WBB Securities, LLC

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Lisata Therapeutics, Inc. (NASDAQ CM: LSTA) INITIATING COVERAGE

Initiating Coverage of the new Lisata with a Speculative Buy Rating and a 12-Month Price Target of $4.50

December 27, 2022

Lisata a Multiple Platforms Company Trading at the Price of an Option

On September 15, 2022, Caladrius Biosciences, Inc. (CLBS) and Cend Therapeutics, Inc. (private) announced the closing of a merger between the two companies, The merged company now operates as Lisata Therapeutics, Inc. (LSTA). Their development efforts focus primarily on advancing the CendR Platform™ product candidates in a range of oncology indications, in addition to existing CD34+ development programs begun under CLBS. WBB has covered LSTA's precursor companies since 2010.

Current Price	**$2.50**
12 Month Target Price	**$4.50**
12 Month Trading Range	$2.36-17.10
Market Capitalization (Mil)	$19.65
Shares Outstanding (Mil)	7.86
Avg. Daily Volume	17.007
L. T. Debt (Mil)	N/A
Dividend/Yield	N/A
Book Value P/S	$8.95
NASDAQ Composite	7,647.02
S&P 500	2,811.87
Historical and Future Performance - Page 8.	

These are the worst biotech capital markets we have experienced since their inception. Given the 70% market cap discount to cash and no debt, LSTA is trading at the price of an option on its technology. Our twelve-month price target is based on what we believe will be cash on hand at the end of 2023 (with no addition from its deep clinical portfolio which we believe to be formidable). We are therefore initiating coverage of LSTA with a Speculative Buy rating and a 12-month price target of $4.50.

LSTA's cash and investments were approximately $75.5 million at last report. Prior to the merger's closing, CLBS effected a 1-for-15 reverse split of its common stock. After the merger, LSTA had approximately 7.8 million shares of common stock issued and outstanding, with prior CLBS stockholders collectively owning approximately 52% of the combined company and prior Cend stockholders collectively owning approximately 48% of the combined company.

On September 28, 2022 Erkki Ruoslahti, M.D., Ph.D., the Scientific Founder of the LSTA's CendR Platform™ technology and a member of the LSTA board of directors, received the 2022 Albert Lasker Basic Medical Research Award.

Dr. Ruoslahti, together with Drs. Richard Hynes and Timothy Springer, discovered integrins and their role as mediators of cell-cell and cell-matrix interactions in physiology and disease. Dr. Ruoslahti's fundamental work in identifying and characterizing integrins is the basis for LSTA's lead clinical development program.

Dr. Ruoslahti's scientific contributions include discovery of fibronectin, and characterization of the RGD peptide. Presently, he is studying peptides that home to specific targets in the body, such as tumors, atherosclerotic plaques, and injured tissues.

Valuation

Rating Legend:

Strong Buy – Should be aggressively purchased.
Buy - Should be purchased on market weakness.
Hold - Fairly valued.
Sell - Stock should be sold on market strength.
Sell Short - Should be aggressively sold.
Speculative Buy – For aggressive accounts only.
Core Holding – Essential holding of a long-term account.

Again we repeat, these have been the most unsettled times for the Bio-Pharmaceutical capital markets in their history and dedicated life-science investors have not only been punished but have unsatisfactory hopes of recovering any of their losses in the near future. Thus, the edge in the micro-cap space goes to those franchises who are funded for the next two-years and have a steady stream of data points to keep their shareholders cognizant of positive clinical news. In both cases, LSTA has the advantage, and we believe given the 70% market cap discount to cash and no debt LSTA is trading at the price of an option on its technology. To keep matters simple, our twelve-month price target is based on what we believe will be cash on hand at the end of 2023 for LSTA. Therefore, we are initiating coverage of LSTA with a Speculative Buy Rating and a 12-month price target of $4.50 per share.

Product Pipeline

Sponsor/Funding Partner [Development Activity Venue]	Trial Products	Indication	Development Stage	Next Development Milestone
CendR Platform™ Programs				
Lisata/AGITG [Australia/New Zealand]	Gemcitabine/nab-paclitaxel with LSTA1 or placebo	First-Line Metastatic Pancreatic Ductal Adenocarcinoma (mPDAC)	Phase 2b (ASCEND)	Enrollment completion target 4Q23 First data expected 2024
Qilu [China]	Gemcitabine/nab-paclitaxel + LSTA1		Phase 1b/2	Preliminary data expected 2H23
Roche/Lisata [Multi-national]	Gemcitabine/nab-paclitaxel/LSTA1 ± atezolizumab		Phase 1b/2 (MORPHEUS)	Trial initiation target 1Q23
KUCC - IIT [United States]	LSTA1 + FOLFIRINOX + panitumumab*	Pancreatic, Colon and Appendiceal Cancers	Phase 1b/2 (CENDIFOX)	Enrollment completion target 4Q23 Data expected 2024
Lisata [United States]	SoC with LSTA1 or placebo	Various Solid Tumors	Phase 2a (Basket trial)	Trial initiation planned 1Q/2Q23
Lisata [United States]	TPN development candidate	Solid Tumor Cancer TBD	Preclinical	Development candidate ID target 2023 Phase 1 planned for 2024
CD34+ Platform Programs				
Lisata [United States]	HONEDRA® (LSTA12)	Critical Limb Ischemia and Buerger's Disease	Registration eligible	PMDA consultation underway
Lisata [Japan]	LSTA201	Diabetic Kidney Disease	Phase 1b – PoC	Data expected 1Q23
Lisata [United States]	XOWNA® (LSTA16)	Coronary Microvascular Dysfunction	Phase 2b (FREEDOM)	Partner sought to advance development

Panitumumab may be added for colorectal or appendiceal patients without Ras mutation

Source: Lisata Therapeutics, Inc. Website December 21, 2022

Product Candidates

CDNDR Platform™ Programs

LSTA1 is LSTA's lead investigational product candidate from the CendR Platform. It is the subject of multiple planned and ongoing combination clinical trials in a variety of solid tumor types and in combination with several chemotherapy and immunotherapy anti-cancer regimens. LSTA1 is being studied in Phase 1b/2a and 2b clinical studies in combination with a variety of anti-cancer regimens used to treat solid tumors, including metastatic pancreatic ductal adenocarcinoma. Clinical studies of the combination of LSTA1 with corresponding standards-of-care in other solid tumor indications is planned for 1H-2023.

LSTA1, (formerly CEND-1) is an investigational drug that actuates the CendR active transport mechanism while having the potential to modify the tumor microenvironment (TME), making tumors less immunosuppressive.

These two capabilities can potentially improve delivery and enhance the effectiveness of cancer therapies. In some cases, only a small fraction of an anti-cancer drug can cross the dense supportive tissue barrier of the TME and reach the tumor. The TME can prevent immune cells from entering the tumor. and protect the tumor from attack by a patient's immune system or immunotherapies.

The ability of LSTA1 and iRGD peptides, to modify the TME to enhance delivery and efficacy of co-administered drugs has been demonstrated in models of a range of solid tumors and has been the subject of over 200 scientific publications. LSTA 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. Clinically, LSTA1 has demonstrated favorable safety, tolerability, and activity in clinical trials to enhance delivery of standard-of-care chemotherapy for pancreatic cancer.

Following are six ongoing or planned trials of LSTA1 in pancreatic and other solid tumors.

Lisata/AGITG [Australia/New Zealand] – is a Phase 2b (ASCEND) trial, combining Gemcitabine/nab-paclitaxel with LSTA1 or placebo. This study will enroll approximately 125 subjects in 40 sites in Australia, New Zealand and possibly Ireland. The primary endpoint is progression-free survival and the secondary endpoint is objective tumor response rate. The study is targeted to complete enrollment in 4Q-2023 with first data expected in 2024.

Qilu [China] – is a Phase 1b/2 trial of LSTA1 combined with Gemcitabine/nab-paclitaxel plus in First-Line Metastatic Pancreatic Ductal Adenocarcinoma (mPDAC). 50 subjects will be enrolled at approximately 15 sites. Primary endpoints are Objective Response Rate, Duration Response Rate, Disease Control Rate, Overall Survival, and Progression-Free Survival. The secondary endpoint is pharmacokinetic parameter. Preliminary data are expected in 2H-2023..

Roche/Lisata [Multi-national] – is a Phase 1b/2 (MORPHEUS) trial of Gemcitabine/nab-paclitaxel/LSTA1 ± atezolizumab with an initiation target of 1Q-2023.

KUCC - IIT [United States] – is a Phase 1b/2 (CENDIFOX) investigator-initiated trial of LSTA1 + FOLFIRINOX + panitumumab in pancreatic, colon and appendiceal cancers. The study is funded by the University of Kansas Medical Center with LSTA providing the LSTA1. The study will enroll 50 subjects and has a primary endpoint of drug safety with secondary endpoints of Overall Survival, Disease-free Survival, Overall Response Rate, R0 Resection Rate and Pathological Response Rate. The enrollment completion date is 4Q-2023

Lisata [United States] – This is a proof-of-concept basket trial conducted in patients with multiple solid tumor types. The study will enroll 160 subjects (assuming four tumor types). The primary endpoint is overall survival and the secondary endpoints are overall response rate and progression-free survival. Trial initiation target date is 1Q-2023.

Lisata [United States] is a Phase 1 trial planned for 2024 of a development candidate and solid tumor cancer target yet to be identified.

CD34+ Platform Programs

CD34+ cells are stem cells that can stimulate new blood vessel formation. No other native cell discovered to date has demonstrated the same capability as CD34+ cells to promote angiogenesis. CD34+ regenerative cell therapy is the basis of investigational products for restoration of restricted blood flow.

HONEDRA® (LSTA12)

HONEDRA is seeking regulatory approval in Japan to treat Critical Limb Ischemia (CLI) and Buerger's Disease. CLI is a severe obstruction of the arteries, reducing blood flow to the extremities (hands, feet, and legs). CLI is the advanced form of peripheral arterial disease (PAD) caused by atherosclerosis.

CLI is a chronic condition that results in severe pain in the hands, feet or toes, even while resting. Initial stages of the disease can cause ulcers and wounds on the extremities that won't heal due to the lack of circulation. Untreated CLI cannecessitate amputation of the affected limb and may result in death. The addressable CLI population is approximately 560,000 patients in the EU, 300,000 in the U.S. and 249,000 in Japan.

Buerger's disease is a rare disease of the arteries and veins in the arms and legs. In Buerger's disease, blood vessels become inflamed, swell and can become blocked with blood clots. This eventually damages or destroys skin tissues and may lead to infection and gangrene. In some cases, amputation may be required. The largest risk factor for Buerger's disease is heavy tobacco use. Buerger's disease is extremely rare in the U.S. and Europe, but more common in Asia and the Middle East. It occurs with greater frequency in countries that have heavy tobacco use.

LSTA completed and reported successful results of a Phase 2 clinical trial of HONEDRA in Japan. HONEDRA is now in the pre-consultation phase of the registration process with Japan's Pharmaceuticals and Medical Devices Agency (PMDA), the pharmaceuticals regulator of Japan. Registration-eligible clinical trial data have been compiled and are being reviewed by the PMDA, after which the PMDA is expected to provide guidance for preparation for the formal

consultation meetings which precede the Japanese new drug application. If successful in the pre-consultation process, LSTA expects formal clinical consultation to occur by mid-year 2023. The company is seeking a Japanese partner to complete the remaining steps to produce registration in Japan.

HONEDRA is a SAKIGAKE-designated product candidate for the treatment of CLI and Buerger's disease in Japan, SAKIGAGE is a drug designation by the PMDA. It is analogous to the Regenerative Medicine Advanced Therapy designation in the U.S. and the Advanced Therapy Medicinal Product designation in the European Union.

LSTA201 (formerly CLBS201)

LSTA201 is a CD34+product candidate for intra-renal artery administration in patients with Chronic Kidney Disease (CKD) and Diabetic Kidney Disease (DKD). Both are caused by the gradual loss of kidney function. When CKD and DKD reach an advanced stages, dangerous levels of fluid, electrolytes and wastes can build up in the body. Diabetes mellitus is the leading cause of kidney disease.

Over time, high blood glucose levels from poorly controlled diabetes can damage the small blood vessels (microvasculature) in the kidneys, leading to kidney damage. This microvascular complication develops in approximately 20% of patients with type 1 diabetes and approximately 50% of patients with type 2 diabetes. All-cause mortality in patients with DKD is higher than in patients with diabetes without kidney disease; the highest risk being DKD. DKD is increasing dramatically. In the 22 years between 1990 and 2012. During that time, the number of deaths attributed to DKD rose by 94%.

LSTA201 has completed a Phase 1b (PoC) clinical trial with data expected in 1Q-2023. It is an 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 are in the pre-dialysis stage of kidney disease and exhibit rapidly progressing stage 3b disease. The first of six patients was treated in April 2022 and treatment for all six subjects concluded during the 3Q- 2022. Top-line data is anticipated from all subjects by the 1Q-2023.

XOWNA® (LSTA16 formerly CLBS16)

XOWNA is a trial in subjects with Coronary Microvasculature Dysfunction (CMD). It was the subject of a positive Phase 2a (ESCaPE-CMD) study, reported in 2020 and is currently being evaluated in a U.S. Phase 2b (FREEDOM) study.

The FREEDOM trial was originally designed as a 105-patient double-blind, randomized, placebo-controlled trial of intracoronary delivery of autologous CD34+ cells in subjects with CMD and without obstructive coronary artery disease. The trial was expected to complete enrollment in approximately 12 months.

Enrollment initially proceeded as planned with the first patient treated in January 2021. The impact of the COVID-19 pandemic in the U.S., coupled with supply chain issues caused the trial

to be suspended. An interim analysis of the data from not less than the first 20 patients enrolled using the 6-month follow-up data was initiated.

Following the analysis of results of the FREEDOM trial subjects, along with Key Opinion Leaders' input, the company determined that execution of a redesigned FREEDOM-like trial would be the appropriate next step, but due to the cost of such a trial, it would only be continued if a strategic partner is identified and secured to contribute the necessary capital.

Risks

In addition to the risks normally anticipated in a development-stage biotechnology company, the following are specific to this company.

Financing Risks – LSTA has $75.5 million in cash and cash equivalents and a low burn rate. Nonetheless, this is a difficult time in which to raise funds and we don't know how long the downturn of investment in development-stage pharmaceuticals and biologics will continue.

Regulatory Risks – LSTA received SAKIGAKE designation in Japan for HONEDRA and is about to receive guidance for continuing advancement of the product. These designations do not ensure that LSTA will experience a faster development, regulatory review or approval process compared to conventional FDA or Japan PMDA procedures.

Collaboration/Licensing Risks – LSTA is a party to several licensing or collaboration agreements to accelerate development, expand market access and increase potential revenue. Should the licensing or collaboration partner fail to fulfill its agreement, there could be substantial harm to the company.

Management

David J. Mazzo, Ph.D., President & Chief Executive Officer since January 2015. Prior to the merger forming Lisata, Dr. Mazzo was Chief Executive Officer and Director of CLBS. Previous experience includes executive positions in R&D at Hoechst Marion Roussel and Schering-Plough. He served as CEO of Chugai USA, Aeterna Zentaris and Regado Biosciences.

Dr. Mazzo served on the boards of the companies for which he was CEO plus Essex Chemie AG (EU subsidiary of Schering-Plough), Avanir Pharmaceuticals, EyePoint Pharmaceuticals (as Chairman of the Board) and Seneca Biopharma. He is the Chairman of the Board of Visioneering Technologies, Inc. and a Director of Feldan Therapeutics.

Dr. Mazzo earned an M.S. in Chemistry and his Ph.D. in Analytical Chemistry at the University of Massachusetts (Amherst). He holds a B.S. in Chemistry and B.A. in Honors (Interdisciplinary Humanities) from Villanova University. He served as a Research Fellow at the Ecole Polytechnique Fédérale de Lausanne in Switzerland.

Erkki Ruoslahti, MD, PhD, Scientific Founder and Director was appointed to the Lisata Board as part of the merger of Lisata and Cent Therapeutics, Inc. where Dr. Ruoslahti served as Chairman of the Board of Directors.

After postdoctoral training at the California Institute of Technology, Dr. Ruoslahti held academic appointments with the University of Helsinki and the University of Turku, both in Finland, and City of Hope National Medical Center in Duarte, CA. He joined the Sanford-Burnham Institute for Medical Research in 1979, where he served as President from 1989-2002. Dr Ruoslahti co-founded the Center for Nanomedicine and was a distinguished professor at the University of California, Santa Barbara in Biological Sciences from 2005-2015. He is an inventor with about 150 patents

Dr. Ruoslahti is a recipient of the 2022 Albert Lasker Basic Medical Research Award, the Japan Prize, the Gardiner Foundation International Award, the G.H.A. Clowes Award, the Robert J. and Claire Pasarow Foundation Award and the Jacobaeus International Prize.

He is a member of the U.S. National Academy of Sciences, the National Academy of Medicine, the American Academy of Arts and Sciences, the European Molecular Biology Organization and a fellow of the National Academy of Inventors.

Dr. Ruoslahti earned his M.D. and Ph.D. from the University of Helsinki in 1967.

David S. Slack, President and Chief Business Officer Prior to the merger forming Lisata, he served as President, Chief Executive Officer and Director of Cend Therapeutics. Prior experience includes co-founding Chief Business Officer at Viracta therapeutics, Vice President for Business Development at Ionis Pharmaceuticals and served in senior management positions at Rhöne-Poulenc, Rorer, Genecell and Aventis Pharmaceuticals

Kristen K. Buck, M.D., Executive Vice President of R&D and Chief Medical Officer Previously, Dr. Buck served as CMO at ICON plc. Prior to that, Dr. Buck was Senior Vice President & Chief of Clinical Development at Optum Insights (part of the United Healthcare Group) Earlier in her career, Dr. Buck worked as a primary care physician and later served as a medical officer in the U.S. Food and Drug Administration's Office of New Drugs Division of Gastrointestinal and Hematology Drug Products. Dr. Buck was Global Safety Physician and Global Study Physician. at AstraZeneca and Vice President of Global Strategic Drug Development at Quintiles/IQVIA.

Dr. Buck is a board certified and licensed physician who received her medical degree from the Pennsylvania State University School of Medicine and completed her internship and residency in Internal Medicine at Abington Memorial Hospital.

Greg Berkin, Chief Information Officer joined Lisata in January 2015. He is responsible for transforming external IT support into an internal team working as a highly efficient operating unit across Lisata. He manages all groups within IT: Networking, PC, Cybersecurity, Applications, Business Solutions, and Telecom. Prior experience includes director and management roles in IT at Regado Biosciences, Aeterna Zentaris, and Chugai Pharma USA. Mr. Berkin currently serves on the BioNJ IT & Cybersecurity Committee. He received a BA and MSc from Fairleigh Dickinson University.

Historical and Future Performance

EPS	2021*	2022*	2023
Q1	(0.19)A	(0.07)A	(1.00)E
Q2	(0.10)A	(0.11)A	(1.00)E
Q3	(1.74)A	(7.88)A	(1.00)E
Q4	1.53A	(1.11)E	(1.00)E
Year	(0.50)A	(9.17)E	(4.00)E
P/E	NM	NM	NM
EPS Growth	NM	NM	NM
FY Rev. (Mil)	0.00A	0.00E	0.00E
FY: DEC			

* Reflects CLBS Earnings

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	Percentage of Covered Securities	Percentage of Banking Clients
Buy	84%	6.25%
Hold	11%	0%
Sell	05%	0%

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