Lisata Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

March 30, 2023

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

BASKING RIDGE, N.J., March 30, 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 and twelve months ended December 31, 2022.

"Last year (2022) was a year of major transformation, excitement and renewed energy for Lisata, allowing us to enter 2023 with growing momentum as we continue to build an enduring pharmaceutical company," stated David J. Mazzo, Ph.D., Chief Executive Officer of Lisata. "We believe in the potential of our new development pipeline and take pride in the advancement of our clinical studies in oncology and other serious diseases. LSTA1, our lead investigational product candidate from the CendR Platform™, is the subject of multiple planned and ongoing clinical trials being conducted globally in a variety of solid tumor types and in combination with several anti-cancer agents. Based on substantial preclinical and, importantly, early human clinical data, we believe that LSTA1 has the potential to become an integral part of a revised standard-of-care therapy for many difficult to treat cancers.

Dr. Mazzo continued, "We are dedicated to continued efficient execution of our studies and, eventually, to producing definitive data hopefully confirming the promise of our clinical development pipeline. We anticipate that such execution and those data will result in increased shareholder value while prompting additional attractive partnering opportunities. I look forward to providing further updates on our progress in the coming weeks and months."

Development Portfolio Update

LSTA1 (formerly CEND-1) 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 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 emerging anti-cancer therapies, including 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 various solid tumors, including metastatic pancreatic ductal adenocarcinoma, in combination with a variety of anti-cancer regimens. The combination of LSTA1 with corresponding standards-of-care in other solid tumor indications is planned for clinical study in the first half of 2023.

HONEDRA® (LSTA12, formerly CLBS12) 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 being reviewed by the PMDA, after which the PMDA is expected to provide important perspective to be considered in preparation for the formal consultation meetings which precede the Japanese new drug application. If successful in the pre-consultation process, Lisata expects formal clinical consultation to occur during 2023. Concomitantly, the Company has reinforced its efforts to secure a Japanese partner to complete the remaining steps of registration as well as eventual commercialization in Japan.

XOWNA® (LSTA16, formerly CLBS16) for the treatment of coronary microvascular dysfunction ("CMD")

XOWNA® is an experimental regenerative therapy for the treatment of CMD. It was the subject of a positive Phase 2a study (the "ESCaPE-CMD trial") reported in 2020 as well as the FREEDOM Trial, a Phase 2b study conducted in the U.S. The FREEDOM Trial was originally designed as a 105-patient double-blind, randomized, placebo-controlled trial to further evaluate the efficacy and safety of intracoronary delivery of autologous CD34+ cells (XOWNA®) in subjects with CMD and without obstructive coronary artery disease and was expected to complete enrollment in approximately 12 months. As previously disclosed, enrollment in the FREEDOM Trial initially proceeded as planned with the first patient treated in January 2021; however, the impact of the COVID-19 pandemic in the U.S., coupled with supply chain issues associated with the catheters used for diagnosis of CMD and/or administration of XOWNA®, as well as with a contrast agent typically used in many catheter laboratories, have made and continue to make enrollment much slower than originally predicted and challenging to accelerate. As a result, the Company announced that enrollment in the FREEDOM Trial had been suspended and that it intended to conduct an interim analysis of the data from not less than the first 20 patients enrolled using the 6-month follow-up data to evaluate the efficacy and safety of XOWNA® in subjects with CMD. Based on that and the input of Key Opinion Leaders, the Company determined that execution of a redesigned FREEDOM-like trial would be the appropriate next step, but the cost of such a trial would be prohibitively expensive to undergo alone. Accordingly, the Company's board of directors concluded that XOWNA® development will only be continued if a strategic partner that can contribute the necessary capital for a redesigned trial is identified and secured.

LSTA201 (formerly CLBS201) for the treatment of diabetic kidney disease ("DKD")

Progressive kidney failure is associated with attrition of the microcirculation of the kidney. Preclinical studies in kidney disease and injury models have demonstrated that protection or replenishment of the microcirculation results in improved kidney function. Based on these observations, 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. Patients selected for the study were in the pre-dialysis stage of kidney disease and exhibited rapidly progressing stage 3b disease. The protocol provided for a cohort of six patients overseen by an independent Data Safety Monitoring Board with the objective of determining the tolerance of intra-renal cell therapy injection in DKD patients as well as the ability of LSTA201 to regenerate kidney function. The principal read-out of data was based on the 6-month follow-up visit for all patients. A key criterion for continued development of LSTA201 was determined, a priori, to be the ability of LSTA201 to demonstrate a therapeutic effect that will make it competitive in the field of DKD treatment, i.e., kidney function regeneration, as indicated by increased Glomerular Filtration Rate ("GFR"). 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.

Fourth Quarter and Full Year 2022 Financial Highlights

Research and development expenses for the fourth quarter of 2022 were $3.2 million, a 22% decrease compared with $4.1 million for the fourth quarter of 2021, and $13.1 million for the year ended December 31, 2022 compared to $17.6 million for the year ended December 31, 2021, representing a decrease of approximately 26%. This was primarily due to a decrease in expenses associated with our XOWNA® Phase 2b study (the FREEDOM Trial) as a result of the suspension in enrollment which commenced in the second quarter of 2022 and study close out activities in the third quarter of 2022, a decrease in expenses associated with HONEDRA® in Japan related to study close out costs and one off recruiting expenses and interim chief medical officer consulting expenses in the prior year partially offset by the addition of manufacturing activities for LSTA1 and enrollment activities for the AGITG ASCEND study. Research and development in both periods related to:

- Expenses associated with our XOWNA® Phase 2b study (the FREEDOM Trial);
- Expenses associated with our registration-eligible study for HONEDRA® in critical limb ischemia in Japan as well as corresponding regulatory discussions support expenses;
- Expenses associated with the preparation of our filing of an Investigational New Drug Application, as well as study execution expenses for the clinical study of LSTA201 for treatment of DKD; and
- Expenses associated with the addition of manufacturing activities for LSTA1, enrollment activities for the LSTA1 Phase 2b ASCEND study and preparatory activities associated with the design of a planned LSTA1 proof-of-concept basket trial in various solid tumors and in combination with the corresponding standards of care.

General and administrative expenses, which focus on general corporate related activities, were $3.3 million for the three months ended December 31, 2022, representing an increase of 22% compared to $2.7 million for the three months ended December 31, 2021, and $14.1 million for the year ended December 31, 2022, representing an increase of 23% compared to $11.5 million for the year ended December 31, 2021. This was primarily due to a one-time increase in fees associated with the review of potential strategic transactions and merger related costs, an increase in equity expense as a result of performance stock unit vesting, merger option assumption expense and departing board member restricted stock unit vesting in addition to an increase in expenses associated with our annual stockholder meeting. Our general and administrative expenses are comprised of general corporate-related activities.

Overall, net losses were $54.2 million (includes non-routine merger related in-process research and development expense of $30.4 million) and $27.5 million for the years ended December 31, 2022 and 2021, respectively.

Balance Sheet Highlights

As of December 31, 2022, the Company had cash, cash equivalents and marketable securities of approximately $69.2 million. Current projections predict operating cash through the first half of 2025, encompassing anticipated data milestones from several ongoing and/or planned clinical studies.

Conference Call Information

Lisata will hold a live conference call today, March 30, 2023, at 4:30 p.m. Eastern time to discuss financial results, provide a business update and answer questions.

The Company is utilizing a new conference call service. 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 for 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 investigational product candidate, LSTA1 (formerly known as CEND-1), 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 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 emerging anti-cancer therapies, including 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. In addition, Lisata has clinical development programs based on its autologous CD34+ cell therapy technology platform. 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 (the "Merger") with Cend Therapeutics, Inc. ("Cend"), 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)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
(in thousands, except per share data)	(unaudited)	(unaudited)		
Statement of Operations Data:				
Research and development	$ 3,219	$ 4,127	$ 13,067	$ 17,576
In-process research and development	-	-	30,393	-
General and administrative	3,322	2,722	14,141	11,474
Total operating expenses	**6,541**	**6,849**	**57,601**	**29,050**
Operating loss	**(6,541)**	**(6,849)**	**(57,601)**	**(29,050)**
Investment income, net	556	40	1,052	151
Other expense, net	(6)	15	(155)	(75)
Net loss before benefit from income taxes and noncontrolling interests	**(5,991)**	**(6,794)**	**(56,704)**	**(28,974)**
Benefit from income taxes	-	-	(2,479)	(1,508)
Net loss	**(5,991)**	**(6,794)**	**(54,225)**	**(27,466)**
Less - net income (loss) attributable to noncontrolling interests	-	-	-	-
Net loss attributable to Lisata Therapeutics, Inc. common stockholders	**$ (5,991)**	**$ (6,794)**	**$ (54,225)**	**$ (27,466)**

Basic and diluted loss per share attributable to Lisata Therapeutics, Inc. common stockholders	**$ (0.76)**	**$ (1.70)**	**$ (10.47)**	**$ (7.45)**
Weighted average common shares outstanding	**7,861**	**3,985**	**5,180**	**3,688**

	December 31, 2022	December 31, 2021
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 69,226	$ 94,970
Total assets	73,034	97,008
Total liabilities	6,710	5,008
Total equity	66,324	92,000