Lisata Therapeutics Reports First Quarter 2024 Financial Results and Provides Business Update

May 9, 2024

Seminal Phase 2b ASCEND trial top-line data expected in fourth quarter of 2024

Projected available cash to fund planned operations into early 2026 covering all studies through data

Conference call scheduled for today at 4:30 p.m. Eastern Time

BASKING RIDGE, N. J., May 09, 2024 (GLOBE NEWSWIRE) -- Lisata Therapeutics, Inc. (Nasdaq: LSTA) ("Lisata" or the "Company"), a clinical-stage pharmaceutical company developing innovative therapies for the treatment of advanced solid tumors and other serious diseases, provided a business update and reported financial results for the three months ended March 31, 2024.

"2024, a pivotal year for Lisata, is off to a very strong start," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Lisata. "Although we project multiple data readouts over the next 18 months, topline results from the Phase 2b ASCEND trial later this year have transformative potential for the Company. These results will be instrumental in determining the future of Lisata, and we plan to use them to explore conditional approvals with various regulatory agencies and/or to design an optimized Phase 3 program in pancreatic ductal adenocarcinoma. Since the start of the year, we have received both U.S. FDA Orphan Drug and Rare Pediatric Disease designations for certepetide, previously known as LSTA1, in osteosarcoma, further validating the broad therapeutic potential of this innovative therapy. We are energized by the progress we are making and excited about Lisata's prospects."

Dr. Mazzo added, "Our continued prudent financial management allows us to reaffirm our projection that currently available cash will fund operations into early 2026, providing a solid foundation to fund all ongoing and planned trials through to completion. More than ever, we remain confident in our ability to execute our development activities with the goal of reaching critical milestones at the earliest possible juncture."

Development Portfolio Highlights

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

Certepetide is an investigational drug designed to activate the CendR uptake pathway that allows co-administered or molecularly bound anti-cancer drugs to target and penetrate solid tumors more effectively. Certepetide is designed to actuate 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, to the exclusion of normal tissues. In preclinical models, certepetide has also shown the ability to modify the tumor microenvironment, leading to the expectation that tumors will become more susceptible to immunotherapies and inhibiting the metastatic cascade (i.e., the spread of cancer to other parts of the body). Lisata and its development partners have amassed 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 test its ability to enhance delivery of standard-of-care ("SOC") chemotherapy for metastatic pancreatic cancer ("mPDAC"). Certepetide has been granted orphan drug designation for pancreatic cancer in the U.S. and Europe as well as for glioblastoma multiforme ("GBM") and osteosarcoma in the U.S. It also received a Fast Track designation from the FDA for pancreatic cancer and, just recently, a Rare Pediatric Disease designation from the FDA for osteosarcoma. Currently, certepetide is the subject of multiple ongoing or planned Phase 2a and 2b clinical studies being conducted globally in a variety of solid tumor types in combination with a variety of anti-cancer regimens:

- ASCEND: Phase 2b double-blind, randomized, placebo-controlled clinical trial evaluating two dosing regimens of certepetide in combination with gemcitabine/nab-paclitaxel SOC chemotherapy in patients with mPDAC. Cohort A of the study receives a single dose of 3.2 mg/kg certepetide essentially simultaneously with SOC, while Cohort B is identical to Cohort A, but with a second dose of 3.2mg/kg of certepetide given four hours after the first. The trial is being conducted at 25 sites in Australia and New Zealand led by the Australasian Gastro-Intestinal Trials Group in collaboration with the University of Sydney and with the National Health and Medical Research Council Clinical Trial Centre at the University of Sydney as the Coordinating Centre. The conclusion of a planned interim futility analysis in 2023 by the Independent Data Safety Monitoring Committee was that the conditions for futility were not met and that the study should proceed to completion. With trial enrollment completed in the fourth quarter of 2023, Lisata expects topline data from the 95 patients assigned to Cohort A of the study to be reported in the fourth quarter of 2024 and the complete data set of all 158 patients from the study to be available by mid-2025.

- BOLSTER: Phase 2a double-blind, placebo-controlled, multi-center, randomized trial in the U.S. evaluating certepetide in combination with SOC in first-line cholangiocarcinoma. The trial is actively enrolling with enrollment completion expected by the end of the third quarter of 2024.

- CENDIFOX: Phase 1b/2a open-label trial in the U.S. of certepetide in combination with neoadjuvant FOLFIRINOX based therapies in pancreatic, colon and appendiceal cancers. The trial continues to make steady progress with enrollment

completion for all three arms expected by the end of 2024.

- Qilu Pharmaceutical, the licensee of certepetide in the Greater China territory, is currently evaluating certepetide in combination with gemcitabine and nab-paclitaxel as a treatment for mPDAC. During the 2023 ASCO Annual Meeting, Qilu Pharmaceutical presented an abstract sharing preliminary data from the study which corroborated previously reported findings from the Phase 1b/2a trial of certepetide plus gemcitabine and nab-paclitaxel conducted in Australia in patients with mPDAC. As recently announced, Qilu has begun treating patients in their Phase 2 placebo-controlled trial in mPDAC. The study is planned to take approximately 18 months to complete enrollment and another 13 months for patient follow-up and data analysis and reporting.

- iLSTA: Phase 1b/2a randomized, single-blind, single-center, safety and pharmacodynamic trial in Australia evaluating certepetide in combination with the checkpoint inhibitor, durvalumab, plus standard-of-care gemcitabine and nab-paclitaxel chemotherapy versus standard-of-care alone in patients with locally advanced non-resectable PDAC. Enrollment completion is expected in the second half of 2024.

- A Lisata-funded Phase 2a, double-blind, placebo-controlled, randomized, proof-of-concept study evaluating certepetide in combination with standard-of-care temozolomide versus temozolomide alone in patients with newly diagnosed GBM is being conducted across multiple sites in Estonia and Latvia and is targeted to enroll 30 patients with a randomization of 2:1 in favor of the certepetide treatment group.

First Quarter 2024 Financial Highlights

For the three months ended March 31, 2024, operating expenses totaled $6.6 million, compared to $6.8 million for the three months ended March 31, 2023, representing a decrease of $0.2 million or 3.6%.

Research and development expenses were approximately $3.2 million for the three months ended March 31, 2024, compared to $3.2 million for the three months ended March 31, 2023, representing an essentially unchanged spend. The minor increase of $62,000 or 2.0% was primarily due to an increase in expenses associated with enrollment activities in the current year for the BOLSTER trial, partially offset by a reduction in expenses associated with the Phase 2b ASCEND trial which completed enrollment in the prior year.

General and administrative expenses were approximately $3.4 million for the three months ended March 31, 2024, compared to $3.7 million for the three months ended March 31, 2023, representing a decrease of $0.3 million or 8.3%. This was primarily due to a decrease in staffing costs associated with the elimination of the Chief Business Officer position on May 1, 2023, a reduction in option assumption equity expense in connection with the Company's merger with Cend Therapeutics, Inc., a decrease in directors and officers insurance premiums, and a reduction in spend on consulting and legal fees partially offset by one-off settlement-related costs.

Overall, net losses were $5.4 million for the three months ended March 31, 2024, compared to $6.2 million for the three months ended March 31, 2023.

Balance Sheet Highlights

As of March 31, 2024, Lisata had cash, cash equivalents, and marketable securities of approximately $43.3 million. Based on its current expected capital needs, the Company believes that its projected capital will fund its current proposed operations into early 2026, encompassing anticipated data milestones from all its ongoing and planned clinical trials.

Conference Call Information

Lisata will hold a live conference call today, May 9, 2024, at 4:30 p.m. Eastern Time to discuss financial results, provide a business update and answer questions.

Those wishing to participate must register for the conference call by way of the following link: **CLICK HERE TO REGISTER**. Registered participants will receive an email containing conference call details with dial-in options. To avoid delays, we encourage participants to dial into the conference call 15 minutes ahead of the scheduled start time.

A live webcast of the call will also be accessible under the **Investors & News** section of Lisata's website and will be available for replay beginning two hours after the conclusion of the call for 12 months.

About Lisata Therapeutics

Lisata Therapeutics is a clinical-stage pharmaceutical company dedicated to the discovery, development and commercialization of innovative therapies for the treatment of advanced solid tumors and other major diseases. Lisata's lead product candidate, certepetide, is an investigational drug designed to activate a novel uptake pathway that allows co-administered or tethered anti-cancer drugs to target and penetrate solid tumors more effectively. Based on Lisata's CendR Platform® Technology, Lisata has already established noteworthy commercial and R&D partnerships. The Company expects to announce numerous clinical study and business milestones over the next two years and has projected that its current business and development plan is funded with available capital through these milestones and into early 2026. For more information on the Company, please visit www.lisata.com.

Forward-Looking Statements

This communication contains "forward-looking statements" that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this communication regarding

strategy, future operations, future financial position, future revenue, projected expenses and capital, prospects, plans and objectives of management are forward-looking statements. In addition, when or if used in this communication, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as they relate to Lisata or its management, may identify forward-looking statements. Examples of forward-looking statements include, but are not limited to, the potential efficacy of certepetide as a treatment for patients with metastatic pancreatic ductal adenocarcinoma and other solid tumors, statements relating to Lisata's continued listing on the Nasdaq Capital Market; expectations regarding the capitalization, resources and ownership structure of Lisata; the approach Lisata is taking to discover and develop novel therapeutics; the adequacy of Lisata's capital to support its future operations and its ability to successfully initiate and complete clinical trials; and the difficulty in predicting the time and cost of development of Lisata's product candidates. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: results observed from a single patient case study are not necessarily indicative of final results and one or more of the clinical outcomes may materially change following more comprehensive reviews of the data and as more patient data becomes available, including the risk that unconfirmed responses may not ultimately result in confirmed responses to treatment after follow-up evaluations; the risk that product candidates that appeared promising in early research and clinical trials do not demonstrate safety and/or efficacy in larger-scale or later clinical trials; the safety and efficacy of Lisata's product candidates, decisions of regulatory authorities and the timing thereof, the duration and impact of regulatory delays in Lisata's clinical programs, Lisata's ability to finance its operations, the likelihood and timing of the receipt of future milestone and licensing fees, the future success of Lisata's scientific studies, Lisata's ability to successfully develop and commercialize drug candidates, the timing for starting and completing clinical trials, rapid technological change in Lisata's markets, the ability of Lisata to protect its intellectual property rights; and legislative, regulatory, political and economic developments. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in Lisata's Annual Report on Form 10-K filed with the SEC on February 29, 2024, and in other documents filed by Lisata with the Securities and Exchange Commission. Except as required by applicable law, Lisata undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

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- Tables to Follow –

Lisata Therapeutics, Inc.
Selected Financial Data
(in thousands, except per share data)

(in thousands, except per share data)	Three Months Ended March 31, 2024 (unaudited)	Three Months Ended March 31, 2023 (unaudited)
Statement of Operations Data:		
Research and development	$ 3,241	$ 3,179
General and administrative	3,360	3,665
Total operating expenses	**6,601**	**6,844**
Operating loss	**(6,601)**	**(6,844)**
Investment income, net	589	670
Other expense, net	(187)	(13)
Net loss before benefit from income taxes and noncontrolling interests	**(6,199)**	**(6,187)**
Benefit from income taxes	(798)	-
Net loss	**(5,401)**	**(6,187)**
Less - net income (loss) attributable to noncontrolling interests	-	-
Net loss attributable to Lisata Therapeutics, Inc. common stockholders	**$ (5,401)**	**$ (6,187)**
Basic and diluted loss per share attributable to Lisata Therapeutics, Inc. common stockholders	**$ (0.65)**	**$ (0.77)**
Weighted average common shares outstanding	**8,294**	**7,987**

	March 31, 2024 (unaudited)	December 31, 2023
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 43,349	$ 50,535
Total assets	48,240	54,694
Total liabilities	5,497	6,800

Total equity	42,743	47,894