



## Lisata Therapeutics Reports First Quarter 2025 Financial Results and Provides Business Update

May 8, 2025

*Encouraging results of Cohort A data from the ASCEND trial presented at ASCO-GI 2025;  
Cohort B results from the ASCEND trial accepted for an oral presentation at ESMO-GI 2025*

*Cash runway extending into the third quarter of 2026 with no debt*

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

BASKING RIDGE, N.J., May 08, 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 three months ended March 31, 2025.

"Lisata maintains momentum into 2025 despite a challenging market for small cap healthcare companies as we continue to make notable progress in both our clinical development portfolio and partnering initiatives," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Lisata. "Overall, our focus remains on evaluating certepetide in multiple clinical and preclinical studies across a variety of solid tumors and non-cancer indications. In January, positive results stemming from both Cohort A of the ASCEND trial as well as the iLSTA trial were presented at ASCO-GI and we maintain our forecast of a data-rich period for the remainder of 2025 and into 2026. Heading the list of anticipated results are those from Cohort B of the ASCEND trial as well as results from Catalent's preclinical evaluation combining certepetide with their SMARTag<sup>®</sup> antibody-drug conjugate (ADC) platform."

Dr. Mazzo added, "Based on concentrated efforts to manage our finances prudently, we now project having operational cash into the third quarter of 2026 as we finalize next steps in certepetide development, based on upcoming conversations with various regulatory agencies including the FDA, TGA and EMA."

### Development Portfolio Highlights

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

Certepetide (formerly LSTA1) is a proprietary, *internalizing* RGD, or iRGD, (arginylglycylaspartic acid) cyclic peptide 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 preclinical and 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. 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, is expected in the coming months with a final analysis of both cohorts available thereafter. Preliminary results from Cohort B data have been accepted for presentation at the ESMO Gastrointestinal Cancers Congress being held July 2-5, 2025.
- 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 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 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 read out 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 WARPINE 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. An interim analysis of the iLSTA trial, presented at the 2025 ASCO GI Symposium, showed preliminary results from the first 17 of the 30 targeted patients, corroborating preclinical data that certepetide enhances the effectiveness of immunotherapy treatment. With 27 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 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 now expected in 2026.
- FORTIFIDE: A proposed Phase 1b/2a, double-blind, placebo-controlled, three-arm, randomized study in the U.S. evaluating the safety, tolerability, and efficacy of a 4-hour continuous infusion of certepetide in combination with SoC in subjects with first-line mPDAC. 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. Initiation of the study remains on hold as the Company is investigating a potentially faster and more cost-effective alternative to achieve the study's objective, which may become the preferred strategy.

Preclinically, 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, an oncolytic virus, and a checkpoint inhibitor in a preclinical murine model for the treatment of melanoma.

Additionally, Lisata recently entered into a research license with Catalent, Inc. ("Catalent"), to evaluate the efficacy of certepetide in a preclinical setting with Catalent's SMARTag® ADC dual payload technology platform for the treatment of various difficult-to-treat diseases. Lisata also entered into an exclusive license and collaboration agreement with Kuva Labs, Inc. ("Kuva"), in which Lisata granted Kuva an exclusive license to explore the synergistic potential of certepetide as a targeting and delivery agent for Kuva's NanoMark™ imaging technology in solid tumors.

#### **First Quarter 2025 Financial Highlights**

For the three months ended March 31, 2025, operating expenses totaled \$5.8 million, compared to \$6.6 million for the three months ended March 31, 2024, representing a decrease of \$0.8 million or 11.4%.

Research and development expenses were approximately \$2.6 million for the three months ended March 31, 2025, compared to \$3.2 million for the three months ended March 31, 2024, representing a decrease of \$0.6 million or 19.7%. This was primarily due to a reduction in clinical research organization expenses and site expenses associated with our Phase 2a proof-of-concept Bolster trial and lower spend on chemistry, manufacturing and controls.

General and administrative expenses were approximately \$3.2 million for the three months ended March 31, 2025, compared to \$3.4 million for the three months ended March 31, 2024, representing a decrease of approximately \$0.1 million or 3.4%. This was primarily due to one-off settlement costs in the prior year partially offset by an increase in consulting expenses and severance costs in the current year.

Overall, net losses were \$4.7 million for the three months ended March 31, 2025, compared to \$5.4 million for the three months ended March 31, 2024.

### **Balance Sheet Highlights**

As of March 31, 2025, Lisata had cash, cash equivalents, and marketable securities of approximately \$25.8 million. Based on its existing and planned activities, the Company believes available funds will support current operations into the third quarter of 2026.

### **Conference Call Information**

Lisata will hold a live conference call today, May 8, 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 third quarter of 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](http://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 of the collaboration with Catalent to develop treatment options; the potential efficacy of certepetide as a treatment for patients with solid tumors; our beliefs about the potential uses and benefits of certepetide; 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 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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**Lisata Therapeutics, Inc.**  
**Selected Financial Data**  
(in thousands, except per share data)

| (in thousands, except per share data)   | <b>Three Months Ended March 31,</b> |                    |
|---|-------------------------------------|--------------------|
|   | <b>2025</b>                         | <b>2024</b>        |
|   | <b>(unaudited)</b>                  | <b>(unaudited)</b> |
| <b>Statement of Operations Data:</b>  |                                     |                    |
| Research and development  | \$ 2,602                            | \$ 3,241           |
| General and administrative  | 3,245                               | 3,360              |
| <b>Total operating expenses</b>   | <b>5,847</b>                        | <b>6,601</b>       |
| <b>Operating loss</b>   | <b>(5,847)</b>                      | <b>(6,601)</b>     |
| Investment income, net  | 266                                 | 589                |
| Other expense, net  | (105)                               | (187)              |
| <b>Net loss before benefit from income taxes and noncontrolling interests</b>                         | <b>(5,686)</b>                      | <b>(6,199)</b>     |
| Benefit from income taxes   | (962)                               | (798)              |
| <b>Net loss</b>   | <b>(4,724)</b>                      | <b>(5,401)</b>     |
| Less - net income (loss) attributable to noncontrolling interests                                     | -                                   | -                  |
| <b>Net loss attributable to Lisata Therapeutics, Inc. common stockholders</b>                         | <b>\$ (4,724)</b>                   | <b>\$ (5,401)</b>  |
| <b>Basic and diluted loss per share attributable to Lisata Therapeutics, Inc. common stockholders</b> | <b>\$ (0.55)</b>                    | <b>\$ (0.65)</b>   |
| <b>Weighted average common shares outstanding</b>   | <b>8,602</b>                        | <b>8,294</b>       |

|  | <b>March 31, 2025</b> | <b>December 31, 2024</b> |
|--|-----------------------|--------------------------|
|  | <b>(unaudited)</b>    |                          |
| <b>Balance Sheet Data:</b>                       |                       |                          |
| Cash, cash equivalents and marketable securities | \$ 25,833             | \$ 31,245                |
| Total assets                                     | 28,981                | 35,002                   |
| Total liabilities                                | 3,879                 | 5,685                    |
| Total equity                                     | 25,102                | 29,317                   |

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