

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

August 12, 2024
Date of Report (date of earliest event reported)

LISATA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

001-33650
(Commission File Number)

22-2343568
(I.R.S. Employer Identification No.)

110 Allen Road, Second Floor, Basking Ridge, NJ 07920
(Address of Principal Executive Offices)(ZipCode)
(908) 842-0100
Registrant's telephone number, including area code

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	LSTA	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

- Emerging growth company
- If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

The information in Item 7.01 is incorporated by reference.

Item 7.01 Regulation FD Disclosure.

On August 12, 2024, Lisata Therapeutics, Inc. (the "Company") issued a press release in connection with its financial results for the second quarter ended June 30, 2024. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 7.01 by reference.

A copy of a slide presentation that the Company will use at investor and industry conferences and presentations is attached to this Current Report as Exhibit 99.2 and is incorporated herein solely for purposes of this Item 7.01 disclosure.

The information in this Item 7.01, including Exhibits 99.1 and 99.2 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Item 7.01, including Exhibits 99.1 and 99.2 attached hereto, shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, except as otherwise expressly stated in such filing.

Item 9.01. Financial Statement and Exhibits.

Exhibit No.	Description
<u>99.1</u>	Press Release, dated August 12, 2024
<u>99.2</u>	Lisata Therapeutics, Inc. Corporate Presentation, August 12, 2024

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

LISATA THERAPEUTICS, INC.

By: /s/ David J. Mazzo
Name: David J. Mazzo, PhD
Title: President & Chief Executive Officer

Dated: August 12, 2024

Lisata Therapeutics Reports Second Quarter 2024 Financial Results and Provides Business Update

Phase 2b ASCEND trial top-line data remains on track to be reported in fourth quarter of 2024

Available cash projected to fund current operations into early 2026 and all active studies through to data

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

BASKING RIDGE, NJ (August 12, 2024) – 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, provided a business update and reported financial results for the second quarter ended June 30, 2024.

“The second quarter generated strong momentum for Lisata as we continued to advance multiple ongoing and planned clinical studies centered around our novel investigational product, certepetide,” stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Lisata. “We have a lot to look forward to with multiple key data readouts projected over the next 18 months, including topline results from the Phase 2b ASCEND trial. These results have transformative potential for the Company as we plan to explore conditional approvals with various regulatory agencies and/or to design an optimized Phase 3 program in metastatic pancreatic ductal adenocarcinoma, an aggressive, often fatal, form of pancreatic cancer. In just the first half of 2024, certepetide has received U.S. FDA Orphan Drug and Rare Pediatric Disease designation in osteosarcoma, and a waiver for evaluating certepetide in a pediatric population with pancreatic cancer in Europe (EMA). These agency recognitions further validate and support our excitement and the broad therapeutic potential of this innovative therapy.”

Dr. Mazzo added, “Our continued prudent, strategic financial management allows us to reaffirm our projection that available cash will fund current operations into early 2026, providing the necessary capital for all planned trials through to completion.”

Development Portfolio Highlights

Certepetide as a treatment for solid tumors in combination with other anti-cancer agents

Certepetide (formerly 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. Certepetide 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. Certepetide has also been shown to modify the tumor microenvironment, diminishing its immunosuppressive nature and inhibiting the metastatic cascade. Along with our collaborators, we have amassed significant non-clinical data demonstrating enhanced delivery of various existing and emerging anti-cancer therapies, including immunotherapies and RNA-based therapeutics. To date, certepetide has also demonstrated favorable safety, tolerability, and clinical activity in completed and ongoing clinical trials designed to test its ability to enhance the effectiveness of standard-of-care (“SoC”) chemotherapy for pancreatic cancer. Lisata is exploring the potential of certepetide to enable a variety of treatment modalities to treat a range of solid tumors more effectively. Certepetide has been awarded Fast Track designation (U.S.) and Orphan Drug Designation for pancreatic cancer (U.S. and E.U.) as well as Orphan Drug Designation for glioma (U.S.) and osteosarcoma (U.S.). Additionally, certepetide has received Rare Pediatric Disease Designation for osteosarcoma (U.S.). Currently, certepetide is the subject of multiple ongoing or planned Phase 2a and 2b clinical studies being conducted globally in a variety of solid tumor types in combination with a variety of anti-cancer regimens, including:

- ASCEND: Phase 2b double-blind, randomized, placebo-controlled clinical trial evaluating two dosing regimens of certepetide in combination with SoC chemotherapy (gemcitabine/nab-paclitaxel) in patients with metastatic pancreatic ductal adenocarcinoma (“mPDAC”). Cohort A of the study receives a single dose of 3.2

mg/kg certepetide essentially simultaneously with SoC, while Cohort B is identical to Cohort A, but with a second dose of 3.2mg/kg of certepetide given four hours after the first. The trial is being conducted at 25 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. The conclusion of a planned interim futility analysis in 2023 by the Independent Data Safety Monitoring Committee was that the conditions for futility were not met and that the study should proceed to completion. With trial enrollment completed in the fourth quarter of 2023, Lisata expects topline data from the 95 patients assigned to Cohort A of the study to be reported in the fourth quarter of 2024 and the complete data set of all 158 patients from the study to be available by mid-2025.

- **BOLSTER:** Phase 2a double-blind, placebo-controlled, multi-center, randomized trial in the U.S. evaluating certepetide in combination with SoC in first- and second-line cholangiocarcinoma (“CCA”). The Company achieved complete enrollment in first-line CCA nearly six months ahead of plan, accelerating anticipated topline data readout to mid-2025. Based on this rapid enrollment rate and the pressing need to improve treatment outcomes in patients that have progressed after first-line CCA treatment, a second cohort has been added to the BOLSTER trial evaluating subjects in second-line CCA. Lisata expects to enroll the first patient by the fourth quarter of 2024.
- **CENDIFOX:** Phase 1b/2a open-label trial in the U.S. of certepetide in combination with neoadjuvant FOLFIRINOX based therapies in pancreatic, colon and appendiceal cancers. The trial has completed enrollment in the pancreatic cohort and expects to complete enrollment in the remaining two cohorts by the end of 2024.
- **Qilu Pharmaceutical,** the licensee of certepetide in the Greater China territory, is currently evaluating certepetide in combination with gemcitabine and nab-paclitaxel as a treatment for mPDAC. During the 2023 ASCO Annual Meeting, Qilu Pharmaceutical presented an abstract sharing preliminary data from the study which corroborated previously reported findings from the Phase 1b/2a trial of certepetide plus gemcitabine and nab-paclitaxel conducted in Australia in patients with mPDAC. As previously reported, Qilu has begun treating patients in their Phase 2 placebo-controlled trial in mPDAC.
- **iLSTA:** Phase 1b/2a randomized, single-blind, single-center, safety and pharmacodynamic trial in Australia evaluating certepetide in combination with the checkpoint inhibitor, durvalumab, plus SoC gemcitabine and nab-paclitaxel chemotherapy versus SoC alone in patients with locally advanced non-resectable PDAC. Enrollment completion is expected in the second half of 2024.
- A Lisata-funded Phase 2a, double-blind, placebo-controlled, randomized, proof-of-concept study evaluating certepetide in combination with SoC temozolomide versus temozolomide alone in patients with newly diagnosed GBM is being conducted across multiple sites in Estonia and Latvia and is targeted to enroll 30 patients with a randomization of 2:1 in favor of the certepetide treatment group.
- **FORTIFIDE:** Phase 1b/2a, double-blind, placebo-controlled, three-arm, randomized study in the U.S. to evaluate the safety, tolerability, and efficacy of a 4-hour continuous infusion of certepetide in combination with SoC in subjects with second-line mPDAC who have progressed on FOLFIRINOX. As part of this study, Lisata has engaged Haystack Oncology to use its MRD™ technology to measure circulating tumor DNA levels at multiple timepoints in patients throughout the study as an exploratory endpoint for analyzing the early therapeutic effect of certepetide. The Company expects to enroll the first patient in the study by the first half of 2025.

Second Quarter 2024 Financial Highlights

For the three months ended June 30, 2024, operating expenses totaled \$5.5 million, compared to \$6.9 million for the three months ended June 30, 2023, representing a decrease of \$1.4 million or 19.7%.

Research and development expenses were approximately \$2.6 million for the three months ended June 30, 2024, compared to \$3.2 million for the three months ended June 30, 2023, representing a decrease of \$0.6 million or 17.7%. This was primarily due to a reduction in expenses associated with the Phase 2b ASCEND trial which completed enrollment in the prior year, lower spend on chemistry, manufacturing and control (“CMC”) related expenses and

lower equity expense partially offset by an increase in expenses associated with our enrollment activities in the current year for our BOLSTER trial.

General and administrative expenses were approximately \$2.9 million for the three months ended June 30, 2024, compared to \$3.7 million for the three months ended June 30, 2023, representing a decrease of \$0.8 million or 21.3%. This was primarily due to one-off related severance costs in the prior year associated with the elimination of the Chief Business Officer position on May 1, 2023, a reduction in equity expense and a decrease in directors and officers insurance premiums in the current year.

Benefit from income taxes was \$0.0 million for the three months ended June 30, 2024, compared to \$2.3 million for the three months ended June 30, 2023. In April 2023, we received net proceeds of \$2.2 million from the sale of tax benefits to a qualified and approved buyer pursuant to the New Jersey Economic Development Authority's Technology Business Tax Certificate Transfer Program.

Overall, net losses were \$5.0 million for the three months ended June 30, 2024, compared to \$4.0 million for the three months ended June 30, 2023.

Balance Sheet Highlights

As of June 30, 2024, Lisata had cash, cash equivalents, and marketable securities of approximately \$38.3 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 today, August 12, 2024, 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 15 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 product candidate, certepetide (formerly LSTA1), is an investigational drug designed to activate a novel uptake pathway that allows co-administered or tethered anti-cancer drugs to selectively target and penetrate solid tumors more effectively. Lisata has already established noteworthy commercial and R&D partnerships based on its CendR Platform® technology. The Company expects to announce numerous milestones over the next two years and believes that its projected capital will fund operations into early 2026, encompassing anticipated data milestones from its ongoing and planned clinical trials. 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 the Company's clinical development programs 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, the potential efficacy of certepetide as a treatment for patients with metastatic pancreatic ductal adenocarcinoma and other solid tumors; 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: results observed from a single patient case study are not necessarily indicative of final results and one or more of the clinical outcomes may materially change following more comprehensive reviews of the data and as more patient data becomes available, including the risk that unconfirmed responses may not ultimately result in confirmed responses to treatment after follow-up evaluations; the risk that product candidates that appeared promising in early research and clinical trials do not demonstrate safety and/or efficacy in larger-scale or later clinical trials; 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 February 29, 2024, 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:

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- Tables to Follow -

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Statement of Operations Data:				
Research and development	\$ 2,601	\$ 3,162	\$ 5,842	\$ 6,341
General and administrative	2,922	3,713	6,282	7,378
Total operating expenses	5,523	6,875	12,124	13,719
Operating loss	(5,523)	(6,875)	(12,124)	(13,719)
Investment income, net	493	668	1,082	1,338
Other expense, net	(14)	(150)	(201)	(163)
Net loss before benefit from income taxes and noncontrolling interests	(5,044)	(6,357)	(11,243)	(12,544)
Benefit from income taxes	—	(2,330)	(798)	(2,330)
Net loss	(5,044)	(4,027)	(10,445)	(10,214)
Less - net income attributable to noncontrolling interests	—	—	—	—
Net loss attributable to Lisata Therapeutics, Inc. common stockholders	\$ (5,044)	\$ (4,027)	\$ (10,445)	\$ (10,214)
Basic and diluted loss per share attributable to Lisata Therapeutics, Inc. common stockholders	\$ (0.61)	\$ (0.50)	\$ (1.26)	\$ (1.28)
Weighted average common shares outstanding	8,308	8,021	8,301	8,004

	June 30, 2024	December 31, 2023
	(unaudited)	
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	\$38,262	\$50,535
Total assets	42,571	54,694
Total liabilities	4,576	6,800
Total equity	37,995	47,894

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Exhibit 99.2



Targeted Therapy *Delivered*

David J. Mazzo, Ph.D.
President and Chief Executive Officer

Corporate Presentation | August 12, 2024
Nasdaq: LSTA

www.lisata.com



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Forward-looking statements advisory

This presentation 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,” “target” 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, develop and commercialize 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 February 29, 2024, 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.



Lisata at a Glance

Company Overview

Lisata Therapeutics (Nasdaq: LSTA)

A clinical stage therapeutics company rapidly developing a novel solid tumor targeting and penetration technology with TME* modifying properties to improve the efficacy of anti-cancer drugs



Seasoned management with successful international drug development experience and expertise



Proprietary field-leading technology in underserved global indications



Multiple product and business milestones projected over the next 18 months



Platform technology “validated” by existing partnerships with potential for many others

Projected cash runway into early 2026, funding all development programs through data

*TME = Tumor Microenvironment

Seasoned leadership with proven track record in drug approvals worldwide

David J. Mazzo, PhD

President and Chief Executive Officer, Member of the Board of Directors



- With >40 years of experience, Dr. Mazzo is a global pharmaceutical executive noted for his strategic prowess and his vast experience developing and launching new products across all therapeutic areas.



Kristen K. Buck, MD

Executive Vice President of R&D and Chief Medical Officer



- Dr. Buck is a board certified and licensed physician with >20 years of strategic global drug development, drug/device safety/epidemiology, FDA, and clinical practice experience.



<p>Gregory Berkin Chief Information Officer and Data Protection Officer</p> 	<p>James Nisco SVP of Finance and Treasury and Chief Accounting Officer</p> 	<p>Tariq Imam VP of BD and Operations and Corporate Counsel</p> 	<p>John Menditto VP of Investor Relations and Corporate Communications</p> 	<p>Bill Sietsema, PhD VP of Global Regulatory Affairs</p> 	<p>Ryan Quick VP of Chemistry, Manufacturing and Controls</p> 
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Detailed bios can be found at www.lisata.com 5

Accomplished, industry veteran, independent board directors



Gregory B. Brown, MD
Chairman

Biopharma executive with expertise in evaluating scientific, technical, clinical, and medical products as well as in healthcare systems and payor/reimbursement dynamics.



Steven M. Klosk
Director

Pharma executive with 25+ years of experience in the pharmaceutical CDMO industry and proven leadership across all stages of product development.



Cynthia L. Flowers
Director

Biopharma executive with extensive experience in leading and managing companies during transformative years of growth, particularly when it comes to commercialization of products in many therapeutic areas including oncology.



Mohammad Azab, MD, MSc, MBA
Director

Pharma executive with 30+ years of experience in clinical research, business management, and global development, bringing multiple drugs to market across oncology and other therapeutic areas.

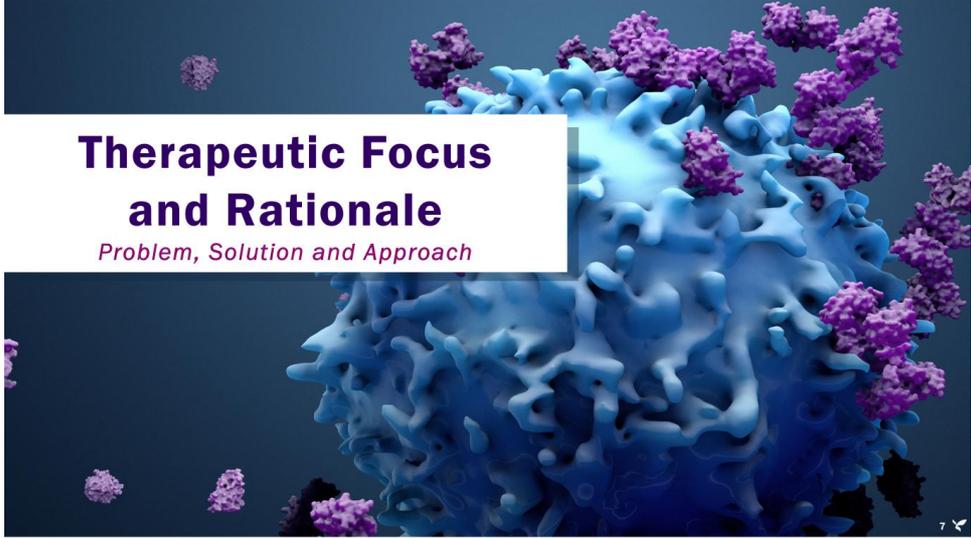


Heidi Henson
Director

Senior executive with over two decades of financial operations experience with both public and private companies.



Detailed bios can be found at www.lisata.com 6

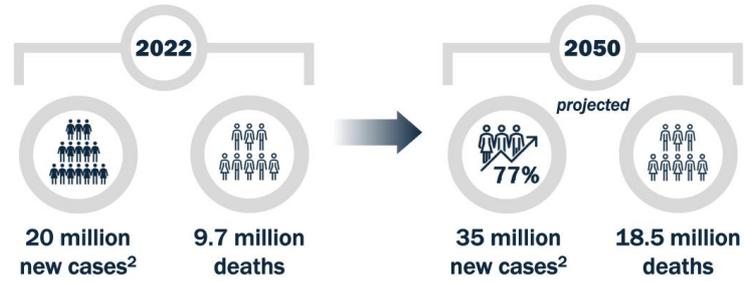


Therapeutic Focus and Rationale

Problem, Solution and Approach

Improved solid tumor treatment remains a vital, growing global need

In 2023, in the U.S. alone, of ~2 million newly diagnosed cancer cases, >90% were solid tumors¹

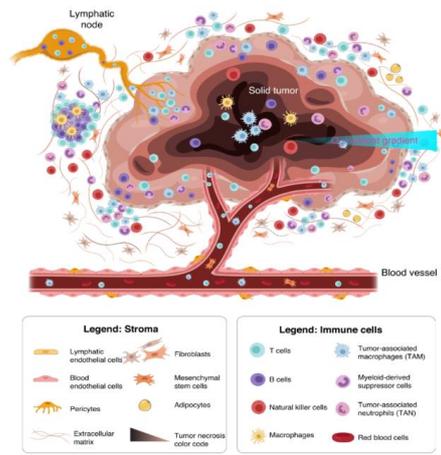


Examples of solid tumors include cancers of the lung, breast, pancreas, liver, bile duct, kidneys, ovaries, brain, colon, prostate, esophagus, and head & neck

¹ <https://seer.cancer.gov/statfacts/html/common.html>; data retrieved November 2, 2023.

² https://go.iarc.who.int/tomorrow/en/dataviz/tables?mode=population&years=2050&types=1&populations=903_904_905_908_909_935_900; data retrieved Feb 12, 2024.

Current solid tumor treatments & patient outcomes are suboptimal

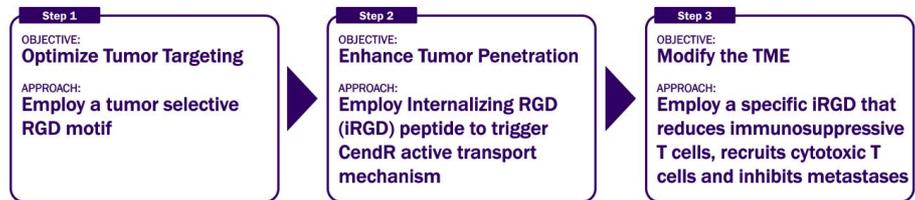


A challenging tumor microenvironment complicates “targeting” and “penetration”

- Tumor stroma acts as a physical barrier to anti-cancer agents
- An immunosuppressive tumor microenvironment (TME) contributes to tumor resistance and/or metastases
- Prolonged or escalated dosing of non-targeted anti-cancer therapies generally leads to intolerable off-target side effects

Maximizing solid tumor treatment success

A rational drug development approach to overcoming the obstacles to achieving optimized outcomes for patients with solid tumors



Result

Certepetide now in mid- to late-stage clinical development for solid tumor treatments based on a large body of preclinical evidence

Certepetide promises optimized solid tumor treatment outcomes



Certepetide converts tumor stroma from a barrier to a conduit for anti-cancer drugs



Certepetide combats resistance and metastases¹

- Selectively depletes immunosuppressive T cells while enhancing the concentration of cytotoxic T cells
- Inhibits the metastatic cascade



Certepetide is agnostic to the modality of the companion anti-cancer therapy

- Effective with co-administered or molecularly bound (tethered) anti-cancer therapies
- Co-administration presents an initial streamlined development path to registration
- Tethering creates a new chemical entity providing new compound patent protection

¹ Sugahara, et al. Mol Cancer Ther; 14(1) January 2015; Hamilton, et al., J MolMed. April 2015; and Miyamura, et al., bioRxiv. May 2023.

Certepetide development strategy is composed of two main pillars

Focus on Pancreatic Cancer & Other Advanced Solid Tumors

- By 2030, pancreatic cancer is predicted to become the second most common cause of cancer mortality¹
 - Today, only 3% of people diagnosed with pancreatic cancer will survive for 5 years
 - Current life expectancy at the time of diagnosis is just 4.6 months

Pursue rapid global registration in pancreatic ductal adenocarcinoma (mPDAC), initially combined with gemcitabine/nab-paclitaxel standard-of-care (SoC)

- *Phase 2b 100% enrolled*

Demonstrate certepetide effectiveness when combined with a variety of SoC regimens (e.g., chemotherapy, immunotherapy, etc.) in a variety of solid tumors

- *Multiple Phase 1b/2a studies underway*

¹ Europe Is Facing a Pancreatic Cancer Emergency - Medscape - January 25, 2024.



Partnerships

Noteworthy existing relationships and potential for many more



Existing partnerships support certepetide's promise and broad applicability



R&D alliances contribute resources with minimal commercial interest in certepetide

- Australasian Gastro-Intestinal Trials Group - Clinical Trialists Consortium (Australia & New Zealand)
- WARPINE - Foundation (Australia)



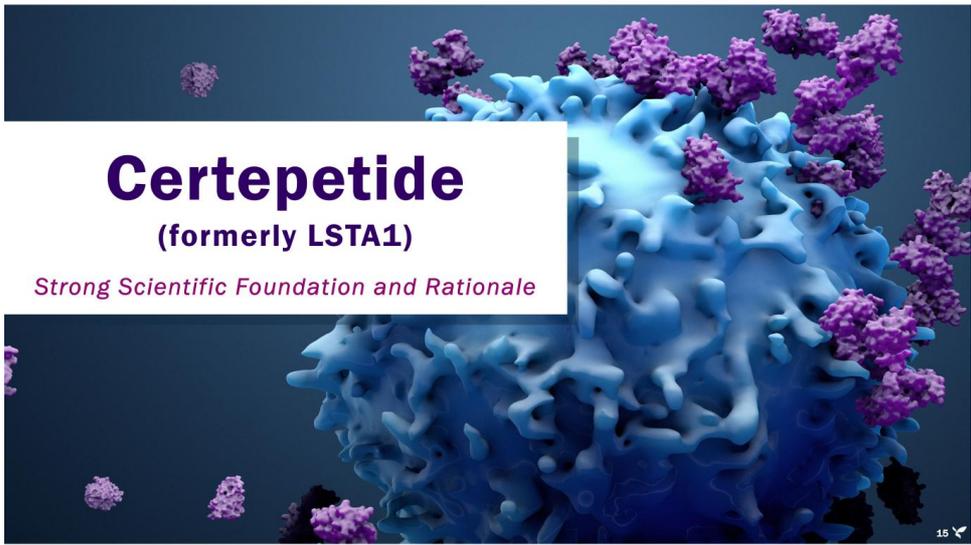
Strategic commercial partnership in China with Qilu Pharmaceutical

- Qilu granted exclusive rights to certepetide in China, Taiwan, Hong Kong and Macau
- Qilu assumes all development and commercialization responsibilities/costs in licensed territories
 - Strategy and activities under the auspices of a Joint Steering Committee with Lisata executives
- Lisata collected \$15 million in milestones to date
- Potential for additional \$221 million in milestones plus royalties on sales to Lisata



Additional partnership opportunities exist for many combinations with certepetide

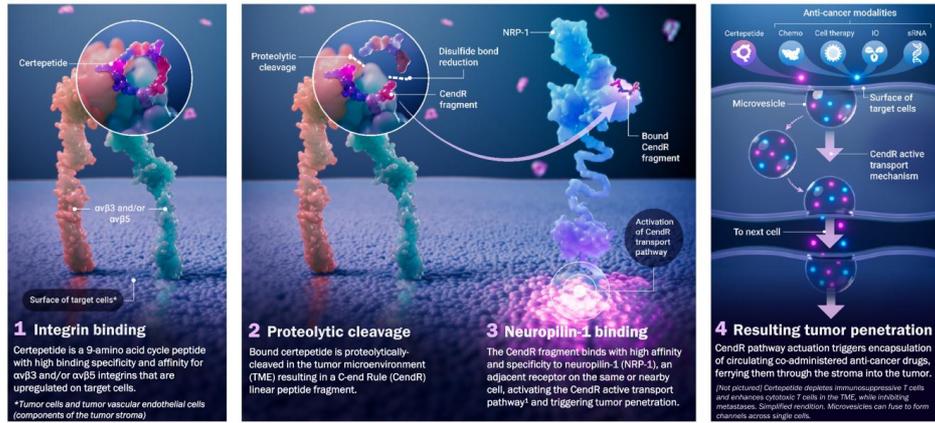
- By indication, modality of co-administered drug(s), and/or geography



Certepetide
(formerly LSTA1)

Strong Scientific Foundation and Rationale

Certepetide selective tumor targeting & penetration mechanism of action

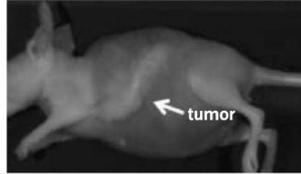


¹Ding et al., Nature Comm, 2019.

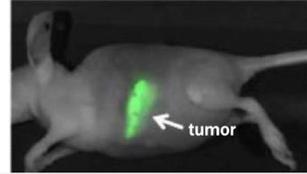
Certepetide selectively and efficiently facilitates intratumoral penetration

Whole body imaging of mice with pancreatic ductal adenocarcinoma (arrow) dosed with Fluorescent Quantum Dots (FQDs) with and without certepetide

- Circulating FQDs result in whole body fluorescence
- Etching solution quenches fluorescence in circulation



FQDs + Etching solution
All FQDs in circulation



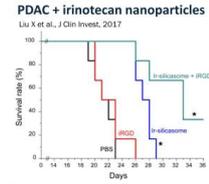
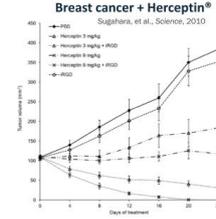
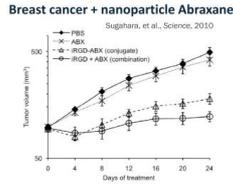
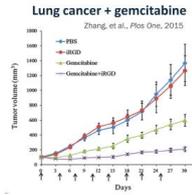
Certepetide + FQDs + Etching solution
All FQDs in tumor

Certepetide provides targeted tumor penetration

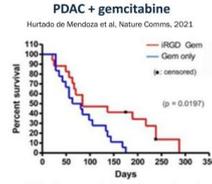
¹Braun et al., Nature Mater. 2014.
²Liu, Braun et al., Nature Comm. 2017.

Certepetide/iRGD activity & broad applicability consistently demonstrated

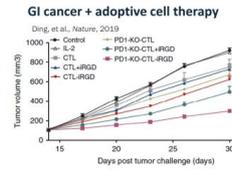
Sampling of >350 scientific publications showing improved survival with certepetide/iRGD



Orthotopically transplanted KPC PDAC tumors
iRGD + irinotecan nanoparticles (i.v. co-admin)



KPC mice genetically engineered to develop
PDAC iRGD + gemcitabine (i.v. co-admin)



Certepetide Ph 1b/2a results: Compelling improvement of SoC efficacy

Endpoints	Gemcitabine + Nab-paclitaxel ¹	Certepetide + Gemcitabine + Nab-paclitaxel ²
N= # of study participants	N=431	N=31
Median Overall Survival	8.5 mos.	13.2 mos.
Median Progression-Free Survival	5.5 mos.	9.7 mos.
Objective Response Rate	23% (99)	59% (17)
Complete Response	0.2% (1)	3.4% (1)
Partial Response	23% (98)	55% (16)
Stable Disease	27% (118)	31% (9)
Progressive Disease	20% (86)	10.3% (3)
Disease Control Rate 16 weeks	48%	79%
CA19-9 >20% drop	61%	96%



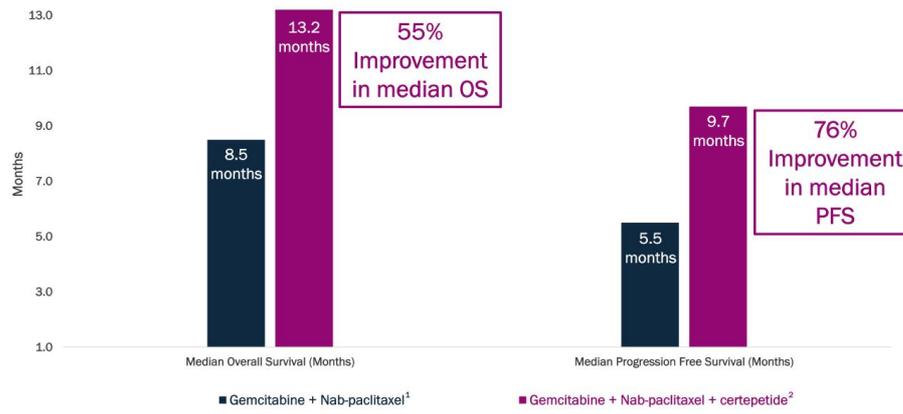
First-line, mPDAC patients from 3 sites in Australia



- Certepetide well-tolerated with no dose-limiting toxicities
- Safety of certepetide + SoC consistent with SoC alone

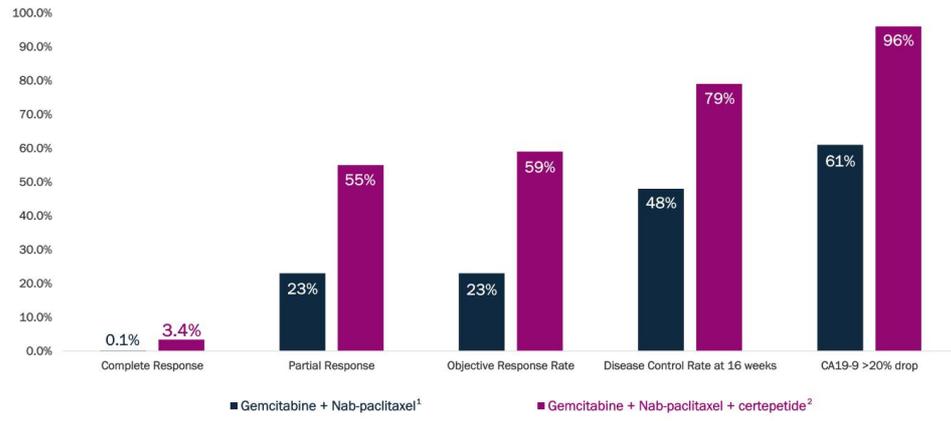
¹ Von Hoff D, et al., *New England Journal of Medicine*, 2013.
² Dean A, et al., *The Lancet Gastroenterology & Hepatology*, 2022.

Certepetide Ph 1b/2a results: Improved survival vs. SoC alone



¹ Von Hoff D, et al., *New England Journal of Medicine*, 2013.
² Dean A, et al., *The Lancet Gastroenterology & Hepatology*, 2022

Certepetide Ph 1b/2a results: Consistent improvement across associated endpoints

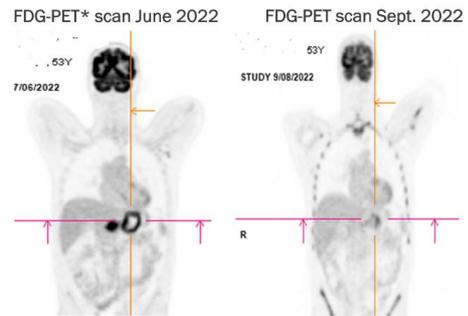


¹ Von Hoff D, et al., *New England Journal of Medicine*, 2013.
² Dean A, et al., *The Lancet Gastroenterology & Hepatology*, 2022

Evidence of certepetide activity in other solid tumors

***Certepetide potentiated a complete response
in metastatic gastroesophageal adenocarcinoma (mGEAC)***

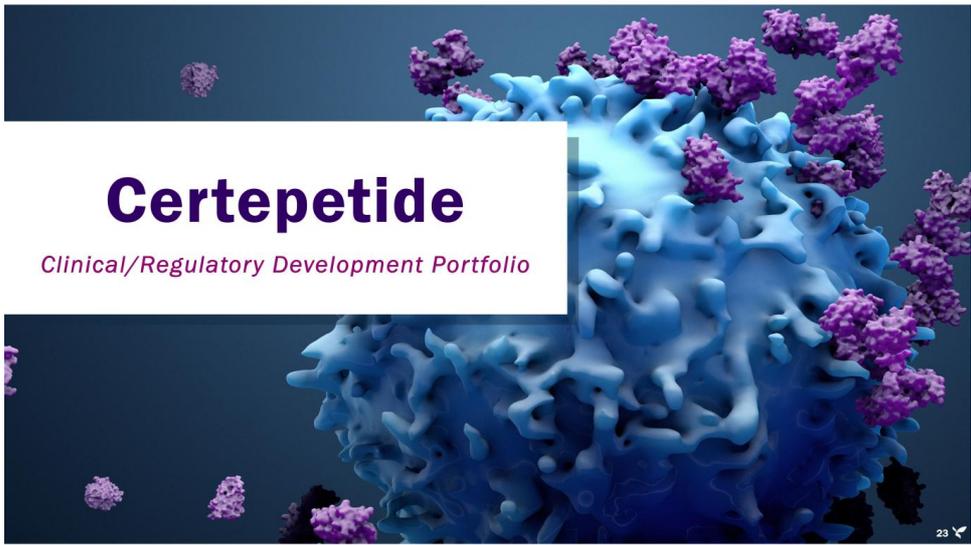
- 53-year-old male with mGEAC with significant (> 5cm) nodal metastases (June 2022)
- SoC combination chemotherapy (FOLFIRINOX) and radiotherapy, with immunotherapy (pembrolizumab) later added resulting in partial response
- Certepetide added to above regimen at cycle 7 and exploratory laparoscopy after cycle 18 (September 2022) showed **no discernable disease – deemed a complete response**



Reduction in FDG activity demonstrated¹

*Fluorodeoxyglucose (FDG)-positron emission tomography (PET)

¹ Buck, K.K, Dean, A., McSweeney, T. LSTA1 Potentiates Complete Response in Metastatic Gastroesophageal Adenocarcinoma. Oncol Cancer Case Rep. 2023, 9(6), 001-003



Certepetide

Clinical/Regulatory Development Portfolio

Certepetide regulatory designations and implications

FDA Fast Track Designation	FDA Rare Pediatric Disease Designation	Orphan Drug Designation
<ul style="list-style-type: none"> ▪ <i>Certepetide received <u>Fast Track Designation</u> from FDA for pancreatic cancer</i> ▪ More frequent communication with and program-specific guidance from FDA ▪ Eligible for <i>Accelerated Approval, Priority Review and Rolling Review</i> 	<ul style="list-style-type: none"> ▪ <i>Certepetide received <u>Rare Pediatric Disease Designation</u> from FDA for osteosarcoma</i> ▪ Eligible for <i>Priority Review Voucher</i> that can be redeemed to receive a priority review for any subsequent marketing application, or may be sold or transferred ▪ Historically, vouchers have sold for \$350 million USD and, more recently, have sold for \$75-\$100 million USD 	<ul style="list-style-type: none"> ▪ <i>Certepetide received <u>Orphan Drug Designation</u> from FDA and EMA for pancreatic cancer, from FDA for malignant glioma, and from FDA for osteosarcoma</i> ▪ Incentives such as <i>tax credits, marketing exclusivity, fee waivers and grant eligibility</i> to support clinical trials ▪ Specialized regulatory assistance from FDA's Office of Orphan Products Development

Certepetide capital efficient development plan

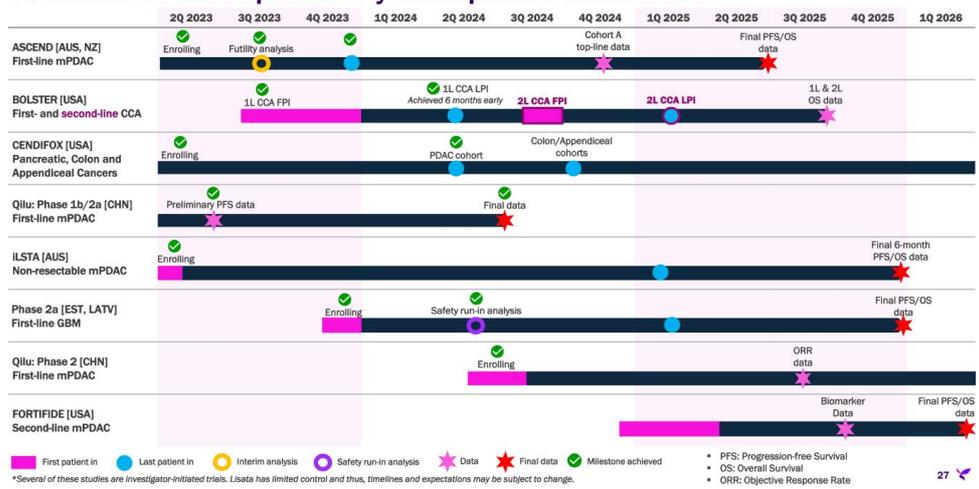
Sponsor(s)	Indication	Description	Current Phase		
			Phase 1	Phase 2	Phase 3
AGITG/Lisata	First-line mPDAC	<ul style="list-style-type: none"> ASCEND: Phase 2b, placebo-controlled trial (N=158) Gemcitabine/nab-paclitaxel + certepetide or placebo Australia/New Zealand BOLSTER: Phase 2a, placebo-controlled trial (N=80) 1L CCA: Gemcitabine/cisplatin/durvalumab with certepetide or placebo 2L CCA: FOLFFOX with certepetide or placebo United States 	Enrollment complete		
Lisata	First- and Second-line Cholangiocarcinoma (CCA)	<ul style="list-style-type: none"> CENDIFOX: Phase 1b/2a, open-label trial (N=51) FOLFIRINOX + panitumumab* + certepetide United States 	1L CCA Enrollment complete	2L CCA Enrolling soon	
KUCC/Lisata Investigator-initiated trial	Pancreatic, Colon, and Appendiceal Cancers	<ul style="list-style-type: none"> Phase 1b/2a, open-label trial (N=41) Gemcitabine/nab-paclitaxel + certepetide China 	Enrolling		
Qilu/Lisata	First-line mPDAC	<ul style="list-style-type: none"> ILSTA: Phase 1b/2a, open-label trial (N=30) Gemcitabine/nab-paclitaxel/durvalumab + certepetide Australia 	Enrollment complete		
WARPINE/Lisata	Locally advanced, non-resectable PDAC	<ul style="list-style-type: none"> Phase 2a, placebo-controlled trial (N=30) Temozolomide +/- certepetide Estonia/Latvia 	Enrolling		
Tartu University/Lisata Investigator-initiated trial	First-line Glioblastoma Multiforme (GBM)	<ul style="list-style-type: none"> Phase 2, placebo-controlled trial (N=120) Gemcitabine/nab-paclitaxel + certepetide China 	Enrolling		
Qilu/Lisata	First-line mPDAC	<ul style="list-style-type: none"> FORTIFIDE: Phase 1b/2a placebo-controlled trial (N=30) Gemcitabine/nab-paclitaxel + continuous infusion of certepetide/placebo United States 	Enrolling		
Lisata	Second-line mPDAC		Enrolling soon		

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

Development Milestones



A wealth of anticipated key certepetide milestones





Financial Highlights

Capital projected to fund all clinical programs to data

Cash & Investments
As of 6/30/2024

\$38.3M

Debt

\$0

Projected Cash Runway Into

1Q2026

Common Shares Outstanding (6/30/2024):

8.3 million shares

Options Outstanding (6/30/2024):

Exercise Price: \$0.02 - \$4.22 = 1,216,100 shares

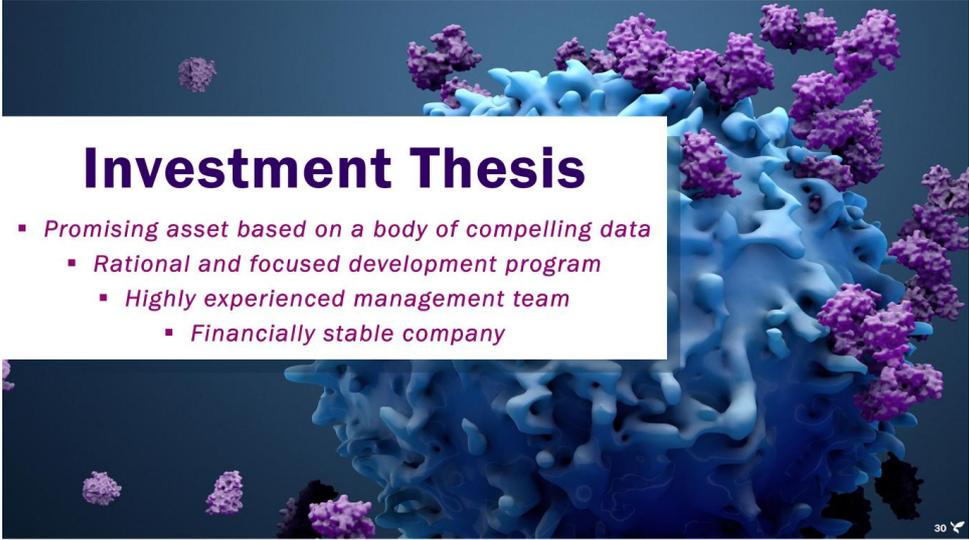
Exercise Price: > \$4.22 = 237,800 shares

1.5 million shares

Warrants Outstanding (6/30/2024):

Weighted Average Exercise Price: \$42.51

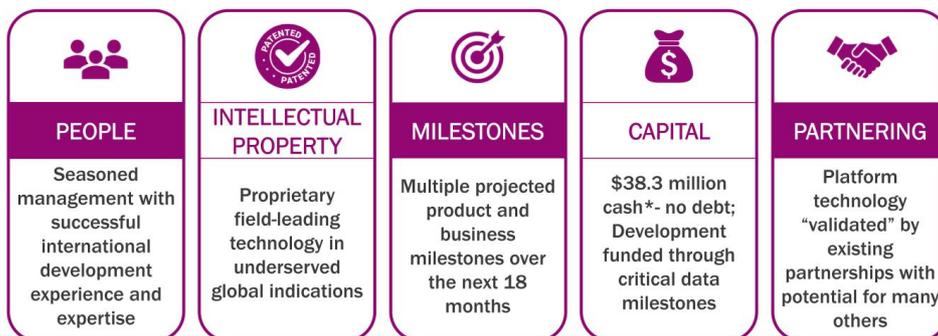
1.4 million shares



Investment Thesis

- *Promising asset based on a body of compelling data*
 - *Rational and focused development program*
 - *Highly experienced management team*
 - *Financially stable company*

Key factors supporting investment in Lisata Therapeutics



* As of 6/30/2024; includes investments



Targeted Therapy *Delivered*

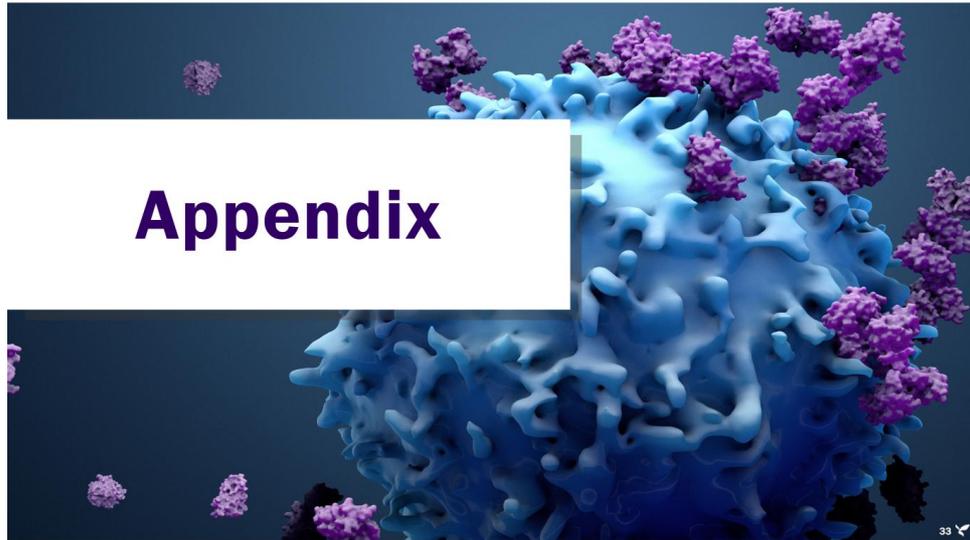
Investor Relations Contact:
John D. Menditto
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Nasdaq: LSTA | www.lisata.com



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Appendix



Certepetide capital efficient development plan

Development Partner(s) [Development Venue]	Indication and Trial Product/Comparator	Stage of Development	Strategic Rationale
Lisata/AGITG [Australia/New Zealand]	First-line mPDAC; Gemcitabine/nab-paclitaxel with certepetide or placebo	Phase 2b (ASCEND)	Corroborate Phase 1b results in a placebo-controlled trial and evaluate 2 dose regimens of certepetide for dose optimization
Lisata [United States]	First- and Second-line Cholangiocarcinoma (CCA): 1L CCA: Gemcitabine/cisplatin/durvalumab + certepetide or placebo 2L CCA: FOLFOX + certepetide or placebo	Phase 2a (BOLSTER)	Assess certepetide safety and effectiveness in cholangiocarcinoma in a placebo-controlled trial (proof-of-concept)
KUCC/Lisata* [United States]	Pancreatic, Colon & Appendiceal Cancers; FOLFIRINOX + panitumumab** with certepetide	Phase 1b/2a (CENDIFOX)	Tumor immuno-profiling pre- & post- treatment and certepetide effectiveness assessment in combination with chemo and an EGFR inhibitor (open-label)
Qilu [China]	First-line mPDAC; Gemcitabine/nab-paclitaxel + certepetide	Phase 1b/2a	Assess safety, PK and therapeutic effect of certepetide in Chinese patients (open-label)
WARPININE/Lisata [Australia]	Locally Advanced, Non-Resectable PDAC; Gemcitabine/nab-paclitaxel/durvalumab + certepetide	Phase 1b/2a (ILSTA)	Assess certepetide safety and effectiveness in combination with IO & Chemo in locally advanced PDAC; determine if inoperable tumors can become operable (open-label)
Tartu University/Lisata* [Estonia/Latvia]	First-line Glioblastoma Multiforme (GBM); Temozolomide +/- certepetide	Phase 2a	Assess certepetide safety and effectiveness in additional tumor type (GBM) in a placebo-controlled trial
Qilu [China]	First-line mPDAC; Gemcitabine/Nab-paclitaxel + certepetide	Phase 2b	Continue development of certepetide in China (placebo controlled)
Lisata [United States]	Second-line mPDAC; Gemcitabine/nab-paclitaxel + continuous infusion of certepetide or placebo	Phase 1b/2a (FORTIFIDE)	Evaluate the safety, tolerability, and efficacy of a 4-hour continuous infusion of certepetide in combination with SoC in subjects with mPDAC who have progressed on FOLFIRINOX. Haystack MRD™ technology to measure ctDNA for early efficacy exploration.

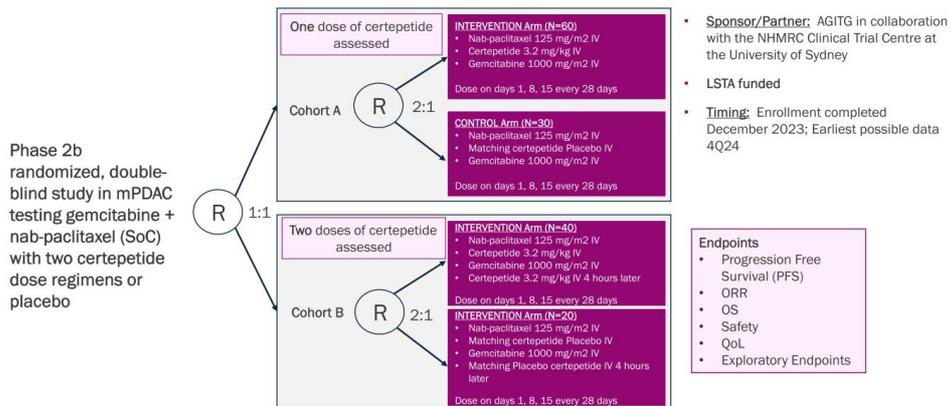
*Investigator-initiated trial

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

ASCEND: Phase 2b, blinded, randomized trial in mPDAC

Sponsor/Partner	<ul style="list-style-type: none">Australasian Gastro-Intestinal Trials Group (AGITG) in collaboration with the NHMRC Clinical Trials Centre at the University of SydneyLisata funded (LSTA eligible for ~43% rebate on all qualified R&D expenses in AUS)
Objective	<ul style="list-style-type: none">Corroborate Phase 1b results in a placebo-controlled studyDetermine if a second dose of certepetide further improves patient outcomes
Design	<ul style="list-style-type: none">Phase 2b randomized, double-blind study in mPDAC testing gemcitabine + nab-paclitaxel SoC with one of two certepetide dose regimens or placebo
Study Size	<ul style="list-style-type: none">N=158 (~30 sites in Australia and New Zealand)
Endpoints	<ul style="list-style-type: none">Primary: Progression Free SurvivalSecondary: AEs, SAEs, Overall Survival, Objective Tumor Response Rate
Timing	<ul style="list-style-type: none">Enrollment completed December 2023Earliest possible data 4Q24

ASCEND: Phase 2b, blinded, randomized trial in mPDAC



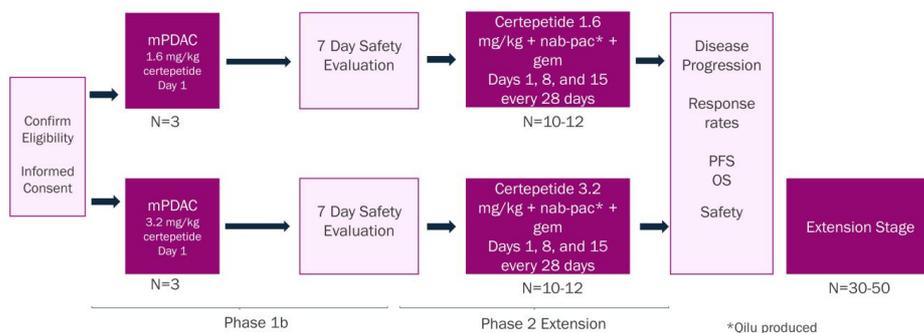
Phase 1b/2a open-label trial in mPDAC in China

Sponsor/Partner	<ul style="list-style-type: none">▪ Qilu Pharmaceutical (funds all development in China)
Objective	<ul style="list-style-type: none">▪ Evaluate safety, pharmacokinetics and preliminary efficacy of certepetide added to SoC in Chinese patients with mPDAC
Design	<ul style="list-style-type: none">▪ Phase 1b/2a open-label study in advanced mPDAC patients of Chinese ethnicity testing SoC chemotherapy (gemcitabine + Qilu-produced nab-paclitaxel) in combination with certepetide
Study Size	<ul style="list-style-type: none">▪ N=50 (~15 sites)
Endpoints	<ul style="list-style-type: none">▪ Primary: AEs, SAEs, Objective Response Rate, Duration of Response, Disease Control Rate, Overall Survival, and Progression Free Survival▪ Secondary: Pharmacokinetic parameters
Timing	<ul style="list-style-type: none">▪ Final data anticipated 2H2024

Phase 1b/2a open-label trial in mPDAC in China

Phase 1b/2a study evaluating the safety, pharmacokinetics, and preliminary efficacy of certepetide for injection in Chinese patients with advanced metastatic pancreatic ductal adenocarcinoma

- **Sponsor/Partner:** Qilu Pharmaceutical (funds all development in China)
- **Timing:** Final data anticipated 2H2024

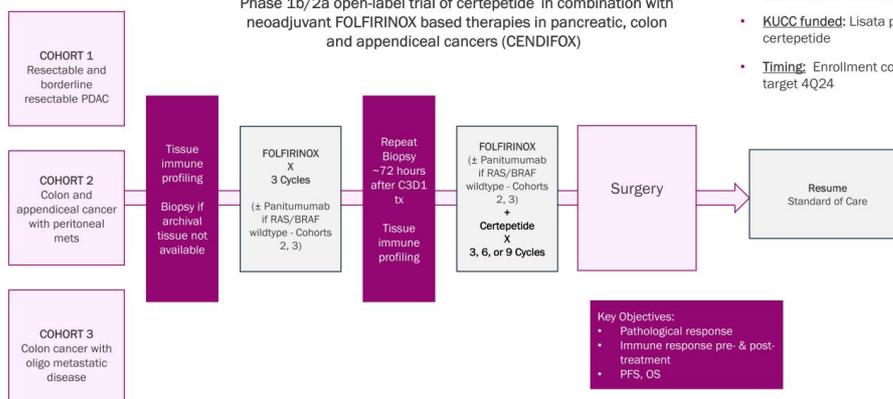


CENDIFOX: Phase 1b/2a open-label trial in PDAC and other cancers

Sponsor/Partner	<ul style="list-style-type: none">University of Kansas Medical Center (Investigator initiated trial in U.S.)KUCC funded; Lisata provides certepetide
Objective	<ul style="list-style-type: none">Evaluate the safety and therapeutic effect of certepetide in combination with neoadjuvant FOLFIRINOX-based therapies and an EGFR inhibitor for the treatment of pancreatic, colon and appendiceal cancers and determine immuno-profiling in tumor pre- & post- treatment
Design	<ul style="list-style-type: none">Phase 1b/2a open-label study in resectable pancreatic, colon with oligo metastases and appendiceal with peritoneal metastases cancers testing SoC chemotherapy (neoadjuvant FOLFIRINOX-based therapies) with certepetide ± panitumumab
Study Size	<ul style="list-style-type: none">N=51 (21 PDAC, 15 colon and 15 appendiceal)
Endpoints	<ul style="list-style-type: none">Primary: Drug SafetySecondary: Overall Survival, Disease-free Survival, Overall Response Rate, R0 Resection Rate, Pathological Response Rate
Timing	<ul style="list-style-type: none">Enrollment completion target 4Q24

CENDIFOX: Phase 1b/2a open-label trial in PDAC and other cancers

Phase 1b/2a open-label trial of certepetide in combination with neoadjuvant FOLFIRINOX based therapies in pancreatic, colon and appendiceal cancers (CENDIFOX)



- **Sponsor/Partner:** University of Kansas Medical Center (ITT)
- **KUCC funded:** Lisata provides certepetide
- **Timing:** Enrollment completion target 4Q24

Key Objectives:

- Pathological response
- Immune response pre- & post-treatment
- PFS, OS

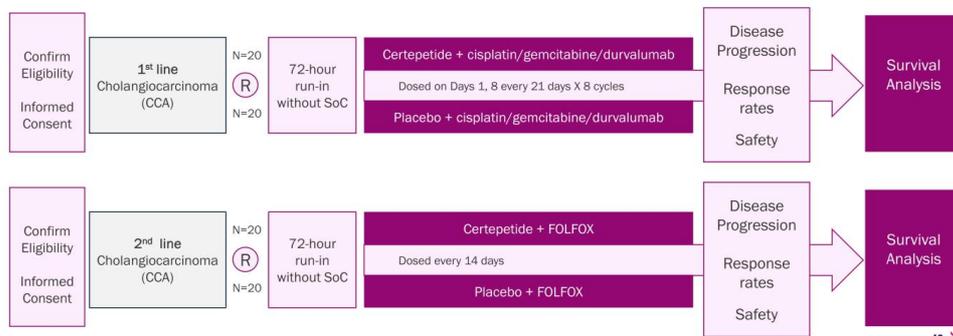
BOLSTER: Phase 2 blinded, randomized trial in Cholangiocarcinoma

Sponsor/Partner	<ul style="list-style-type: none">▪ Lisata (U.S.)
Objective	<ul style="list-style-type: none">▪ Evaluate the preliminary efficacy, safety and tolerability of certepetide in combination with standards of care in subjects with first- and second-line cholangiocarcinoma
Design	<ul style="list-style-type: none">▪ Phase 2 randomized, double-blind, placebo-controlled, proof-of-concept trial in first- and second-line cholangiocarcinoma testing corresponding SoC with certepetide or placebo
Study Size	<ul style="list-style-type: none">▪ N=80 (N=40 per tumor type)▪ 1:1 SoC + certepetide or SoC + placebo
Endpoints	<ul style="list-style-type: none">▪ Primary: OS▪ Secondary: Safety, ORR, PFS
Timing	<ul style="list-style-type: none">▪ Enrollment completed for 1L CCA▪ Enrollment anticipated July 2024 for 2L CCA

BOLSTER: Phase 2 blinded, randomized PoC trial in various cancers

Phase 2a, double-blind, placebo-controlled, multi-center, randomized study evaluating certepetide when added to standard of care (SoC) versus standard of care alone in subjects with first- and second-line cholangiocarcinoma

- **Sponsor:** Lisata
- **Timing:**
 - Enrollment completed for 1L CCA
 - Enrollment anticipated July 2024 for 2L CCA



Phase 2 double-blind, placebo-controlled trial in mPDAC in China

Sponsor/Partner	<ul style="list-style-type: none">▪ Qilu Pharmaceutical (funds all development in China)
Objective	<ul style="list-style-type: none">▪ Further evaluate safety and therapeutic efficacy of certepetide when added to SoC in Chinese patients with locally advanced unresectable mPDAC
Design	<ul style="list-style-type: none">▪ Phase 2b, double-blind, placebo-controlled, randomized study evaluating certepetide + SoC (Qilu-produced nab-paclitaxel and gemcitabine) vs. placebo + SoC
Study Size	<ul style="list-style-type: none">▪ N=120 (1:1 SoC + certepetide or SoC + placebo)
Endpoints	<ul style="list-style-type: none">▪ Objective response rate, progression free survival, duration of response, disease control rate, overall survival▪ Safety
Timing	<ul style="list-style-type: none">▪ Trial initiated 2Q24

Phase 2 blinded, placebo-controlled trial in mPDAC in China

Phase 2b, double-blind, placebo-controlled, randomized, multicenter study evaluating the safety and efficacy of certepetide when added to standard of care (nab-paclitaxel and gemcitabine) vs. standard of care alone and placebo in Chinese subjects with locally advanced unresectable mPDAC

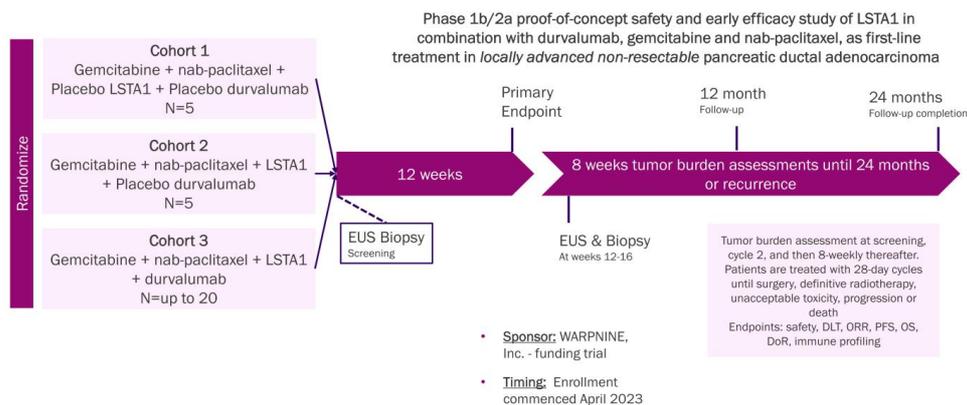
- **Sponsor/Partner:** Qilu Pharmaceutical (funds all development in China)
- **Timing:** Trial initiated 2Q24



iLSTA: Phase 1b/2a trial in locally advanced PDAC with chemo & IO

Sponsor/Partner	<ul style="list-style-type: none">WARPNINE, Inc. (registered charity in Australia) is funding trialLisata providing study drug
Objective	<ul style="list-style-type: none">Evaluate safety and therapeutic effect of LSTA1 in combination with IO & Chemo in locally advanced non-resectable pancreatic ductal adenocarcinoma (PDAC); determine if inoperable tumors can become operable
Design	<ul style="list-style-type: none">Phase 1b/2a proof-of-concept safety and early efficacy study of LSTA1 in combination with durvalumab, gemcitabine and nab-paclitaxel, as first-line treatment in <i>locally advanced</i> non-resectable pancreatic adenocarcinoma
Study Size	<ul style="list-style-type: none">N=30
Endpoints	<ul style="list-style-type: none">Safety and tolerability; 28-day DLTsObjective response rate, PFS, OS, duration of response, immune cell infiltration
Timing	<ul style="list-style-type: none">Enrollment commenced April 2023

iLSTA: Phase 1b/2a trial in locally advanced PDAC with chemo & IO



Phase 2a trial of certepetide with SoC in first-line GBM

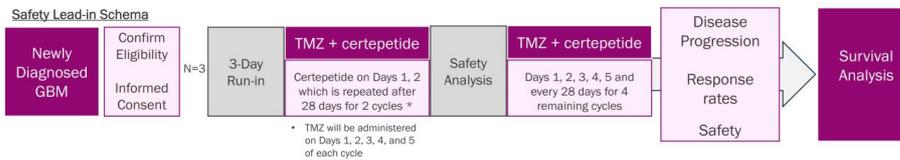
Sponsor/Partner	<ul style="list-style-type: none">▪ Tartu University Hospital (Investigator initiated trial in Estonia)▪ Lisata providing study drug and funding trial
Objective	<ul style="list-style-type: none">▪ Evaluate safety, tolerability, and therapeutic effect of certepetide in combination with standard-of-care (temozolomide) in patients with previously untreated Glioblastoma Multiforme
Design	<ul style="list-style-type: none">▪ Phase 2a proof-of-concept, double-blind, placebo-controlled, randomized study evaluating certepetide when added to standard of care (temozolomide) versus SoC and placebo in subjects with newly diagnosed Glioblastoma Multiforme (GBM)
Study Size	<ul style="list-style-type: none">▪ N=30 total (N=3 safety run-in, N=18 in main study schema)
Endpoints	<ul style="list-style-type: none">▪ Safety, tolerability▪ ORR, PFS, OS, disease control rate
Timing	<ul style="list-style-type: none">▪ Enrollment commenced December 2023

Phase 2a trial of certepetide with SoC in first-line in GBM

Phase 2a proof-of-concept double-blind, placebo-controlled, randomized, proof-of-concept study evaluating certepetide when added to standard of care (temozolomide) versus temozolomide and matching certepetide placebo in subjects with newly diagnosed GBM

- **Sponsor:** Tartu University Hospital; Estonia
- **Funding:** Lisata
- **Timing:** Enrollment commenced December 2023

Safety Lead-in Schema



Main Study Schema



FORTIFIDE: Phase 1b/2a continuous infusion study of certepetide

Sponsor/Partner	<ul style="list-style-type: none">▪ Lisata (U.S. only)
Objective	<ul style="list-style-type: none">▪ Evaluate the safety, tolerability, pharmacodynamics, pharmacokinetics, and efficacy of certepetide when given as a 4-hour continuous infusion in combination with SoC in subjects with second-line mPDAC who have progressed on FOLFIRINOX. Haystack Oncology MRD™ technology to measure ctDNA for early efficacy exploration.
Design	<ul style="list-style-type: none">▪ Phase 1b/2a, double-blind, placebo-controlled, three-arm, randomized study evaluating the following treatment arms in subjects with second-line mPDAC who have progressed on FOLFIRINOX:<ul style="list-style-type: none">▪ an intravenous push of certepetide with continuous 4-hour infusion + SoC▪ a single intravenous push of certepetide with continuous infusion of matching placebo + SoC▪ an intravenous push of matching placebo with a continuous infusion of matching placebo + SoC
Study Size	<ul style="list-style-type: none">▪ N=30
Endpoints	<ul style="list-style-type: none">▪ Safety and tolerability▪ PFS, OS
Timing	<ul style="list-style-type: none">▪ First patient treated target 4Q24

FORTIFIDE: Phase 1b/2a continuous infusion study of certepetide

