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

November 6, 2025

Data rich period continues to support certepetide's broad applicability and effectiveness

Catalent enters into global license agreement for the use of certepetide as part of their SMARTag® Antibody-Drug Conjugate Technology Platform

Strategic Alliance formed with GATC Health to exploit their Multiomics Advanced Technology™ artificial intelligence drug discovery platform

Cash runway extended into the first quarter of 2027 with no debt

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

BASKING RIDGE, N.J., Nov. 06, 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 third quarter ended September 30, 2025.

"Once again, the recent quarter saw the reporting of positive data from a number of clinical studies involving certepetide, including from the ASCEND, iLSTA, and CENDIFOX trials. Importantly, we also announced a strategic alliance with GATC Health to use their Multiomics Advanced Technology™ artificial intelligence drug discovery platform to identify product candidates for development, as well as a global license agreement in which Catalent gained access to certepetide for use across various Antibody-Drug Conjugates. Overall, it was a productive and positive quarter marked by our continued vigilance in managing expenses. As a result, we now project that our available cash will fund current operations into the first quarter of 2027," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Lisata. "We anticipate a steady flow of additional data through the remainder of 2025 and into 2026."

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 clinical and non-clinical data demonstrating enhanced efficacy and acceptable safety of various existing and emerging anti-cancer therapies, including chemotherapies, immunotherapies, RNA-based therapeutics, and Antibody-Drug Conjugates ("ADCs") in solid tumor models.

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 and proposed (subject to sufficient funding) global clinical studies 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 standard-of-care ("SoC") chemotherapy (gemcitabine/nab-paclitaxel) in patients with previously untreated metastatic pancreatic ductal adenocarcinoma ("mPDAC"). The trial was 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. 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. Additionally, pooled data from both Cohorts A and B, which was presented at the ESMO Congress in October 2025, further corroborated previous findings and indicated no increase in adverse events in the certepetide-treated groups beyond those experienced in the SoC alone groups. Final data and key findings from both cohorts of the ASCEND study are anticipated for the first quarter of next year.
- 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 investigator enthusiasm, a second cohort was added, evaluating certepetide in combination with SoC in subjects with second-line CCA. In September 2024, Lisata announced the first patient treated in the second-line CCA cohort and more recently, completed enrollment at approximately 20 patients to accelerate data read out and optimize capital allocation.

- CENDIFOX: Investigator-initiated 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 ductal adenocarcinoma (“PDAC”), 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. Preliminary data from the PDAC cohort, presented at the AACR Special Conference in September 2025, showed that the combination of certepetide with FOLFIRINOX was safe and feasible. In the 10 patients who completed the therapy and underwent surgery, treatment resulted in a 50% R0 resection rate and a 70% pathologic partial response, alongside promising early survival data, including a 60% two-year overall survival rate. Importantly, the combination therapy appears to transform tumors from "immune-cold" to "immune-hot" by enhancing immune cell infiltration and increasing markers like PD-1 and PD-L1, which could significantly improve the efficacy of subsequent immunotherapies. Additional CENDIFOX data are expected in the coming months under the auspices of the investigator. 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 developing 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 2026.
- iLSTA: Phase 1b/2a randomized, single-blind, single-center, safety and pharmacodynamic trial in Australia, funded by WARPNINE Inc., a non-profit foundation, 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. Study enrollment is complete and results from an interim analysis were presented at the ESMO-GI Congress on July 3, 2025, showing compelling new corroborative data for certepetide. Consistent with the earlier findings presented at the 2025 ASCO-GI meeting, the data demonstrate certepetide's potential to enhance immunotherapy effectiveness by provoking significant RECIST responses and improving overall response and disease control rates. Final data from this study are anticipated in the first quarter of 2026.
- GBM: A Lisata-funded Phase 2a, double-blind, placebo-controlled, randomized, proof-of-concept study evaluating certepetide in combination with SoC temozolomide versus SOC 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 is progressing according to plan and completion is expected in 2026.

Notable business development achievements in the third quarter:

- Lisata and Catalent entered into a nonexclusive license agreement that grants Catalent global rights to evaluate certepetide and its analogs for use as SMARTag® payloads across multiple ADCs designed to address difficult-to-treat diseases. As presented at the World ADC conference earlier this week, compelling positive data from Catalent’s preclinical study evaluating certepetide and its analogs as non-cytotoxic SMARTag® ADC payloads showed not only improved ADC efficacy but broadened distribution of the cytotoxic payload within the tumor, supporting certepetide’s potential to enhance the targeting, penetration, and effectiveness of ADCs in advanced solid tumors.
- Lisata entered into a strategic alliance with GATC Health to exploit GATC's AI-powered Multiomics Advanced Technology™ artificial intelligence drug discovery platform to optimize and accelerate drug discovery and development, including analyzing certepetide for new indications and identifying combination therapies.

Third Quarter 2025 Financial Highlights

Operating Expenses

For the three months ended September 30, 2025, operating expenses totaled $4.4 million, compared to $5.3 million for the three months ended September 30, 2024, representing a decrease of $0.9 million or 17.3%.

Research and development expenses were approximately $2.0 million for the three months ended September 30, 2025, compared to $2.5 million for the three months ended September 30, 2024, representing a decrease of $0.6 million or 22.9%. This was primarily due to lower spend on chemistry, manufacturing and controls and a reduction in Clinical department expenses partially offset by an increase in the BOLSTER trial costs.

General and administrative expenses were approximately $2.5 million for the three months ended September 30, 2025, compared to $2.8 million for the three months ended September 30, 2024, representing a decrease of $0.3 million or 12.1%. This was primarily due to lower spend on consulting and the elimination of an employee position.

Overall, net losses were $4.2 million for the three months ended September 30, 2025, compared to $4.9 million for the three months ended September 30, 2024.

Balance Sheet Highlights

As of September 30, 2025, we had cash and cash equivalents of approximately $19.0 million. Based on its existing and planned activities, the Company believes available funds will support current operations into the first quarter of 2027.

Conference Call Information

Lisata will hold a live conference call today, November 6, 2025, at 4:30 p.m. Eastern Time to discuss financial results, provide a business update and answer questions. To join the conference call, please refer to the dial-in information provided below:

Dial-in information:
Participant Toll-Free dial: (800) 715-9871
Participant Toll/Int'l dial: (646) 307-1963
Conference ID: 6375221

To avoid delays, we encourage participants to dial into the conference call 10 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 first quarter of 2027, encompassing anticipated data milestones from its ongoing 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.

Contact:

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

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

(in thousands, except per share data)	Three Months Ended September 30		Nine Months Ended September 30	
	2025	2024	2025	2024
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Statement of Operations Data:				
Revenue	-	$ -	$ 70	**$ -**
Research and development	1,959	2,542	6,815	8,384
General and administrative	2,455	2,794	8,385	9,076
Total operating expenses	**4,414**	**5,336**	**15,200**	**17,460**
Operating loss	**(4,414)**	**(5,336)**	**(15,130)**	**(17,460)**
Investment income, net	183	451	665	1,533
Other expense, net	(18)	(45)	(129)	(246)
Net loss before benefit from income taxes and noncontrolling interests	**(4,249)**	**(4,930)**	**(14,594)**	**(16,173)**
Benefit from income taxes	-	-	(962)	(798)
Net loss	**(4,249)**	**(4,930)**	**(13,632)**	**(15,375)**
Less - net income (loss) attributable to noncontrolling interests	-	-	-	-
Net loss attributable to Lisata Therapeutics, Inc. common stockholders	**$ (4,249)**	**$ (4,930)**	**$ (13,632)**	**$ (15,375)**
Basic and diluted loss per share attributable to Lisata Therapeutics, Inc. common stockholders	**$ (0.49)**	**$ (0.59)**	**$ (1.58)**	**$ (1.85)**
Weighted average common shares outstanding	**8,738**	**8,321**	**8,649**	**8,307**

	September 30, 2025 (unaudited)	December 31, 2024
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 18,998	$ 31,245
Total assets	21,759	35,002
Total liabilities	4,640	5,685
Total equity	17,119	29,317

This press release was published by a CLEAR® Verified individual.