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

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

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

Delaware	**001-33650**	**22-2343568**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(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 November 12, 2024, Lisata Therapeutics, Inc. (the "Company") issued a press release in connection with its financial results for the third quarter ended September 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
99.1	Press Release, dated November 12, 2024
99.2	Lisata Therapeutics, Inc. Corporate Presentation, November 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: November 12, 2024

Exhibit 99.1

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

Robust and expanding development portfolio with multiple key data readouts projected over the next 18 months

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

BASKING RIDGE, N.J. (November 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 third quarter ended September 30, 2024.

"We are pleased to share the progress made in the third quarter of 2024, highlighted by the advancement of our robust development portfolio centered around our novel product candidate, certepetide," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Lisata. "While we await preliminary results from Cohort A of the Phase 2b ASCEND trial expected this quarter, we continue to explore the broad application of certepetide's unique mechanism of action. Our development portfolio now encompasses multiple clinical and preclinical trials evaluating certepetide for the treatment of various solid tumors, including pancreatic, cholangiocarcinoma, glioblastoma, colon, appendiceal, and melanoma. In addition, certepetide is being evaluated in a preclinical non-cancerous setting for endometriosis. All our studies are designed to yield data during the coming year, and we look forward to a data-rich 2025."

Development Portfolio Highlights

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

Certepetide is an investigational drug designed to selectively activate the C-end rule active transport mechanism in a tumor specific manner, resulting in systemically co-administered anti-cancer agents more efficiently penetrating and accumulating in the tumor. Additionally, certepetide has been shown to modify the tumor microenvironment, diminishing its immunosuppressive nature, enhancing cytotoxic T cell concentration and inhibiting the metastatic cascade. Lisata and its collaborators have amassed significant non-clinical data demonstrating enhanced delivery of various existing and emerging anti-cancer therapies, including chemotherapies, 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 demonstrate its ability to enhance the effectiveness of standard-of-care ("SoC") chemotherapy for pancreatic cancer as well as the combination of chemotherapy and immunotherapy in a variety of solid tumors. 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, osteosarcoma, and cholangiocarcinoma (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"). The trial is being conducted at 25 sites in Australia and New Zealand led by the Australasian Gastro-Intestinal Trials Group ("AGITG") 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. Following the completion of enrollment in the fourth quarter of 2023, data from an interim analysis of the 95 Cohort A patients (single dose of certepetide administered with SoC) will be presented at the American Society of Clinical Oncology Gastrointestinal Cancers Symposium in January of 2025. Data from the 60 patients in Cohort B patients (single dose of certepetide administered with SoC plus a second dose of certepetide four hours after the first) is expected in mid-2025 with a final analysis of both Cohorts available thereafter.
- 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 previously announced that the first patient has been treated in the second-line CCA cohort, with enrollment completion expected in the first half of 2025.

- 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. With 24 of the 30 patients enrolled, enrollment remains on track to be completed by the first half of 2025.
- 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 glioblastoma multiforme (“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. Enrollment completion is expected in the second half of 2025.
- 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 quarter of 2025.

As recently announced, Lisata has entered into multiple research collaborations, including a sponsored research agreement with the University of Cincinnati to assess certepetide in combination with bevacizumab (a VEGF inhibitor) in a preclinical murine model for the treatment of endometriosis. Lisata is also partnering with Valo Therapeutics (“ValoTx”) to investigate the benefits of combining certepetide with ValoTx's platform technology, PeptiCRAd, and a checkpoint inhibitor in a preclinical murine model for the treatment of melanoma.

Third Quarter 2024 Financial Highlights

For the three months ended September 30, 2024, operating expenses totaled $5.3 million, compared to $6.0 million for the three months ended September 30, 2023, representing a decrease of $0.6 million or 10.5%.

Research and development expenses were approximately $2.5 million for the three months ended September 30, 2024, compared to $3.4 million for the three months ended September 30, 2023, representing a decrease of $0.8 million or 24.8%. This was primarily due to a reduction in clinical research organization expenses associated with the Company’s Phase 2a BOLSTER trial as a result of trial protocol modifications and lower equity expenses. In addition, there were start-up expenses in the prior year related to the GBM study.

General and administrative expenses were approximately $2.8 million for the three months ended September 30, 2024, compared to $2.6 million for the three months ended September 30, 2023, representing an increase of $0.2 million or 8.1%. This was primarily due to higher consulting expenses.

Overall, net losses were $4.9 million for the three months ended September 30, 2024, compared to $5.3 million for the three months ended September 30, 2023.

Balance Sheet Highlights

As of September 30, 2024, Lisata had cash, cash equivalents, and marketable securities of approximately $35.9 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, November 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 internalizing RGD, or Arginylglycylaspartic acid, (iRGD) cyclic peptide product candidate, certepetide, 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 1.5 years and believes that its projected capital will fund operations into early 2026, encompassing anticipated data milestones from its ongoing and planned clinical trials. Learn more about certepetide's mechanism of action in our short film. 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 cholangiocarcinoma 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Statement of Operations Data:				
Research and development	$ 2,542	$ 3,380	$ 8,384	$ 9,721
General and administrative	2,794	2,584	9,076	9,962
Total operating expenses	**5,336**	**5,964**	**17,460**	**19,683**
Operating loss	**(5,336)**	**(5,964)**	**(17,460)**	**(19,683)**
Investment income, net	451	714	1,533	2,053
Other expense, net	(45)	(11)	(246)	(175)
Net loss before benefit from income taxes and noncontrolling interests	**(4,930)**	**(5,261)**	**(16,173)**	**(17,805)**
Benefit from income taxes	—	—	(798)	(2,330)
Net loss	**(4,930)**	**(5,261)**	**(15,375)**	**(15,475)**
Less - net income attributable to noncontrolling interests	—	—	—	—
Net loss attributable to Lisata Therapeutics, Inc. common stockholders	**$ (4,930)**	**$ (5,261)**	**$ (15,375)**	**$ (15,475)**
Basic and diluted loss per share attributable to Lisata Therapeutics, Inc. common stockholders	**$ (0.59)**	**$ (0.65)**	**$ (1.85)**	**$ (1.92)**
Weighted average common shares outstanding	**8,321**	**8,141**	**8,307**	**8,050**

	September 30, 2024	December 31, 2023
	(unaudited)	
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$35,856	$50,535
Total assets	38,199	54,694
Total liabilities	4,763	6,800
Total equity	33,436	47,894

# # #

Exhibit 99.2

LISATA THERAPEUTICS

Targeted Therapy *Delivered*

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

Corporate Presentation | November 12, 2024
Nasdaq: LSTA

www.lisata.com

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
3

Lisata Therapeutics (Nasdaq: LSTA)

WHAT WE ARE

Clinical-stage therapeutics company rapidly developing a novel solid tumor targeting and penetration technology with tumor microenvironment (TME) modifying properties.

OUR MISSION

To enhance the treatment benefits of existing and emerging therapies for solid tumors and similar diseases without additional side effects utilizing an approach that is patient-friendly and pharmacoeconomically attractive.

Lisata Therapeutics (Nasdaq: LSTA): Key attributes

Seasoned management with successful international drug development experience and expertise

Proprietary field-leading technology with global IP protection extending beyond 2040

Multiple product and business milestones projected over the next 12 - 18 months

Platform technology validated by existing partnerships with potential for many others

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

Seasoned leadership with proven history of 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 therapeutical areas. He recently was recognized as a *2024 PharmaVoice Top 100 Standout Leader*.

Regado Biosciences · Schering-Plough · Æterna Zentaris · Hoechst Marion Roussel · Ciba-Geigy · Rhône-Poulenc Rorer

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.

ICON · IQVIA · FDA · OPTUMInsight · AstraZeneca · B|BRAUN

Gregory Berkin
Chief Information Officer and Data Protection Officer

James Nisco
SVP of Finance and Treasury and Chief Accounting Officer

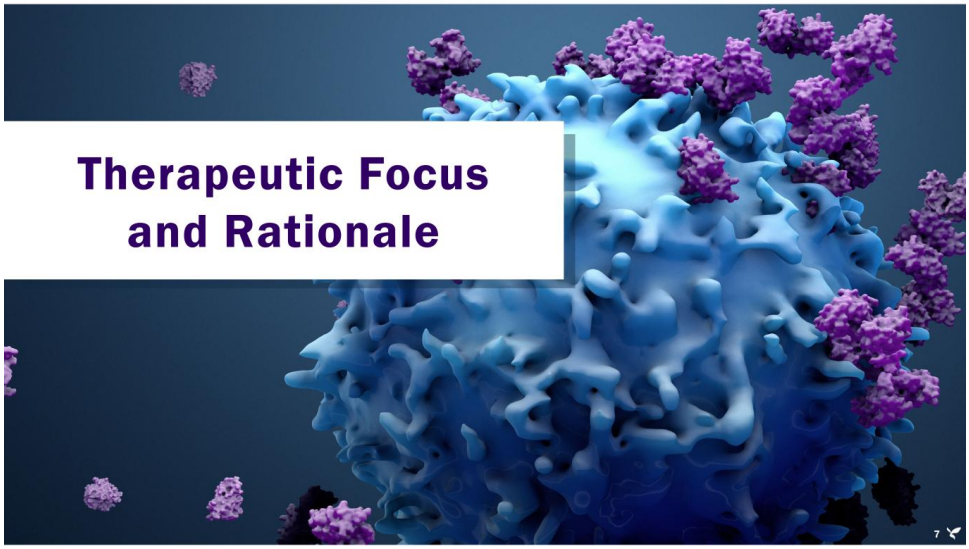
Tariq Imam
VP of BD and Operations and Corporate Counsel

John Menditto
VP of Investor Relations and Corporate Communications

Bill Sietsema, PhD
VP of Global Regulatory Affairs

Ryan Quick
VP of Chemistry, Manufacturing and Controls

Detailed bios can be found at www.lisata.com


Therapeutic Focus
and Rationale

Improved solid tumor treatment remains a vital, growing global need

Over the next 30 years, cancer will cost the world $25 trillion[1]

Globally in 2022[2],[3]

- 20 million new cancer cases
- 10 million deaths
- >90% solid tumors

Globally in 2050[4]

- 35 million new cancer cases
- 18.5 million deaths
- >90% solid tumors

Examples of solid tumors: Lung, breast, pancreas, liver, bile duct (cholangiocarcinoma), kidneys, ovaries, brain, colon, prostate, esophagus, and head & neck.

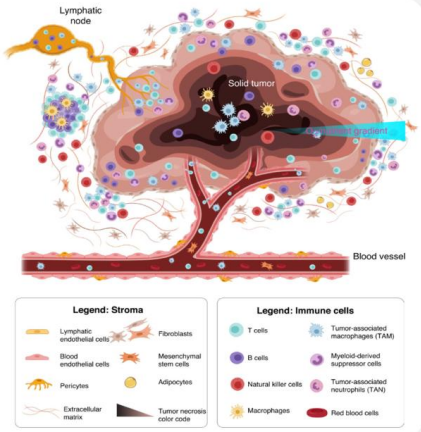
Pancreatic Cancer Stats

- By 2030, PDAC* is predicted to be the second most common cause of cancer mortality[5]
- Today, only 3% of PDAC patients survive for 5 years, with life expectancy at diagnosis of just 4.6 months

**Pancreatic ductal adenocarcinoma (PDAC)*

[1] Cancer will cost the world $25 trillion over next 30 years (nature.com)
[2] https://gco.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.
[3] https://seer.cancer.gov/statfacts/html/common.html; data retrieved Nov 2, 2023.
[4] https://www.who.int/news/item/01-02-2024-global-cancer-burden-growing--amidst-mounting-need-for-services; data retrieved Oct 14, 2024.
[5] Europe Is Facing a Pancreatic Cancer Emergency - Medscape - January 25, 2024.

Current solid tumor treatments & patient outcomes are suboptimal



Challenging tumor morphology and tumor microenvironment (TME) present major obstacles to optimized outcomes

- Tumor stroma acts as a physical barrier to anti-cancer agents
- An immunosuppressive 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

Diagram source: Abizanda-Campo, S. et al, *Microsyst Nanoeng* **9**, 154 (2023)

Certepetide designed to optimize solid tumor treatment outcomes

CHALLENGE	APPROACH
Dense stromal barrier physically inhibiting drug entry	Employ *internalizing* RGD* (iRGD) peptide to target tumor and trigger CendR active transport
Immunosuppressive TME which impedes the immune system	Employ specific iRGD that reduces immunosuppressive T cells and recruits cytotoxic T cells
Frequent metastases	Employ specific iRGD that inhibits the metastatic cascade

SOLUTION: *Certepetide*

- In late-stage clinical development in several solid tumors based on strong preclinical and early clinical evidence
- **Converts tumor stroma from a barrier to a conduit for anti-cancer drugs**
- **Selectively reduces immunosuppressive T cells and increases cytotoxic T cells(1)**
- **Inhibits the metastatic cascade(2)**
- Agnostic to the anti-cancer modality with which it is applied; can be co-administered or molecularly bound (tethered)

*internalizing Arginylglycylaspartic acid (iRGD)

[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.
[2] Yuan, D., Duda, D., et al. CCA Foundation Conf. 2024 Poster. *Enhancing the efficacy of standard therapy in intrahepatic cholangiocarcinoma using LSTA1, a novel tumor targeting and penetration agent*


Partnerships
Noteworthy existing relationships and potential for many more
11

Existing partnerships support certepetide's promise & broad applicability

R&D alliances contribute resources with little to no commercial interest in certepetide

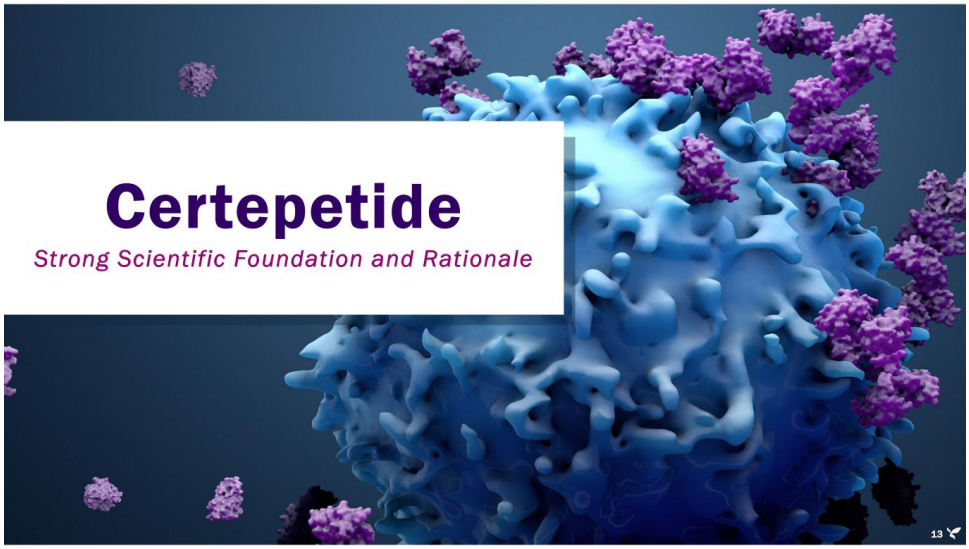
- ***Australasian Gastro-Intestinal Trials Group*** - Clinical Trialists Consortium (Australia & New Zealand)
- ***WARPNINE*** - Foundation (Australia)

*Strategic commercial partnership in China with **Qilu Pharmaceutical***

- Qilu granted exclusive rights in China, Taiwan, Hong Kong and Macau
- Qilu assumes all development and commercialization responsibilities/costs in licensed territories
- 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
Strong Scientific Foundation and Rationale
13

Certepetide mechanism of action: Unique, multi-step approach

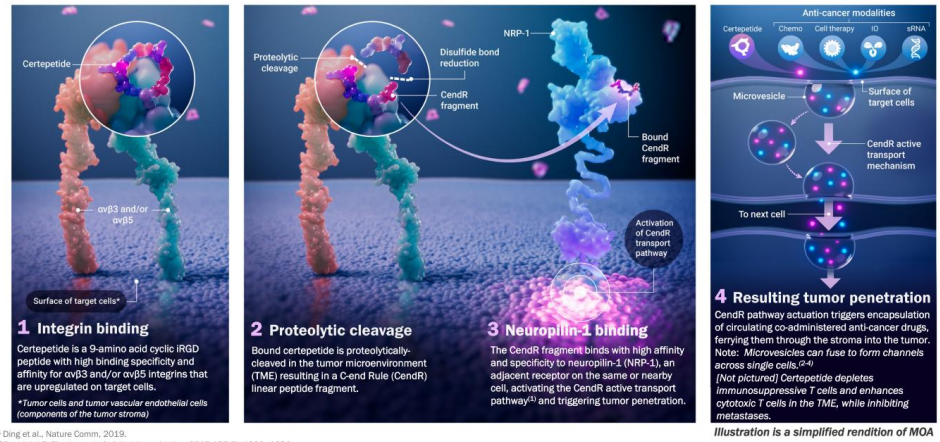


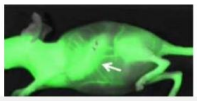
Illustration is a simplified rendition of MOA

[1] Ding et al., Nature Comm, 2019.
[2] Ruoslahti E. *The Journal of clinical investigation*. 2017;127(5), 1622–1624.
[3] Liu, X., et al. *J Clin Invest*. 2017;127(5):2007-2018.
[4] De Mendoza, T. H., Suzuki, K., et al. Tumor-penetrating therapy for β5 integrin-rich pancreas cancer. *Nat Commun* 12, 1541 (2021).

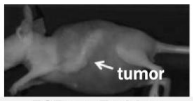
Certepetide/iRGD selectively promotes intratumoral penetration

Whole body imaging of mice with pancreatic ductal adenocarcinoma (arrow) dosed with Fluorescent Quantum Dots (FQDs) with and without certepetide[1],[2]

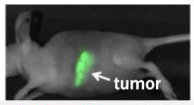
- Circulating FQDs result in whole body fluorescence
- Etching solution quenches fluorescence in circulation



FQDs

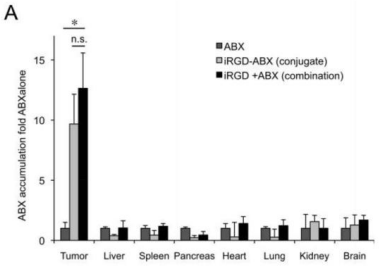


FQDs + Etching solution



Certepetide + FQDs + Etching solution

In the presence of iRGD, Abraxane (ABX) is selectively taken up by tumor tissue in mice[3]



[1] Braun et al., Nature Mater. 2014.
[2] Liu, Braun et al., Nature Comm. 2017.
[3] Sugahara et al 2010.

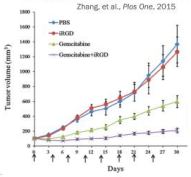
Certepetide is a proprietary iRGD; experiments denoting iRGD use a non-proprietary certepetide analog with differs in structure by a single acetyl group.

Broad applicability & activity of certepetide/iRGD consistently demonstrated

Sampling of >350 scientific publications showing improved survival

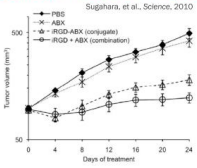
Lung cancer + gemcitabine

Zhang, et al., *Plos One*, 2015



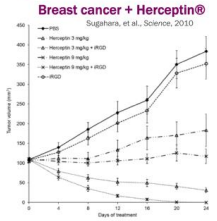
Breast cancer + nanoparticle nab-paclitaxel

Sugahara, et al., *Science*, 2010



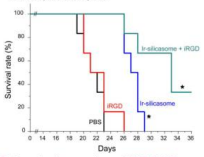
Breast cancer + Herceptin®

Sugahara, et al., *Science*, 2010



PDAC + irinotecan nanoparticles

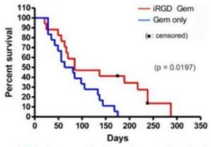
Liu X et al., J Clin Invest, 2017



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

PDAC + gemcitabine

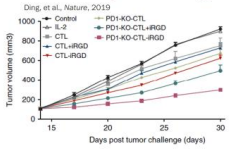
Hurtado de Mendoza et al, Nature Comms, 2021



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

GI cancer + adoptive cell therapy

Ding, et al., *Nature*, 2019



Certepetide is a proprietary iRGD; experiments denoting iRGD use a non-proprietary certepetide analog with differs in structure by a single acetyl group.

Certepetide/iRGD consistently improves immunotherapy efficacy in multiple preclinical solid tumor models

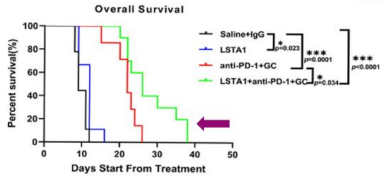
Study Description	Certepetide/iRGD vs. Control Group
▪ **Intrahepatic cholangiocarcinoma (ICC)** murine model ▪ Certepetide + anti-PD-1 + cytotoxics vs. controls	→ Significantly improved overall survival → Significantly reduced tumor volume → Significantly reduced metastases
▪ **Pancreatic adenocarcinoma (PDAC)** murine model ▪ Certepetide + anti-PD-L1 + cytotoxics vs. controls	
▪ **Prostate cancer** murine model ▪ iRGD vs. scrambled iRGDD control	→ Significantly reduced tumor size
▪ **Breast cancer** (human BT474) murine model ▪ Trastuzumab + iRGD vs. trastuzumab control	
▪ **Non-Small Cell Lung Cancer (NSCLC)** murine model ▪ Cetuximab + iRGD vs. cetuximab and iRGD control	
▪ **Gastric cancer** HGC27 tumor spheroids ▪ iRGD + natural killer T cells (NKT cells vs. NKT cells alone)	→ Significantly increased NKT cell penetration
▪ **Hepatocellular carcinoma (HCC)** murine model ▪ iRGD + NKT cells vs. NKT cells alone	→ Significantly reduced tumor size

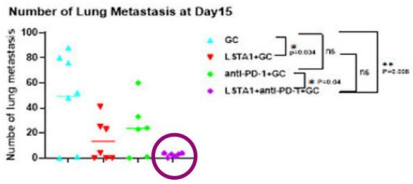
Certepetide is a proprietary iRGD; experiments denoting iRGD use a non-proprietary certepetide analog with differs in structure by a single acetyl group.

Certepetide improves immunotherapy impact in cholangiocarcinoma

- Intrahepatic cholangiocarcinoma (ICC) has an immunosuppressive TME and a dense desmoplastic stroma with abnormal vasculature which together impede anti-cancer agent efficacy
- Lung metastases often lead to a significant decline in survival
- Human ICC SoC (gemcitabine/cisplatin/durvalumab) efficacy improved with certepetide in murine model

ICC mouse model





**Certepetide was formerly known as LSTA1*

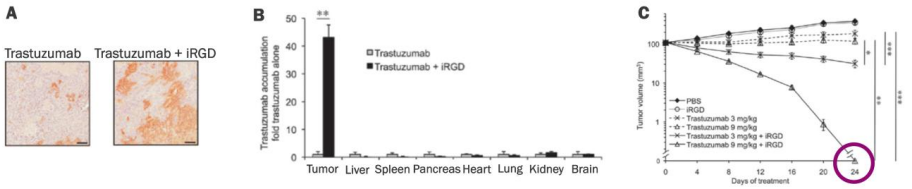
Certepetide combined with chemo- and immunotherapy improves survival, reduces morbidity and inhibits metastasis in cholangiocarcinoma mouse model

Yuan, D., Duda, D., et al. CCA Foundation Conf. (2024) Poster. *Enhancing the efficacy of standard therapy in intrahepatic cholangiocarcinoma using LSTA1, a novel tumor targeting and penetration agent*

iRGD enhances selective tumor penetration of trastuzumab

Mouse model injected with human BT474 breast tumors

Trastuzumab is a monoclonal Ab that inhibits HER2



- Panel A shows greater staining for trastuzumab in breast cancer tissue with iRGD
- Panel B shows remarkable selectivity for tumor tissue with iRGD
- Panel C shows iRGD co-administered with trastuzumab leads to **tumor shrinkage**

Sugahara, et al. 2010

Certepetide is a proprietary iRGD; experiments denoting iRGD use a non-proprietary certepetide analog with differs in structure by a single acetyl group.

Certepetide development strategy is composed of two main pillars

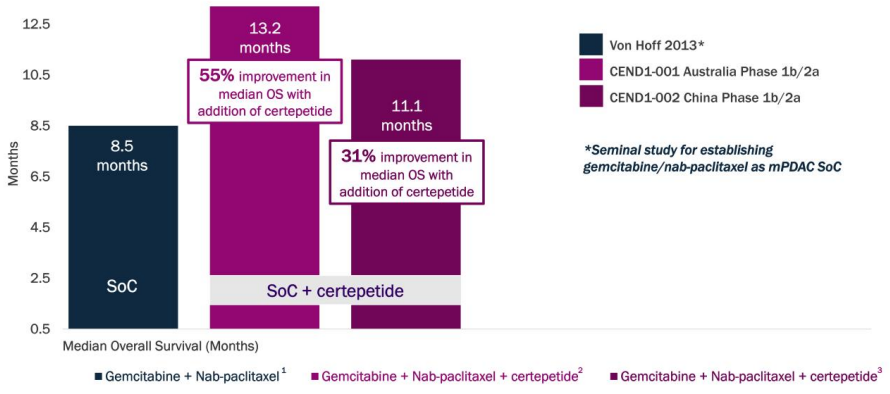
Pursue rapid global registration in pancreatic ductal adenocarcinoma (mPDAC), initially combined with gemcitabine/nab-paclitaxel standard-of-care (SoC)

- *Phase 2b 100% enrolled*
- *Phase 3 preparation underway*

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

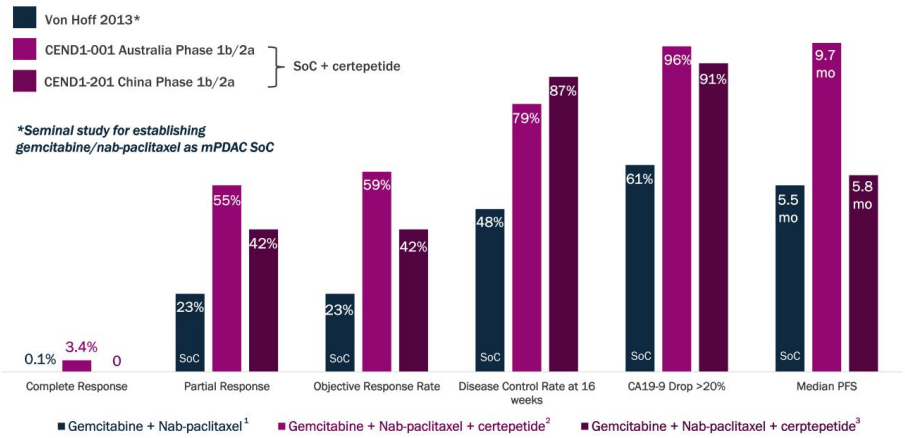
- *Multiple Phase 1b/2a studies underway*

Certepetide improved survival in *metastatic* pancreatic cancer in two independent multicenter, Phase 1b/2a studies



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

Certepetide demonstrated internal consistency of response in two Phase 1b/2a studies



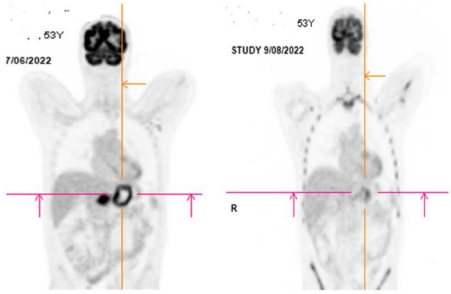
[1] Von Hoff D. et al., *New England Journal of Medicine*, 2013.
[2] Dean A. et al., *The Lancet Gastroenterology & Hepatology*, 2022
[3] QILU Pharmaceutical

Remarkable 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
- **25+ months with sustained complete response**

FDG-PET* scan June 2022 | FDG-PET scan Sept. 2022



Reduction in FDG activity demonstrated(1)

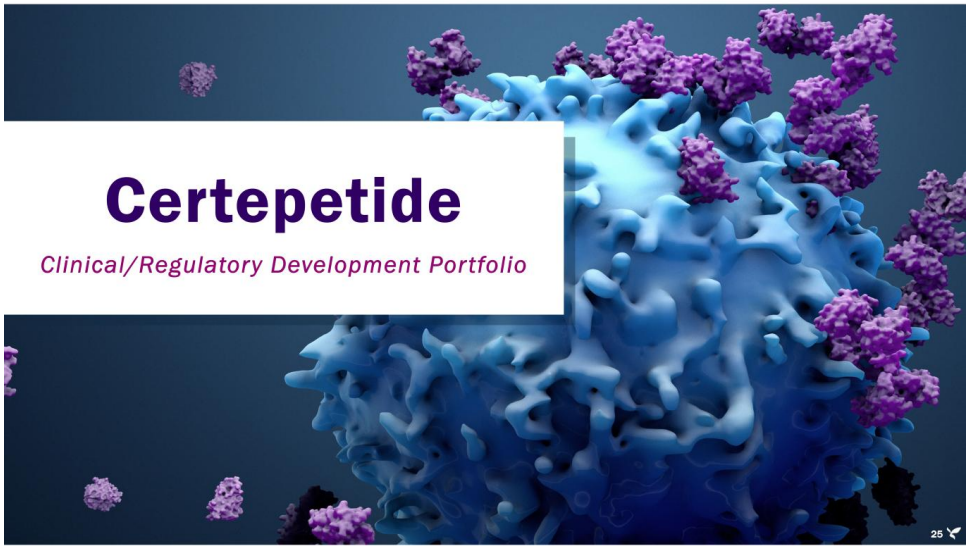
**Fluorodeoxyglucose (FDG)-positron emission tomography (PET)*

[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

Accumulating clinical data demonstrate certepetide's ability to augment anti-cancer efficacy of chemotherapy alone and with immunotherapy

Certepetide Clinical Data Summary to Date

- Two Phase 1b/2a clinical trials (CEND1-001 – Australia and CEND1-201 - China) demonstrate that certepetide plus chemotherapy SoC **improves overall survival in *metastatic* PDAC**
- Well-tolerated with no dose-limiting toxicity; AEs similar to companion therapy alone
- Sustained complete response in patient with metastatic gastroesophageal cancer
- Phase 1b/2a trial (iLSTA): randomized, patient-blinded interim data demonstrate:
  - Certepetide plus chemotherapy SoC and immunotherapy ***improves clinical outcomes in locally advanced* PDAC**


Certepetide
Clinical/Regulatory Development Portfolio
25

Certepetide special regulatory designations and benefits

FDA Fast Track Designation

- ***Pancreatic cancer (FDA)***

- Eligible for *Accelerated Approval, Priority Review and Rolling Review*
- Provides for program-specific guidance from and frequent communication with FDA

FDA Rare Pediatric Disease Designation

- ***Osteosarcoma (FDA)***

- Eligible for *Priority Review Voucher* upon approval; redeemable for a priority review for any subsequent marketing application, or may be sold or transferred
- Vouchers have sold recently for $75-$100 million and, historically, for up to $350 million

Orphan Drug Designations

- ***Pancreatic cancer (FDA & EMA)***
- ***Malignant glioma (FDA)***
- ***Osteosarcoma (FDA)***
- ***Cholangiocarcinoma (FDA)***

- Eligible for tax credits, marketing exclusivity, fee waivers and development grants
- Provides for specialized regulatory assistance from FDA's Office of Orphan Products Development

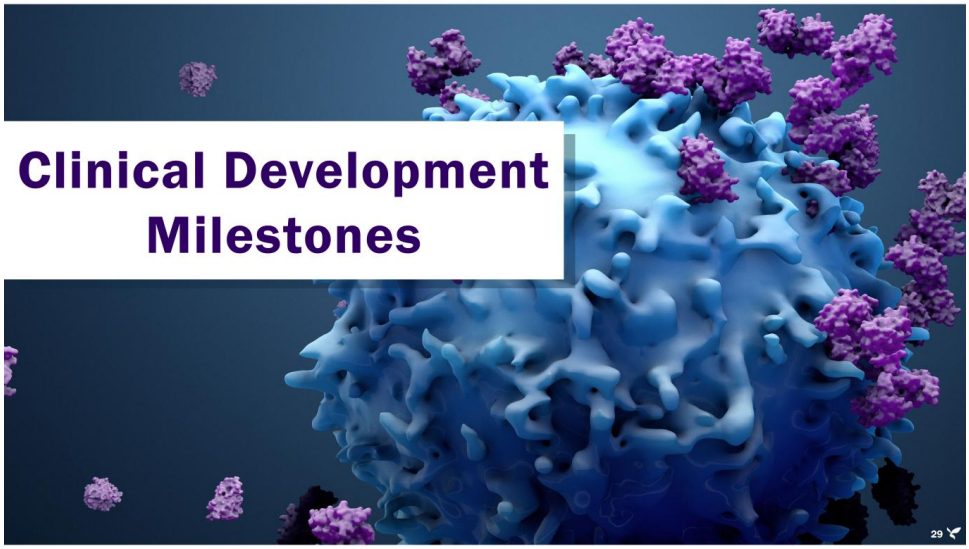
Certepetide capital efficient clinical development plan

Sponsor(s)	Indication	Description	Current Phase		
			Phase 1	Phase 2	Phase 3
AGITG/Lisata	***First-line mPDAC***	▪ **ASCEND:** Phase 2b, placebo-controlled trial **(N=158)** ▪ *Gemcitabine/nab-paclitaxel + certepetide or placebo* ▪ Australia/New Zealand	**Enrollment complete**		
Lisata	***First- and Second-line Cholangiocarcinoma (CCA)***	▪ **BOLSTER:** Phase 2a, placebo-controlled trial **(N=80)** ▪ *1L CCA: Gemcitabine/cisplatin/durvalumab with certepetide or placebo* ▪ *2L CCA: FOLFOX with certepetide or placebo* ▪ United States	**1L CCA Enrollment complete** **2L CCA Enrolling**		
KUCC/Lisata *Investigator-initiated trial*	***Pancreatic, Colon, and Appendiceal Cancers***	▪ **CENDIFOX:** Phase 1b/2a, open-label trial **(N=51)** ▪ *FOLFIRINOX + panitumumab* + certepetide* ▪ United States	**Enrolling**		
Qilu/Lisata	***First-line mPDAC***	▪ Phase 1b/2a, open-label trial **(N=41)** ▪ *Gemcitabine/nab-paclitaxel + certepetide* ▪ China	**Enrollment complete**		
WARPNINE/Lisata	***Locally advanced, non-resectable PDAC***	▪ **iLSTA:** Phase 1b/2a, open-label trial **(N=30)** ▪ *Gemcitabine/nab-paclitaxel/durvalumab + certepetide* ▪ Australia	**Enrolling**		
Tartu University/Lisata *Investigator-initiated trial*	***First-line Glioblastoma Multiforme (GBM)***	▪ Phase 2a, placebo-controlled trial **(N=30)** ▪ *Temozolomide +/- certepetide* ▪ Estonia/Latvia	**Enrolling**		
Qilu/Lisata	***First-line mPDAC***	▪ Phase 2, placebo-controlled trial **(N=120)** ▪ *Gemcitabine/nab-paclitaxel + certepetide* ▪ China	**Enrolling**		
Lisata	***Second-line mPDAC***	▪ **FORTIFIDE:** Phase 1b/2a placebo-controlled trial **(N=30)** ▪ Gemcitabine/nab-paclitaxel + continuous infusion of certepetide/placebo ▪ United States	**Enrolling soon**		

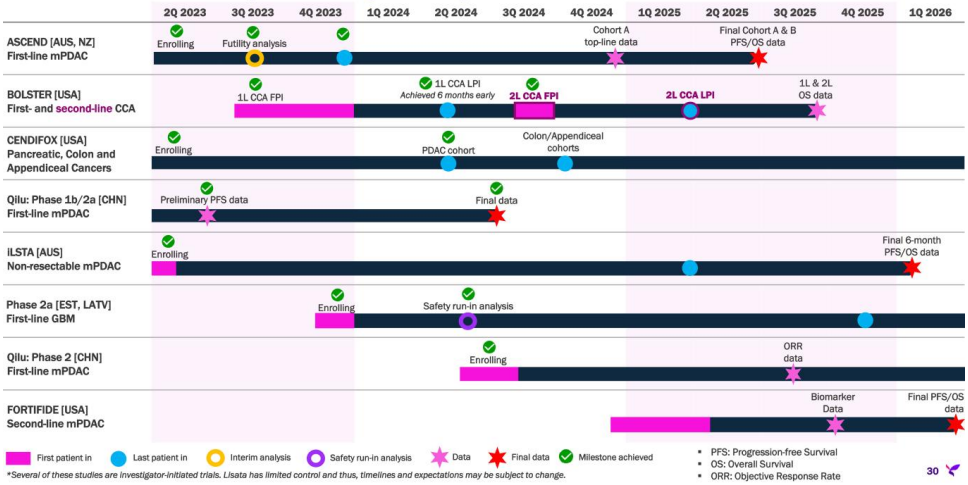
**Panitumumab may be added for colorectal or appendiceal patients without Ras mutation.*

Certepetide preclinical activities and milestones

Sponsor(s)	Indication	Objective and Description	Upcoming Milestones
University of Cincinnati/Lisata	*Endometriosis*	Assess the therapeutic effect of adding certepetide to bevacizumab (VEGF inhibitor) on the size and number of endometriotic lesions. ▪ Certepetide + bevacizumab ▪ Murine endometriosis model C57BL/6J ▪ United States	Target date for data: 1Q2025
Valo Therapeutics/Lisata	*Melanoma*	Assess the therapeutic effects of PeptiCRAd (oncolytic virus), certepetide, and a checkpoint inhibitor (CPI) on systemic T cell responses, T cell infiltration into tumors, and impact on tumor growth control. ▪ Certepetide + PeptiCRAd + CPI ▪ Murine melanoma model B16-OVA ▪ Finland	Target date for data: 2Q2025


Clinical Development
Milestones
29

A wealth of anticipated key certepetide clinical milestones



- PFS: Progression-free Survival
- OS: Overall Survival
- ORR: Objective Response Rate

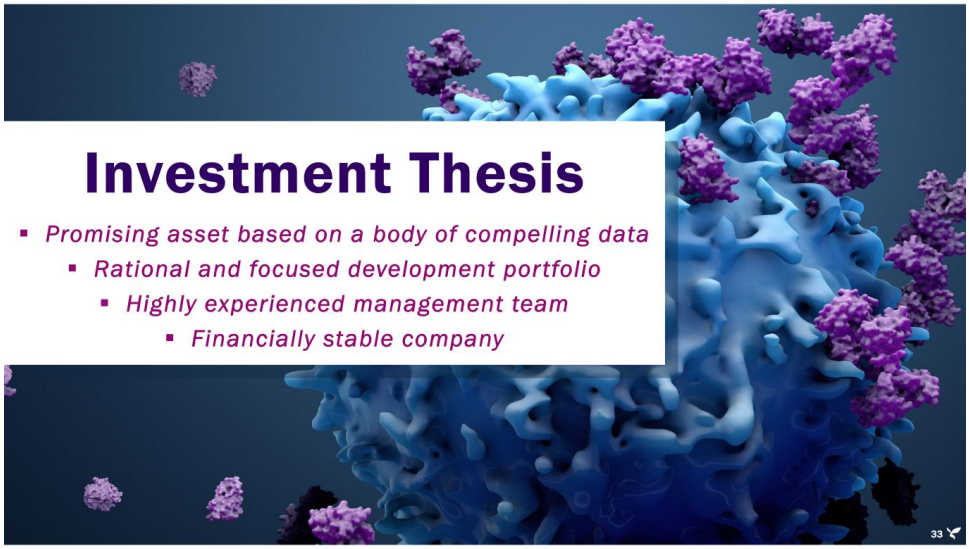
Several of these studies are investigator-initiated trials. Lisata has limited control and thus, timelines and expectations may be subject to change.


Financial
Highlights
31

Capital projected to fund all clinical programs to data

Cash & Investments As of 9/30/2024	Debt	Projected Cash Runway Into
$35.9M	**$0**	**1Q2026**

Common Shares Outstanding (9/30/2024):	8.3 million shares
Options Outstanding (9/30/2024): Exercise Price: $0.02 - $4.22 = 1,217,400 shares Exercise Price: > $4.22 = 237,100 shares	1.5 million shares
Warrants Outstanding (9/30/2024): Weighted Average Exercise Price: $40.52	1.5 million shares


Investment Thesis
Promising asset based on a body of compelling data
Rational and focused development portfolio
Highly experienced management team
Financially stable company
33

Key factors supporting investment in Lisata Therapeutics

PEOPLE	INTELLECTUAL PROPERTY	MILESTONES	CAPITAL	PARTNERING
Seasoned management with successful international drug development experience and expertise	Proprietary field-leading technology with global IP protection extending beyond 2040	Multiple product and business milestones projected over the next 12 - 18 months	$35.9 million cash*- no debt; Current development funded through critical data milestones	Platform technology validated by existing partnerships with potential for many others

* As of 9/30/2024; includes investments

LISATA THERAPEUTICS

Targeted Therapy *Delivered*

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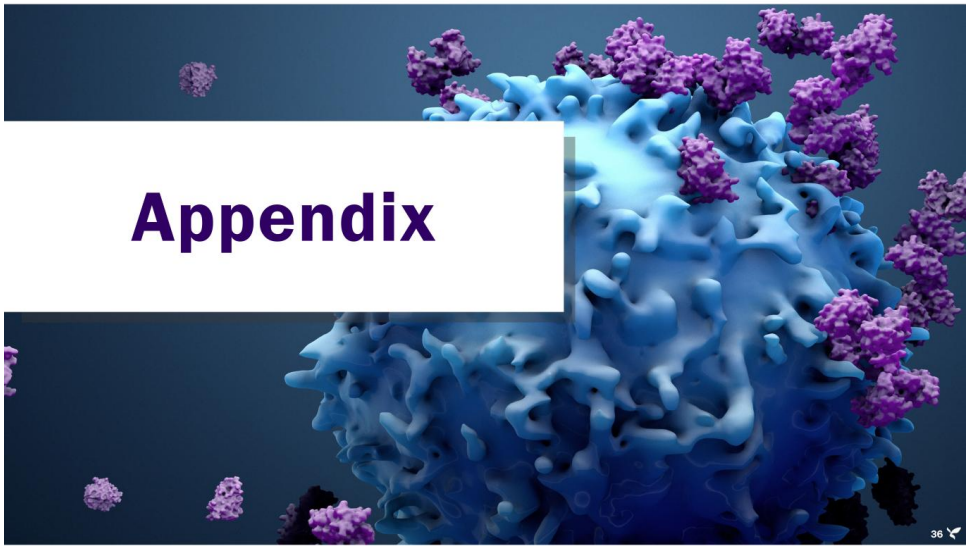
Nasdaq: LSTA | *www.lisata.com*


Appendix
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Certepetide capital efficient clinical 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)
WARPNINE/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.

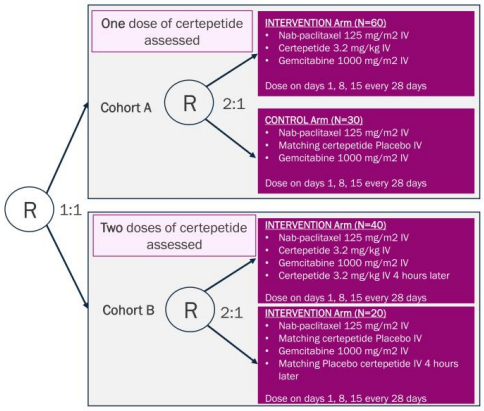
**Investigator-initiated trial*
***Panitumumab may be added for colorectal or appendiceal patients without Ras mutation*

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

Sponsor/Partner	▪ Australasian Gastro-Intestinal Trials Group (AGITG) in collaboration with the NHMRC Clinical Trials Centre at the University of Sydney ▪ Lisata funded (LSTA eligible for ~43% rebate on all qualified R&D expenses in AUS)
Objective	▪ Corroborate Phase 1b results in a placebo-controlled study ▪ Determine if a second dose of certepetide further improves patient outcomes
Design	▪ Phase 2b randomized, double-blind study in mPDAC testing gemcitabine + nab-paclitaxel SoC with one of two certepetide dose regimens or placebo
Study Size	▪ N=158 (~30 sites in Australia and New Zealand)
Endpoints	▪ Primary: Progression Free Survival ▪ Secondary: AEs, SAEs, Overall Survival, Objective Tumor Response Rate
Timing	▪ Enrollment completed December 2023 ▪ Earliest possible data 4Q24

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

Phase 2b randomized, double-blind study in mPDAC testing gemcitabine + nab-paclitaxel (SoC) with two certepetide dose regimens or placebo



- Sponsor/Partner: AGITG in collaboration with the NHMRC Clinical Trial Centre at the University of Sydney
- LSTA funded
- Timing: Enrollment completed December 2023; Earliest possible data 4Q24

Endpoints
- Progression Free Survival (PFS)
- ORR
- OS
- Safety
- QoL
- Exploratory Endpoints

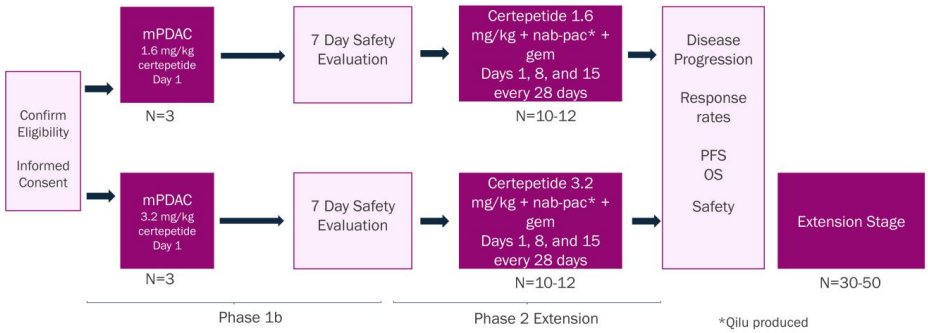
Phase 1b/2a open-label trial in mPDAC in China (CEND1-201)

Sponsor/Partner	▪ Qilu Pharmaceutical (funds all development in China)
Objective	▪ Evaluate safety, pharmacokinetics and preliminary efficacy of certepetide added to SoC in Chinese patients with mPDAC
Design	▪ 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	▪ N=50 (~15 sites)
Endpoints	▪ Primary: AEs, SAEs, Objective Response Rate, Duration of Response, Disease Control Rate, Overall Survival, and Progression Free Survival ▪ Secondary: Pharmacokinetic parameters
Timing	▪ Final data anticipated 2H2024

Phase 1b/2a open-label trial in mPDAC in China (CEND1-201)

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

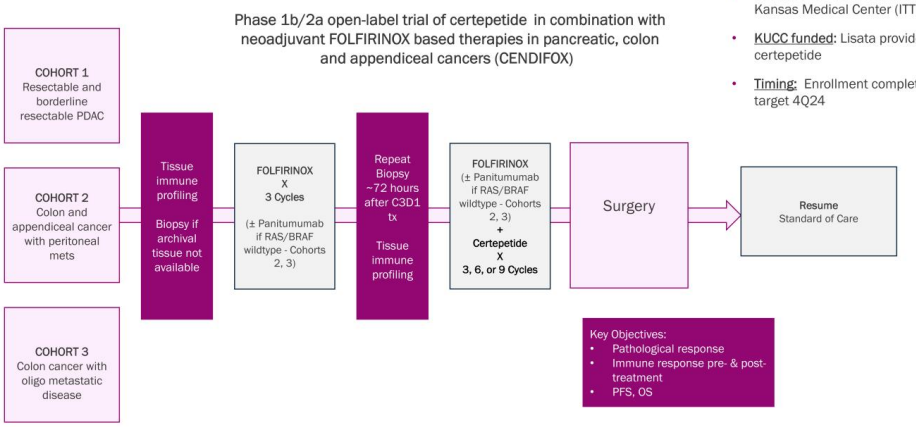


*Qilu produced

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

Sponsor/Partner	▪ University of Kansas Medical Center (Investigator initiated trial in U.S.) ▪ KUCC funded; Lisata provides certepetide
Objective	▪ 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	▪ 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	▪ N=51 (21 PDAC, 15 colon and 15 appendiceal)
Endpoints	▪ Primary: Drug Safety ▪ Secondary: Overall Survival, Disease-free Survival, Overall Response Rate, RO Resection Rate, Pathological Response Rate
Timing	▪ Enrollment completion target 4Q24

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



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

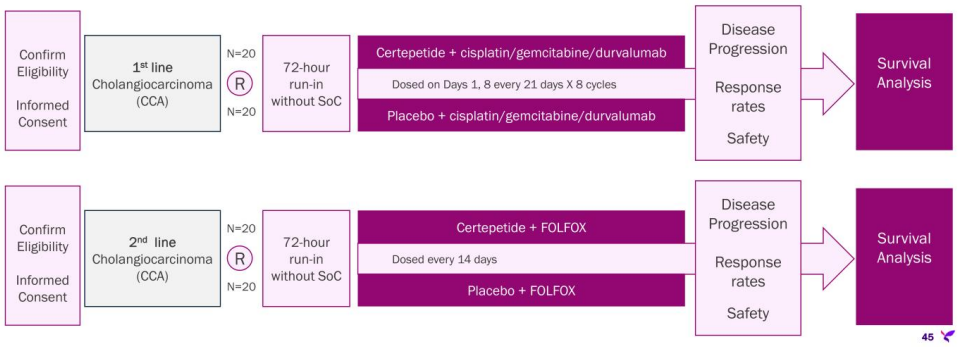
BOLSTER: Phase 2 blinded, randomized trial in Cholangiocarcinoma

Sponsor/Partner	▪ Lisata (U.S.)
Objective	▪ Evaluate the preliminary efficacy, safety and tolerability of certepetide in combination with standards of care in subjects with first- and second-line cholangiocarcinoma
Design	▪ 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	▪ N=80 (N=40 per tumor type) ▪ 1:1 SoC + certepetide or SoC + placebo
Endpoints	▪ Primary: OS ▪ Secondary: Safety, ORR, PFS
Timing	▪ Enrollment completed for 1L CCA ▪ Enrollment commenced July 2024 for 2L CCA

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

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

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



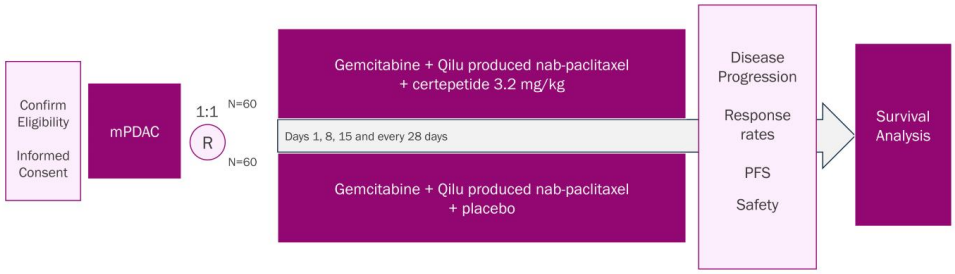
Phase 2 double-blind, placebo-controlled trial in mPDAC in China

Sponsor/Partner	▪ Qilu Pharmaceutical (funds all development in China)
Objective	▪ Further evaluate safety and therapeutic efficacy of certepetide when added to SoC in Chinese patients with locally advanced unresectable mPDAC
Design	▪ Phase 2b, double-blind, placebo-controlled, randomized study evaluating certepetide + SoC (Qilu-produced nab-paclitaxel and gemcitabine) vs. placebo + SoC
Study Size	▪ N=120 (1:1 SoC + certepetide or SoC + placebo)
Endpoints	▪ Objective response rate, progression free survival, duration of response, disease control rate, overall survival ▪ Safety
Timing	▪ 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

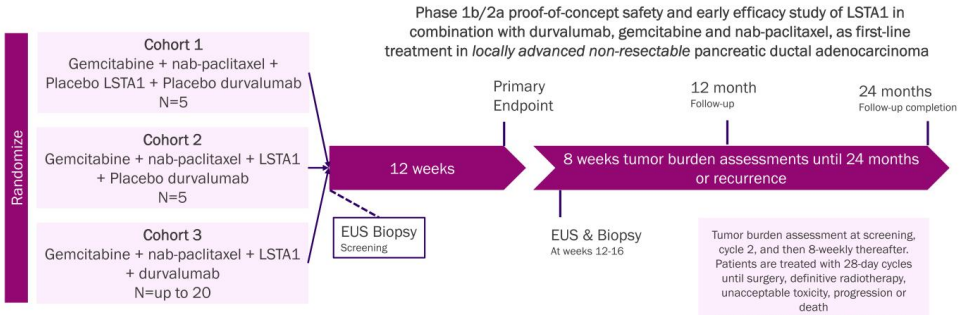
- Sponsor/Partner: Qilu Pharmaceutical (funds all development in China)
- Timing: Trial initiated 2Q24



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

Sponsor/Partner	▪ WARPNINE, Inc. (registered charity in Australia) is funding trial ▪ Lisata providing study drug
Objective	▪ 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	▪ 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 *locally advanced* non-resectable pancreatic adenocarcinoma
Study Size	▪ N=30
Endpoints	▪ Safety and tolerability; 28-day DLTs ▪ Objective response rate, PFS, OS, duration of response, immune cell infiltration
Timing	▪ Enrollment commenced April 2023

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



- Sponsor: WARPNINE, Inc. - funding trial
- Timing: Enrollment commenced April 2023

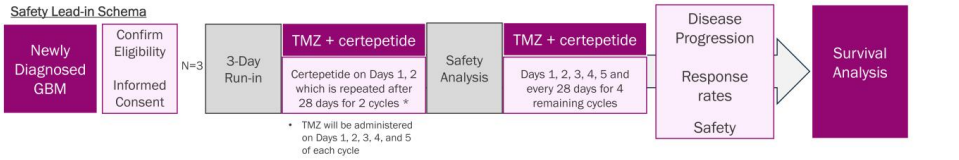
Phase 2a trial of certepetide with SoC in first-line GBM

Sponsor/Partner	▪ Tartu University Hospital (Investigator initiated trial in Estonia) ▪ Lisata providing study drug and funding trial
Objective	▪ Evaluate safety, tolerability, and therapeutic effect of certepetide in combination with standard-of-care (temozolomide) in patients with previously untreated Glioblastoma Multiforme
Design	▪ 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	▪ N=30 total (N=3 safety run-in, N=18 in main study schema)
Endpoints	▪ Safety, tolerability ▪ ORR, PFS, OS, disease control rate
Timing	▪ 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



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

Sponsor/Partner	▪ Lisata (U.S. only)
Objective	▪ 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	▪ 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: ▪ 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	▪ N=30
Endpoints	▪ Safety and tolerability ▪ PFS, OS
Timing	▪ First patient treated target 4Q24

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