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

November 12, 2024

Robust and expanding development portfolio with multiple key data readouts projected over the next 18 months

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

BASKING RIDGE, N.J., Nov. 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 third quarter ended September 30, 2024.

"We are pleased to share the progress made in the third quarter of 2024, highlighted by the advancement of our robust development portfolio centered around our novel product candidate, certepetide," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Lisata. "While we await preliminary results from Cohort A of the Phase 2b ASCEND trial expected this quarter, we continue to explore the broad application of certepetide's unique mechanism of action. Our development portfolio now encompasses multiple clinical and preclinical trials evaluating certepetide for the treatment of various solid tumors, including pancreatic, cholangiocarcinoma, glioblastoma, colon, appendiceal, and melanoma. In addition, certepetide is being evaluated in a preclinical non-cancerous setting for endometriosis. All our studies are designed to yield data during the coming year, and we look forward to a data-rich 2025."

Development Portfolio Highlights

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

Certepetide is an investigational drug designed to selectively activate the C-end rule active transport mechanism in a tumor specific manner, resulting in systemically co-administered anti-cancer agents more efficiently penetrating and accumulating in the tumor. Additionally, certepetide has been shown to modify the tumor microenvironment, diminishing its immunosuppressive nature, enhancing cytotoxic T cell concentration and inhibiting the metastatic cascade. Lisata and its collaborators have amassed significant non-clinical data demonstrating enhanced delivery of various existing and emerging anti-cancer therapies, including chemotherapies, 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 demonstrate its ability to enhance the effectiveness of standard-of-care ("SoC") chemotherapy for pancreatic cancer as well as the combination of chemotherapy and immunotherapy in a variety of solid tumors. 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, osteosarcoma, and cholangiocarcinoma (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"). The trial is being conducted at 25 sites in Australia and New Zealand led by the Australasian Gastro-Intestinal Trials Group ("AGITG") 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. Following the completion of enrollment in the fourth quarter of 2023, data from an interim analysis of the 95 Cohort A patients (single dose of certepetide administered with SoC) will be presented at the American Society of Clinical Oncology Gastrointestinal Cancers Symposium in January of 2025. Data from the 60 patients in Cohort B patients (single dose of certepetide administered with SoC plus a second dose of certepetide four hours after the first) is expected in mid-2025 with a final analysis of both Cohorts available thereafter.

- 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 previously announced that the first patient has been treated in the second-line CCA cohort, with enrollment completion expected in the first half of 2025.

- 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. With 24 of the 30 patients enrolled, enrollment remains on track to be completed by the first half of 2025.

- 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 glioblastoma multiforme ("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. Enrollment completion is expected in the second half of 2025.

- 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 quarter of 2025.

As recently announced, Lisata has entered into multiple research collaborations, including a sponsored research agreement with the University of Cincinnati to assess certepetide in combination with bevacizumab (a VEGF inhibitor) in a preclinical murine model for the treatment of endometriosis. Lisata is also partnering with Valo Therapeutics ("ValoTx") to investigate the benefits of combining certepetide with ValoTx's platform technology, PeptiCRAd, and a checkpoint inhibitor in a preclinical murine model for the treatment of melanoma.

Third Quarter 2024 Financial Highlights

For the three months ended September 30, 2024, operating expenses totaled $5.3 million, compared to $6.0 million for the three months ended September 30, 2023, representing a decrease of $0.6 million or 10.5%.

Research and development expenses were approximately $2.5 million for the three months ended September 30, 2024, compared to $3.4 million for the three months ended September 30, 2023, representing a decrease of $0.8 million or 24.8%. This was primarily due to a reduction in clinical research organization expenses associated with the Company's Phase 2a BOLSTER trial as a result of trial protocol modifications and lower equity expenses. In addition, there were start-up expenses in the prior year related to the GBM study.

General and administrative expenses were approximately $2.8 million for the three months ended September 30, 2024, compared to $2.6 million for the three months ended September 30, 2023, representing an increase of $0.2 million or 8.1%. This was primarily due to higher consulting expenses.

Overall, net losses were $4.9 million for the three months ended September 30, 2024, compared to $5.3 million for the three months ended September 30, 2023.

Balance Sheet Highlights

As of September 30, 2024, Lisata had cash, cash equivalents, and marketable securities of approximately $35.9 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, November 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 internalizing RGD, or Arginylglycylaspartic acid, (iRGD) cyclic peptide product candidate, certepetide, 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 1.5 years and believes that its projected capital will fund operations into early 2026, encompassing anticipated data milestones from its ongoing and planned clinical

trials. Learn more about certepetide's mechanism of action in our short film . 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 cholangiocarcinoma 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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
(in thousands, except per share data)	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Statement of Operations Data:				
Research and development	$ 2,542	$ 3,380	$ 8,384	$ 9,721
General and administrative	2,794	2,584	9,076	9,962
Total operating expenses	**5,336**	**5,964**	**17,460**	**19,683**
Operating loss	**(5,336)**	**(5,964)**	**(17,460)**	**(19,683)**
Investment income, net	451	714	1,533	2,053
Other expense, net	(45)	(11)	(246)	(175)
Net loss before benefit from income taxes and noncontrolling interests	**(4,930)**	**(5,261)**	**(16,173)**	**(17,805)**
Benefit from income taxes	-	-	(798)	(2,330)
Net loss	**(4,930)**	**(5,261)**	**(15,375)**	**(15,475)**
Less - net income (loss) attributable to noncontrolling interests	-	-	-	-

Net loss attributable to Lisata Therapeutics, Inc. common stockholders	**$ (4,930)**	**$ (5,261)**	**$ (15,375)**	**$ (15,475)**
Basic and diluted loss per share attributable to Lisata Therapeutics, Inc. common stockholders	**$ (0.59)**	**$ (0.65)**	**$ (1.85)**	**$ (1.92)**
Weighted average common shares outstanding	**8,321**	**8,141**	**8,307**	**8,050**

	September 30, 2024 (unaudited)	December 31, 2023
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 35,856	$ 50,535
Total assets	38,199	54,694
Total liabilities	4,763	6,800
Total equity	33,436	47,894