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 2, 2023
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

o 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 2, 2023, Lisata Therapeutics, Inc. (the "Company") issued a press release in connection with its financial results for the third quarter ended September 30, 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 November 2, 2023
99.2	Lisata Therapeutics, Inc. Corporate Presentation, November 2, 2023

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 2, 2023

Exhibit 99.1

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

Significant clinical progress achieved in studies evaluating LSTA1 including first patients treated in BOLSTER (3 solid tumor basket trial) and continued rapid enrollment in ASCEND

Orphan drug designations granted for LSTA1 in malignant glioma (U.S.) and pancreatic cancer (EU)

Company to host conference call Thursday, November 2 at 4:30 p.m. Eastern time

BASKING RIDGE, NJ (November 2, 2023) – Lisata Therapeutics, Inc. (Nasdaq: LSTA) ("Lisata" or the "Company"), a clinical-stage pharmaceutical company developing innovative therapies for the treatment of advanced solid tumors and other serious diseases, today announced its financial results for the third quarter ended September 30, 2023.

"Momentum we established during the first half of the year continued during the third quarter with the achievement of several milestones related to ongoing and planned clinical studies of our lead investigational product, LSTA1," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Lisata. "For example, LSTA1 is now the recipient of multiple orphan drug designations including pancreatic cancer in both the U.S. and Europe, as well as malignant glioma in the U.S. Additionally, as we recently announced, we have successfully treated the first patient in each of the head and neck squamous cell carcinoma and cholangiocarcinoma cohorts of the BOLSTER trial ("BOLSTER"), and we expect a steady uptake in enrollment over the coming quarters. In September, we announced that the ASCEND study ("ASCEND") in Australia received a positive outcome from the planned interim futility analysis by the study's Independent Data Safety Monitoring Committee ("IDSMC"), which recommended continuation of the study without modification. We are also happy to report that full enrollment in Cohort A of ASCEND has been achieved and that overall enrollment in the study is now approximately 95% complete. With that, we now expect that we could have topline data from Cohort A as early as the fourth quarter of 2024, a full year earlier than originally anticipated. We intend to use the results of the ASCEND trial to explore possible conditional approvals in several jurisdictions and to design an optimized Phase 3 program in Pancreatic Ductal Adenocarcinoma ("PDAC"). Finally, the iLSTA study, done in collaboration with WARPNINE in Australia, a foundation dedicated to accelerating the development of treatments for gastrointestinal cancers, is enrolling rapidly."

Dr. Mazzo continued, "With continued careful management of capital, we reiterate that our expected cash runway projects into early 2026, funding each of our trials through to data. We believe we remain well-positioned to focus on the execution of our development plans and achieve our goal of getting to meaningful clinical data readouts as soon as possible."

Development Portfolio Highlights

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

LSTA1 is an investigational drug designed to activate a novel uptake pathway that allows co-administered or tethered (i.e., molecularly bound) anti-cancer drugs to target and penetrate solid tumors more effectively. LSTA1 actuates this active transport system in a tumor-specific manner, resulting in systemically co-administered anti-cancer drugs more efficiently penetrating and accumulating in the tumor, while normal tissues are not expected to be affected. In preclinical models, LSTA1 has also shown the ability to modify the tumor microenvironment, thereby making tumors more susceptible to immunotherapies 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 pancreatic cancer. Currently, LSTA1 is the subject of multiple ongoing or planned Phase 1b/2a and 2b clinical studies being conducted globally in a variety of solid tumor types in combination with a variety of anti-cancer regimens. These studies include:

- ASCEND: Phase 2b double-blind, randomized, placebo-controlled clinical trial evaluating LSTA1 in patients with metastatic Pancreatic Ductal Adenocarcinoma ("mPDAC"). The trial is being conducted at up to 40 sites in Australia and New Zealand led by the Australasian Gastro-Intestinal Trials Group in collaboration with the University of Sydney and with the National Health and Medical Research Council Clinical Trial Centre at the University of Sydney as the Coordinating Centre. Planned interim futility analysis by the IDMC received a positive outcome. Cohort A has been fully enrolled. Total enrollment completion is projected for the second quarter of 2024; however, current total enrollment is at approximately 95% of target, so earlier total enrollment completion may be achieved.
- BOLSTER: Phase 2a double-blind, placebo-controlled, multi-center, randomized basket trial in the U.S., Europe, Canada, and Asia evaluating LSTA1 in combination with standards of care in advanced solid tumors including head and neck, esophageal and cholangiocarcinoma. Enrollment is open and proceeding as planned. First patients have been treated in head and neck cancer as well as cholangiocarcinoma cohorts.
- CENDIFOX: Phase 1b/2a open-label trial in the U.S. of LSTA1 in combination with neoadjuvant FOLFIRINOX based therapies in pancreatic, colon and appendiceal cancers. The trial continues to make steady progress with enrollment completion expected by the fourth quarter of 2023 and data readouts expected in 2024.
- LSTA1 is currently being evaluated in combination with gemcitabine and nab-paclitaxel in a Phase 1b/2a open-label trial in China led by Qilu Pharmaceutical. During the 2023 ASCO Annual Meeting, Qilu Pharmaceutical presented an abstract sharing preliminary data from the study which, thus far, has corroborated previously reported findings from the phase 1b/2a trial of LSTA1 plus gemcitabine and nab-paclitaxel conducted in Australia in patients with mPDAC. Final data is expected by the end of the second quarter of 2024.
- iLSTA: Phase 1b/2a randomized, single-blind, single-center, safety and pharmacodynamic trial in Australia evaluating LSTA1 in combination with the checkpoint inhibitor, durvalumab, plus standard-of-care chemotherapy, nab-paclitaxel, and gemcitabine, versus standard-of-care alone in patients with locally advanced non-resectable PDAC. Enrollment completion is expected by the end of the second quarter of 2024.
- The Company will soon initiate the study of LSTA1 in combination with temozolomide in Glioblastoma Multiforme ("GBM"). This study is designed as a Phase 2a double-blind, placebo-controlled, randomized, proof-of-concept study evaluating LSTA1 when added to standard of care ("SoC") temozolomide versus temozolomide and matching LSTA1 placebo in subjects with newly diagnosed GBM. It will be conducted across multiple sites in Estonia and Latvia and is targeted to enroll 30 patients with a randomization of 2:1 LSTA1 + SoC versus Placebo + SoC. Target for the first patient treated is in the fourth quarter of 2023. Importantly and as the Company recently announced, LSTA1 has been granted orphan drug designation by the U.S. FDA for malignant glioma. This action by the FDA not only highlights the unmet medical need but also recognizes the potential of LSTA1 to benefit patients in this indication.
- Lisata will also soon initiate a study of LSTA1 in combination with HIPEC interoperative intraperitoneal lavage in peritoneal carcinomatosis, a condition which develops as a result of the contiguous spread of primary cancers such as ovarian, colorectal and appendiceal along the peritoneum. The study is a Phase I single-center, unblinded, randomized controlled trial to determine the safety and tolerability of LSTA1 administered intraperitoneally in patients with peritoneal metastases from colorectal, appendiceal, or ovarian cancer undergoing Cytoreductive Surgery ("CRS") and HIPEC. Twenty-one total participants will be randomized 2:1 to receive LSTA1 with HIPEC versus HIPEC alone after CRS. We anticipate the first patient treated to be in the fourth quarter of 2023.

Third Quarter 2023 Financial Highlights

Research and development expenses were approximately $3.4 million for the three months ended September 30, 2023, compared to $3.3 million for the three months ended September 30, 2022, representing an increase of $45,000 or 1.3%. Expenses this quarter were primarily due to study activities associated with the BOLSTER trial, enrollment activities for the ASCEND study, startup activities for the LSTA1 GBM study and chemistry, manufacturing and control activities for LSTA1 to support all development activities.

General and administrative expenses were approximately $2.6 million for the three months ended September 30, 2023, compared to $4.0 million for the three months ended September 30, 2022, representing a decrease of $1.4 million or 35.3%. This 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, departing board member restricted stock unit vesting and timing of our annual stockholder meeting versus the prior year.

Overall, net losses were $5.3 million for the three months ended September 30, 2023, compared to $37.4 million for the three months ended September 30, 2022. Excluding the in-process research and development expense of $30.4 million relating to our merger with Cend Therapeutics in September 2022, net losses for the three months ended September 30, 2023 decreased by $1.7 million or 24.7% compared to the three months ended September 30, 2022.

Balance Sheet Highlights

As of September 30, 2023, the Company had cash, cash equivalents and marketable securities of approximately $54.4 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, November 2, 2023, 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 projected capital through these milestones and into early 2026. For more information on the Company, please visit www.lisata.com.

Forward-Looking Statements

This communication contains "forward-looking statements" that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this communication regarding strategy, future operations, future financial position, future revenue, projected expenses and capital, prospects, plans and objectives of management are forward-looking statements. In addition, when or if used in this communication, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants,

as they relate to Lisata or its management, may identify forward-looking statements. Examples of forward-looking statements include, but are not limited to, statements relating to Lisata's continued listing on the Nasdaq Capital Market; expectations regarding the capitalization, resources and ownership structure of Lisata; the approach Lisata is taking to discover and develop novel therapeutics; the adequacy of Lisata's capital to support its future operations and its ability to successfully initiate and complete clinical trials; and the difficulty in predicting the time and cost of development of Lisata's product candidates. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: the safety and efficacy of Lisata's product candidates, decisions of regulatory authorities and the timing thereof, the duration and impact of regulatory delays in Lisata's clinical programs, Lisata's ability to finance its operations, the likelihood and timing of the receipt of future milestone and licensing fees, the future success of Lisata's scientific studies, Lisata's ability to successfully develop and commercialize drug candidates, the timing for starting and completing clinical trials, rapid technological change in Lisata's markets, the ability of Lisata to protect its intellectual property rights; and legislative, regulatory, political and economic developments. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in Lisata's Annual Report on Form 10-K filed with the SEC on March 30, 2023, and in other documents filed by Lisata with the Securities and Exchange Commission. Except as required by applicable law, Lisata undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

Contact:

Investors and Media:

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

- Tables to Follow -

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Statement of Operations Data:				
Research and development	$ 3,380	$ 3,335	$ 9,721	$ 9,853
In-process research and development	—	30,393	—	30,393
General and administrative	2,584	3,992	9,962	10,815
Total operating expenses	**5,964**	**37,720**	**19,683**	**51,061**
Operating loss	**(5,964)**	**(37,720)**	**(19,683)**	**(51,061)**
Investment income, net	714	337	2,053	496
Other expense, net	(11)	—	(175)	(149)
Net loss before benefit from income taxes and noncontrolling interests	**(5,261)**	**(37,383)**	**(17,805)**	**(50,714)**
Benefit from income taxes	—	—	(2,330)	(2,479)
Net loss	**(5,261)**	**(37,383)**	**(15,475)**	**(48,235)**
Less - net income attributable to noncontrolling interests	—	—	—	—
Net loss attributable to Lisata Therapeutics, Inc. common stockholders	**$ (5,261)**	**$ (37,383)**	**$ (15,475)**	**$ (48,235)**
Basic and diluted loss per share attributable to Lisata Therapeutics, Inc. common stockholders	**$ (0.65)**	**$ (7.88)**	**$ (1.92)**	**$ (11.28)**
Weighted average common shares outstanding	**8,141**	**4,747**	**8,050**	**4,276**

	September 30, 2023	December 31, 2022
	(unaudited)	
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$54,394	$69,226
Total assets	58,089	73,034
Total liabilities	5,385	6,710
Total equity	52,704	66,324

# # #

Exhibit 99.2

LISATA THERAPEUTICS

Targeted Therapy *Delivered*

Corporate Presentation | November 2, 2023
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 impact of the ongoing COVID-19 pandemic on Lisata's business, 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 March 30, 2023, and in other documents filed by Lisata with the Securities and Exchange Commission. Except as required by applicable law, Lisata undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

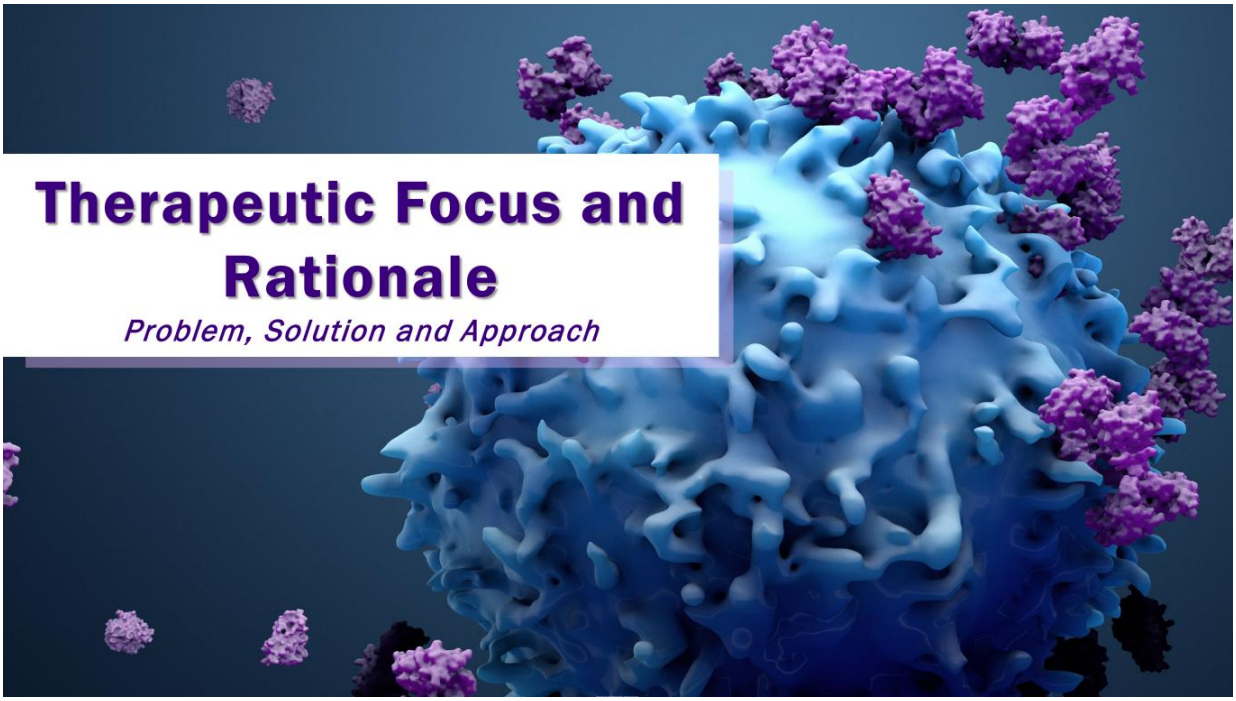

Company Overview
Lisata at a Glance

Lisata Therapeutics (Nasdaq: LSTA): Summary

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 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 2026, funding all development programs through to data


Therapeutic Focus and Rationale
Problem, Solution and Approach

Improved solid tumor cancer treatment is a vital global need

Cancer is a leading cause of death worldwide, accounting for nearly 10 million deaths in 2020, or nearly one in six deaths[1]

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[2]

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

[1] www.who.int/news-room/fact-sheets/detail/cancer
[2] https://seer.cancer.gov/statfacts/html/common.html; As of November 2, 2023

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
  - Translation of animal model results to human safety and efficacy has been inconsistent and challenging

Targeted penetration technology enhances drug delivery to solid tumors

- RGD peptides serve as targeting agents to 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 peptide 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 a streamlined development path to registration
    - Tethering creates a new chemical entity providing prolonged compound exclusivity
- LSTA1 combats resistance and metastases[1]
  - Preclinical data demonstrates 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 >95% 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

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)*
- LSTA1/gemcitabine/nab-paclitaxel treatment regimen ± atezolizumab with *ROCHE*

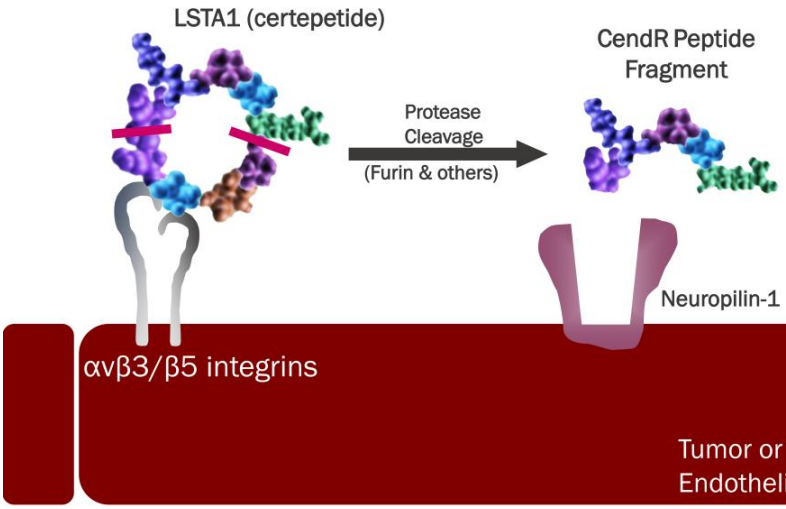
Strategic partnership in China with Qilu Pharmaceutical

- 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 $220 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

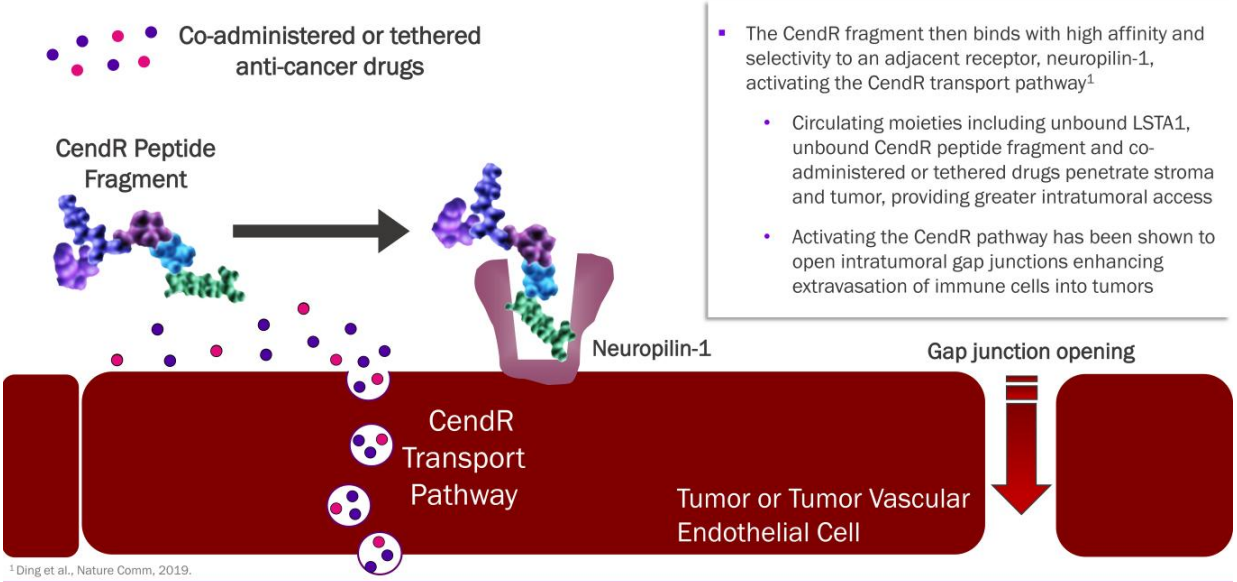

LSTA1
Strong Scientific Foundation and Rationale

LSTA1 Mechanism of Action: Steps 1 & 2 of 3



- LSTA1: 9 amino acid cyclic peptide; high binding specificity and affinity to αvβ3/β5 integrins that are upregulated on:
  - Tumor vascular endothelium
  - 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

LSTA1 Mechanism of Action: Step 3 of 3



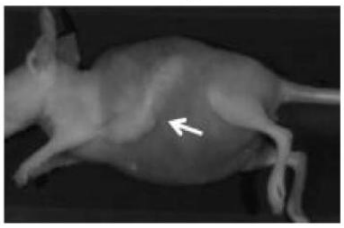
- The CendR fragment then binds with high affinity and selectivity to an adjacent receptor, neuropilin-1, activating the CendR transport pathway[1]
  - Circulating moieties including unbound LSTA1, unbound CendR peptide fragment and co-administered or tethered drugs penetrate stroma and tumor, providing greater intratumoral access
  - Activating the CendR pathway has been shown to open intratumoral gap junctions enhancing extravasation of immune cells into tumors

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

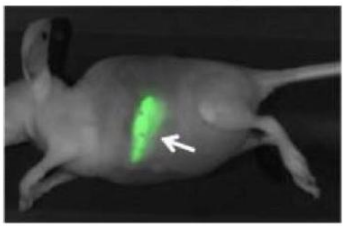
LSTA1 selectively and efficiently facilitates intratumoral penetration

Whole body imaging of mice with pancreatic ductal adenocarcinoma (arrow) dosed with Fluorescent Quantum Dots (FQDs) with and without LSTA1

FQD + Etching solution



LSTA1 + FQD + Etching solution



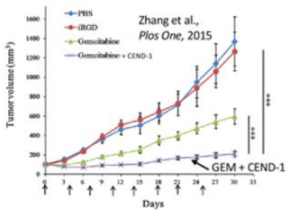
- Etching solution quenches fluorescence in circulation
- LSTA1 provides selective tumor penetration

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

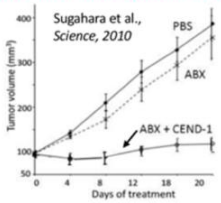
Large body of work shows consistent LSTA1 activity/broad applicability

Sampling of >300 scientific publications showing LSTA1/iRGD augmentation effects

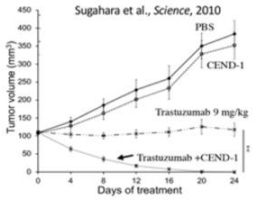
Lung cancer + gemcitabine + LSTA1



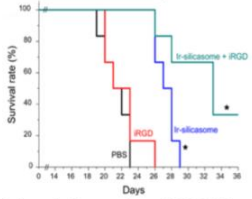
Breast cancer + nanoparticle Abraxane + LSTA1



Breast cancer + Herceptin® + LSTA1

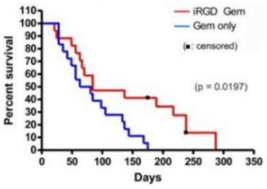


PDAC + irinotecan nanoparticles + LSTA1



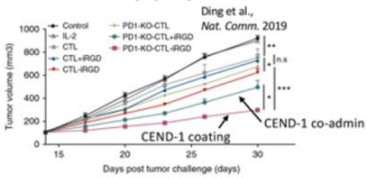
Orthotopically transplanted KPC PDAC tumors
CEND-1 + irinotecan nanoparticles (i.v. co-admin)

PDAC + gemcitabine + LSTA1



KPC mice genetically engineered to develop
PDAC CEND-1 + gemcitabine (i.v. co-admin)

GI cancer + adoptive cell therapy + LSTA1



[1] Hurtado de Mendoza et al, *Nature Comms*, 2021.
[2] Liu X et al., J Clin Invest, 2017.

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

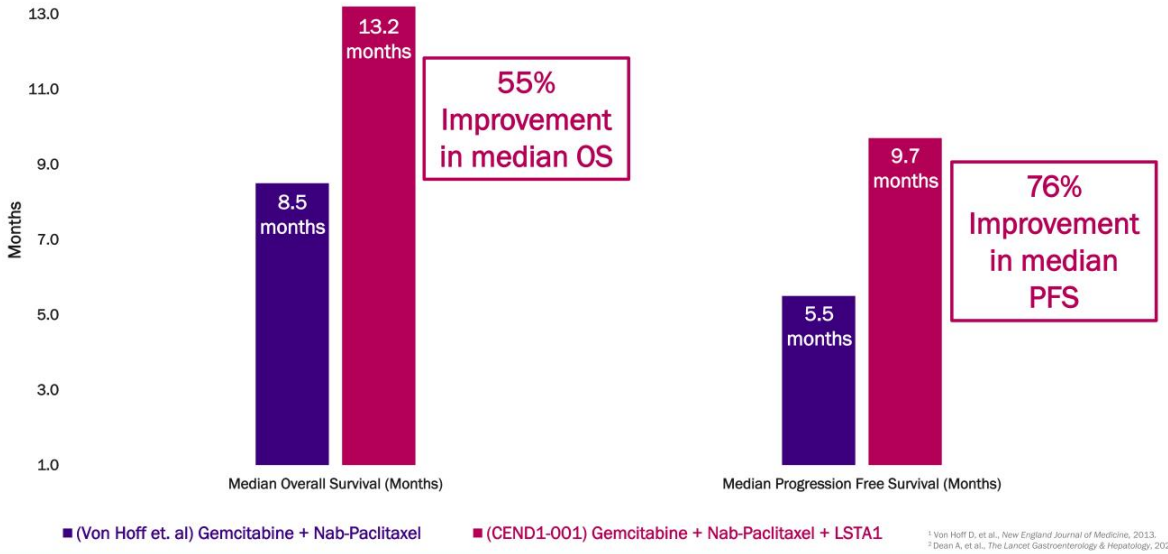
Endpoints	Gemcitabine[1]	Gemcitabine + Nab-paclitaxel[2]	LSTA1 + Gemcitabine + Nab-paclitaxel[3]
N= # of study participants	N=171	N=431	**N=31**
Median Overall Survival	6.8 mos.	8.5 mos.	**13.2 mos.**
Median Progression-Free Survival	3.3 mos.	5.5 mos.	**9.7 mos.**
Objective Response Rate	9.4% (16)	23% (99)	**59% (17)**
Complete Response	0% (0)	0.2% (1)	**3.4% (1)**
Partial Response	9.5% (16)	23% (98)	**55% (16)**
Stable Disease	41.5% (71)	27% (118)	**31% (9)**
Progressive Disease	34.5% (59)	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 with LSTA1 consistent with SoC alone

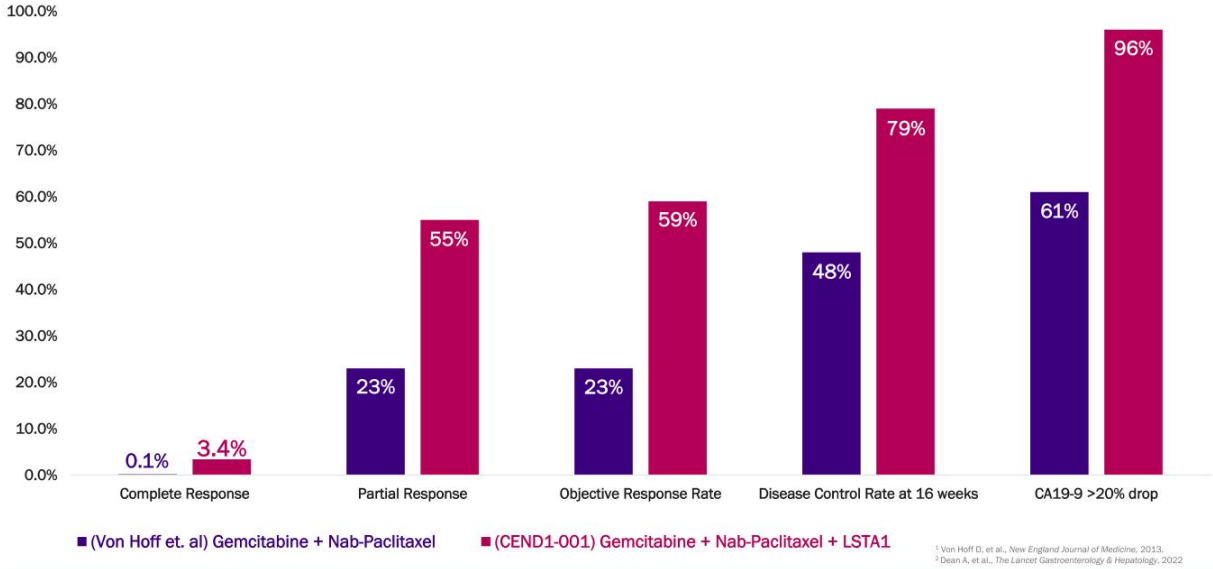
[1] Conroy T, et al., *New England Journal of Medicine*, 2011.
[2] Von Hoff D, et al., *New England Journal of Medicine*, 2013.
[3] Dean A, et al., *The Lancet Gastroenterology & Hepatology*, 2022.

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


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

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 the opportunity to apply for *grants* 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	Region	Indication and Test Articles	Status
AGITG/Lisata	Australia & New Zealand	**First-line mPDAC** Gemcitabine/nab-paclitaxel with LSTA1 or placebo	Phase 2b (**ASCEND**) Placebo-controlled *Enrolling*
Lisata	USA, Canada, EU and Asia	**Various Solid Tumors** Standard of Care with LSTA1 or placebo	Phase 2a (**BOLSTER**) Placebo-controlled *Enrolling*
KUCC/Lisata	USA	**Pancreatic, Colon, & Appendiceal Cancers** LSTA1 + FOLFIRINOX + panitumumab*	Phase 1b/2a (**CENDIFOX**) Open-label *Enrolling*
Qilu/Lisata	China	**First-line mPDAC** Gemcitabine/nab-paclitaxel + LSTA1	Phase 1b/2a Open-label *Enrolling*
WARPNINE/Lisata	Australia	**Locally advanced, non-resectable PDAC** Durvalumab/gemcitabine/nab-paclitaxel + LSTA1	Phase 1b/2a (**iLSTA**) Open-label *Enrolling*

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

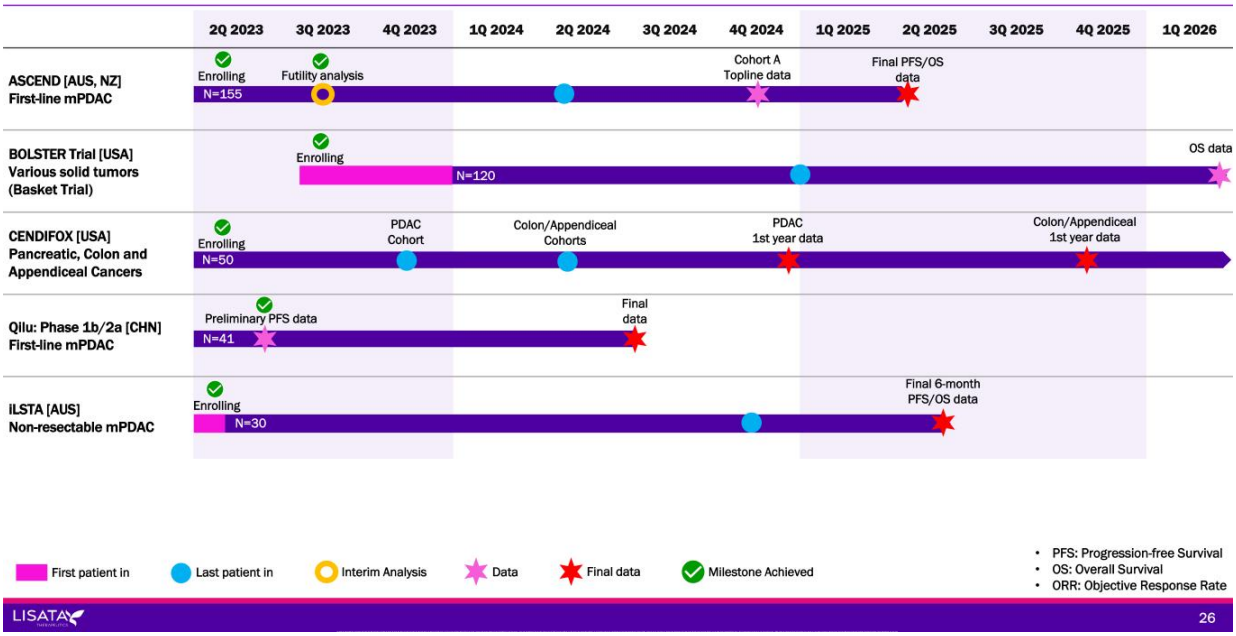
LSTA1 capital efficient development plan; shared costs & selective geography

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

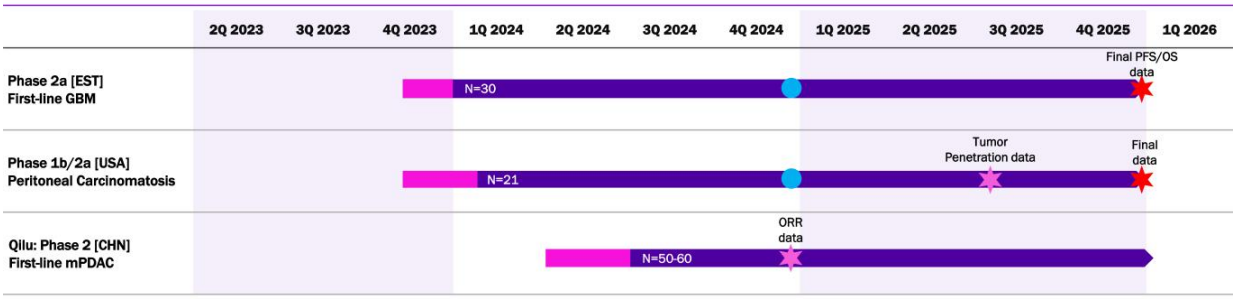
**Hyperthermic intraperitoneal chemotherapy*


Development
Milestones

A wealth of anticipated key milestones



A wealth of anticipated key milestones (contd.)



First patient in | Last patient in | Interim Analysis | Data | Final data | Milestone Achieved

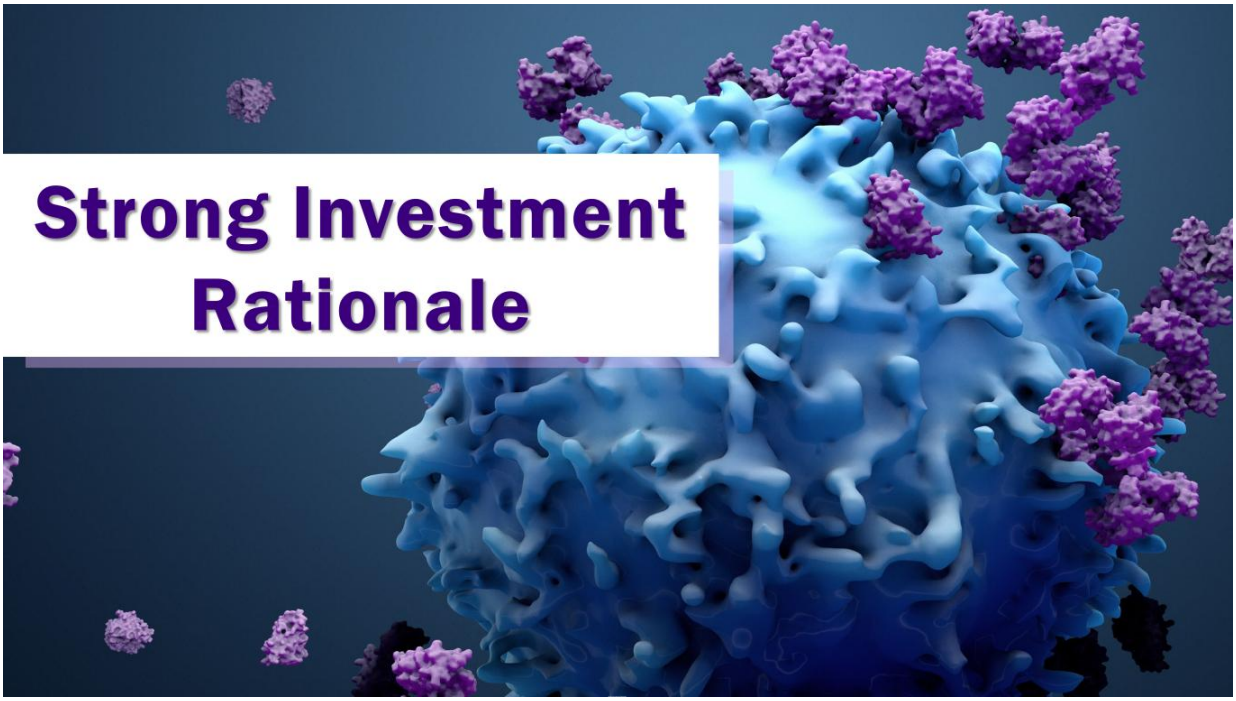
- PFS: Progression-free Survival
- OS: Overall Survival
- ORR: Objective Response Rate


Financial
Highlights

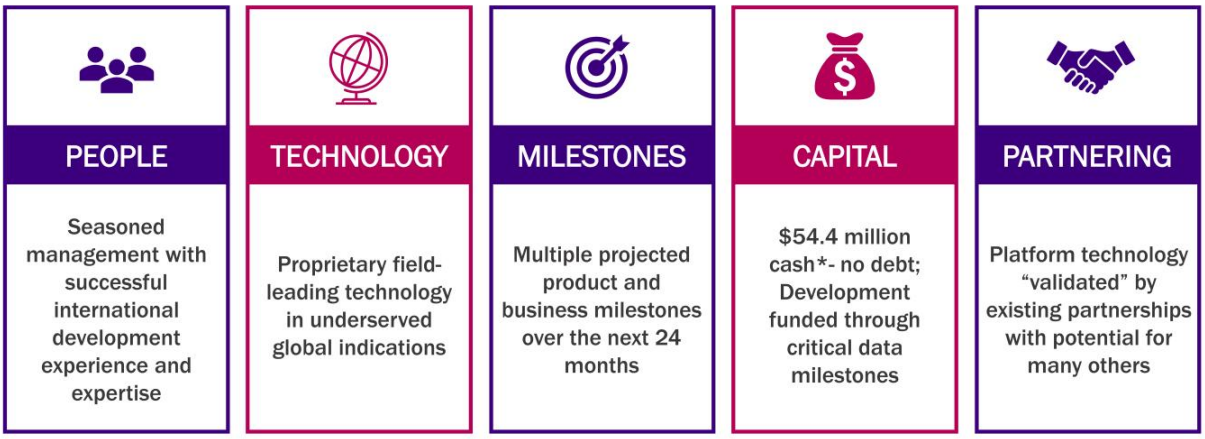
Capital projected to fund all clinical programs to data

Cash & Investments *As of 9/30/2023*	Debt	Projected Cash Runway Into
$54.4M	**$0**	**1Q2026**

Common Shares Outstanding (9/30/2023):	8.1 million shares
Options Outstanding (9/30/2023): Exercise Price: $0.02 - $4.22 = 1,082,000 shares Exercise Price: > $4.22 = 239,000 shares	1.3 million shares
Warrants Outstanding (9/30/2023): Weighted Average Exercise Price: $42.51	1.4 million shares


Strong Investment
Rationale

Key factors supporting investment in Lisata Therapeutics



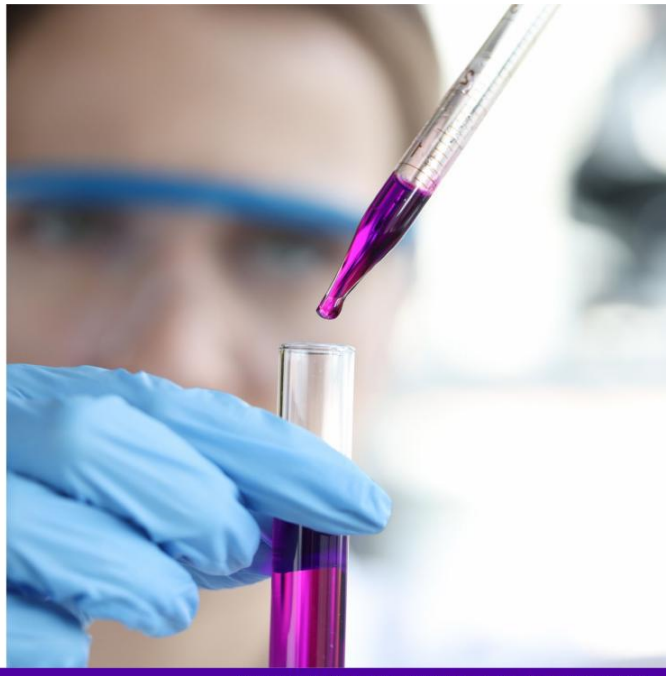
* As of 9/30/2023; includes investments

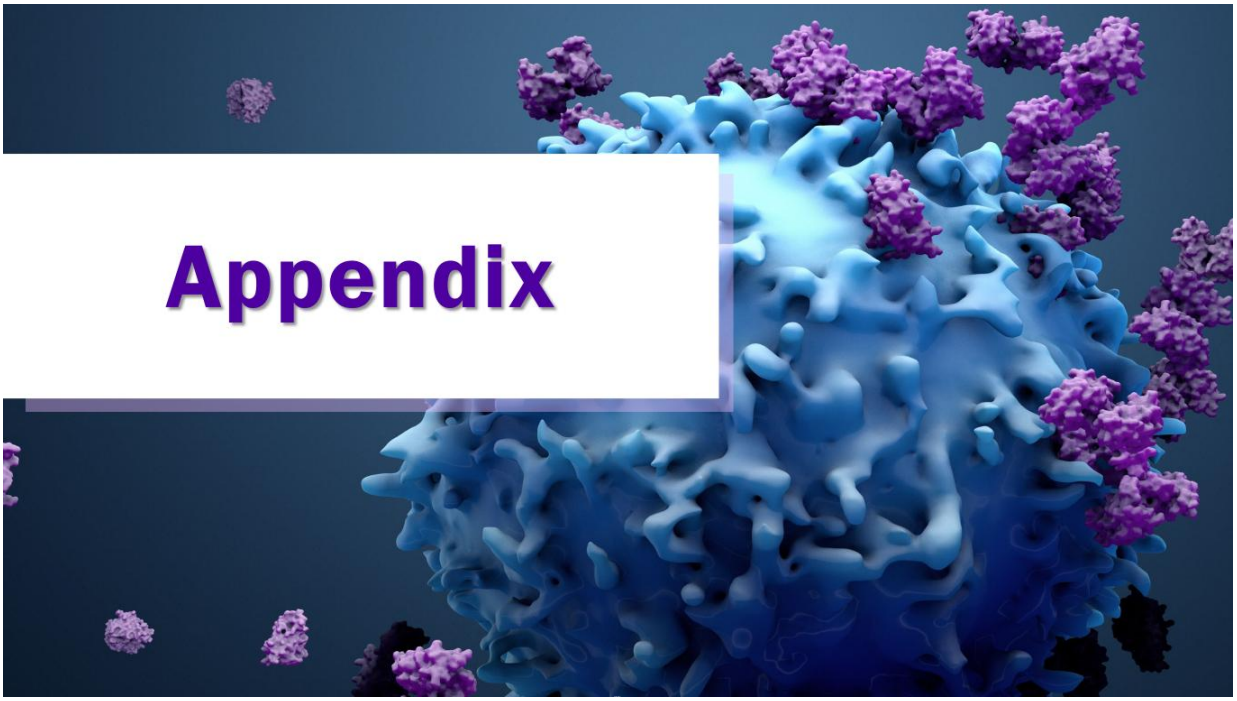
LISATA THERAPEUTICS

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

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

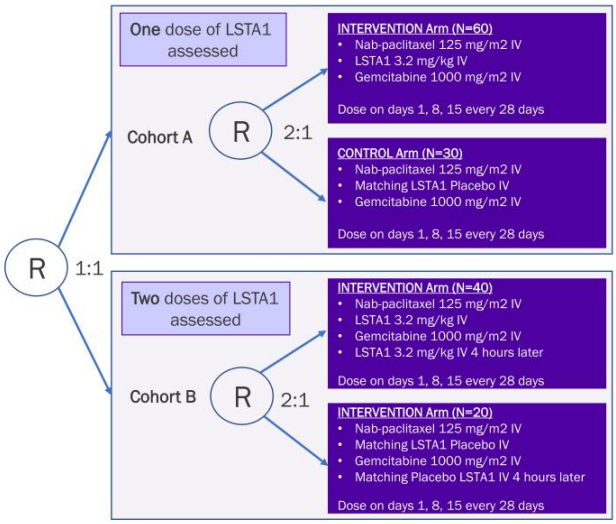
Development Partner(s) [Development Venue]	Indication and Trial Product/Comparator	Stage of Development	Strategic Rationale
Tartu University/Lisata [Estonia]	First-line Glioblastoma Multiforme; Temozolomide ± LSTA1	Phase 2a	Assess LSTA1 safety and effectiveness in additional tumor type (GBM) a in placebo-controlled 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	▪ ~150 subjects (~40 sites planned in Australia and New Zealand)
Endpoints	▪ Primary: Progression Free Survival ▪ Secondary: AEs, SAEs, Overall Survival, Objective Tumor Response Rate
Timing	▪ Enrollment completion target late 2Q24 ▪ 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 completion target late 2Q24; Earliest possible data 2024

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

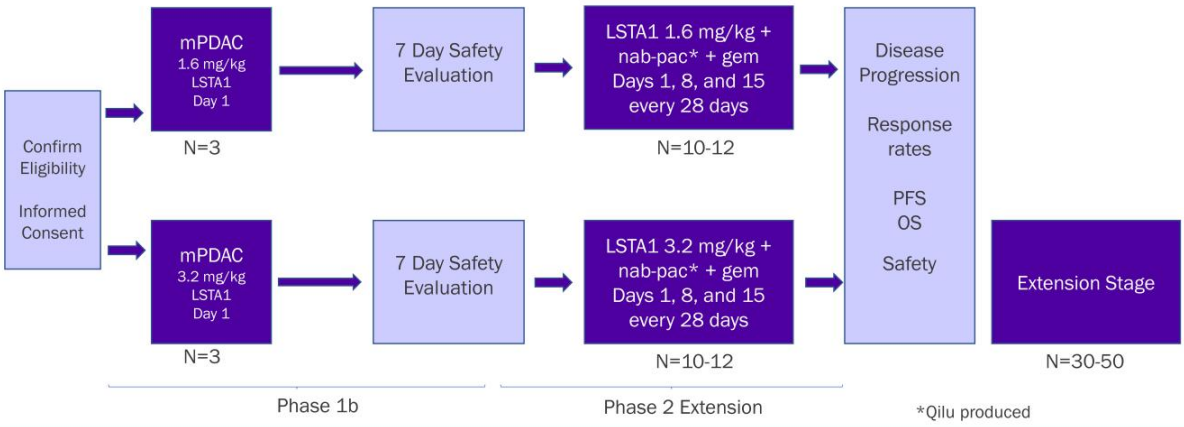
Phase 1b/2a open-label trial in mPDAC in China

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

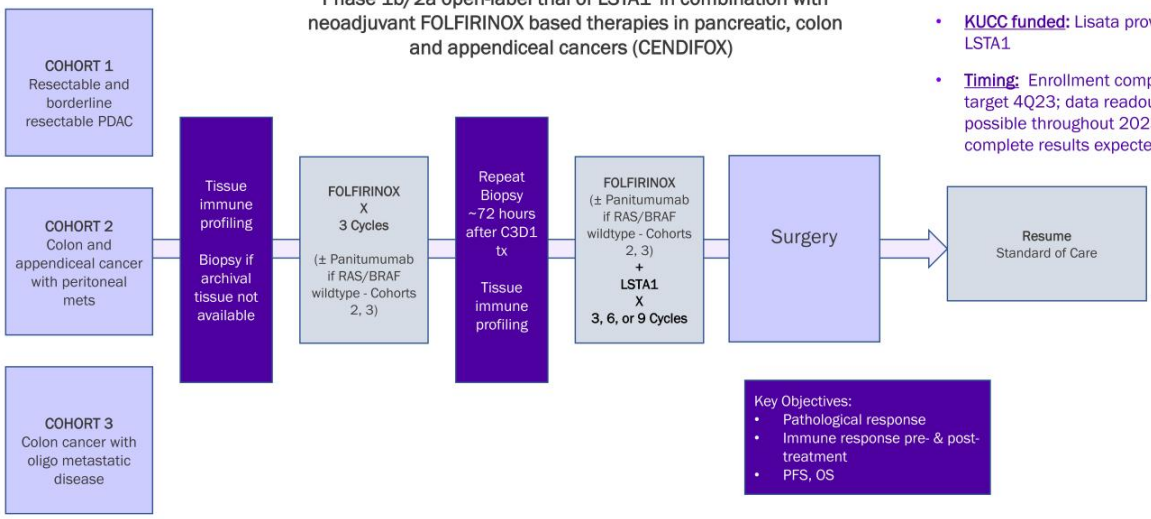


*Qilu produced

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

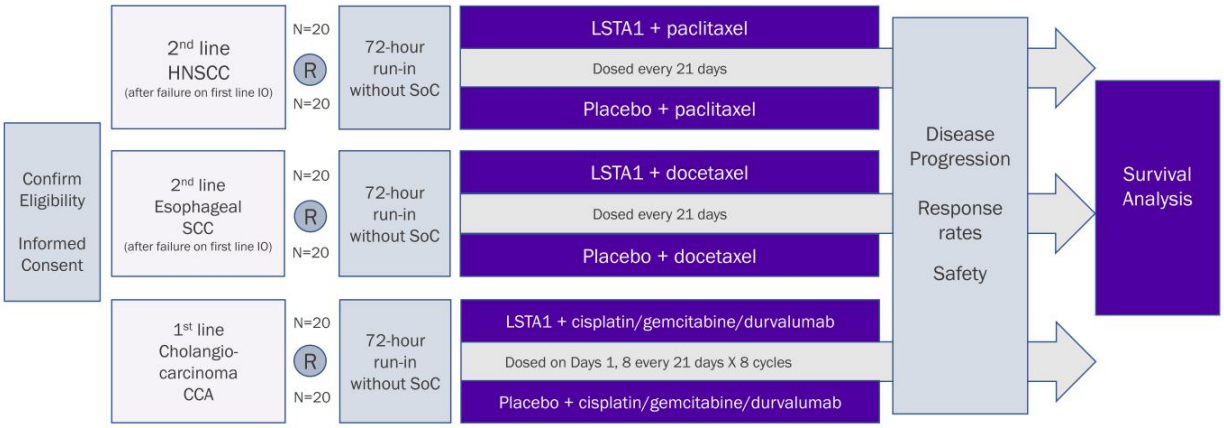
BOLSTER: Phase 2 blinded, randomized PoC trial in various cancers

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, 2nd line esophageal SCC and 1st line cholangiocarcinoma testing corresponding SoC with LSTA1 or placebo
Study Size	▪ 120 (40 per tumor type split 1:1 SoC + LSTA1 or SoC + placebo)
Endpoints	▪ Primary: OS ▪ Secondary: Safety, ORR, PFS
Objective	▪ Evaluate the preliminary efficacy, safety and tolerability of LSTA1 in combination with standards of care in subjects with advanced solid tumors
Timing	▪ First patient in target 3Q23

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: First patient in target 3Q23



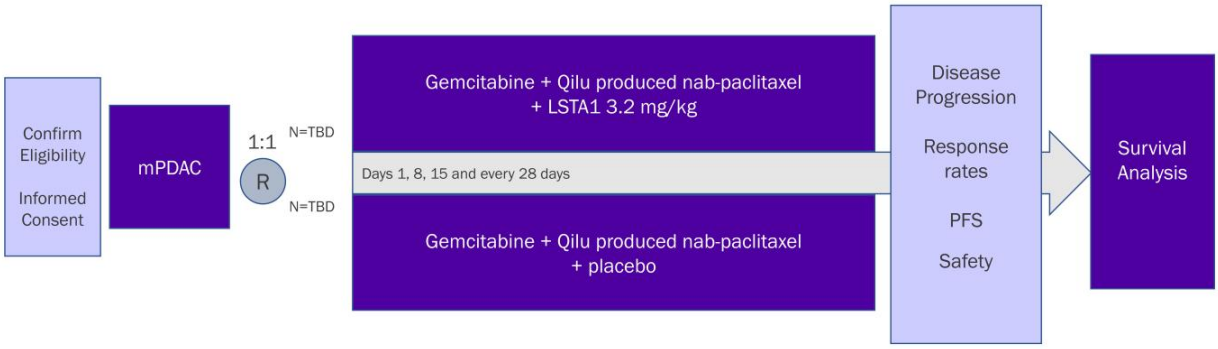
Phase 2 blinded, placebo-controlled trial in mPDAC in China

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

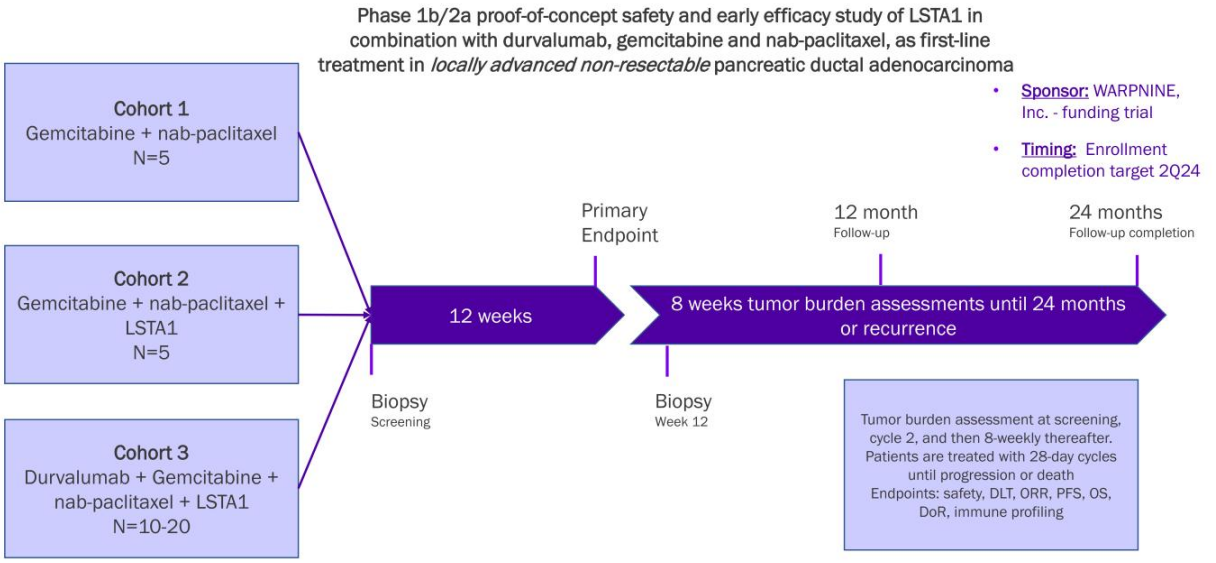
- Sponsor/Partner: Qilu Pharmaceutical (funds all development in China)
- Timing: Trial initiation target 4Q23



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	▪ N=30
Endpoints	▪ Safety and tolerability; 28-day DLTs ▪ Objective response rate, PFS, OS, duration of response, immune cell infiltration
Timing	▪ Enrollment completion target 2Q24

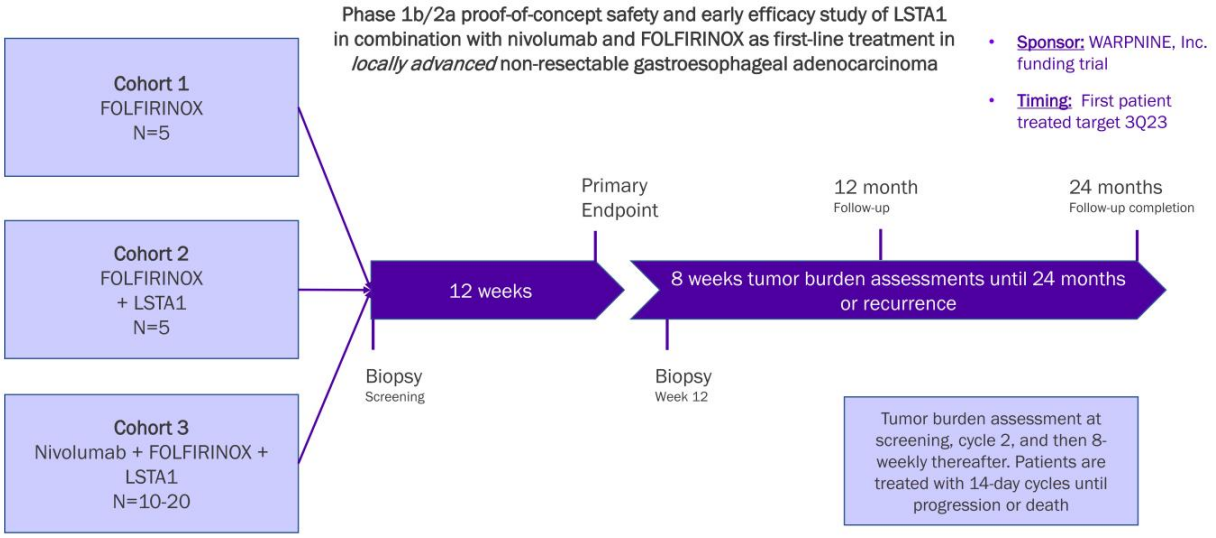
iLSTA: Phase 1b/2a trial in locally advanced PDAC with chemo & IO



iGoLSTA: Phase 1b/2a trial in locally advanced GEAC 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 with IO & Chemo in locally advanced non-resectable gastroesophogeal adenocarcinoma (GEAC); determine if inoperable tumors can become operable
Design	▪ Phase 1b/2a proof-of-concept, safety and early efficacy study of LSTA1 in combination with nivolumab and FOLFIRINOX, as first-line treatment in *locally advanced* non-resectable gastroesophageal adenocarcinoma
Study Size	▪ N=30
Endpoints	▪ Safety and tolerability; 28-day DLTs ▪ Objective response rate, PFS, OS, duration of response, immune cell infiltration
Timing	▪ First patient treated target 3Q23

iGoLSTA: Phase 1b/2a trial in locally advanced GEAC with chemo & IO



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 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=30
Endpoints	▪ Safety, tolerability ▪ ORR, PFS, OS, disease control rate
Timing	▪ First patient treated target 4Q23

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

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

- Sponsor: Tartu University Hospital; Estonia
- Funding: Lisata
- Timing: First patient treated target 4Q23