Lisata Therapeutics Reports Full Year 2023 Financial Results and Provides Business Update

February 29, 2024

Phase 2b ASCEND trial fully enrolled and on track for top-line data in fourth quarter of 2024

Company affirms projection of operational funds into early 2026

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

BASKING RIDGE, N.J., Feb. 29, 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, provides a business update and reports financial results for the twelve months ended December 31, 2023.

"2023 was a testament to our unwavering commitment to operational excellence and focused, efficient development. Our entire organization worked seamlessly to achieve significant milestones in the advancement of our lead investigational product, LSTA1," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Lisata. "Throughout 2024, we look to maintain and even build on this momentum as we project numerous data announcements in the coming 12 to 24 months, including the release of topline data from the Phase 2b ASCEND trial ("ASCEND") later this year. We intend to use these results to explore conditional approvals in several jurisdictions around the world and/or to design an optimized Phase 3 program in pancreatic ductal adenocarcinoma. Concurrently, we remain committed to the advancement of our other active and planned studies investigating LSTA1 in combination with a variety of standard-of-care regimens across multiple solid tumor indications."

Dr. Mazzo added, "Our prudent stewardship of our financial resources allows us to reaffirm our projection that our cash runway extends into early 2026 and funds all our trials until data completion. More than ever, we remain confident in our ability to execute our development activities efficiently with the goal of reaching significant clinical milestones at the earliest possible juncture."

Development Portfolio Highlights

LSTA1 as a treatment for solid tumors in combination with other anti-cancer agents

LSTA1 is an investigational drug designed to activate the CendR uptake pathway that allows co-administered or molecularly bound anti-cancer drugs to target and penetrate solid tumors more effectively. LSTA1 is designed to actuate 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, to the exclusion of normal tissues. In preclinical models, LSTA1 has also shown the ability to modify the tumor microenvironment, leading to the expectation that tumors will become more susceptible to immunotherapies and inhibiting the metastatic cascade (i.e., the spread of cancer to other parts of the body). Lisata and its development collaborators have amassed significant non-clinical data demonstrating enhanced delivery of a range of existing and emerging anti-cancer therapies, including chemotherapeutics, immunotherapies, and RNA-based therapeutics. To date, LSTA1 has also demonstrated favorable safety, tolerability, and activity in completed and ongoing clinical trials designed to test its ability to enhance delivery of standard-of-care chemotherapy for metastatic pancreatic cancer. Currently, LSTA1 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. As previously announced, LSTA1 has been granted orphan drug designation for pancreatic cancer in the U.S. and Europe as well as for glioblastoma multiforme ("GBM") in the U.S. The product candidate has also received a Fast Track designation from the U.S. Food and Drug Administration for pancreatic cancer.

- ASCEND: Phase 2b double-blind, randomized, placebo-controlled clinical trial evaluating two dosing regimens of LSTA1 in combination with gemcitabine/nab-paclitaxel standard-of-care ("SOC") chemotherapy in patients with metastatic pancreatic ductal adenocarcinoma ("mPDAC"). Cohort A of the study receives a single dose of 3.2 mg/kg LSTA1 essentially simultaneously with SOC, while Cohort B is identical to Cohort A, but with a second dose of 3.2mg/kg of LSTA1 given 4 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 ("IDSMC") 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 98 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 basket trial in the U.S., Europe, Canada, and Australia evaluating LSTA1 in combination with standards-of-care in second line head and neck cancer and first line cholangiocarcinoma. The trial is actively enrolling with enrollment completion expected by the end of 2024.

- CENDIFOX: Phase 1b/2a open-label trial in the U.S. of LSTA1 in combination with neoadjuvant FOLFIRINOX based therapies in pancreatic, colon and appendiceal cancers. The trial continues to make steady progress with enrollment completion expected by the end of the second quarter of 2024.

- Qilu Pharmaceutical, the licensee of LSTA1 in the Greater China territory, is currently evaluating LSTA1 in combination with gemcitabine and nab-paclitaxel in a Phase 1b/2a open-label trial in China. 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 LSTA1 plus gemcitabine and nab-paclitaxel conducted in Australia in patients with mPDAC. Final data is expected by the end of the second quarter of 2024, with the initiation of Phase 2 in China expected shortly thereafter.

- iLSTA: Phase 1b/2a randomized, single-blind, single-center, safety and pharmacodynamic trial in Australia evaluating LSTA1 in combination with the checkpoint inhibitor, durvalumab, plus standard-of-care gemcitabine and nab-paclitaxel chemotherapy versus standard-of-care 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 LSTA1 in combination with standard-of-care 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 LSTA1 treatment group.

Full Year 2023 Financial Highlights

For the year ended December 31, 2023, operating expenses totaled $25.7 million compared to $57.6 million for the year ended December 31, 2022, representing a decrease of $31.9 million or 55.4%. Excluding the in-process research and development expense of $30.4 million associated with the merger with Cend Therapeutics, Inc. (the “Merger”), operating expenses decreased by $1.5 million or 5.5% compared to the year ended December 31, 2022.

Research and development expenses were approximately $12.7 million for the year ended December 31, 2023, compared to $13.1 million for the year ended December 31, 2022, representing a decrease of approximately $0.3 million, or 2.5%. This decrease was primarily due to lower costs associated with our LSTA1 programs in the current year versus our legacy CD34+ cell therapy technology programs in the prior year. Current year expenses were associated with study activities for LSTA1 Phase 2a proof-of-concept Bolster trial in various solid tumors in combination with the corresponding standards of care, enrollment activities for the LSTA1 Phase 2b ASCEND study, chemistry, manufacturing and control activities for LSTA1 and study start up activities for the LSTA1 Phase 2a study for the treatment of GBM.

General and administrative expenses were approximately $13.0 million for the year ended December 31, 2023, compared to $14.1 million for the year ended December 31, 2022, representing a decrease of approximately $1.2 million or 8.3%. This decrease was primarily due to non-recurring Merger related costs in the prior year, a decrease in equity expense due to prior year performance stock unit vesting, Merger option assumption expense and departing board member restricted stock unit vesting, lower annual stockholder meeting expenses and a decrease in directors and officers insurance premiums, partially offset by severance costs associated with the elimination of the Chief Business Officer position on May 1, 2023.

Overall, net losses were $20.8 million and $54.2 million for the years ended December 31, 2023 and 2022, respectively.

Balance Sheet Highlights

As of December 31, 2023, Lisata had cash, cash equivalents, and marketable securities of approximately $50.5 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 on Thursday, February 29, 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 fifteen 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 lead product candidate, LSTA1, is an investigational drug designed to activate a novel uptake pathway that allows co-administered or tethered anti-cancer drugs to target and penetrate solid tumors more effectively. Based on Lisata’s CendR Platform® Technology, Lisata has already established noteworthy commercial and R&D partnerships. The Company expects to announce numerous clinical study and business milestones over the next two years and has projected that its current business and development plan is funded with available capital through these milestones and into early 2026. 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

strategy, future operations, future financial position, future revenue, projected expenses and capital, prospects, plans and objectives of management 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 LSTA-1 as a treatment for patients with GBM, metastatic gastroesophageal 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.

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- Tables to Follow –

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

	Twelve Months Ended December 31,	
	2023	**2022**
(in thousands, except per share data)		
Statement of Operations Data:		
Research and development	$ 12,734	$ 13,067
In-process research and development	-	30,393
General and administrative	12,974	14,141
Total operating expenses	**25,708**	**57,601**
Operating loss	**(25,708)**	**(57,601)**
Investment income, net	2,724	1,052
Other expense, net	(186)	(155)
Net loss before benefit from income taxes and noncontrolling interests	**(23,170)**	**(56,704)**
Benefit from income taxes	(2,330)	(2,479)
Net loss	**(20,840)**	**(54,225)**
Less - net income attributable to noncontrolling interests	-	-
Net loss attributable to Lisata Therapeutics, Inc. common stockholders	**$ (20,840)**	**$ (54,225)**
Basic and diluted loss per share attributable to Lisata Therapeutics, Inc. common stockholders	**$ (2.58)**	**$ (10.47)**
Weighted average common shares outstanding	**8,073**	**5,180**

	December 31, 2023	December 31, 2022
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 50,535	$ 69,226

Total assets	54,694	73,034
Total liabilities	6,800	6,710
Total equity	47,894	66,324