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

August 12, 2024

Phase 2b ASCEND trial top-line data remains on track to be reported in fourth quarter of 2024

Available cash projected to fund current operations into early 2026 and all active studies through to data

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

BASKING RIDGE, N.J., Aug. 12, 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 second quarter ended June 30, 2024.

"The second quarter generated strong momentum for Lisata as we continued to advance multiple ongoing and planned clinical studies centered around our novel investigational product, certepetide," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Lisata. "We have a lot to look forward to with multiple key data readouts projected over the next 18 months, including topline results from the Phase 2b ASCEND trial. These results have transformative potential for the Company as we plan to explore conditional approvals with various regulatory agencies and/or to design an optimized Phase 3 program in metastatic pancreatic ductal adenocarcinoma, an aggressive, often fatal, form of pancreatic cancer. In just the first half of 2024, certepetide has received U.S. FDA Orphan Drug and Rare Pediatric Disease designation in osteosarcoma, and a waiver for evaluating certepetide in a pediatric population with pancreatic cancer in Europe (EMA). These agency recognitions further validate and support our excitement and the broad therapeutic potential of this innovative therapy."

Dr. Mazzo added, "Our continued prudent, strategic financial management allows us to reaffirm our projection that available cash will fund current operations into early 2026, providing the necessary capital for all planned trials through to completion."

Development Portfolio Highlights

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

Certepetide (formerly LSTA1) is an investigational drug designed to activate a novel uptake pathway that allows co-administered or tethered anti-cancer drugs to 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. Certepetide has also been shown to modify the tumor microenvironment, diminishing its immunosuppressive nature and inhibiting the metastatic cascade. Along with our collaborators, we have amassed significant non-clinical data demonstrating enhanced delivery of various existing and emerging anti-cancer therapies, including immunotherapies and RNA-based therapeutics. To date, certepetide has also demonstrated favorable safety, tolerability, and clinical activity in completed and ongoing clinical trials designed to test its ability to enhance the effectiveness of standard-of-care ("SoC") chemotherapy for pancreatic cancer. Lisata is exploring the potential of certepetide to enable a variety of treatment modalities to treat a range of solid tumors more effectively. Certepetide has been awarded Fast Track designation (U.S.) and Orphan Drug Designation for pancreatic cancer (U.S. and E.U.) as well as Orphan Drug Designation for glioma (U.S.) and osteosarcoma (U.S.). Additionally, certepetide has received Rare Pediatric Disease Designation for osteosarcoma (U.S.). 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, including:

- ASCEND: Phase 2b double-blind, randomized, placebo-controlled clinical trial evaluating two dosing regimens of certepetide in combination with SoC chemotherapy (gemcitabine/nab-paclitaxel) in patients with metastatic pancreatic ductal adenocarcinoma ("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- and second-line cholangiocarcinoma ("CCA"). The Company achieved complete enrollment in first-line CCA nearly six months ahead of plan, accelerating anticipated topline data readout to mid-2025. Based on this rapid enrollment rate and the pressing need to improve treatment outcomes in patients that have progressed after first-line CCA treatment, a second cohort has been added to the BOLSTER trial evaluating subjects in second-line CCA. Lisata expects to enroll the first patient by the fourth 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 has completed enrollment in the pancreatic cohort and expects to complete enrollment in the remaining two cohorts 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 previously reported, Qilu has begun treating patients in their Phase 2 placebo-controlled trial in mPDAC.

- 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 SoC gemcitabine and nab-paclitaxel chemotherapy versus SoC 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 SoC 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.

- FORTIFIDE: Phase 1b/2a, double-blind, placebo-controlled, three-arm, randomized study in the U.S. to evaluate the safety, tolerability, and efficacy of a 4-hour continuous infusion of certepetide in combination with SoC in subjects with second-line mPDAC who have progressed on FOLFIRINOX. As part of this study, Lisata has engaged Haystack Oncology to use its MRD™ technology to measure circulating tumor DNA levels at multiple timepoints in patients throughout the study as an exploratory endpoint for analyzing the early therapeutic effect of certepetide. The Company expects to enroll the first patient in the study by the first half of 2025.

Second Quarter 2024 Financial Highlights

For the three months ended June 30, 2024, operating expenses totaled $5.5 million, compared to $6.9 million for the three months ended June 30, 2023, representing a decrease of $1.4 million or 19.7%.

Research and development expenses were approximately $2.6 million for the three months ended June 30, 2024, compared to $3.2 million for the three months ended June 30, 2023, representing a decrease of $0.6 million or 17.7%. This was primarily due to a reduction in expenses associated with the Phase 2b ASCEND trial which completed enrollment in the prior year, lower spend on chemistry, manufacturing and control ("CMC") related expenses and lower equity expense partially offset by an increase in expenses associated with our enrollment activities in the current year for our BOLSTER trial.

General and administrative expenses were approximately $2.9 million for the three months ended June 30, 2024, compared to $3.7 million for the three months ended June 30, 2023, representing a decrease of $0.8 million or 21.3%. This was primarily due to one-off related severance costs in the prior year associated with the elimination of the Chief Business Officer position on May 1, 2023, a reduction in equity expense and a decrease in directors and officers insurance premiums in the current year.

Benefit from income taxes was $0.0 million for the three months ended June 30, 2024, compared to $2.3 million for the three months ended June 30, 2023. In April 2023, we received net proceeds of $2.2 million from the sale of tax benefits to a qualified and approved buyer pursuant to the New Jersey Economic Development Authority's Technology Business Tax Certificate Transfer Program.

Overall, net losses were $5.0 million for the three months ended June 30, 2024, compared to $4.0 million for the three months ended June 30, 2023.

Balance Sheet Highlights

As of June 30, 2024, Lisata had cash, cash equivalents, and marketable securities of approximately $38.3 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, August 12, 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 product candidate, certepetide (formerly LSTA1), is an investigational drug designed to activate a novel uptake pathway that allows co-administered or tethered anti-cancer drugs to selectively target and penetrate solid tumors more effectively. Lisata has already established noteworthy commercial and R&D partnerships based on its CendR Platform® technology. The Company expects to announce numerous milestones over the next two years and believes that its projected capital will fund operations into early 2026, encompassing anticipated data milestones from its ongoing and planned clinical trials. 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 the Company's clinical development programs 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.

Contact:

Investors:

Lisata Therapeutics, Inc.
John Menditto
Vice President, Investor Relations and Corporate Communications
Phone: 908-842-0084
Email: jmenditto@lisata.com

Media:

ICR Westwicke
Elizabeth Coleman
Senior Associate
Phone: 203-682-4783
Email: elizabeth.coleman@westwicke.com

- Tables to Follow –

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
(in thousands, except per share data)	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Statement of Operations Data:				
Research and development	$ 2,601	$ 3,162	$ 5,842	$ 6,341
General and administrative	2,922	3,713	6,282	7,378
Total operating expenses	**5,523**	**6,875**	**12,124**	**13,719**
Operating loss	**(5,523)**	**(6,875)**	**(12,124)**	**(13,719)**
Investment income, net	493	668	1,082	1,338
Other expense, net	(14)	(150)	(201)	(163)
Net loss before benefit from income taxes and noncontrolling interests	**(5,044)**	**(6,357)**	**(11,243)**	**(12,544)**
Benefit from income taxes	-	(2,330)	(798)	(2,330)

Net loss	**(5,044)**	**(4,027)**	**(10,445)**	**(10,214)**
Less - net income (loss) attributable to noncontrolling interests	-	-	-	-
Net loss attributable to Lisata Therapeutics, Inc. common stockholders	**$ (5,044)**	**$ (4,027)**	**$ (10,445)**	**$ (10,214)**
Basic and diluted loss per share attributable to Lisata Therapeutics, Inc. common stockholders	**$ (0.61)**	**$ (0.50)**	**$ (1.26)**	**$ (1.28)**
Weighted average common shares outstanding	**8,308**	**8,021**	**8,301**	**8,004**

	June 30, 2024 (unaudited)	December 31, 2023
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 38,262	$ 50,535
Total assets	42,571	54,694
Total liabilities	4,576	6,800
Total equity	37,995	47,894