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

May 9, 2023

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

BASKING RIDGE, N. J., May 09, 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, provides a business update and reports financial results for the three months ended March 31, 2023.

"During the first quarter of 2023, our team continued its focus on the advancement of multiple ongoing and planned clinical studies evaluating LSTA1, our lead investigational product," stated David J. Mazzo, Ph.D., Chief Executive Officer of Lisata. "We expect to report progress on several of these activities over the coming months and quarters. Just recently, we, along with our research partner, WARPNINE, announced the treatment of the first patient in the iLSTA Trial in Australia evaluating LSTA1 in combination with standard-of-care chemotherapy and immunotherapy as a first-line treatment in locally advanced non-resectable pancreatic ductal adenocarcinoma. We are hopeful that this and our other trials will continue to show the potential of LSTA1 in combination with corresponding standards-of-care as well as with emerging treatment modalities, such as immunotherapies, as an effective treatment against various solid tumors.

Dr. Mazzo continued, "Our overarching goal is to report meaningful clinical data to benefit patients and to support our development pipeline in the most expeditious manner possible. Positive data should also bring value to shareholders and encourage additional partnering opportunities."

Development Portfolio Update

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 anti-cancer drugs to 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. LSTA1 also has the potential to modify the tumor microenvironment, with the objective of making tumors more susceptible to immunotherapies. We and our 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 Phase 1b/2a and 2b clinical studies being conducted globally in metastatic pancreatic ductal adenocarcinoma in combination with each of the two standards-of-care for this disease. The combination of LSTA1 with corresponding standards-of-care in other solid tumor indications is planned for clinical study commencing before the end of the second quarter of 2023.

HONEDRA® (LSTA12) for the treatment of critical limb ischemia ("CLI")

- HONEDRA® is the Company's SAKIGAKE-designated product candidate for the treatment of CLI and Buerger's disease in Japan, which is now in the pre-consultation phase of the registration process with the Pharmaceuticals and Medical Devices Agency ("PMDA") in Japan. Data from the follow-up of all patients completed in the registration-eligible clinical trial in Japan have been compiled and are the subject of discussions with the PMDA as part of the Japanese regulatory pre-consultation process and in preparation for the formal clinical consultation meetings which precede a Japanese new drug application. To date, the PMDA has provided advice on how to prepare for the formal consultation meeting. Concomitantly, the Company has reinforced its efforts to secure a partner to complete the remaining steps of development/registration and potential commercialization in Japan through the engagement of an advisory firm specializing in Japanese partnerships.

LSTA201 for the treatment of diabetic kidney disease ("DKD")

The Company initiated a Phase 1b, open-label, proof-of-concept trial evaluating LSTA201, a CD34+ regenerative cell therapy investigational product, for intra-renal artery administration in patients with DKD. Preclinical studies in kidney disease and injury models have demonstrated that protecting or replenishing the microcirculation of the kidney may result in improved kidney function. A key criterion for continued development of LSTA201 was determined, a priori, to be the ability of LSTA201 to regenerate kidney function as indicated by increased Glomerular Filtration Rate. The Company treated the first patient in the LSTA201 proof-of-concept study in April 2022 and completed treatment for all six subjects during the third quarter of 2022. Top line results, which were reported on February 6, 2023, showed that LSTA201 was safe and well-tolerated by patients with no serious adverse events related to the therapy. However, the study did not demonstrate a consistent improvement in kidney function among patients. Nevertheless, the Company, based on the encouragement of the study's principal investigator/key opinion leader, believes there may still be potential for use of CD34+ cell therapy for the treatment of DKD. However, it is expected that further development of LSTA201 would require significantly larger studies and capital investment. Thus, LSTA201 development will only be continued if a strategic partner that can contribute the necessary capital for future development is identified.

First Quarter 2023 Financial Highlights

Research and development expenses were approximately $3.2 million for the three months ended March 31, 2023, compared to $3.3 million for the three months ended March 31, 2022, representing a decrease of $0.1 million or 3.2%. This was primarily due to expenses associated with our XOWNA® Phase 2b study (the FREEDOM Trial) in the prior year, partially offset by study start up activities in the current year associated with the planned LSTA1 Phase 2 proof-of-concept basket trial in various solid tumors in combination with the corresponding standards of care, enrollment activities for the LSTA1 Phase 2b ASCEND study and chemistry, manufacturing and control activities for LSTA1.

General and administrative expenses were approximately $3.7 million for the three months ended March 31, 2023, compared to $3.3 million for the three months ended March 31, 2022, representing an increase of $0.3 million or 9.8%. This was primarily due to the addition of one employee acquired through the Company's merger with Cend Therapeutics, Inc., an increase in external legal fees and an increase in accounting and tax-related fees.

Overall, net losses were $6.2 million for the three months ended March 31, 2023, compared to $4.2 million for the three months ended March 31, 2022.

Balance Sheet Highlights

As of March 31, 2023, the Company had cash, cash equivalents and marketable securities of approximately $61.1 million. These figures do not include the recently announced $2.2 million in non-dilutive funding received as an approved participant of the Technology Business Tax Certificate Transfer Program (the "Program") sponsored by the New Jersey Economic Development Authority, which will be recorded in the second quarter of 2023. The Program enables qualifying New Jersey-based biotechnology or technology companies to sell a percentage of their New Jersey net operating losses and research and development tax credits to unrelated qualifying corporations. The Company is confident that its projected capital will fund its operations into the first quarter of 2026 encompassing anticipated data milestones from all of its ongoing and planned clinical trials.

Conference Call Information

Lisata will hold a live conference call today, May 9, 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. 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 affected. LSTA1 also has the potential to modify the tumor microenvironment, with the objective of making tumors more susceptible to immunotherapies. LSTA1 has demonstrated favorable safety, tolerability, and activity in clinical trials to enhance delivery of standard-of-care chemotherapy for pancreatic cancer. Lisata and its collaborators have also 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. Lisata is exploring the potential of LSTA1 to enable a variety of treatment modalities to treat a range of solid tumors more effectively. 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, 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 the long-term success of Lisata's recently completed Merger, including the ongoing integration of Cend's operations; 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 ongoing COVID-19 pandemic on Lisata's business, 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; unexpected costs, charges or expenses resulting from the Merger; potential adverse reactions or changes to business relationships resulting from the completion of the Merger; potential underperformance of Lisata's business following the Merger as compared to management's initial expectations; 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)

(in thousands, except per share data)	Three Months Ended Mar 31, 2023 (unaudited)	Three Months Ended Mar 31, 2022 (unaudited)
Statement of Operations Data:		
Research and development	$ 3,179	$ 3,283
General and administrative	3,665	3,337
Total operating expenses	**6,844**	**6,620**
Operating loss	**(6,844)**	**(6,620)**
Investment income, net	670	63
Other expense, net	(13)	(148)
Net loss before benefit from income taxes and noncontrolling interests	**(6,187)**	**(6,705)**
Benefit from income taxes	-	(2,479)
Net loss	**(6,187)**	**(4,226)**
Less - net income attributable to noncontrolling interests	-	-
Net loss attributable to Lisata Therapeutics, Inc. common stockholders	**$ (6,187)**	**$ (4,226)**
Basic and diluted loss per share attributable to Lisata Therapeutics, Inc. common stockholders	**$ (0.77)**	**$ (1.05)**
Weighted average common shares outstanding	**7,987**	**4,037**

	March 31, 2023 (unaudited)	December 31, 2022
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 61,095	$ 69,226
Total assets	66,326	73,034
Total liabilities	5,623	6,710
Total equity	60,703	66,324