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

February 29, 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 February 29, 2024, Lisata Therapeutics, Inc. (the "Company") issued a press release in connection with its financial results for the fiscal year ended December 31, 2023. 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 February 29, 2024
99.2	Lisata Therapeutics, Inc. Corporate Presentation, February 29, 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 and Chief Executive Officer

Dated: February 29, 2024

Exhibit 99.1

Lisata Therapeutics Reports Full Year 2023 Financial Results and Provides Business Update

Phase 2b ASCEND trial fully enrolled and on track for top-line data in fourth quarter of 2024

Company affirms projection of operational funds into early 2026

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

BASKING RIDGE, NJ (February 29, 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, provides a business update and reports financial results for the twelve months ended December 31, 2023.

"2023 was a testament to our unwavering commitment to operational excellence and focused, efficient development. Our entire organization worked seamlessly to achieve significant milestones in the advancement of our lead investigational product, LSTA1," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Lisata. "Throughout 2024, we look to maintain and even build on this momentum as we project numerous data announcements in the coming 12 to 24 months, including the release of topline data from the Phase 2b ASCEND trial ("ASCEND") later this year. We intend to use these results to explore conditional approvals in several jurisdictions around the world and/or to design an optimized Phase 3 program in pancreatic ductal adenocarcinoma. Concurrently, we remain committed to the advancement of our other active and planned studies investigating LSTA1 in combination with a variety of standard-of-care regimens across multiple solid tumor indications."

Dr. Mazzo added, "Our prudent stewardship of our financial resources allows us to reaffirm our projection that our cash runway extends into early 2026 and funds all our trials until data completion. More than ever, we remain confident in our ability to execute our development activities efficiently with the goal of reaching significant clinical milestones at the earliest possible juncture."

Development Portfolio Highlights

LSTA1 as a treatment for solid tumors in combination with other anti-cancer agents

LSTA1 is an investigational drug designed to activate the CendR uptake pathway that allows co-administered or molecularly bound anti-cancer drugs to target and penetrate solid tumors more effectively. LSTA1 is designed to actuate 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, to the exclusion of normal tissues. In preclinical models, LSTA1 has also shown the ability to modify the tumor microenvironment, leading to the expectation that tumors will become more susceptible to immunotherapies and inhibiting the metastatic cascade (i.e., the spread of cancer to other parts of the body). Lisata and its development collaborators have amassed significant non-clinical data demonstrating enhanced delivery of a range of existing and emerging anti-cancer therapies, including chemotherapeutics, immunotherapies, and RNA-based therapeutics. To date, LSTA1 has also demonstrated favorable safety, tolerability, and activity in completed and ongoing clinical trials designed to test its ability to enhance delivery of standard-of-care chemotherapy for metastatic pancreatic cancer. Currently, LSTA1 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. As previously announced, LSTA1 has been granted orphan drug designation for pancreatic cancer in the U.S. and Europe as well as for glioblastoma multiforme ("GBM") in the U.S. The product candidate has also received a Fast Track designation from the U.S. Food and Drug Administration for pancreatic cancer.

- ASCEND: Phase 2b double-blind, randomized, placebo-controlled clinical trial evaluating two dosing regimens of LSTA1 in combination with gemcitabine/nab-paclitaxel standard-of-care ("SOC") chemotherapy

in patients with metastatic pancreatic ductal adenocarcinoma ("mPDAC"). Cohort A of the study receives a single dose of 3.2 mg/kg LSTA1 essentially simultaneously with SOC, while Cohort B is identical to Cohort A, but with a second dose of 3.2mg/kg of LSTA1 given 4 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 ("IDSMC") 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 98 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 basket trial in the U.S., Europe, Canada, and Australia evaluating LSTA1 in combination with standards-of-care in second line head and neck cancer and first line cholangiocarcinoma. The trial is actively enrolling with enrollment completion expected by the end of 2024.
- CENDIFOX: Phase 1b/2a open-label trial in the U.S. of LSTA1 in combination with neoadjuvant FOLFIRINOX based therapies in pancreatic, colon and appendiceal cancers. The trial continues to make steady progress with enrollment completion expected by the end of the second quarter of 2024.
- Qilu Pharmaceutical, the licensee of LSTA1 in the Greater China territory, is currently evaluating LSTA1 in combination with gemcitabine and nab-paclitaxel in a Phase 1b/2a open-label trial in China. 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 LSTA1 plus gemcitabine and nab-paclitaxel conducted in Australia in patients with mPDAC. Final data is expected by the end of the second quarter of 2024, with the initiation of Phase 2 in China expected shortly thereafter.
- iLSTA: Phase 1b/2a randomized, single-blind, single-center, safety and pharmacodynamic trial in Australia evaluating LSTA1 in combination with the checkpoint inhibitor, durvalumab, plus standard-of-care gemcitabine and nab-paclitaxel chemotherapy versus standard-of-care alone in patients with locally advanced non-resectable PDAC. Enrollment completion is expected in the second half of 2024.
- Lisata-funded Phase 2a, double-blind, placebo-controlled, randomized, proof-of-concept study evaluating LSTA1 in combination with standard-of-care 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 LSTA1 treatment group.

Full Year 2023 Financial Highlights

For the year ended December 31, 2023, operating expenses totaled $25.7 million compared to $57.6 million for the year ended December 31, 2022, representing a decrease of $31.9 million or 55.4%. Excluding the in-process research and development expense of $30.4 million associated with the merger with Cend Therapeutics, Inc. (the "Merger"), operating expenses decreased by $1.5 million or 5.5% compared to the year ended December 31, 2022.

Research and development expenses were approximately $12.7 million for the year ended December 31, 2023, compared to $13.1 million for the year ended December 31, 2022, representing a decrease of approximately $0.3 million, or 2.5%. This decrease was primarily due to lower costs associated with our LSTA1 programs in the current year versus our legacy CD34+ cell therapy technology programs in the prior year. Current year expenses were associated with study activities for LSTA1 Phase 2a proof-of-concept Bolster trial in various solid tumors in combination with the corresponding standards of care, enrollment activities for the LSTA1 Phase 2b ASCEND study, chemistry, manufacturing and control activities for LSTA1 and study start up activities for the LSTA1 Phase 2a study for the treatment of GBM.

General and administrative expenses were approximately $13.0 million for the year ended December 31, 2023, compared to $14.1 million for the year ended December 31, 2022, representing a decrease of approximately $1.2 million or 8.3%. This decrease was primarily due to non-recurring Merger related costs in the prior year, a decrease in

equity expense due to prior year performance stock unit vesting, Merger option assumption expense and departing board member restricted stock unit vesting, lower annual stockholder meeting expenses and a decrease in directors and officers insurance premiums, partially offset by severance costs associated with the elimination of the Chief Business Officer position on May 1, 2023.

Overall, net losses were $20.8 million and $54.2 million for the years ended December 31, 2023 and 2022, respectively.

Balance Sheet Highlights

As of December 31, 2023, Lisata had cash, cash equivalents, and marketable securities of approximately $50.5 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 on Thursday, February 29, 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 fifteen minutes ahead of the scheduled start time.

A live webcast of the call will also be accessible under the **Investors & News** section of Lisata's website and will be available for replay beginning two hours after the conclusion of the call for 12 months.

About Lisata Therapeutics

Lisata Therapeutics is a clinical-stage pharmaceutical company dedicated to the discovery, development and commercialization of innovative therapies for the treatment of advanced solid tumors and other major diseases. Lisata's lead product candidate, LSTA1, is an investigational drug designed to activate a novel uptake pathway that allows co-administered or tethered anti-cancer drugs to target and penetrate solid tumors more effectively. Based on Lisata's CendR Platform® Technology, Lisata has already established noteworthy commercial and R&D partnerships. The Company expects to announce numerous clinical study and business milestones over the next two years and has projected that its current business and development plan is funded with available capital through these milestones and into early 2026. For more information on the Company, please visit www.lisata.com.

Forward-Looking Statements

This communication contains "forward-looking statements" that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this communication regarding strategy, future operations, future financial position, future revenue, projected expenses and capital, prospects, plans and objectives of management are forward-looking statements. In addition, when or if used in this communication, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as they relate to Lisata or its management, may identify forward-looking statements. Examples of forward-looking statements include, but are not limited to, the potential efficacy of LSTA-1 as a treatment for patients with GBM, metastatic gastroesophageal 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:

Investors and Media:

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

- Tables to Follow -

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

	Twelve Months Ended December 31,	
	2023	**2022**
(in thousands, except per share data)		
Statement of Operations Data:		
Research and development	$ 12,734	$ 13,067
In-process research and development	—	30,393
General and administrative	12,974	14,141
Total operating expenses	**25,708**	**57,601**
Operating loss	**(25,708)**	**(57,601)**
Investment income, net	2,724	1,052
Other expense, net	(186)	(155)
Net loss before benefit from income taxes and noncontrolling interests	**(23,170)**	**(56,704)**
Benefit from income taxes	(2,330)	(2,479)
Net loss	**(20,840)**	**(54,225)**
Less - net income (loss) attributable to noncontrolling interests	—	—
Net loss attributable to Lisata Therapeutics, Inc. common stockholders	**$ (20,840)**	**$ (54,225)**
Basic and diluted loss per share attributable to Lisata Therapeutics, Inc. common stockholders	**$ (2.58)**	**$ (10.47)**
Weighted average common shares outstanding	**8,073**	**5,180**

	December 31, 2023	December 31, 2022
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 50,535	$ 69,226
Total assets	54,694	73,034
Total liabilities	6,800	6,710
Total equity	47,894	66,324

# # #

Exhibit 99.2

LISATA THERAPEUTICS

Targeted Therapy *Delivered*

Corporate Presentation | February 29, 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 the long-term success of Lisata's recently completed merger (the "Merger") with Cend Therapeutics, Inc. ("Cend"), including the ongoing integration of Cend's operations; Lisata's continued listing on the Nasdaq Capital Market; expectations regarding the capitalization, resources and ownership structure of Lisata; the approach Lisata is taking to discover, 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 extent to which any future public health crisis and their long-term effects may impact, directly or indirectly, Lisata's business, including our clinical trials and financial condition, the safety and efficacy of Lisata's product candidates, decisions of regulatory authorities and the timing thereof, the duration and impact of regulatory delays in Lisata's clinical programs, Lisata's ability to finance its operations, the likelihood and timing of the receipt of future milestone and licensing fees, the future success of Lisata's scientific studies, Lisata's ability to successfully develop and commercialize drug candidates, the timing for starting and completing clinical trials, rapid technological change in Lisata's markets, the ability of Lisata to protect its intellectual property rights; unexpected costs, charges or expenses resulting from the Merger; potential adverse reactions or changes to business relationships resulting from the completion of the Merger; potential underperformance of Lisata's business following the Merger as compared to management's initial expectations; and legislative, regulatory, political and economic developments. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in Lisata's Annual Report on Form 10-K filed with the SEC on 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.


Company Overview
Lisata at a Glance
3

Lisata Therapeutics (Nasdaq: LSTA)

A clinical stage therapeutics development company rapidly advancing a novel solid tumor targeting and penetration technology to improve the efficacy of anti-cancer drugs

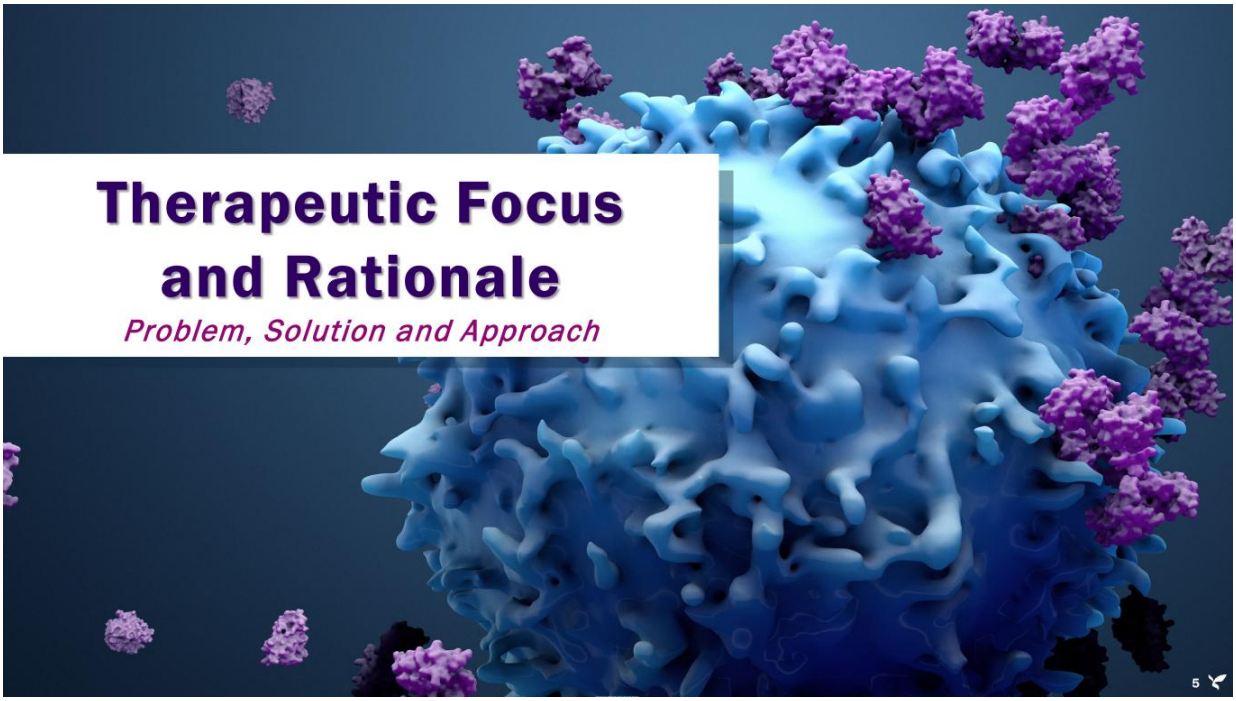
Seasoned management with successful international drug development experience and expertise

Proprietary field-leading technology in underserved global indications

Multiple projected product and business milestones over the next 24 months

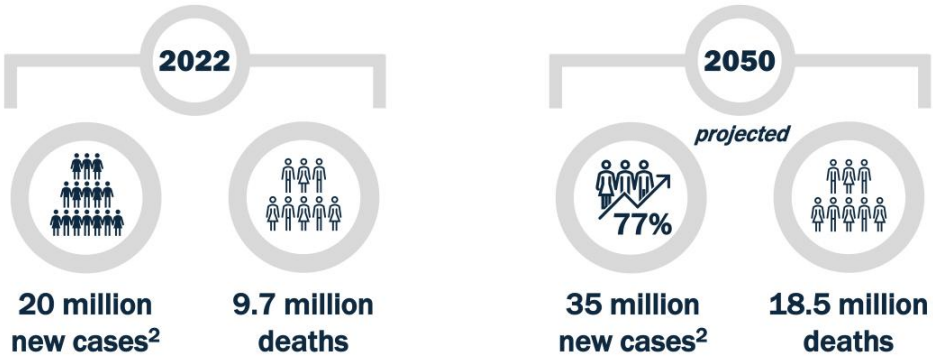
Platform technology "validated" by existing partnerships with potential for many others

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


Therapeutic Focus
and Rationale
Problem, Solution and Approach
5

Improved solid tumor cancer treatment is a vital global need

In 2023, in the U.S. alone, there were ~2 million newly diagnosed cancer cases, with solid tumors comprising over 90% of these newly reported cases[1]



Examples of solid tumor cancers 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://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.

Current solid tumor treatments are suboptimal

Targeting and penetrating tumors present distinct challenges

- Tumor stroma acts as a physical barrier, limiting the penetration and distribution of anti-cancer agents into the tumor
- Tumor microenvironment (TME) immunosuppressive cells contribute to tumor resistance and/or metastases
- Prolonged or escalated dosing of non-targeted anti-cancer therapy generally leads to intolerable off-target side effects

Leveraging the CendR transport mechanism to improve solid tumor treatment

Targeted penetration technology enhances drug delivery to solid tumors

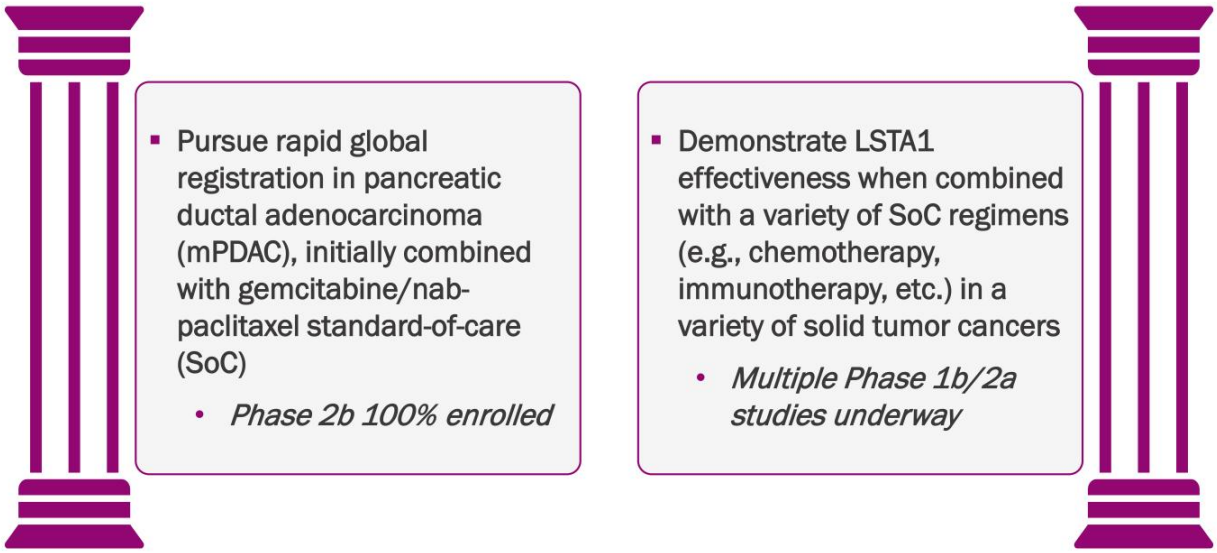
- RGD peptides can target tumor cells, but do not enhance penetration and delivery of therapeutic agents
- *Internalizing* RGD peptides (iRGDs) combine targeting and penetration enhancement
- LSTA1 (certepetide) is an iRGD that exploits the C-end Rule (CendR) active transport mechanism to target solid tumors and enhance tumor penetration
- LSTA1 is in clinical development as a ***tumor targeting and penetration enhancer*** for solid tumor treatment

LSTA1 promises optimized solid tumor treatment

- LSTA1 converts tumor stroma from a barrier to a conduit for anti-cancer drugs
- LSTA1 is agnostic to the modality of the companion anti-cancer therapy
  - Mechanism 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 prolonged compound exclusivity
- LSTA1 combats resistance and metastases[1]
  - Preclinical data demonstrate that in highly fibrotic tumors, LSTA1 selectively depletes immunosuppressive T cells, enhances cytotoxic T cells and inhibits the metastatic cascade

[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.

LSTA1 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*

- Demonstrate LSTA1 effectiveness when combined with a variety of SoC regimens (e.g., chemotherapy, immunotherapy, etc.) in a variety of solid tumor cancers
  - *Multiple Phase 1b/2a studies underway*


Partnerships
Noteworthy existing relationships and potential for many more
11

Existing partnerships support LSTA1 promise and broad applicability

Clinical development alliances exploring combinations with chemo- & immunotherapy

- LSTA1/gemcitabine/nab-paclitaxel treatment regimen with ***AGITG (AUS & NZ)***
- LSTA1/gemcitabine/nab-paclitaxel treatment regimen ± durvalumab with ***WARPNINE (AUS)***
- LSTA1/FOLFIRINOX treatment regimen ± nivolumab with ***WARPNINE (AUS)***

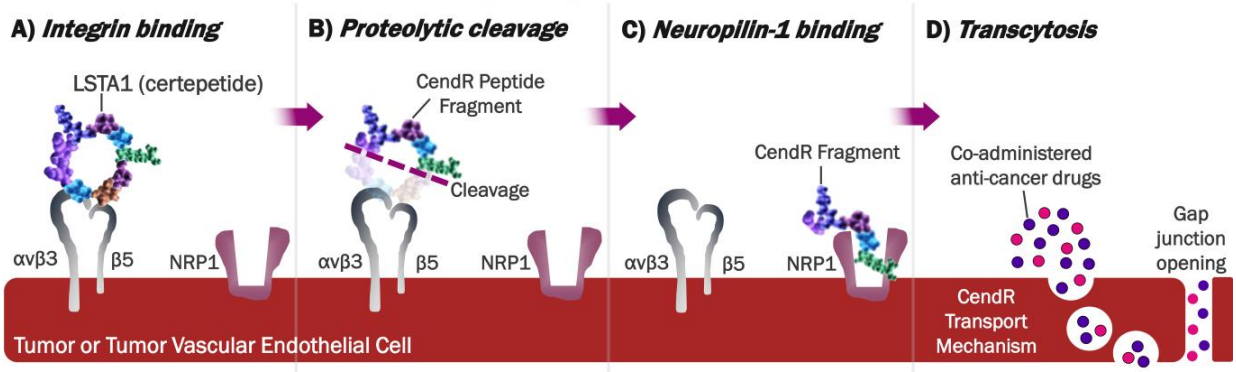
Strategic partnership in China with Qilu Pharmaceutical

- Exclusive rights to LSTA1 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
- Potential for up to $221 million to Lisata for milestones & tiered double-digit royalties on sales

Additional partnership opportunities exist for many combinations with LSTA1 in a variety of solid tumor indications


LSTA1
Strong Scientific Foundation and Rationale
13

LSTA1 Selective Tumor Targeting & Penetration Mechanism of Action



LSTA1: 9 amino acid cyclic peptide; high binding specificity and affinity to αvβ3/β5 integrins that are upregulated on tumor endothelial cells and tumor cells

Once bound to αvβ3 & β5 integrins, LSTA1 is cleaved by proteases in the tumor microenvironment, releasing a C-end Rule (CendR) linear peptide fragment

The CendR fragment then binds to an adjacent receptor, neuropilin-1 (NRP1), activating the CendR transport pathway[1] and triggering penetration into the tumor tissue

Activation of the CendR transport mechanism triggers:

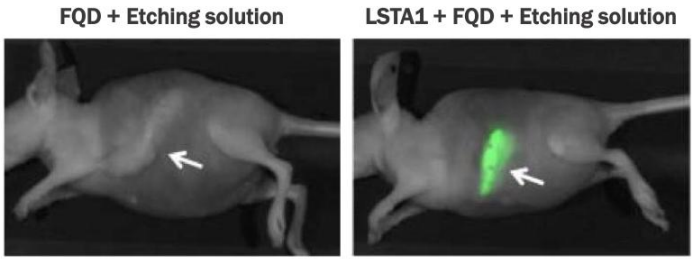
1) Tumor penetration of circulating moieties including unbound LSTA1 & co-administered anti-cancer drugs

2) Opening intratumoral gap junctions enhancing extravasation of immune cells

[1] Ding et al., Nature Comm, 2019.

LSTA1 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 LSTA1



- Etching solution quenches fluorescence in circulation
- LSTA1 provides targeted tumor penetration

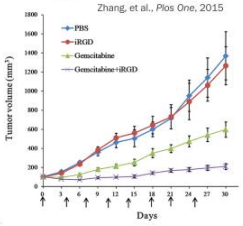
[1] Braun et al., Nature Mater. 2014.
[2] Liu, Braun et al., Nature Comm. 2017.

LSTA1/iRGD activity & broad applicability consistently demonstrated

Sampling of >350 scientific publications showing augmentation effects

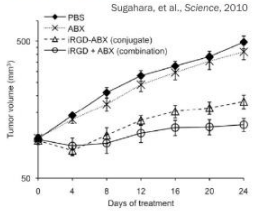
Lung cancer + gemcitabine

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



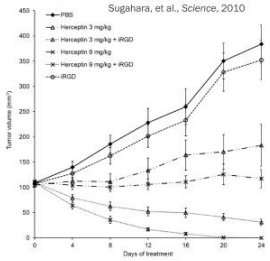
Breast cancer + nanoparticle Abraxane

Sugahara, et al., *Science*, 2010



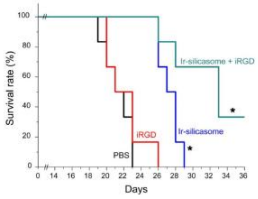
Breast cancer + Herceptin®

Sugahara, et al., *Science*, 2010



PDAC + irinotecan nanoparticles

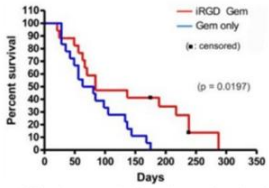
Liu X et al., J Clin Invest, 2017



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

PDAC + gemcitabine

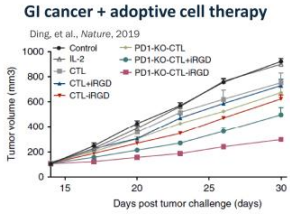
Hurtado de Mendoza et al, Nature Comms, 2021



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

GI cancer + adoptive cell therapy

Ding, et al., *Nature*, 2019



LSTA1 Phase 1b/2a results: Compelling improvement of SoC efficacy

Pancreatic Cancer Stats:

- By 2030, pancreatic cancer is predicted to become the second most common cause of cancer mortality[1]
- Only 3% of people diagnosed with pancreatic cancer will survive for 5 years
- Life expectancy at the time of diagnosis is just 4.6 months

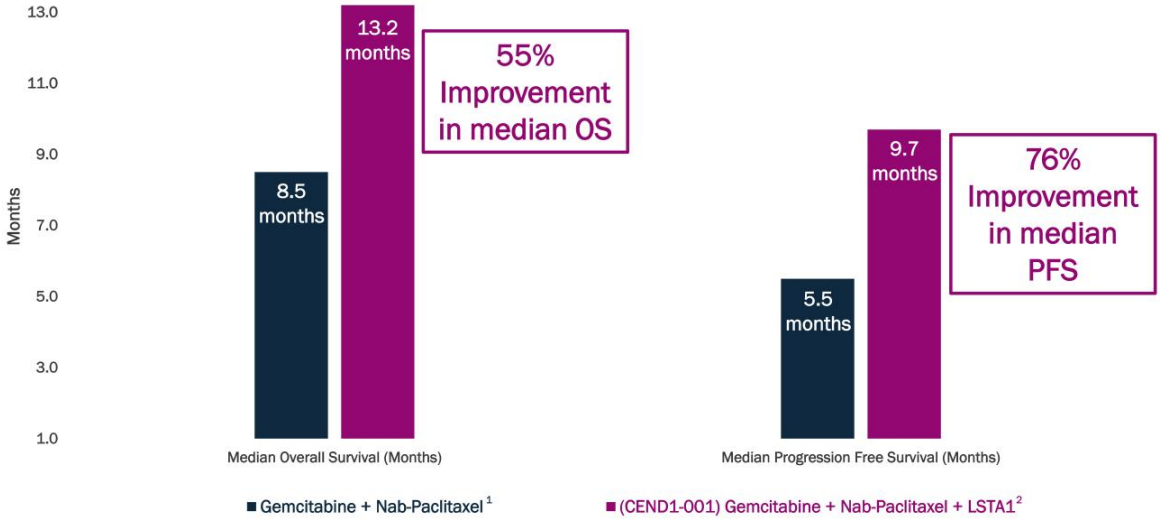
Endpoints	Gemcitabine + Nab-paclitaxel[2]	LSTA1 + Gemcitabine + Nab-paclitaxel[3]
N= # of study participants	N=431	N=31
Median Overall Survival	8.5 mos.	13.2 mos.
Median Progression-Free Survival	5.5 mos.	9.7 mos.
Objective Response Rate	23% (99)	59% (17)
Complete Response	0.2% (1)	3.4% (1)
Partial Response	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

LSTA1 well-tolerated, no dose-limiting toxicities; safety of LSTA1 + SoC consistent with SoC alone

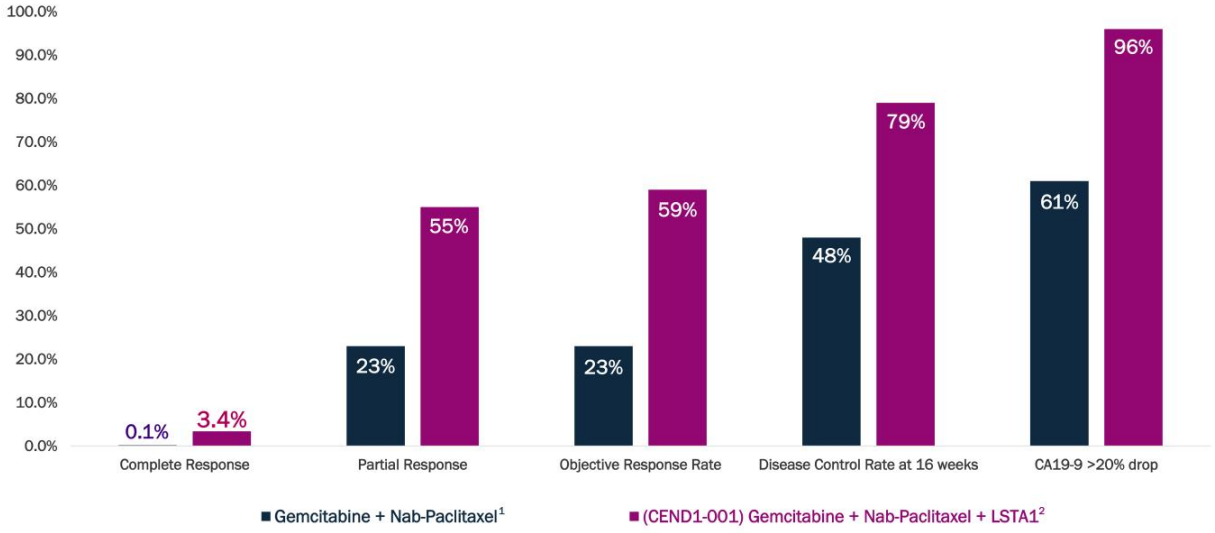
[1] Europe Is Facing a Pancreatic Cancer Emergency - Medscape - January 25, 2024.
[2] Von Hoff D, et al., *New England Journal of Medicine*, 2013.
[3] Dean A, et al., *The Lancet Gastroenterology & Hepatology*, 2022.

LSTA1 Phase 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

LSTA1 Phase 1b/2a results: Consistent improvement across associated endpoints



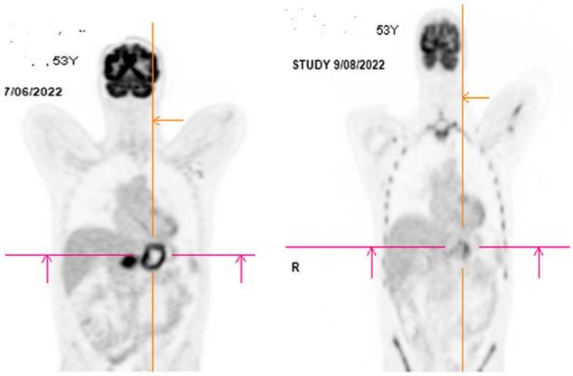
[1] Von Hoff D. et al., *New England Journal of Medicine*, 2013.
[2] Dean A. et al., *The Lancet Gastroenterology & Hepatology*, 2022

Growing evidence of LSTA1 activity in other solid tumors

LSTA1 potentiated a complete response in metastatic gastroesophageal adenocarcinoma

- 53 y/o male diagnosed with metastatic gastroesophageal adenocarcinoma in June 2022 with significant (> 5cm) nodal metastases
- Commenced neoadjuvant chemotherapy with radiotherapy including FOLFIRINOX and pembrolizumab resulting in partial response
- At cycle 7 – LSTA1 was added to the FOLFIRINOX/pembrolizumab regimen
- After cycle 18 – Patient underwent an exploratory laparoscopy for surgical resection – **no disease present** – only scar tissue

PET scan June 2022 | PET scan September 2022



Reduction in FDG activity demonstrated[1]

[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


LSTA1
Clinical Development Portfolio
Fast Track (PDAC - USA)
Orphan Drug designated (PDAC – USA/EU & GBM – USA)
21

Implications of Fast Track and Orphan Drug designations

FDA Fast Track Designation

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

Orphan Drug Designation

- Incentives such as *tax credits, marketing exclusivity, fee waivers* and grant eligibility to support clinical trials
- Specialized regulatory assistance from FDA's Office of Orphan Products Development (OOPD)

LSTA1 capital efficient development plan; shared costs & selective geography

Partners/Sponsors	Region	Indication and Test Articles	Status
AGITG/Lisata	Australia & New Zealand	**First-line mPDAC** Gemcitabine/nab-paclitaxel with LSTA1 or placebo N=158	Phase 2b (**ASCEND**) Placebo-controlled *Enrollment complete; patients in follow-up*
Lisata	USA, Canada, EU and Asia	**Various Solid Tumors** Standard of Care with LSTA1 or placebo N=80	Phase 2a (**BOLSTER**) Placebo-controlled *Enrolling*
KUCC/Lisata	USA	**Pancreatic, Colon, & Appendiceal Cancers** LSTA1 + FOLFIRINOX + panitumumab* N=50	Phase 1b/2a (**CENDIFOX**) Open-label *Enrolling*
Qilu/Lisata	China	**First-line mPDAC** Gemcitabine/nab-paclitaxel + LSTA1 N=41	Phase 1b/2a Open-label *Enrollment complete*
WARPNINE/Lisata	Australia	**Locally advanced, non-resectable PDAC** Durvalumab/gemcitabine/nab-paclitaxel + LSTA1 N=30	Phase 1b/2a (**iLSTA**) Open-label *Enrolling*

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

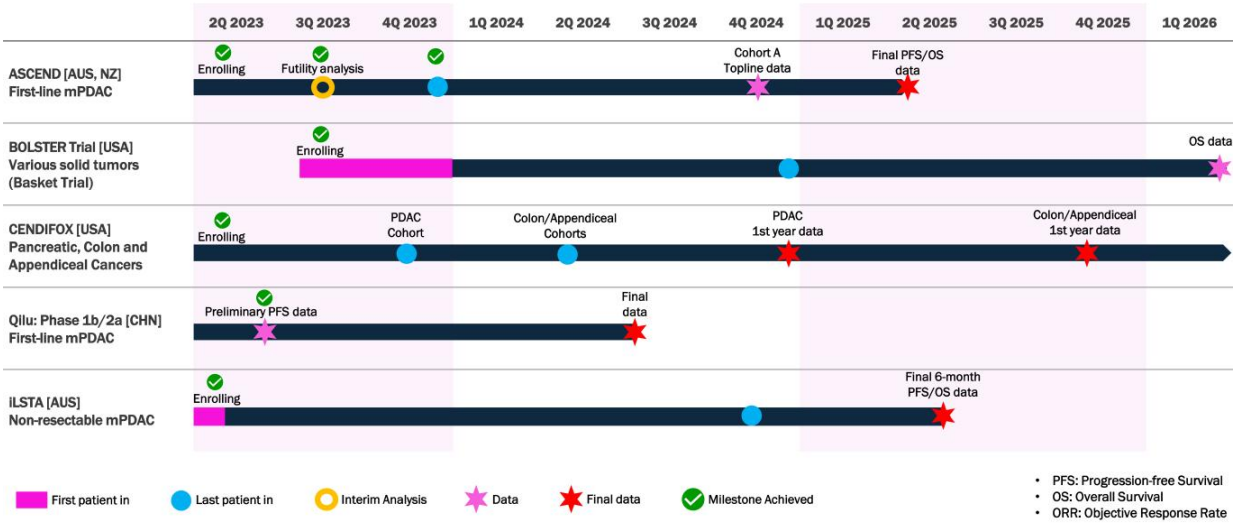
LSTA1 capital efficient development plan; shared costs & selective geography

Partners/Sponsors	Region	Indication and Test Articles	Status
Tartu University Lisata	Estonia & Latvia	**First-line Glioblastoma Multiforme (GBM)** Temozolomide +/- LSTA1 N=30	Phase 2a Placebo-controlled *Enrolling*
UCSD/Columbia University/Lisata	USA	**Peritoneal Carcinomatosis (Colon & Ovarian)** LSTA1 + HIPEC* intraoperative intraperitoneal lavage N=21	Phase 1b/2a Open-label *Enrolling*
Qilu/Lisata	China	**First-line mPDAC** Gemcitabine/Nab-paclitaxel + LSTA1 N=TBD	Phase 2 Placebo-controlled *Pending initiation*
WARPNINE/Lisata	Australia	**Locally advanced, non-resectable Gastroesophageal Adenocarcinoma** Nivolumab/FOLFIRINOX + LSTA1 N=40	Phase 1b/2a (**iGoLSTA**) Open-label *Pending initiation*

*Hyperthermic intraperitoneal chemotherapy

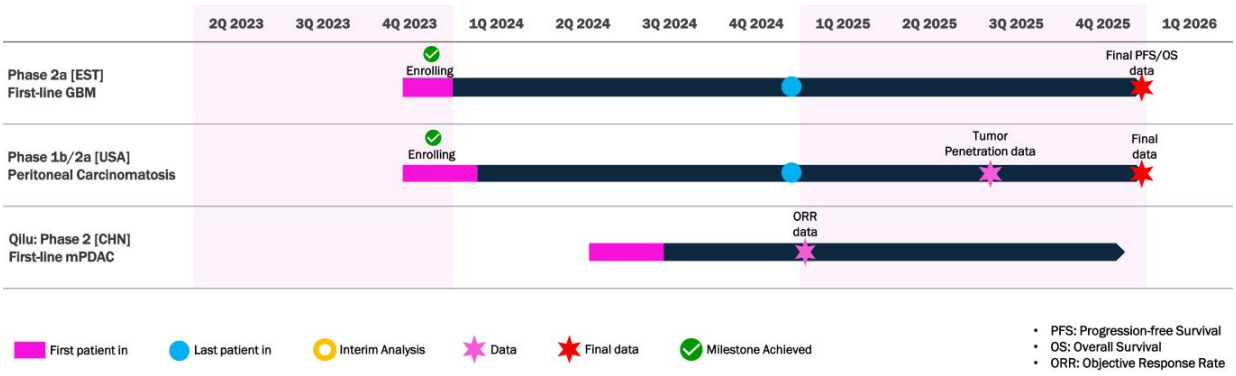

Development
Milestones
25

A wealth of anticipated key milestones



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

A wealth of anticipated key milestones (contd.)



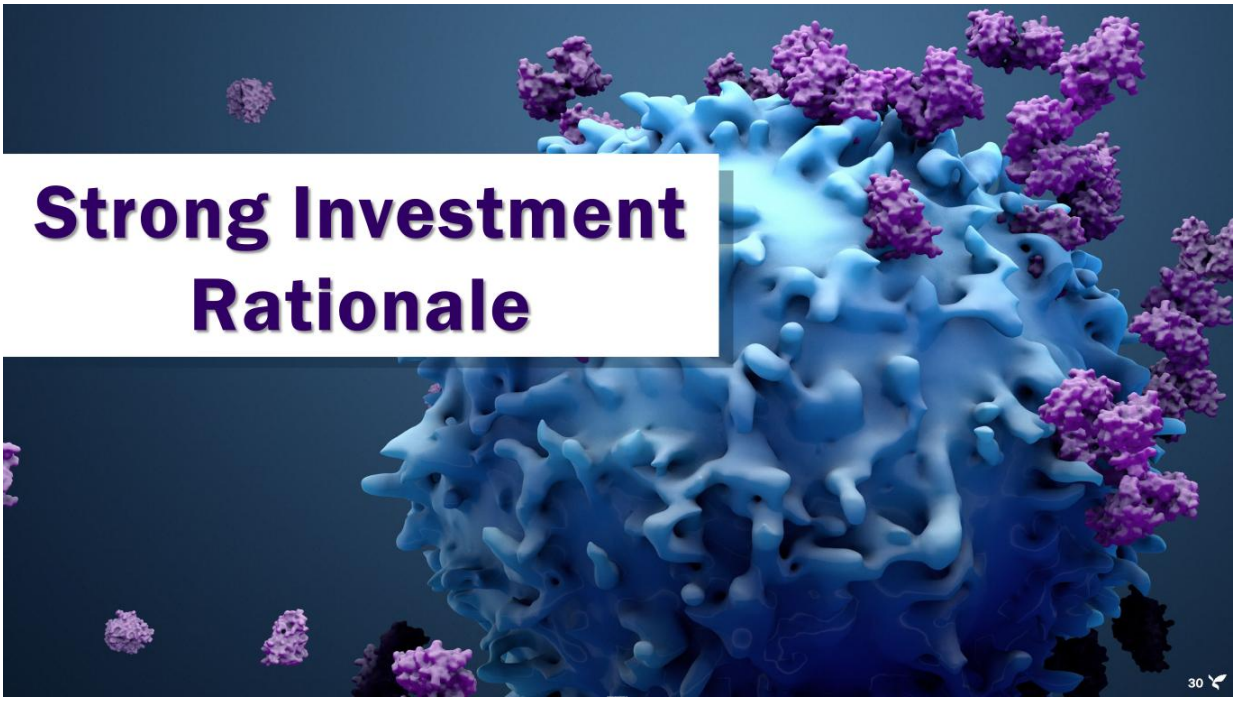
- PFS: Progression-free Survival
- OS: Overall Survival
- ORR: Objective Response Rate


Financial
Highlights
28

Capital projected to fund all clinical programs to data

Cash & Investments	Debt	Projected Cash Runway Into
As of 12/31/2023		
$50.5M	**$0**	**1Q2026**

Common Shares Outstanding (12/31/2023):	8.1 million shares
Options Outstanding (12/31/2023): Exercise Price: $0.02 - $4.22 = 1,084,000 shares Exercise Price: > $4.22 = 239,000 shares	1.3 million shares
Warrants Outstanding (12/31/2023): Weighted Average Exercise Price: $42.51	1.4 million shares


Strong Investment Rationale
30

Key factors supporting investment in Lisata Therapeutics

PEOPLE	TECHNOLOGY	MILESTONES	CAPITAL	PARTNERING
Seasoned management with successful international development experience and expertise	Proprietary field-leading technology in underserved global indications	Multiple projected product and business milestones over the next 24 months	$50.5 million cash*- no debt; Development funded through critical data milestones	Platform technology "validated" by existing partnerships with potential for many others

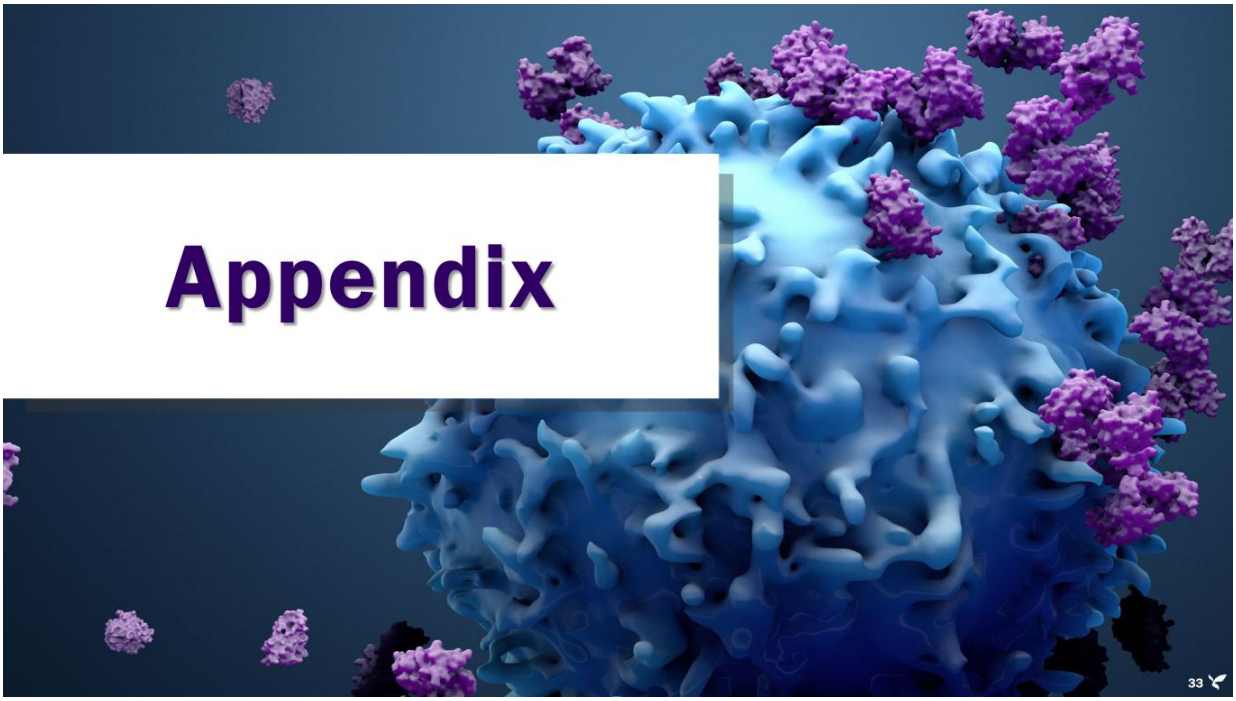
* As of 12/31/2023; includes investments

LISATA THERAPEUTICS

Targeted Therapy *Delivered*

Investor Relations Contact:
John D. Menditto
VP, IR & Corporate Communications
o: (908) 842-0084 | e: jmenditto@lisata.com

Nasdaq: LSTA | *www.lisata.com*


Appendix
33

LSTA1 capital efficient development plan; shared costs & selective geography

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 LSTA1 or placebo	**Phase 2b (ASCEND)**	Corroborate Phase 1b results in a placebo-controlled trial and evaluate 2 dose regimens of LSTA1 for dose optimization
Lisata [United States]	**Various Solid Tumors;** SoC with LSTA1 or placebo	**Phase 2a (BOLSTER)**	Assess LSTA1 safety and effectiveness in several tumor types in a placebo-controlled trial (Proof-of-Concept)
KUCC/Lisata [United States]	**Pancreatic, Colon & Appendiceal Cancers;** LSTA1 + FOLFIRINOX + panitumumab*	**Phase 1b/2a (CENDIFOX)**	Tumor immuno-profiling pre- & post- treatment and LSTA1 effectiveness assessment in combination with chemo and an EGFR inhibitor (open label)
Qilu [China]	**First-line mPDAC;** Gemcitabine/nab-paclitaxel + LSTA1	**Phase 1b/2a**	Assess safety, PK and therapeutic effect of LSTA1 in Chinese patients (open label)
WARPNINE/Lisata [Australia]	**Locally advanced non-resectable PDAC;** Durvalumab/gemcitabine/nab-paclitaxel + LSTA1	**Phase 1b/2a (iLSTA)**	Assess LSTA1 safety and effectiveness in combination with IO & Chemo in locally advanced PDAC; determine if inoperable tumors can become operable (open label)
WARPNINE/Lisata [Australia]	**Locally advanced non-resectable Gastroesophageal (GE) adenocarcinoma;** Nivolumab + FFX + LSTA1	**Phase 1b/2a (iGoLSTA)**	Assess LSTA1 safety and effectiveness in combination with IO & chemo in locally advanced GE AdenoCa; determine if inoperable tumors can become operable (open label)

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

LSTA1 capital efficient development plan; shared costs & selective geography

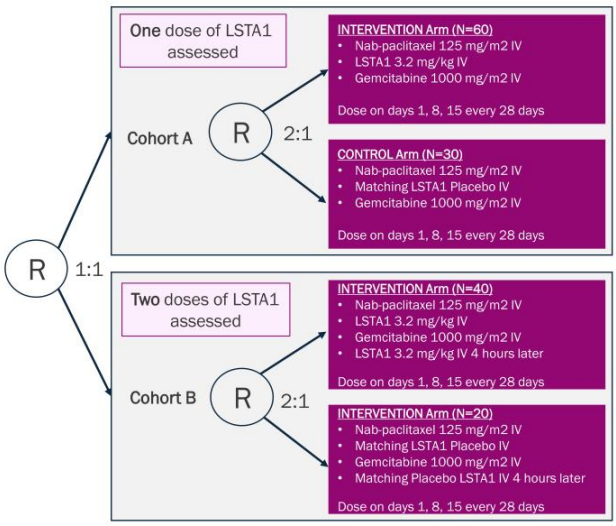
Development Partner(s) [Development Venue]	Indication and Trial Product/Comparator	Stage of Development	Strategic Rationale
Tartu University/Lisata [Estonia]	First-line Glioblastoma Multiforme; Temozolomide ± LSTA1	Phase 2a	Assess LSTA1 safety and effectiveness in additional tumor type (GBM) a in placebo-controlled trial
UCSD/Columbia University/Lisata [United States]	Peritoneal Carcinomatosis LSTA+HIPEC intraoperatively	Phase 1b/2a	Assess safety and intraoperative tumor penetration of HIPEC in combination with LSTA1 (open label)
Qilu [China]	First-line mPDAC; Gemcitabine/nab-paclitaxel + LSTA1	Phase 2b	Continue development of LSTA1 in China (placebo controlled)
Roche/Lisata [Multi-national]	First-line mPDAC; Gemcitabine/nab-paclitaxel/LSTA1 ± atezolizumab	Phase 1b/2 (MORPHEUS)	Assess LSTA1 safety and effectiveness in combination with SoC chemotherapy & immunotherapy (controlled trial)

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 LSTA1 further improves patient outcomes
Design	▪ Phase 2b randomized, double-blind study in mPDAC testing gemcitabine + nab-paclitaxel SoC with one of two LSTA1 dose regimens or placebo
Study Size	▪ 158 subjects (~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 2024

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

Phase 2b randomized, double-blind study in mPDAC testing gemcitabine + nab-paclitaxel (SoC) with two LSTA1 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 2024

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

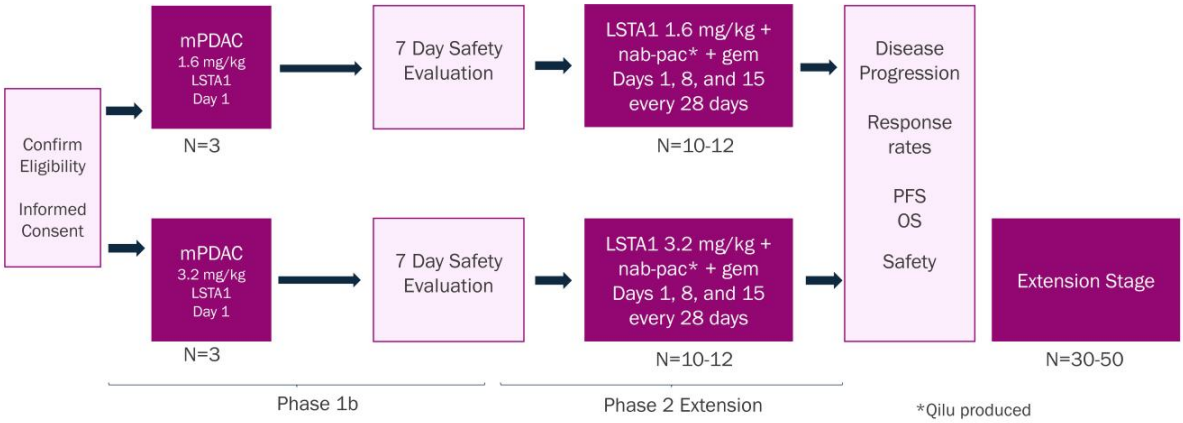
Phase 1b/2a open-label trial in mPDAC in China

Sponsor/Partner	▪ Qilu Pharmaceutical (funds all development in China)
Objective	▪ Evaluate safety, pharmacokinetics and preliminary efficacy of LSTA1 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 LSTA1
Study Size	▪ 50 subjects (~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	▪ Preliminary data expected 1H23

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

Phase 1b/2a study evaluating the safety, pharmacokinetics, and preliminary efficacy of LSTA1 for injection in Chinese patients with advanced metastatic pancreatic ductal adenocarcinoma

- Sponsor/Partner: Qilu Pharmaceutical (funds all development in China)
- Timing: Preliminary data expected 1H23

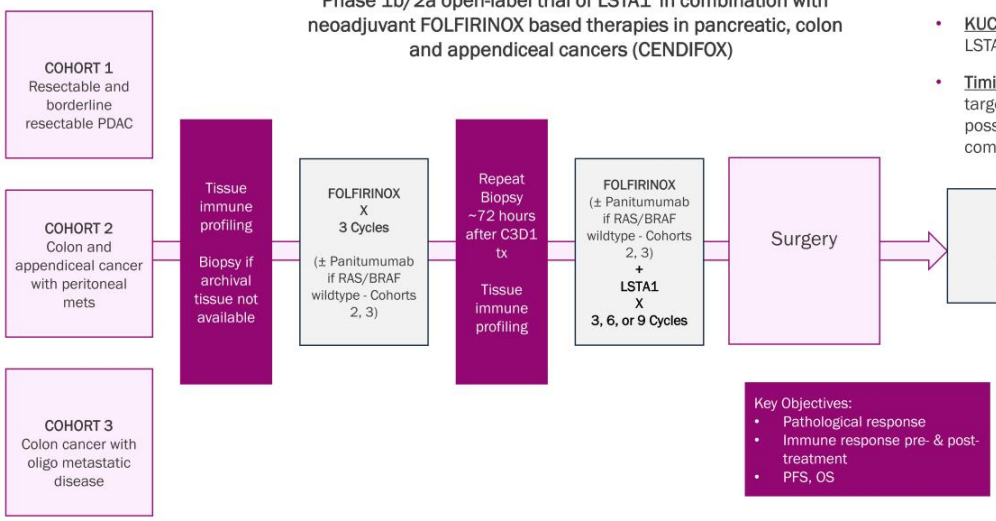


*Qilu produced

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 LSTA1
Objective	▪ Evaluate the safety and therapeutic effect of LSTA1 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 LSTA1 ± panitumumab
Study Size	▪ 50 subjects (20 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 4Q23 ▪ Data readouts possible throughout 2023 with complete results expected 2024

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



- Sponsor/Partner: University of Kansas Medical Center (ITT)
- KUCC funded: Lisata provides LSTA1
- Timing: Enrollment completion target 4Q23; data readouts possible throughout 2023; complete results expected 2024

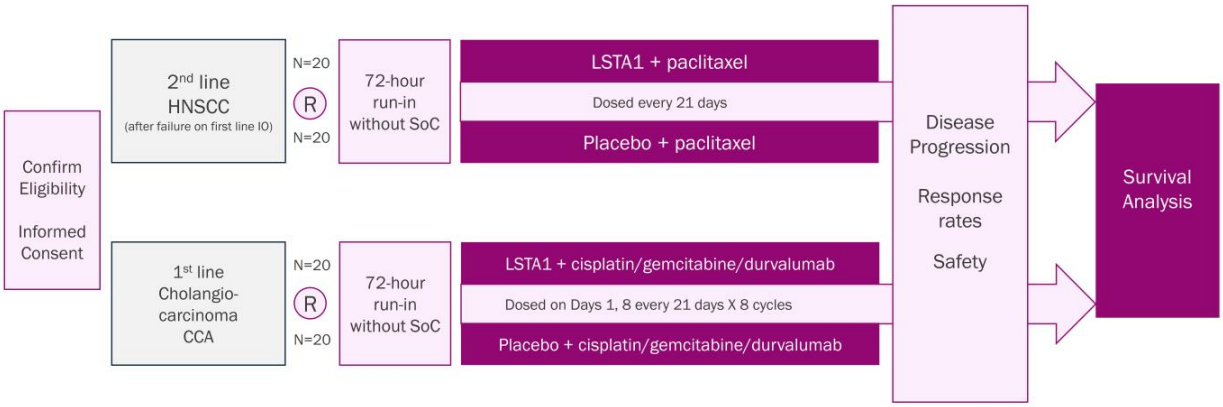
BOLSTER: Phase 2 blinded, randomized PoC trial in various cancers

Sponsor/Partner	▪ Lisata (U.S.)
Objective	▪ Evaluate the preliminary efficacy, safety and tolerability of LSTA1 in combination with standards of care in subjects with advanced solid tumors
Design	▪ Phase 2 randomized, double-blind, placebo-controlled, proof-of-concept trial in 2nd line head and neck SCC and 1st line cholangiocarcinoma testing corresponding SoC with LSTA1 or placebo
Study Size	▪ 80 (40 per tumor type split 1:1 SoC + LSTA1 or SoC + placebo)
Endpoints	▪ Primary: OS ▪ Secondary: Safety, ORR, PFS
Timing	▪ Trial initiation target: 2Q23 ▪ Enrollment commenced September 2023

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

Phase 2a, double-blind, placebo-controlled, multi-center, randomized study evaluating LSTA1 when added to standard of care (SoC) versus standard of care alone in subjects with advanced solid tumors

- Sponsor: Lisata
- Timing: Trial initiation target 2Q23



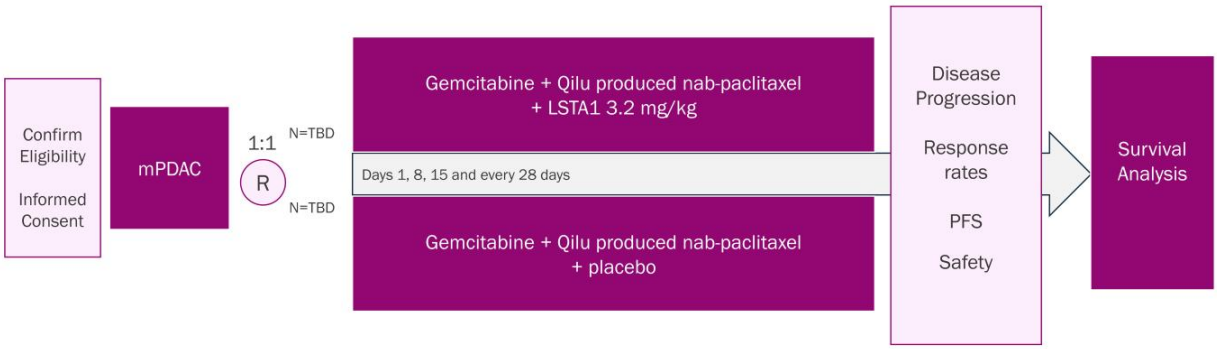
Phase 2 blinded, placebo-controlled trial in mPDAC in China

Sponsor/Partner	▪ Qilu Pharmaceutical (funds all development in China)
Objective	▪ Further evaluate safety and therapeutic efficacy of LSTA1 when added to SoC in Chinese patients with mPDAC
Design	▪ Phase 2b, double-blind, placebo-controlled, randomized study evaluating LSTA1 + SoC (Qilu-produced nab-paclitaxel and gemcitabine) vs. placebo + SoC
Study Size	▪ TBD
Endpoints	▪ Objective response rate, progression free survival, overall survival ▪ Safety
Timing	▪ Trial initiation target 1Q24

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

Phase 2b, double-blind, placebo-controlled, randomized, study evaluating LSTA1 when added to standard of care (nab-paclitaxel and gemcitabine) vs. standard of care alone and placebo in Chinese subjects with mPDAC

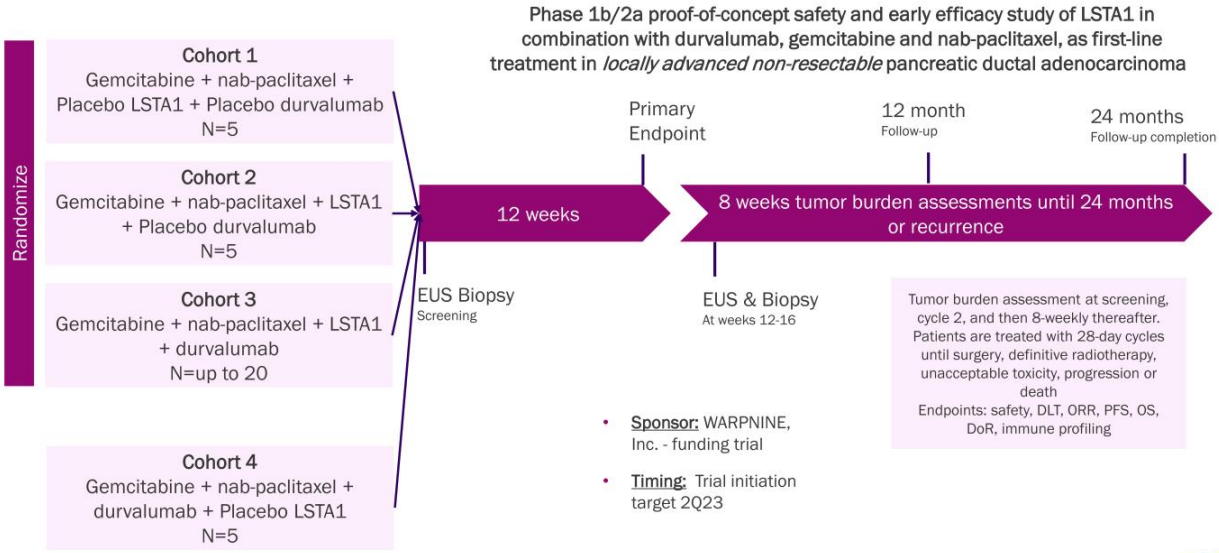
- Sponsor/Partner: Qilu Pharmaceutical (funds all development in China)
- Timing: Trial initiation target 4Q23



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	▪ Up to N=35
Endpoints	▪ Safety and tolerability; 28-day DLTs ▪ Objective response rate, PFS, OS, duration of response, immune cell infiltration
Timing	▪ Trial initiation target 2Q23 ▪ Enrollment commenced April 2023

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

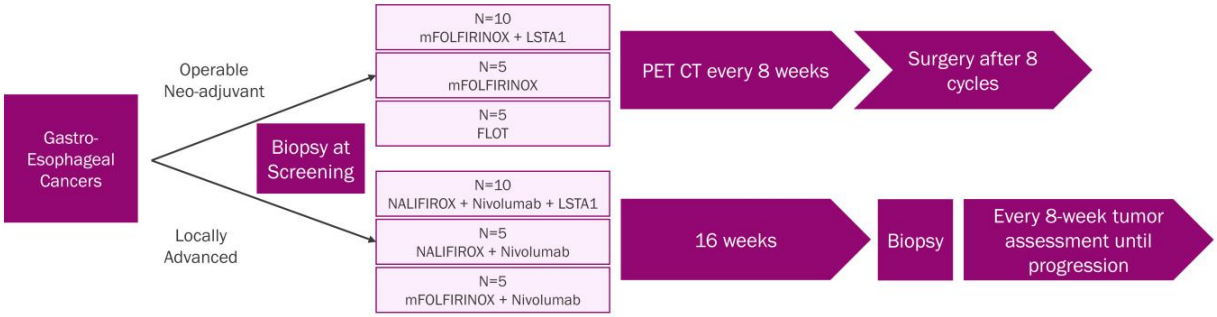


iGoLSTA: Phase 1b/2a trial in operable/inoperable GEC with chemo & IO

Sponsor/Partner	▪ WARPNINE, Inc. (registered charity in Australia) is funding trial ▪ Lisata providing study drug
Objective	▪ Evaluate LSTA1 safety & therapeutic effect in combination neoadjuvant chemo in operable gastroesophageal (GE) cancers. ▪ Evaluate LSTA1 safety and therapeutic effect in combination with immunotherapy and chemotherapy for advanced non-resectable GE cancers
Design	▪ Phase 1b/2a proof-of-concept, two cohort, 6 arm safety and early efficacy study of LSTA1 in combination with chemo as treatment in *resectable* GE cancers as well as in combination with chemotherapy and immunotherapy in *advanced non-resectable* GE cancers
Study Size	▪ N=40 (20 per cohort)
Endpoints	▪ Safety and tolerability ▪ Objective response rate, PFS, OS, duration of response, immune cell infiltration
Timing	▪ Trial initiation target 3Q23

iGoLSTA: Phase 1b/2a trial in operable/inoperable GEC with chemo & IO

Phase 1b/2a proof-of-concept safety and early efficacy study of LSTA1 in combination with chemotherapy and immunotherapy in *resectable* and *locally advanced non-resectable* gastroesophageal cancers



Phase 2a trial of LSTA1 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 LSTA1 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 LSTA1 when added to standard of care (temozolomide) versus SoC and placebo in subjects with newly diagnosed Glioblastoma Multiforme (GBM)
Study Size	▪ N=40
Endpoints	▪ Safety, tolerability ▪ ORR, PFS, OS, disease control rate
Timing	▪ Trial initiation target 3Q23 ▪ Enrollment commenced December 2023

Phase 2a trial of LSTA1 with SoC in first-line in GBM

Phase 2a proof-of-concept double-blind, placebo-controlled, randomized, proof-of-concept study evaluating LSTA1 when added to standard of care (temozolomide) versus temozolomide and matching LSTA1 placebo in subjects with newly diagnosed GBM

- Sponsor: Tartu University Hospital; Estonia
- Funding: Lisata
- Timing: Trial initiation target 3Q23