Lisata Therapeutics Reports Second Quarter 2025 Financial Results and Provides Business Update

August 7, 2025

Cash runway extending into the fourth quarter of 2026 with no debt, funding current clinical programs through to their next data milestone

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

BASKING RIDGE, N.J., Aug. 07, 2025 (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, 2025.

"We continued to advance our clinical development portfolio and partnering initiatives during the second quarter of 2025," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Lisata. "All of our activities are to support our core mission of exploiting the broad applicability of certepetide across a variety of advanced solid tumors and other difficult-to-treat indications. To this end, we recently announced positive preliminary results from the ASCEND and iLSTA trials, and we anticipate a number of additional data events through the remainder of 2025 and into 2026."

Dr. Mazzo added, "Our continued rigorous financial management allows us to reaffirm our projection that available cash will fund current operations into the fourth quarter of 2026, including all active clinical studies through to their next data milestone."

Development Portfolio Highlights

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

Certepetide (formerly LSTA1), a proprietary, *internalizing* RGD (arginyl-glycyl-aspartic acid or iRGD), cyclic peptide product candidate, is an investigational drug designed to 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 ("TME"), diminishing its immunosuppressive nature, enhancing cytotoxic T cell concentration in the TME and inhibiting the metastatic cascade. Lisata and its collaborators have amassed significant non-clinical data demonstrating enhanced efficacy of various existing and emerging anti-cancer therapies, including chemotherapies, immunotherapies, and RNA-based therapeutics in solid tumor models.

In addition, 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 clinical studies being conducted globally across several solid tumor types in combination with a variety of anti-cancer regimens, including:

- ASCEND: Phase 2b double-blind, randomized (2:1 ratio), placebo-controlled trial evaluating two dosing regimens of certepetide in combination with SoC chemotherapy (gemcitabine/nab-paclitaxel) in patients with previously untreated metastatic pancreatic ductal adenocarcinoma ("mPDAC"). The trial is being conducted across 25 sites in Australia and New Zealand led by the Australasian Gastro-Intestinal Trials Group ("AGITG") and coordinated by the National Health and Medical Research Council Clinical Trial Centre at the University of Sydney. Cohort A, with 95 patients receiving a single intravenous ("IV") dose of certepetide 3.2 mg/kg or placebo in combination with SoC, completed enrollment in the third quarter of 2023. Preliminary Cohort A data presented at the 2025 ASCO-GI Symposium showed a positive trend in overall survival, including four complete responses in the certepetide-treated group compared to none in the placebo treated group. As recently announced, preliminary data from 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, was presented at the ESMO Gastrointestinal Cancers ("ESMO-GI") Congress on July 2, 2025. The preliminary Cohort B data demonstrate a positive signal in progression-free survival and objective response rate observed in the certepetide-treated group compared to the placebo-treated group, indicating that the addition of two doses of certepetide (Cohort B regimen) to SoC resulted in a clinically meaningful treatment effect and an attractive safety profile. Final data and key findings from both cohorts of the ASCEND study are anticipated to be available later this year, with more information to follow as it becomes available.

- BOLSTER: Phase 2a double-blind, placebo-controlled, multi-center, randomized trial in the U.S. evaluating certepetide in combination with SoC chemotherapy 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 fourth quarter of 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 was added to the BOLSTER trial evaluating certepetide in combination with SoC in subjects with second-line CCA. In September 2024, Lisata announced first patient treated in the

second-line CCA cohort and recently decided to stop enrollment at approximately 20 patients to accelerate data readout and optimize capital allocation.

- CENDIFOX: Phase 1b/2a open-label trial in the U.S. evaluating certepetide in combination with neoadjuvant FOLFIRINOX based therapies in pancreatic, colon and appendiceal cancers. In December 2024, the Company announced enrollment completion in all three cohorts. The single-center study, conducted solely at the University of Kansas Cancer Center, was designed with a 3-cycle run-in period to ensure patients met specific criteria before receiving treatment. Of the 66 patients enrolled, 50 patients met the criteria and were treated with certepetide across three cohorts, including 24 with resectable or borderline resectable pancreatic cancer, 15 with high-grade colon or appendiceal cancer and peritoneal metastasis, and 11 with oligometastatic colon cancer. The trial is expected to provide Lisata with valuable pre- and post-treatment tumor tissue data for immune profiling, along with long-term patient outcome information. CENDIFOX data are expected in the coming months; however, given that this is an investigator-initiated study, the exact timing is not in Lisata's control. The trial is funded by the University of Kansas Cancer Center and Lisata is supplying certepetide.

- 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 first-line 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 first-line mPDAC. Qilu has completed enrollment in its Phase 2 trial and data are expected in the near future. Progression of Qilu's certepetide development program into Phase 3 in China will trigger a $10 million milestone payment due to Lisata under the terms of the license agreement with Qilu.

- iLSTA: Phase 1b/2a randomized, single-blind, single-center, safety and pharmacodynamic trial in Australia, funded by WARPNINE Inc., evaluating certepetide in combination with SoC chemotherapy (nab-paclitaxel and gemcitabine) plus SoC immunotherapy (durvalumab) versus SoC alone in patients with locally advanced non-resectable PDAC. As recently announced, enrollment in this study has been completed. Updated interim analyses from the iLSTA trial, presented at the ESMO-GI Congress on July 3, 2025, show compelling new preliminary data for certepetide. Consistent with earlier preliminary findings from the 2025 ASCO-GI meeting, the data reinforce certepetide's potential to enhance immunotherapy effectiveness by provoking significant RECIST responses and improving overall response and disease control rates. Final data and key findings from this study are anticipated in the first quarter of 2026.

- 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 planned to also include a site in Lithuania. The study is targeted to enroll 30 patients with a randomization of 2:1 in favor of the certepetide treatment group. Enrollment completion is expected in 2026.

Lisata entered into a research license with Catalent, Inc. ("Catalent"), to preclinically evaluate the efficacy of certepetide in combination with Catalent's SMARTag® ADC dual payload technology platform for the treatment of various difficult-to-treat diseases. Additionally, Lisata has expanded its strategic collaboration with GATC Health Corp ("GATC") to combine Lisata's drug development expertise with GATC's AI-powered Multiomics Advanced Technology™ platform to optimize and accelerate drug discovery and development, including analyzing certepetide for new indications and identifying combination therapies.

Lisata recently announced that the United States Patent and Trademark Office ("USPTO") issued the Company a new composition of matter patent for certepetide (U.S. Patent No. 12,351,653), which extends its patent protection until March 2040, with potential for further extensions. The patent grants Lisata exclusive rights to the drug itself, preventing others from manufacturing or selling certepetide. The patent's claims cover certepetide's chemical structure, pharmacokinetic properties, methods of manufacturing, and applications for treating solid tumors.

Second Quarter 2025 Financial Highlights

Revenue

For the three months ended June 30, 2025, revenue totaled $70 thousand in connection with an upfront license fee related to the Research License Agreement with Catalent, Inc. We did not have any revenue for the three months ended June 30, 2024.

Operating Expenses

For the three months ended June 30, 2025, operating expenses totaled $4.9 million, compared to $5.5 million for the three months ended June 30, 2024, representing a decrease of $0.6 million or 10.6%.

Research and development expenses were approximately $2.3 million for the three months ended June 30, 2025, compared to $2.6 million for the three months ended June 30, 2024, representing a decrease of $0.3 million or 13.4%. This was primarily due to a reduction in patient treatment costs and clinical research organization expenses associated with our Phase 2a BOLSTER trial and lower spend on chemistry, manufacturing and controls.

General and administrative expenses were approximately $2.7 million for the three months ended June 30, 2025, compared to $2.9 million for the three months ended June 30, 2024, representing a decrease of $0.2 million or 8.1%. This was primarily due to savings resulting from the elimination of

an employee position and lower spend on consulting and travel and entertainment expenses.

Overall, net losses were $4.7 million for the three months ended June 30, 2025, compared to $5.0 million for the three months ended June 30, 2024.

Balance Sheet Highlights

As of June 30, 2025, we had cash, cash equivalents and marketable securities of approximately $22.0 million. Based on its existing and planned activities, the Company believes available funds will support current operations into the fourth quarter of 2026.

Conference Call Information

Lisata will hold a live conference call today, August 7, 2025, 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 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 the fourth quarter of 2026, encompassing anticipated data milestones from its ongoing and planned clinical trials. For a comprehensive overview of certepetide's mechanism of action, please view our informative 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 solid tumors; our beliefs about the potential uses and benefits of certepetide; the potential of the collaboration with Catalent to develop new treatment options; the expected expiration of our patents for certepetide; our ability to obtain patent term extension on our U.S. composition of matter patent; 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 preliminary data 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 27, 2025, 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 June 30, 2025 (unaudited)	Three Months Ended June 30, 2024 (unaudited)	Six Months Ended June 30, 2025 (unaudited)	Six Months Ended June 30, 2024 (unaudited)
Statement of Operations Data:				
Revenue	70	$ -	$ 70	**$ -**
Research and development	2,253	2,601	4,856	5,842
General and administrative	2,685	2,922	5,930	6,282
Total operating expenses	**4,938**	**5,523**	**10,786**	**12,124**
Operating loss	**(4,868)**	**(5,523)**	**(10,716)**	**(12,124)**
Investment income, net	216	493	482	1,082
Other expense, net	(7)	(14)	(111)	(201)
Net loss before benefit from income taxes and noncontrolling interests	**(4,659)**	**(5,044)**	**(10,345)**	**(11,243)**
Benefit from income taxes	-	-	(962)	(798)
Net loss	**(4,659)**	**(5,044)**	**(9,383)**	**(10,445)**
Less - net income (loss) attributable to noncontrolling interests	-	-	-	-
Net loss attributable to Lisata Therapeutics, Inc. common stockholders	**$ (4,659)**	**$ (5,044)**	**$ (9,383)**	**$ (10,445)**
Basic and diluted loss per share attributable to Lisata Therapeutics, Inc. common stockholders	**$ (0.54)**	**$ (0.61)**	**$ (1.09)**	**$ (1.26)**
Weighted average common shares outstanding	**8,605**	**8,308**	**8,604**	**8,301**

	June 30, 2025 (unaudited)	December 31, 2024
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 21,970	$ 31,245
Total assets	25,160	35,002
Total liabilities	4,385	5,685
Total equity	20,775	29,317

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