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

August 14, 2023

Cash runway projected into first quarter 2026 based on capital conservation measures implemented without impact to clinical development pipeline

Technology transfer agreement executed for Company's tumor penetrating nanocomplex (TPN) platform

Company to host conference call Tuesday, August 15 at 8:30 a.m. Eastern time

BASKING RIDGE, N.J., Aug. 14, 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 second quarter ended June 30, 2023.

"The second quarter generated strong momentum for Lisata. We continued to advance multiple ongoing and planned clinical studies centered around our lead investigational product, LSTA1," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Lisata. "Of note, we implemented key changes to the Phase 2b ASCEND trial which now includes an additional cohort of subjects for the evaluation of a second dose of LSTA1 in patients with first-line, metastatic pancreatic ductal adenocarcinoma ("mPDAC"). We intend to use the results of ASCEND to explore possible conditional approvals globally and to design an optimized Phase 3 program. We also saw the initiation of the iLSTA study in Australia and the launch of our BOLSTER trial, which is the first fully sponsored study of LSTA1 by Lisata. Finally, we are delighted to announce that we have entered into a technology transfer agreement for our Tumor Penetrating Nanocomplex (TPN) Platform with Impilo Therapeutics, Inc. ("Impilo"), a newly formed company being led by former Lisata Chief Business Officer, David Slack. We are pleased that the TPN technology will be in the hands of a team of people with deep expertise in the field of RNA-based therapeutics development."

Dr. Mazzo continued, "Also, notably, in this quarter we took a number of cash conservation decisions which resulted in the extension of projected capital supporting operations into the first quarter of 2026. Now with more than two years of capital available on our balance sheet based on our current expected capital needs, we believe we are well-placed 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 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. In preclinical models, LSTA1 has also shown the ability to modify the tumor microenvironment, thereby making tumors more susceptible to immunotherapies. 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 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. Enrollment completion is projected for the second quarter of 2024; however, current enrollment already exceeds 70% of the target, so earlier enrollment completion may be achieved.
- BOLSTER: Phase 2a placebo-controlled 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 now open and the Company hopes to soon announce the first patient treated.
- 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 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 plans to study 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 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 first patient treated is in the fourth quarter of 2023. Importantly and as the Company recently announced, LSTA1 has been granted orphan 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 is also planning to study LSTA1 in combination with HIPEC interoperative intraperitoneal lavage in peritoneal carcinomatosis, 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 that this study will also be up and running in the fourth quarter of 2023 and the first patient being treated shortly thereafter.

Tumor Penetrating Nanocomplex (TPN) Platform Technology Transfer

The tumor penetrating nanocomplex (TPN) platform targets intracellular delivery of RNA-based drugs to prevent solid tumor growth. The TPN is designed so that it could not only bind a protein overexpressed on the surface of human cancer cells, but also pass through the membrane by way of a cell-penetrating peptide. Once inside the cells, the TPN is expected to release an RNA-based drug directed against the tumor. Lisata has agreed to transfer this technology to Impilo. Under the terms of the technology transfer agreement, Lisata will receive an equity stake in Impilo upon closing. Lisata is not obliged to commit any capital or additional resources to the program's future development.

Second Quarter 2023 Financial Highlights

Research and development expenses remained constant at approximately $3.2 million for the three months ended June 30, 2023 and three months ended June 30, 2022. Expenses this quarter were primarily due to study start up activities associated with the LSTA1 BOLSTER trial, enrollment activities for the LSTA1 ASCEND study and chemistry, manufacturing and control (CMC) activities for LSTA1 to support all development activities.

General and administrative expenses were approximately $3.7 million for the three months ended June 30, 2023, compared to $3.5 million for the three months ended June 30, 2022, representing an increase of $0.2 million or 6.5%. This was primarily due to severance costs associated with the elimination of the Chief Business Officer position on May 1, 2023, partially offset by non-recurring merger related costs in the prior year.

Overall, net losses were $4.0 million for the three months ended June 30, 2023, compared to $6.6 million for the three months ended June 30, 2022, a decrease of approximately 40% primarily due to $2.2 million in non-dilutive funding received as an approved participant of the Technology Business Tax Certificate Transfer Program sponsored by the New Jersey Economic Development Authority.

Balance Sheet Highlights

As of June 30, 2023, the Company had cash, cash equivalents and marketable securities of approximately $57.6 million. Based on its current expected capital needs, the Company believes that its projected capital will fund its current proposed operations into the first quarter of 2026 encompassing anticipated data milestones from all its ongoing and planned clinical trials.

Conference Call Information

Lisata will hold a live conference call on Tuesday, August 15, 2023, at 8:30 a.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, 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.

Contact:

Investors and Media:

Lisata Therapeutics, Inc.
John Menditto
Vice President, Investor Relations and Corporate Communications
Phone: 908-842-0084
Email: jmenditto@lisata.com

- Tables to Follow –

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

	Three Months Ended Jun 30, (QTD)		Six Months Ended Jun 30, (YTD)	
	2023	2022	2023	2022
(in thousands, except per share data)	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Statement of Operations Data:				
Research and development	$ 3,162	$ 3,234	$ 6,341	$ 6,516
General and administrative	3,713	3,486	7,378	6,824
Total operating expenses	**6,875**	**6,720**	**13,719**	**13,340**
Operating loss	**(6,875)**	**(6,720)**	**(13,719)**	**(13,340)**
Investment income, net	668	94	1,338	158
Other expense, net	(150)	-	(163)	(149)
Net loss before benefit from income taxes and noncontrolling interests	**(6,357)**	**(6,626)**	**(12,544)**	**(13,331)**
Benefit from income taxes	(2,330)	-	(2,330)	(2,479)
Net loss	**(4,027)**	**(6,626)**	**(10,214)**	**(10,852)**
Less - net income attributable to noncontrolling interests	-	-	-	-
Net loss attributable to Lisata Therapeutics, Inc. common stockholders	**$ (4,027)**	**$ (6,626)**	**$ (10,214)**	**$ (10,852)**
Basic and diluted loss per share attributable to Lisata Therapeutics, Inc. common stockholders	**$ (0.50)**	**$ (1.64)**	**$ (1.28)**	**$ (2.69)**
Weighted average common shares outstanding	**8,021**	**4,035**	**8,004**	**4,036**

	Jun 30, 2023 (unaudited)	December 31, 2022
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 57,626	$ 69,226
Total assets	62,365	73,034
Total liabilities	4,651	6,710
Total equity	57,714	66,324