on the date of issuance. The vesting terms of restricted stock issuances are generally between one and four years.

The following is a summary of the changes in non-vested restricted stock for the three months ended March 31, 2025:

	Restricted Stock Shares	Weighted Average Grant-Date Fair Value
Non-vested at December 31, 2024	228,428	$ 3.67
Changes during the Year:		
Granted	215,550	$ 3.80
Vested	(149,367)	$ 4.26
Forfeited	—	$ —
Non-vested at March 31, 2025	294,611	$ 3.47

Restricted Stock Units

During the three months ended March 31, 2025 and 2024, the Company issued restricted stock units for services as follows (in thousands, except share data):

	Three Months Ended March 31,	
	2025	2024
Number of restricted stock units issued	78,945	205,300
Value of restricted stock units issued	$ 300	$ 632

The weighted average estimated fair value of restricted stock units issued for services in the three months ended March 31, 2025 and 2024 was $3.80 and $3.08 per share, respectively. The fair value of the restricted stock units was determined using the Company's closing stock price on the date of issuance. The vesting terms of restricted stock unit issuances are generally one year, or upon the achievement of performance-based milestones.

The following is a summary of the changes in non-vested restricted stock units for the three months ended March 31, 2025:

	Restricted Stock Units	Weighted Average Grant-Date Fair Value
Non-vested at December 31, 2024	103,800	$ 3.28
Changes during the Year:		
Granted	78,945	$ 3.80
Vested	(97,400)	$ 3.08
Forfeited	—	$ —
Non-vested at March 31, 2025	85,345	$ 3.98

Note 10 – Share-Based Compensation

Share-Based Compensation

The Company utilizes share-based compensation in the form of stock options, restricted stock, restricted stock units and warrants. The following table summarizes the components of share-based compensation expense for the three months ended March 31, 2025 and 2024 (in thousands):

	Three Months Ended March 31,	
	2025	2024
Research and development	$ 126	$ 86
General and administrative	404	368
Total share-based compensation expense	$ 530	$ 454

Total compensation cost related to unvested awards not yet recognized and the weighted-average periods over which the awards were expected to be recognized at March 31, 2025 were as follows (in thousands):

	Stock Options	Restricted Stock Units	Restricted Stock
Unrecognized compensation cost	$ 393	$ 251	$ 925
Expected weighted-average period in years of compensation cost to be recognized	2.21	0.75	2.32

Total fair value of shares vested and the weighted average estimated fair values of shares granted for the three months ended March 31, 2025 and 2024 were as follows (in thousands):

	Stock Options		Warrants	
	Three Months Ended March 31,		Three Months Ended March 31,	
	2025	2024	2025	2024
Total fair value of shares vested	$ 263	$ 199	$ 150	$ —
Weighted average estimated fair value of shares granted	$ 2.60	$ 2.16	$ 1.99	$ —

Valuation Assumptions

The fair value of stock options and warrants at the date of grant was estimated using the Black-Scholes option pricing model. The expected volatility is based upon historical volatility of the Company's stock. The expected term for the options is based upon observation of actual time elapsed between date of grant and exercise of options for all employees. The expected term for the warrants is based upon the contractual term of the warrants.

Note 11 – Income Taxes

In assessing the realizability of deferred tax assets, including the net operating loss carryforwards (NOLs), the Company assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to utilize its existing deferred tax assets. Based on its assessment, the Company has provided a full valuation allowance against its net deferred tax assets as their future utilization remains uncertain at this time.

As of December 31, 2024 and 2023, the Company had approximately $57.9 million and $43.7 million, respectively, of Federal NOLs available to offset future taxable income expiring from 2030 through 2036. The Company performed an analysis and determined that they had an ownership change of greater than 50% on September 15, 2022. As a result of the ownership change, $88.2 million of Federal NOLs will expire unutilized. The Company wrote off that portion of the deferred tax asset and reduced the corresponding valuation allowance resulting in $34.0 million of remaining Federal NOLs as of December 31, 2022. The write-off of the deferred tax asset and the corresponding reduction in valuation allowance has no impact to the consolidated balance sheet or income statement. Losses incurred before the ownership change on September 15, 2022 will be subject to an annual limitation of zero while losses incurred after September 15, 2022 will not be subject to limitations.

As of December 31, 2022, Cend Therapeutics, Inc. ("Cend") had approximately $3.6 million of Federal NOLs available to offset future taxable income. The Company performed an analysis and determined that there was an ownership change of greater than 50% on September 15, 2022. As of September 15, 2022 Cend has approximately $3.1 million of Federal and $4.3 million of state NOLs. The state NOLs will expire from the 2036 through 2042 tax years. Using a fair market value of $36.1 million and applying an applicable federal rate of 2.54% Cend will have an annual limitation of approximately $917 thousand each year. The Federal NOL of $459 thousand incurred in the post-acquisition period September 15, 2022 to December 31, 2022 is not subject to limitation, and does not expire.

As of December 31, 2024 and 2023, the Company's wholly owned Australian subsidiary had approximately $2.3 million and $2.4 million, respectively, of NOLs which will be carried forward and do not expire. There is a full valuation allowance against the NOLs.

As of December 31, 2024, the Company had federal research and development credit carryforwards of $0.5 million expiring from 2027 through 2034 if unutilized, and state research and development credit carryforwards of $0.1 million, which carryforward indefinitely. Utilization of these credits may be subject to an annual limitation based on changes in ownership.

As of December 31, 2024 and 2023, the Company had State NOLs available in New Jersey of $24.6 million and $19.4 million, respectively, California of $9.2 million and $9.2 million, respectively, and New York City of $1.9 million and $1.9 million, respectively, to offset future taxable income expiring from 2032 through 2044. The usage of the Company's NOLs is limited given the change in ownership.

The Company applies the Financial Accounting Standards Board provisions for uncertain tax positions. The Company utilizes the two-step process to determine the amount of recognized tax benefit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the consolidated financial statements is the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the relevant taxing authority. The Company recognizes interest and penalties associated with certain tax positions as a component of income tax expense.

As of December 31, 2024 and 2023, the Company's uncertain tax positions were $344 thousand and $344 thousand, respectively. The uncertain tax positions are due to the acquisition of Cend related to Federal and state credits and certain state NOLs. The Company will continue to evaluate its uncertain tax positions in future periods. The Company does not believe there will be any material changes in its unrecognized tax positions over the next year.

For years prior to 2021, the federal statute of limitations is closed for assessing tax. The Company's state tax returns remain open to examination for a period of three to four years from the date of the tax return filing.

In January 2025, the Company sold a portion of their unused New Jersey net operating losses through the State of New Jersey Economic Development Authority's ("NJEDA") Technology Business Tax Certificate Transfer Program ("Program"). Under the Program, the Company sold $10.7 million of its New Jersey net operating losses ("NJ NOLs") for net proceeds of $871 thousand. The sale of NJ NOLs resulted in a $962 thousand deferred income tax benefit and a loss on sale of $91 thousand recorded in other income (expense) in the consolidated financial statements.

Note 12 – Segment Information

The Company operates as one operating segment, the research and development of its investigational drug product. The Company used the management approach to determine its reportable operating segment. The Company's Chief Operating Decision Maker ("CODM") is its Chief Executive Officer, who reviews financial information presented on a consolidated basis. The Company is a clinical-stage pharmaceutical company and has limited revenue associated with a license and collaboration agreement. The CODM uses net loss as a measure of profit and loss, and assesses Company performance through the achievement of its clinical development goals. The CODM is regularly provided with budgeted and forecasted expense information which is used to determine the Company's liquidity needs and cash allocation to its development programs. The CODM uses cash and marketable securities as a measure of segment assets in managing the enterprise.

The Company had no revenue during the three months ended March 31, 2025 and 2024. Depreciation and amortization expense was $43 thousand and $46 thousand for the three months ended March 31, 2025 and 2024, respectively. Equity method investment expense was $0 and $100 thousand for the three months ended March 31, 2025 and 2024, respectively.
The following table illustrates our segment information for significant operating expenses and includes a reconciliation to net loss for the three months ended March 31, 2025 and 2024:

	Three Months Ended March 31	
	2025	2024
Operating Expenses:		
Research and development by significant expense:		
BOLSTER trial	$ 788	$ 1,270
ASCEND trial	21	44
Chemistry, manufacturing and controls	220	655
Clinical department	1,156	1,133
Other [1]	417	139
Research and development	2,602	3,241
General and administrative by significant expense:		
Corporate	1,144	1,132
Investor relations/public relations/communications	331	285
Finance	629	580
Legal	224	671
Business development	127	172
Share based compensation expense	404	368
Other [2]	386	152
General and administrative	3,245	3,360
Operating loss	(5,847)	(6,601)
Other income, net	161	402
Benefit from income taxes	(962)	(798)
Net loss	**$ (4,724)**	**$ (5,401)**
Cash and marketable securities	**$ 25,833**	**$ 43,349**

[1] Included in Other are the GBM study, FORTIFIDE study and research oncology expenses

[2] Included in Other are facilities expense, human resource and information technology expenses

Note 13 – Australia Research and Development Tax Incentive

The Company's Australian subsidiary, which conducts core research and development activities, is eligible to receive a refundable tax incentive between 43.5% to 48.5% (depending upon the income tax rate) for qualified research and development activities. As of March 31, 2025 and December 31, 2024, the Company had $0.6 million and $0.6 million, respectively, recorded as an income tax incentive receivable in prepaid and other current assets in the consolidated balance sheets, as the Company determined that the expenses met the eligibility criteria and the amounts claimed are expected to be received shortly after the related tax returns are filed.

Note 14 – Contingencies

From time to time, the Company is subject to legal proceedings and claims, either asserted or unasserted, that arise in the ordinary course of business. While the outcome of pending claims cannot be predicted with certainty, the Company does not believe that the outcome of any pending claims will have a material adverse effect on the Company's financial condition or operating results. The Company has elected to recognize expense for legal fees as incurred when the legal services are provided.

In May 2021, Cend received a written threat of litigation on behalf of a Chinese entity called Lingmed Limited ("Lingmed") claiming Lingmed was entitled to a success fee based on Cend's Collaboration and License Agreement with Qilu Pharmaceuticals. Cend responded by denying that Lingmed is entitled to a success fee under the terms of their agreement. In May 2022, Cend was served with a complaint filed by Lingmed in the San Diego County Superior Court, alleging claims for breach of contract, fraud and declaratory relief. Cend's response to the complaint was filed on June 6, 2022 and denied all of Lingmed's material allegations. Lingmed filed an answer to Cend's response on July 11, 2022, denying all of the Company's material allegations. On March 25, 2024 the Company entered into a settlement agreement whereby the Company was required to pay Lingmed $0.5 million within 30 days of the effective date and the Company effected payment on April 4, 2024. Lingmed is also entitled to 5.0% of any future milestone payments received by the Company under the license agreement with Qilu in addition to a sum of $250 thousand with respect to the first future milestone received by the Company. On April 9, 2024, pursuant to the parties' joint request, the Court entered a dismissal with prejudice of the entire action as to all parties and all claims and the matter was settled.

Note 15 – Technology Transfer Agreement

Impilo Therapeutics

In July 2023, the Company entered into a technology transfer agreement with Impilo Therapeutics ("Impilo") under which the Company transferred its rights to its tumor penetrating nanocomplex (TPN) platform to Impilo. As consideration for the technology transfer, Impilo issued a total of 766,000 shares of its pre-seed preferred stock to the Company. On October 3, 2023, in connection with the Sanford Burnham Prebys license agreement (see Note 16 - License Agreements) Impilo cancelled the original stock certificate for 766,000 shares and reissued 574,500 shares of its pre-seed preferred stock to the Company.

On March 15, 2024, the Company purchased a Simple Agreement for Future Equity ("SAFE") from Impilo for $100 thousand. On July 12, 2024, the Company purchased an additional SAFE from Impilo for $30 thousand. As of March 31, 2025 and December 31, 2024, the Company owned 38.6% of Impilo. These investments were expensed under the equity method of accounting in the prior year in other expense, net in the accompanying statement of operations. The SAFE has a valuation cap of $30.0 million and an 80% discount rate.

Note 16 – License Agreements

Sanford Burnham Prebys

In December 2015, Cend entered into a license agreement with Sanford Burnham Prebys ("SBP") under which Cend was granted an exclusive, worldwide, royalty-bearing license to certain patent rights and know-how controlled by SBP related to the development of certepetide. At the time the license agreement was entered into, Cend's founding shareholder was an executive at SBP. The agreement provides the Company with the rights to grant and authorize sublicenses to use, sell, and otherwise exploit the patent rights. As consideration for the license, Cend issued a total of 382,030 shares of common stock, as adjusted for the Reverse Stock Split and Exchange Ratio. The Company is required to pay an annual license maintenance fee of $10 thousand increasing to $20 thousand on year seven of the agreement. The Company could also be required to make milestone payments to SBP upon completion of certain regulatory and commercial milestones. The aggregate potential milestone payments are approximately $10.6 million. The Company has also agreed to pay SBP royalties of 4% of net sales of products sold by the Company, or through a sublicense, subject to certain reductions. Additionally, the Company is obligated to pay SBP 25% of any sublicensing income received, which, pursuant to the technology transfer agreement with Impilo, resulted in SBP receiving 191,500 shares of the Company's pre-seed preferred stock in Impilo on October 3, 2023.

The agreement will expire upon the later of (i) the final abandonment of all pending patent applications within the licensed patents or (ii) the expiration of the last to expire patent within the licensed patents. The agreement may be terminated in its entirety by the Company at any time by giving SBP sixty days' prior written notice. The agreement may be terminated in its entirety by SBP if the Company, at any time, defaults in the payment of any sum when due and fails to make such payment within thirty days after receipt of written notice. The agreement may be terminated in its entirety by either SBP or the Company (i) in the event of an uncured material breach by the other party, or (ii) in the event the other party (a) files for, or is

involuntarily petitioned with, bankruptcy (other than dissolution or winding up for the purposes of reconstruction or amalgamation), (b) makes an assignment of all or substantially all of its assets for the benefit of creditors, or (c) has a receiver or trustee is appointed and is unable to secure a dismissal, stay or other suspension of such proceedings within thirty days. Upon termination of the agreement for any reason, all rights and obligations of the Company with respect to the patents and patent applications shall terminate and revert to SBP.

SBP did not own shares of the Company's common stock as of March 31, 2025.

Note 17 – Research Collaboration and License Agreements

Exclusive License and Collaboration Agreement - Qilu Pharmaceuticals

In February 2021, Cend entered into an Exclusive License and Collaboration Agreement (the "Qilu Agreement") in which Cend granted an exclusive license to Qilu for the development and commercialization of certepetide in the Territory (defined as the Greater Area of China including China, Macau, Hong Kong, and Taiwan). Under the terms of the agreement, Qilu is solely responsible for the development of certepetide in its Territory. In consideration for the license, Qilu made an upfront payment of $10.0 million to Cend, which was recognized as revenue by Cend prior to the Company's acquisition of Cend on September 15, 2022 (the "Cend Merger"). In addition, Cend received and recognized as revenue a $5.0 million development milestone prior to the Cend Merger. The Company is eligible to receive additional development and commercial milestone payments up to $96.0 million and $125.0 million, respectively, tiered royalties on net sales ranging from 10% to 15%, and tiered sublicensing revenues ranging from 12% to 35%.

On March 25, 2024, the Company entered into a settlement agreement with Lingmed whereby Lingmed is entitled to 5.0% of any future milestone payments received by the Company under the Qilu Agreement, in addition, Lingmed is also entitled to a sum of $250 thousand with respect to the first future milestone received by the Company.

Unless terminated early, the Qilu Agreement will continue in effect until the expiration of all Qilu payment obligations. Either party may terminate the Qilu Agreement if an undisputed material breach by the other party is not cured within a defined period of time, or upon notice for insolvency-related events of the other party that are not discharged within a defined time period. Qilu may terminate the Qilu Agreement in its entirety, at any time with at least sixty days written notice. All rights and obligations of Qilu with respect to such licensed patents and patent applications would terminate simultaneously.

Exclusive License and Collaboration Agreement - Kuva Labs

In November 2024, the Company entered into an Exclusive License and Collaboration Agreement in which the Company granted an exclusive license to Kuva Labs, Inc. (Kuva) to explore the synergistic potential of the Company's certepetide as a targeting and delivery agent for Kuva's NanoMark™ imaging technology in solid tumors. Under the Agreement, Kuva will assume full responsibility for research, development, and commercialization costs, while the Company will be responsible for supplying certepetide for additional consideration pursuant to a Clinical Supply Agreement. In consideration for the license, the Company recognized $1.0 million as revenue upon delivery of the license in November 2024. The Company is eligible to receive additional development and commercial milestone payments up to $1.5 million and $17.5 million, respectively, a 5.0% percent royalty on net sales, and sublicensing revenues of 50%.

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements that are subject to significant risks and uncertainties. There is no guarantee that our clinical development programs will be successful or result in the necessary regulatory approvals. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Cautionary Note Regarding Forward-Looking Statements" herein and under "Risk Factors" in our 2024 Form 10-K. The following discussion should be read in conjunction with our consolidated financial statements and related notes thereto included elsewhere in this Quarterly Report and in our 2024 Form 10-K.

Overview

We are a clinical-stage pharmaceutical company dedicated to the discovery, development, and commercialization of innovative therapies for the treatment of solid tumors and other major diseases. Our investigational product, certepetide (formerly known as LSTA1 or CEND-1), is designed to activate a novel uptake pathway that allows co-administered or tethered (i.e., molecularly bound) anti-cancer drugs to target and penetrate solid tumors more effectively. Certepetide actuates this active transport system in a tumor-specific manner, resulting in systemically co-administered anti-cancer drugs more efficiently penetrating and accumulating in the tumor, while normal tissues are expected to remain unaffected. Certepetide has also been shown to modify the tumor microenvironment ("TME") by reducing T-regulatory cells and augmenting cytotoxic T cells, thereby making tumors more susceptible to immunotherapies while also inhibiting the metastatic cascade (i.e., the spread of cancer to other parts of the body). We, our collaborators and other researchers have amassed and continue to amass significant non-clinical data demonstrating enhanced delivery of a range of existing and emerging anti-cancer therapies, including chemotherapeutics, immunotherapies, and RNA-based therapeutics. To date, certepetide has also demonstrated favorable safety, tolerability and activity in completed and ongoing clinical trials designed to enhance delivery of standard-of-care chemotherapy for pancreatic cancer. We are exploring certepetide as a means to enable a variety of therapeutic modalities to treat a range of solid tumors more effectively. Currently, certepetide is the subject of several Phase 2 clinical studies being conducted globally in a variety of solid tumor types, including metastatic pancreatic ductal adenocarcinoma (mPDAC), cholangiocarcinoma, appendiceal cancer, colon cancer and glioblastoma multiforme in combination with a variety of anti-cancer regimens.

Our leadership team has decades of collective biopharmaceutical and pharmaceutical product development experience across a variety of therapeutic categories and at all stages of development from preclinical through to product registration and launch. Our goal is to develop and commercialize products that address important unmet medical needs.

Targeted Solid Tumor Penetration via CendR Active Transport

Many solid tumor cancers, including, for example, pancreatic ductal adenocarcinoma ("PDAC") and cholangiocarcinoma, are surrounded by dense fibrotic tissue, known as the tumor stroma. This stroma often limits the penetration of anti-cancer therapies including chemotherapy into the tumor and thus limits their efficacy. Emerging immunotherapies, including but not limited to checkpoint inhibitors and adoptive cell therapies (e.g., chimeric antigen receptor T cells (CAR-Ts)), also face challenges in effectively treating solid tumors. Many tumors exhibit an immunosuppressive TME, which suppresses a patient's immune system and can thus limit the effectiveness of immunotherapies and/or contribute to metastases. These factors, i.e., the combination of a dense stroma and an immunosuppressive TME, negatively impact the ability of many therapeutic agents to optimally treat these cancers.

To address the tumor stroma's role as a key impediment to effective treatment, our approach is to activate the C-end rule ("CendR"), or CendR active transport mechanism, a naturally occurring transport system. Our investigational drug, certepetide (a specific, proprietary *internalizing* R-G-D or iRGD peptide), activates this transport system in a tumor-specific manner (Sugahara, Science, 2010). Certepetide enables more selective and efficient uptake of systemically administered anti-cancer drugs resulting in more intratumoral drug accumulation. The overall expected result is enhanced anticancer activity without an increase in systemic adverse side effects. While it is possible to couple/tether or conjugate some anticancer drugs to certepetide, we believe that our initial approach of co-administration of certepetide with anti-cancer therapies is advantageous. Co-administration does not create a new chemical entity ("NCE") with its attendant development and regulatory hurdles, thereby providing an anticipated faster-to-clinic and faster-to-market product opportunity for a range of combination therapies. That said, an attractive life-cycle management strategy for certepetide would be to molecularly bind it to a variety of anti-cancer agents (as an alternative to co-administration), thereby creating new NCEs with the potential for distinct patent protection, compositionally or otherwise.

Certepetide has demonstrated favorable safety, tolerability, and activity to date in clinical trials enhancing the selective delivery of standard-of-care chemotherapies for mPDAC. Certepetide's cancer targeting characteristics may also enable

emerging solid tumor treatment modalities to prove more effective. For example, preliminary results of certepetide in combination with both immunotherapy and chemotherapy are promising.

Certepetide as a treatment for solid tumor cancers in combination with other anti-cancer agents

Certepetide is an investigational drug that actuates the CendR active transport mechanism. Certepetide has been shown to modify the TME, making it less immunosuppressive and thereby making the tumor more susceptible to attack by the immune system while also inhibiting the metastatic cascade. It targets tumor vasculature, endothelial cells, tumor cells and some intratumoral immunosuppressive cells by its selective affinity for alpha-v beta-3 and alpha-v beta-5 integrins that are upregulated on these cells. Certepetide is a nine amino acid cyclic proprietary internalizing RGD ("iRGD") peptide that, once bound to these integrins, undergoes proteolytic cleavage to release a linear peptide fragment, called a CendR peptide fragment. After dissociation from the integrin receptor, the CendR peptide fragment then binds with high selectivity and affinity to an adjacent receptor, called neuropilin-1, also upregulated in solid tumors, to activate the novel uptake pathway that allows circulating anticancer drugs to more selectively and effectively penetrate solid tumors. The ability of certepetide and iRGD peptides to modify the TME to enhance delivery and efficacy of co-administered drugs has been demonstrated in many preclinical models in a range of solid tumors. Lisata, its collaborators, and research groups around the world have published more than 370 scientific papers related to the benefits of internalizing RGD peptides and the CendR pathway.

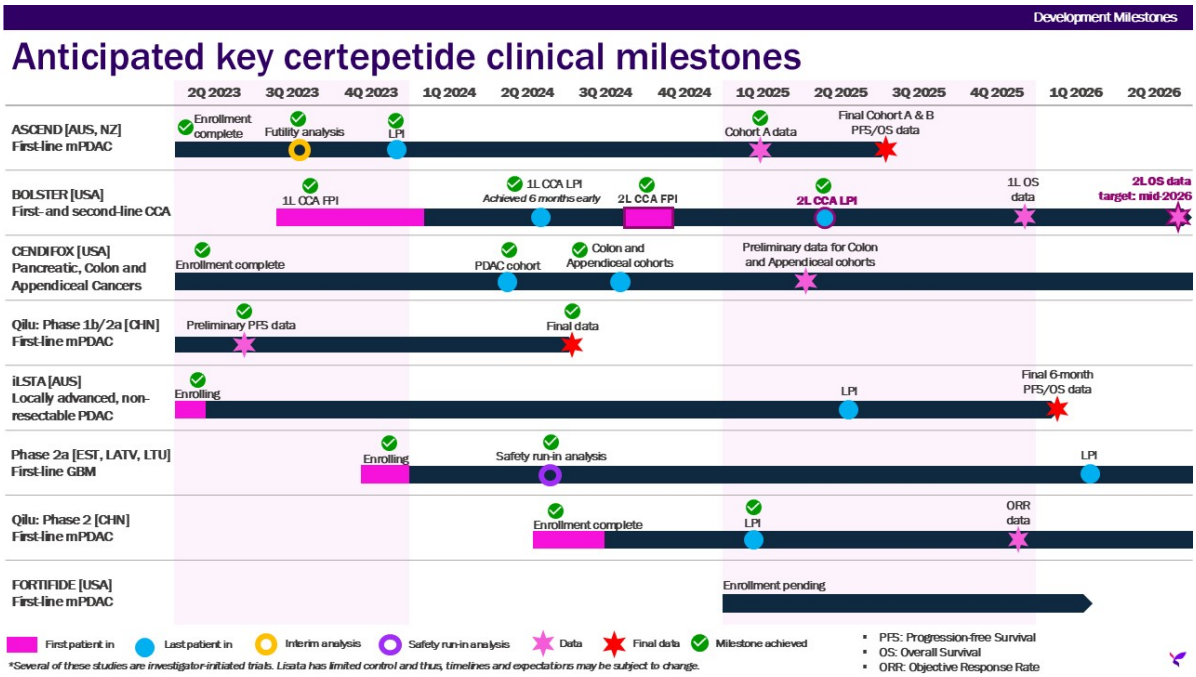
Clinically, certepetide was the subject of a completed Phase 1b/2a trial inclusive of 31 first-line mPDAC patients, of which 29 were evaluable. Results from the trial showed that the safety profile of the certepetide combination regimen was similar to standard of care ("SoC") chemotherapy alone, with certepetide being well-tolerated with no dose limiting toxicities. An Objective Response Rate ("ORR") of 59% was observed, compared to the 23% ORR observed in the "MPACT" clinical trial that served as the basis for approval of the chemotherapy combination nab-paclitaxel and gemcitabine for the treatment of first line mPDAC (Von Hoff, et al. 2013). A Disease Control Rate ("DCR") (partial and complete responses plus stable disease) of over 79% was also observed in comparison to a DCR of 48% observed in the MPACT trial. Reduction in the level of circulating tumor biomarker CA19-9 was observed in 96% of patients versus 61% in the MPACT trial. Importantly, median progression-free survival and median overall survival of nearly ten months and over thirteen months were observed versus less than six months and less than nine months, respectively, in the MPACT trial. These results have been published in The Lancet Gastroenterology and Hepatology (Dean, et al. 2022).

Certepetide was also examined in another Phase 1b/2a study in first line mPDAC patients. Study CEND1-201 was conducted in China by our development partner, Qilu Pharmaceutical. Two dose levels of certepetide (1.6 and 3.2 mg/kg) were combined with SoC chemotherapy (gemcitabine and nab-paclitaxel). There were 55 patients in the study, 53 of whom were evaluable for efficacy. Twenty-five (25) patients were treated with 1.6 mg/kg certepetide, and 28 patients with 3.2 mg/kg certepetide. In the 1.6 mg/kg certepetide group, partial response occurred in 11/25 (44.0%) patients, and stable disease occurred in 12/25 (48%) patients. In the 3.2 mg/kg certepetide group, partial response occurred in 11/28 (39.3%) patients, and stable disease occurred in 12/28 (42.9%) patients. The ORR was 41.5% for all doses. The ORR was 44.0% and 39.3% in 1.6 mg/kg group and in 3.2 mg/kg group, respectively. The DCR was 86.8% for all doses. The DCR in 1.6 and 3.2 mg/kg groups was 92.0% and 82.1%, respectively. The median PFS was 5.82 months for all doses combined. The median PFS was 7.36 months and 5.75 months in 1.6 mg/kg group and in 3.2 mg/kg group, respectively. The median OS was 11.10 months for all doses combined. The median OS was 10.35 months and 11.10 months in 1.6 mg/kg group and in 3.2 mg/kg group, respectively. The adverse event profile at both dose levels was similar to that for SoC alone. Qilu has completed Phase 2 enrollment (n=96) in first line mPDAC in combination with SoC gemcitabine and nab-paclitaxel.

Finally, certepetide is also the subject of a Phase 2 trial in first-line mPDAC patients, the ASCEND trial. ASCEND is being conducted in collaboration with the Australasian Gastrointestinal Clinical Trials Group (AGITG) and the University of Sydney at 25 sites in Australia and New Zealand. The Phase 2 double-blind, randomized (2:1), placebo-controlled, multi-center ASCEND trial is evaluating certepetide in combination with SoC chemotherapy (gemcitabine and nab-paclitaxel) for the treatment of mPDAC. The original ASCEND protocol included one dosing scheme for certepetide. Following the acquisition of Cend Therapeutics and, by extension, certepetide in September 2022, Lisata collaborated with AGITG to amend the protocol to ensure it respected international regulatory standards. Thus, endpoints typically recognized by regulators as primary in registration studies and more effective in guiding next stages of clinical development (e.g., overall survival), were added. The amended protocol was designed to assess the efficacy of two different dosing regimens of certepetide in two separate cohorts: Cohort A, with 95 patients receiving a single intravenous (IV) dose of certepetide 3.2 mg/kg or placebo in combination with SoC, and Cohort B, with 63 patients receiving two IV doses of certepetide 3.2 mg/kg or placebo administered 4 hours apart in combination with SoC. The preliminary data from Cohort A were reported at the ASCO GI meeting on January 24, 2025, demonstrating a median overall survival (mOS) of 12.68 months for the certepetide treated group, compared to 9.72 months for the placebo treated group. Despite a numerical trend in 6-month PFS favoring the certepetide treatment group, no significant improvement in median PFS was observed (mPFS of 5.5 months in both groups). However, the objective response rate (ORR) benefit are positive with 4/65 (6.2%) complete responses in the certepetide treated group, compared to 0/28 (0%) the placebo

treated group. The adverse event profile of Cohort A was similar in subjects treated with certepetide and placebo confirming previous observations of certepetide's benign safety profile. Preliminary data from Cohort B will be presented at the ESMO-GI meeting in July 2025 with a final analysis of both cohorts available thereafter.

Additionally, certepetide is currently the subject of multiple ongoing and planned clinical trials being conducted globally in a variety of solid tumor types and in combination with several chemotherapy and immunotherapy anti-cancer regimens. The following diagram summarizes these studies.



Additional Out-licensing Opportunities

Our intellectual property portfolio comprises notable programs available for out-licensing and/or partnering in order to augment or continue their clinical development. Our current long-term strategy focuses on advancing our therapies through development with the ultimate objective of obtaining market authorizations and entering commercialization, either alone or with partners, to provide treatment options to patients suffering from life-threatening medical conditions. We believe that we are well-positioned to realize potentially meaningful value increases within our own proprietary pipeline if we are successful in advancing our product candidates to their next significant development milestones.

Results of Operations

Three Months Ended March 31, 2025 Compared to Three Months Ended March 31, 2024

The following table summarizes our results of operations for the three months ended March 31, 2025 and March 31, 2024 (in thousands):

	Three Months Ended March 31,		
	2025	2024	Change
Operating Expenses:			
Research and development	$ 2,602	$ 3,241	$ (639)
General and administrative	3,245	3,360	(115)
Total operating expenses	5,847	6,601	(754)
Loss from operations	(5,847)	(6,601)	754
Total other income	161	402	(241)
Benefit from income taxes	(962)	(798)	164
Net loss	$ (4,724)	$ (5,401)	$ 677

Overall, net losses were $4.7 million for the three months ended March 31, 2025, compared to $5.4 million for the three months ended March 31, 2024.

Operating Expenses

For the three months ended March 31, 2025, operating expenses totaled $5.8 million, compared to $6.6 million for the three months ended March 31, 2024, representing a decrease of $0.8 million or 11.4%. Operating expenses are comprised of the following:

- Research and development expenses were approximately $2.6 million for the three months ended March 31, 2025, compared to $3.2 million for the three months ended March 31, 2024, representing a decrease of $0.6 million or 19.7%. This was primarily due to a reduction in clinical research organization (“CRO”) expenses and site expenses associated with our Phase 2a proof-of-concept Bolster trial and lower spend on chemistry, manufacturing and controls (“CMC”).
- General and administrative expenses were approximately $3.2 million for the three months ended March 31, 2025, compared to $3.4 million for the three months ended March 31, 2024, representing a decrease of $0.1 million or 3.4%. This was primarily due to one off settlement costs in the prior year partially offset by an increase in consulting expenses and severance costs in the current year.

Historically, to minimize our use of cash, we have used a variety of equity instruments to compensate employees, consultants and other service providers. The use of these instruments has resulted in charges to the results of operations, which have been significant in the past.

Other Income (Expense)

Total other income (expense) is comprised primarily of investment income from cash, cash equivalents and marketable securities and losses on sales of our New Jersey net operating losses for the three months ended March 31, 2025 and 2024.

Income Tax Benefit

In January 2025, we received final approval from the New Jersey Economic Development Authority (“NJEDA”) under the Technology Business Tax Certificate Transfer Program (the “Program”) to sell a percentage of our NJ NOLs, which were subsequently sold to a qualifying and approved buyer pursuant to the Program for net proceeds of $0.9 million. The $1.0

million of our NJ NOL tax benefits have been recorded as a benefit from income taxes and the loss on sale of $0.1 million recorded in other income (expense).

In March 2024, we received final approval from the NJEDA under the Program to sell a percentage of our NJ NOLs, which were subsequently sold to a qualifying and approved buyer pursuant to the Program for net proceeds of $0.7 million. The $0.8 million of NJ NOLs related tax benefits have been recorded as a benefit from income taxes and the loss on sale of $0.1 million recorded in other income (expense).

Analysis of Liquidity and Capital Resources

As of March 31, 2025, we had cash, cash equivalents and marketable securities of approximately $25.8 million, working capital of approximately $24.8 million, and stockholders' equity of approximately $25.4 million.

During the three months ended March 31, 2025, we met our immediate cash requirements through existing cash balances. Additionally, we used equity and equity-linked instruments to pay for services and compensation.

Net cash (used in) or provided by, operating, investing and financing activities were as follows (in thousands):

	Three Months Ended March 31,	
	2025	2024
Net cash used in operating activities	$ (5,402)	$ (7,027)
Net cash provided by investing activities	9,431	6,436
Net cash used in financing activities	(23)	(142)

Operating Activities

Our cash used in operating activities during the three months ended March 31, 2025 was $5.4 million, which is comprised of (i) our net loss of $4.7 million, adjusted for non-cash expenses totaling $0.5 million (which includes adjustments for equity-based compensation, depreciation and amortization, and amortization/accretion of marketable securities), and (ii) changes in operating assets and liabilities using approximately $1.2 million.

Our cash used in operating activities during the three months ended March 31, 2024 was $7.0 million, which is comprised of (i) our net loss of $5.4 million, adjusted for non-cash expenses totaling $0.4 million (which includes adjustments for equity-based compensation, depreciation and amortization, loss from equity method investment, and amortization/accretion of marketable securities) and (ii) changes in operating assets and liabilities using approximately $2.1 million.

Investing Activities

Our cash provided by investing activities during the three months ended March 31, 2025 totaled $9.4 million and was primarily due to net sales of marketable securities (net of purchases of marketable securities).

Our cash provided by investing activities during the three months ended March 31, 2024 totaled $6.4 million and was primarily due to net sales of marketable securities (net of purchases of marketable securities) partially offset by an investment of $0.1 million in Impilo Therapeutics.

Financing Activities

Our cash used in financing activities during the three months ended March 31, 2025 totaled $23.0 thousand and consisted primarily of tax withholding-related payments on net share settlement equity awards to employees of $0.2 million partially offset by $0.2 million in proceeds from the issuance of shares through our ATM Agreement (as defined below).

Our cash used in financing activities during the three months ended March 31, 2024 totaled $0.1 million and consisted of tax withholding-related payments on net share settlement equity awards to employees.

Liquidity and Capital Requirements Outlook

To meet our short and long-term liquidity needs, we expect to use existing cash balances, marketable securities and a variety of other means. Other sources of liquidity could include additional potential issuances of debt or equity securities in public or private financings, partnerships and/or collaborations and/or sale of assets. Our history of operating losses and liquidity challenges may make it difficult for us to raise capital on acceptable terms or at all. The demand for the equity and debt of pharmaceutical companies like ours is dependent upon many factors, including the general state of the financial markets. During times of extreme market volatility, capital may not be available on favorable terms, if at all. Our inability to obtain such additional capital could materially and adversely affect our business operations. We will also continue to seek, as appropriate, grants for scientific and clinical studies from various governmental agencies and foundations, and other sources of non-dilutive funding. We believe that our cash on hand and marketable securities will enable us to fund current operating expenses for at least the next 12 months following the issuance of our financial statements. Our future capital requirements are difficult to forecast and will depend on many factors including the timing and nature of any other strategic transactions that we undertake; and our ability to establish and maintain collaboration partnerships, in-license/out-license or other similar arrangements and the financial terms of such agreements.

On June 4, 2021, we entered into the ATM Agreement with H.C. Wainwright & Co., LLC as sales agent, in connection with an "at the market offering" under which we from time to time may offer and sell shares of our common stock having an aggregate offering price of up to $50.0 million. As of the date of this filing and so long as our public float remains below $75.0 million, we are subject to limitations pursuant to General Instruction I.B.6 of Form S-3 (the "Baby Shelf Limitation"), which limits the amount we can offer to up to one-third of our public float during any trailing 12-month period. Subsequent to the filing of a prospectus supplement to our Registration Statement on Form S-3 (File No. 333-279034) relating to the at the market offering on August 21, 2024, the aggregate market value of our outstanding common stock held by non-affiliates was approximately $29.6 million. Pursuant to the Baby Shelf Limitation, since the aggregate market value of our outstanding common stock held by non-affiliates was below $75.0 million at the time of such prospectus supplement filing, the aggregate amount of securities that we are permitted to offer and sell is now $9,855,890, which was equal to one-third of the aggregate market value of our common stock held by non-affiliates as of August 20, 2024. If our public float exceeds $75.0 million on a future measurement date, the Company will no longer be subject to the Baby Shelf Limitation. During the three months ended March 31, 2025, we issued 55,578 shares of common stock under the ATM Agreement for net proceeds of $211,369. Since inception, we have issued 123,751 shares of common stock under the ATM Agreement for net proceeds of $492,216.

While we continue to seek capital through a number of means, there can be no assurance that additional financing will be available on acceptable terms, if at all, and our negotiating position in capital generating efforts may worsen as existing resources are used. Additional equity financing may be dilutive to our stockholders; debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate as a business; our stock price may not reach levels necessary to induce option or warrant exercises; and asset sales may not be possible on terms we consider acceptable. If we are unable to access capital necessary to meet our long-term liquidity needs, we may have to delay the expansion of our business or raise funds on terms that we currently consider unfavorable.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

There have been no material changes in our critical accounting policies and estimates during the three months ended March 31, 2025, compared to those reported in our 2024 Form 10-K.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures

Disclosure controls and procedures are our controls and other procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934 (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934), as amended (the "Exchange Act") is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports that we file under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer, who serves as our principal executive officer, and our Senior Vice President, Finance and Treasury and Chief Accounting Officer, who serves as our principal financial officer (together, the "Evaluating Officers"), as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well-designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Due to the inherent limitations of control systems, not all misstatements may be detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Controls and procedures can only provide reasonable, not absolute, assurance that the above objectives have been met.

As of March 31, 2025, we evaluated, with the participation of our management, including our Evaluating Officers, the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act.

Based on that evaluation, our Evaluating Officers concluded that our disclosure controls and procedures were effective, at the reasonable assurance level, in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and is accumulated and communicated to management, including the Evaluating Officers, as appropriate to allow timely decisions regarding required disclosure.

(b) Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15, that occurred during our last quarter to which this Quarterly Report relates that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II

OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings.

ITEM 1A. RISK FACTORS

There have been no material changes to the risk factors previously reported in our 2024 Form 10-K. See the risk factors set forth in our 2024 Annual Report on Form 10-K under the caption “Item 1A - Risk Factors.”

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

During the three months ended March 31, 2025, no director or officer of the Company adopted, modified or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408(a) of Regulation S-K.

ITEM 6. EXHIBITS

The Exhibit Index appearing immediately after the signature page to this Form 10-Q is incorporated herein by reference.

SIGNATURES

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

LISATA THERAPEUTICS, INC.

May 8, 2025
By: /s/ David J. Mazzo, PhD
Name: David J. Mazzo, PhD
Title: President & Chief Executive Officer
(Principal Executive Officer)

May 8, 2025
By: /s/ James Nisco
Name: James Nisco
Title: SVP, Finance and Treasury and Chief Accounting Officer (Principal Financial Officer and Principal Accounting Officer)

LISATA THERAPEUTICS, INC.
FORM 10-Q

Exhibit Index

31.1	*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	*	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	**	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	**	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS		Inline XBRL Instance Document - the 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
101.CAL		Inline XBRL Taxonomy Extension Calculation Linkbase
101.DEF		Inline XBRL Taxonomy Extension Definition Linkbase
101.LAB		Inline XBRL Taxonomy Extension Label Linkbase
101.PRE		Inline XBRL Taxonomy Extension Presentation Linkbase
104		Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Filed herewith.

** Furnished herewith.

Exhibit 31.1

CERTIFICATIONS UNDER SECTION 302

I, David J. Mazzo, PhD, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Lisata Therapeutics, 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. The registrant's other certifying officer and I are 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. The registrant's other certifying officer and 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 the 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 8, 2025

/s/ David J. Mazzo, PhD
Name: David J. Mazzo, PhD
Title: President & Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, James Nisco, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Lisata Therapeutics, 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. The registrant's other certifying officer and I are 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. The registrant's other certifying officer and 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 the 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 8, 2025

/s/ James Nisco
Name: James Nisco
Title: Senior Vice President, Finance and Treasury and Chief Accounting Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Lisata Therapeutics, Inc. (the "Company") for the quarter ended March 31, 2025 filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David J. Mazzo, PhD, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition of the Company as of the dates presented and the results of operations of the Company for the periods presented.

Dated: May 8, 2025

/s/ David J. Mazzo, PhD
David J. Mazzo, PhD
President & Chief Executive Officer (Principal Executive Officer)

The foregoing certification is being furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and is not being filed as part of the Form 10-Q or as a separate disclosure document.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Lisata Therapeutics, Inc. (the "Company") for the quarter ended March 31, 2025 filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James Nisco, Senior Vice President, Finance and Treasury and Chief Accounting Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition of the Company as of the dates presented and the results of operations of the Company for the periods presented.

Dated: May 8, 2025

/s/ James Nisco
James Nisco
Senior Vice President, Finance and Treasury and Chief Accounting Officer (Principal Financial Officer and Principal Accounting Officer)

The foregoing certification is being furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and is not being filed as part of the Form 10-Q or as a separate disclosure document.