Lisata Therapeutics Reports Third Quarter 2023 Financial Results and Provides Business Update

November 2, 2023

Significant clinical progress achieved in studies evaluating LSTA1 including first patients treated in BOLSTER (3 solid tumor basket trial) and continued rapid enrollment in ASCEND

Orphan drug designations granted for LSTA1 in malignant glioma (U.S.) and pancreatic cancer (EU)

Company to host conference call Thursday, November 2 at 4:30 p.m. Eastern time

BASKING RIDGE, N.J., Nov. 02, 2023 (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, today announced its financial results for the third quarter ended September 30, 2023.

"Momentum we established during the first half of the year continued during the third quarter with the achievement of several milestones related to ongoing and planned clinical studies of our lead investigational product, LSTA1," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Lisata. "For example, LSTA1 is now the recipient of multiple orphan drug designations including pancreatic cancer in both the U.S. and Europe, as well as malignant glioma in the U.S. Additionally, as we recently announced, we have successfully treated the first patient in each of the head and neck squamous cell carcinoma and cholangiocarcinoma cohorts of the BOLSTER trial ("BOLSTER"), and we expect a steady uptake in enrollment over the coming quarters. In September, we announced that the ASCEND study ("ASCEND") in Australia received a positive outcome from the planned interim futility analysis by the study's Independent Data Safety Monitoring Committee ("IDSMC"), which recommended continuation of the study without modification. We are also happy to report that full enrollment in Cohort A of ASCEND has been achieved and that overall enrollment in the study is now approximately 95% complete. With that, we now expect that we could have topline data from Cohort A as early as the fourth quarter of 2024, a full year earlier than originally anticipated. We intend to use the results of the ASCEND trial to explore possible conditional approvals in several jurisdictions and to design an optimized Phase 3 program in Pancreatic Ductal Adenocarcinoma ("PDAC"). Finally, the iLSTA study, done in collaboration with WARPNINE in Australia, a foundation dedicated to accelerating the development of treatments for gastrointestinal cancers, is enrolling rapidly."

Dr. Mazzo continued, "With continued careful management of capital, we reiterate that our expected cash runway projects into early 2026, funding each of our trials through to data. We believe we remain well-positioned to focus on the execution of our development plans and achieve our goal of getting to meaningful clinical data readouts as soon as possible."

Development Portfolio Highlights

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

LSTA1 is an investigational drug designed to activate a novel uptake pathway that allows co-administered or tethered (i.e., molecularly bound) anti-cancer drugs to target and penetrate solid tumors more effectively. LSTA1 actuates 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, while normal tissues are not expected to be affected. In preclinical models, LSTA1 has also shown the ability to modify the tumor microenvironment, thereby making tumors 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 pancreatic cancer. Currently, LSTA1 is the subject of multiple ongoing or planned Phase 1b/2a and 2b clinical studies being conducted globally in a variety of solid tumor types in combination with a variety of anti-cancer regimens. These studies include:

- ASCEND: Phase 2b double-blind, randomized, placebo-controlled clinical trial evaluating LSTA1 in patients with metastatic Pancreatic Ductal Adenocarcinoma ("mPDAC"). The trial is being conducted at up to 40 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. Planned interim futility analysis by the IDMC received a positive outcome. Cohort A has been fully enrolled. Total enrollment completion is projected for the second quarter of 2024; however, current total enrollment is at approximately 95% of target, so earlier total enrollment completion may be achieved.

- BOLSTER: Phase 2a double-blind, placebo-controlled, multi-center, randomized basket trial in the U.S., Europe, Canada, and Asia evaluating LSTA1 in combination with standards of care in advanced solid tumors including head and neck, esophageal and cholangiocarcinoma. Enrollment is open and proceeding as planned. First patients have been treated in head and neck cancer as well as cholangiocarcinoma cohorts.

- 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 fourth quarter of 2023 and data readouts expected in 2024.

- LSTA1 is currently being evaluated in combination with gemcitabine and nab-paclitaxel in a Phase 1b/2a open-label trial in China led by Qilu Pharmaceutical. During the 2023 ASCO Annual Meeting, Qilu Pharmaceutical presented an abstract sharing preliminary data from the study which, thus far, has 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.

- 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 chemotherapy, nab-paclitaxel, and gemcitabine, versus standard-of-care alone in patients with locally advanced non-resectable PDAC. Enrollment completion is expected by the end of the second quarter of 2024.

- The Company will soon initiate the study of LSTA1 in combination with temozolomide in Glioblastoma Multiforme ("GBM"). This study is designed as a Phase 2a double-blind, placebo-controlled, randomized, proof-of-concept study evaluating LSTA1 when added to standard of care ("SoC") temozolomide versus temozolomide and matching LSTA1 placebo in subjects with newly diagnosed GBM. It will be conducted across multiple sites in Estonia and Latvia and is targeted to enroll 30 patients with a randomization of 2:1 LSTA1 + SoC versus Placebo + SoC. Target for the first patient treated is in the fourth quarter of 2023. Importantly and as the Company recently announced, LSTA1 has been granted orphan drug designation by the U.S. FDA for malignant glioma. This action by the FDA not only highlights the unmet medical need but also recognizes the potential of LSTA1 to benefit patients in this indication.

- Lisata will also soon initiate a study of LSTA1 in combination with HIPEC interoperative intraperitoneal lavage in peritoneal carcinomatosis, a condition which develops as a result of the contiguous spread of primary cancers such as ovarian, colorectal and appendiceal along the peritoneum. The study is a Phase I single-center, unblinded, randomized controlled trial to determine the safety and tolerability of LSTA1 administered intraperitoneally in patients with peritoneal metastases from colorectal, appendiceal, or ovarian cancer undergoing Cytoreductive Surgery ("CRS") and HIPEC. Twenty-one total participants will be randomized 2:1 to receive LSTA1 with HIPEC versus HIPEC alone after CRS. We anticipate the first patient treated to be in the fourth quarter of 2023.

Third Quarter 2023 Financial Highlights

Research and development expenses were approximately $3.4 million for the three months ended September 30, 2023, compared to $3.3 million for the three months ended September 30, 2022, representing an increase of $45,000 or 1.3%. Expenses this quarter were primarily due to study activities associated with the BOLSTER trial, enrollment activities for the ASCEND study, startup activities for the LSTA1 GBM study and chemistry, manufacturing and control activities for LSTA1 to support all development activities.

General and administrative expenses were approximately $2.6 million for the three months ended September 30, 2023, compared to $4.0 million for the three months ended September 30, 2022, representing a decrease of $1.4 million or 35.3%. This 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, departing board member restricted stock unit vesting and timing of our annual stockholder meeting versus the prior year.

Overall, net losses were $5.3 million for the three months ended September 30, 2023, compared to $37.4 million for the three months ended September 30, 2022. Excluding the in-process research and development expense of $30.4 million relating to our merger with Cend Therapeutics in September 2022, net losses for the three months ended September 30, 2023 decreased by $1.7 million or 24.7% compared to the three months ended September 30, 2022.

Balance Sheet Highlights

As of September 30, 2023, the Company had cash, cash equivalents and marketable securities of approximately $54.4 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, November 2, 2023, 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 projected 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, 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: 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 March 30, 2023, 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,	
	2023	2022	2023	2022
(in thousands, except per share data)	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Statement of Operations Data:				
Research and development	$ 3,380	$ 3,335	$ 9,721	$ 9,853
In-process research and development	-	30,393	-	30,393
General and administrative	2,584	3,992	9,962	10,815
Total operating expenses	**5,964**	**37,720**	**19,683**	**51,061**
Operating loss	**(5,964)**	**(37,720)**	**(19,683)**	**(51,061)**
Investment income, net	714	337	2,053	496
Other expense, net	(11)	-	(175)	(149)
Net loss before benefit from income taxes and noncontrolling interests	**(5,261)**	**(37,383)**	**(17,805)**	**(50,714)**
Benefit from income taxes	-	-	(2,330)	(2,479)
Net loss	**(5,261)**	**(37,383)**	**(15,475)**	**(48,235)**
Less - net income attributable to noncontrolling interests	-	-	-	-
Net loss attributable to Lisata Therapeutics, Inc. common stockholders	**$ (5,261)**	**$ (37,383)**	**$ (15,475)**	**$ (48,235)**
Basic and diluted loss per share attributable to Lisata Therapeutics, Inc. common stockholders	**$ (0.65)**	**$ (7.88)**	**$ (1.92)**	**$ (11.28)**
Weighted average common shares outstanding	**8,141**	**4,747**	**8,050**	**4,276**

	September, 2023 (unaudited)	December 31, 2022
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 54,394	$ 69,226
Total assets	58,089	73,034
Total liabilities	5,385	6,710
Total equity	52,704	66,324