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

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

August 14, 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 August 14, 2023, Lisata Therapeutics, Inc. (the "Company") issued a press release in connection with its financial results for the second quarter ended June 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 August 14, 2023
99.2	Lisata Therapeutics, Inc. Corporate Presentation, August 14, 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: August 14 2023

Exhibit 99.1

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

Cash runway projected into first quarter 2026 based on capital conservation measures implemented without impact to clinical development pipeline

Technology transfer agreement executed for Company's tumor penetrating nanocomplex (TPN) platform

Company to host conference call Tuesday, August 15 at 8:30 a.m. Eastern time

BASKING RIDGE, NJ (August 14, 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 second quarter ended June 30, 2023.

"The second quarter generated strong momentum for Lisata. We continued to advance multiple ongoing and planned clinical studies centered around our lead investigational product, LSTA1," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Lisata. "Of note, we implemented key changes to the Phase 2b ASCEND trial which now includes an additional cohort of subjects for the evaluation of a second dose of LSTA1 in patients with first-line, metastatic pancreatic ductal adenocarcinoma ("mPDAC"). We intend to use the results of ASCEND to explore possible conditional approvals globally and to design an optimized Phase 3 program. We also saw the initiation of the iLSTA study in Australia and the launch of our BOLSTER trial, which is the first fully sponsored study of LSTA1 by Lisata. Finally, we are delighted to announce that we have entered into a technology transfer agreement for our Tumor Penetrating Nanocomplex (TPN) Platform with Impilo Therapeutics, Inc. ("Impilo"), a newly formed company being led by former Lisata Chief Business Officer, David Slack. We are pleased that the TPN technology will be in the hands of a team of people with deep expertise in the field of RNA-based therapeutics development."

Dr. Mazzo continued, "Also, notably, in this quarter we took a number of cash conservation decisions which resulted in the extension of projected capital supporting operations into the first quarter of 2026. Now with more than two years of capital available on our balance sheet based on our current expected capital needs, we believe we are well-placed 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 anti-cancer drugs to 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. 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 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. Enrollment completion is projected for the second quarter of 2024; however, current enrollment already exceeds 70% of the target, so earlier enrollment completion may be achieved.
- BOLSTER: Phase 2a placebo-controlled 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 now open and the Company hopes to soon announce the first patient treated.
- 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 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 plans to study 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 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 first patient treated is in the fourth quarter of 2023. Importantly and as the Company recently announced, LSTA1 has been granted orphan 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 is also planning to study LSTA1 in combination with HIPEC interoperative intraperitoneal lavage in peritoneal carcinomatosis, 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 that this study will also be up and running in the fourth quarter of 2023 and the first patient being treated shortly thereafter.

Tumor Penetrating Nanocomplex (TPN) Platform Technology Transfer

The tumor penetrating nanocomplex (TPN) platform targets intracellular delivery of RNA-based drugs to prevent solid tumor growth. The TPN is designed so that it could not only bind a protein overexpressed on the surface of human cancer cells, but also pass through the membrane by way of a cell-penetrating peptide. Once inside the cells, the TPN is expected to release an RNA-based drug directed against the tumor. Lisata has agreed to transfer this technology to Impilo. Under the terms of the technology transfer agreement, Lisata will receive an equity stake in Impilo upon closing. Lisata is not obliged to commit any capital or additional resources to the program’s future development.

Second Quarter 2023 Financial Highlights

Research and development expenses remained constant at approximately $3.2 million for the three months ended June 30, 2023 and three months ended June 30, 2022. Expenses this quarter were primarily due to study start up activities associated with the LSTA1 BOLSTER trial, enrollment activities for the LSTA1 ASCEND study and chemistry, manufacturing and control (CMC) activities for LSTA1 to support all development activities.

General and administrative expenses were approximately $3.7 million for the three months ended June 30, 2023, compared to $3.5 million for the three months ended June 30, 2022, representing an increase of $0.2 million or 6.5%. This was primarily due to severance costs associated with the elimination of the Chief Business Officer position on May 1, 2023, partially offset by non-recurring merger related costs in the prior year.

Overall, net losses were $4.0 million for the three months ended June 30, 2023, compared to $6.6 million for the three months ended June 30, 2022, a decrease of approximately 40% primarily due to $2.2 million in non-dilutive funding received as an approved participant of the Technology Business Tax Certificate Transfer Program sponsored by the New Jersey Economic Development Authority.

Balance Sheet Highlights

As of June 30, 2023, the Company had cash, cash equivalents and marketable securities of approximately $57.6 million. Based on its current expected capital needs, the Company believes that its projected capital will fund its current proposed operations into the first quarter of 2026 encompassing anticipated data milestones from all its ongoing and planned clinical trials.

Conference Call Information

Lisata will hold a live conference call on Tuesday, August 15, 2023, at 8:30 a.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, 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 up

date 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
(in thousands, except per share data)	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Statement of Operations Data:				
Research and development	$ 3,162	$ 3,234	$ 6,341	$ 6,516
General and administrative	3,713	3,486	7,378	6,824
Total operating expenses	**6,875**	**6,720**	**13,719**	**13,340**
Operating loss	**(6,875)**	**(6,720)**	**(13,719)**	**(13,340)**
Investment income, net	668	94	1,338	158
Other expense, net	(150)	—	(163)	(149)
Net loss before benefit from income taxes and noncontrolling interests	**(6,357)**	**(6,626)**	**(12,544)**	**(13,331)**
Benefit from income taxes	(2,330)	—	(2,330)	(2,479)
Net loss	**(4,027)**	**(6,626)**	**(10,214)**	**(10,852)**
Less - net income attributable to noncontrolling interests	—	—	—	—
Net loss attributable to Lisata Therapeutics, Inc. common stockholders	**$ (4,027)**	**$ (6,626)**	**$ (10,214)**	**$ (10,852)**
Basic and diluted loss per share attributable to Lisata Therapeutics, Inc. common stockholders	**$ (0.50)**	**$ (1.64)**	**$ (1.28)**	**$ (2.69)**
Weighted average common shares outstanding	**8,021**	**4,035**	**8,004**	**4,036**

	June 30, 2023	December 31, 2022
	(unaudited)	
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$57,626	$69,226
Total assets	62,365	73,034
Total liabilities	4,651	6,710
Total equity	57,714	66,324

# # #

Exhibit 99.2

LISATA THERAPEUTICS

Targeted Therapy *Delivered*

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

Corporate Presentation | August 14, 2023
Nasdaq: LSTA

www.lisata.com

Forward-looking Statements

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

Nasdaq-listed clinical stage therapeutics development company with a novel solid tumor targeting and penetration technology to improve the efficacy of anti-cancer drugs

Investment rationale – key company differentiation

* As of 6/30/2023; includes investments

Experienced executive leadership team

David J. Mazzo, PhD
President and Chief Executive Officer

Kristen Buck, MD
EVP of R&D and Chief Medical Officer

Gregory Berkin
VP of IT and Chief Informational Officer

Tariq Imam
VP of BD & Operations and Corporate Counsel

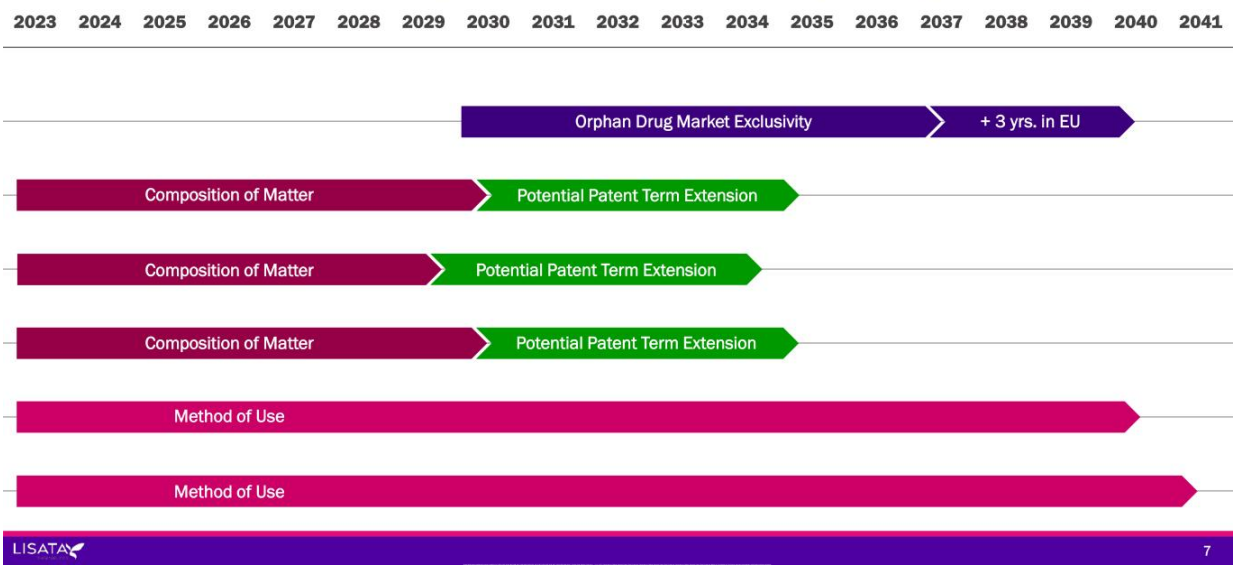
James Nisco
VP of Finance and Treasury

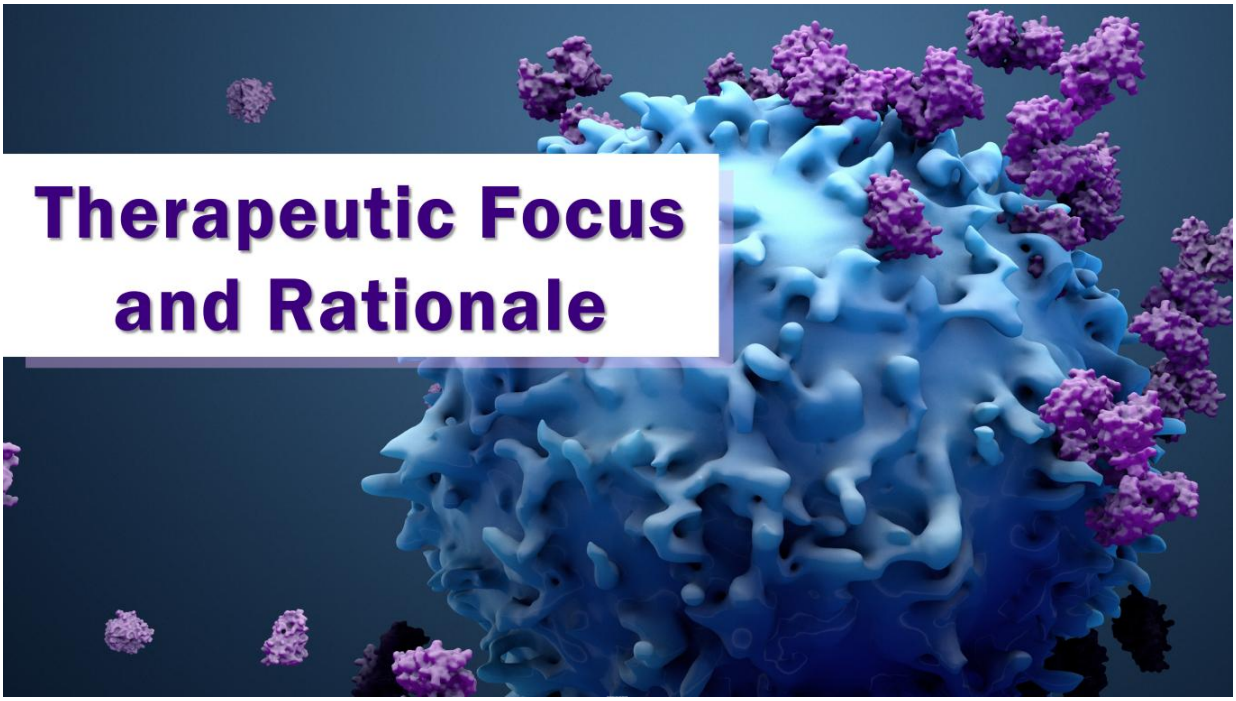
John Menditto
VP of IR and Corporate Communications

Please visit the management team page on the corporate website for more information: www.lisata.com

Lisata holds strong intellectual property portfolio for LSTA1

Patent extension opportunities could further prolong exclusivity




Therapeutic Focus
and Rationale

Improved 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]

– World Health Organization

[1] www.who.int/news-room/fact-sheets/detail/cancer

Solid tumor treatment is a large & growing market

Estimated New Cancer Cases and Deaths in the United States, 2022[1]

Estimated New Cases

Males			Females		
Prostate	268,490	27%	Breast	287,850	31%
Lung & bronchus	117,910	12%	Lung & bronchus	118,830	13%
Colon & rectum	80,690	8%	Colon & rectum	70,340	8%
Urinary bladder	61,700	6%	Uterine corpus	65,950	7%
Melanoma of the skin	57,180	6%	Melanoma of the skin	42,600	5%
Kidney & renal pelvis	50,290	5%	Non-Hodgkin lymphoma	36,350	4%
Non-Hodgkin lymphoma	44,120	4%	Thyroid	31,940	3%
Oral cavity & pharynx	38,700	4%	Pancreas	29,710	3%
Leukemia	35,810	4%	Kidney & renal pelvis	28,710	3%
Pancreas	32,970	3%	Leukemia	28,840	3%
All sites	983,160	100%	All sites	934,870	100%

Estimated Deaths

Males			Females		
Lung & bronchus	68,820	21%	Lung & bronchus	61,360	21%
Prostate	34,500	15%	Breast	43,250	15%
Colon & rectum	28,400	9%	Colon & rectum	24,180	8%
Pancreas	25,970	8%	Pancreas	23,860	8%
Liver & intrahepatic bile duct	20,420	6%	Ovary	12,810	5%
Leukemia	14,020	4%	Uterine corpus	12,550	4%
Esophagus	13,250	4%	Liver & intrahepatic bile duct	10,100	4%
Urinary bladder	12,120	4%	Leukemia	9,980	3%
Non-Hodgkin lymphoma	11,700	4%	Non-Hodgkin lymphoma	8,550	3%
Brain & other nervous system	10,710	3%	Brain & other nervous system	7,570	3%
All sites	322,090	100%	All sites	287,270	100%

>1.9 million new cases of cancer will be diagnosed in 2022

In the U.S. alone, solid tumors account for >90% of new cancer cases

[1] CA A Cancer J Clinicians, Volume: 72, Issue: 1, Pages: 7-33, First published: 12 January 2022, DOI: (10.3322/caac.21708)

Current solid tumor treatments offer inadequate results

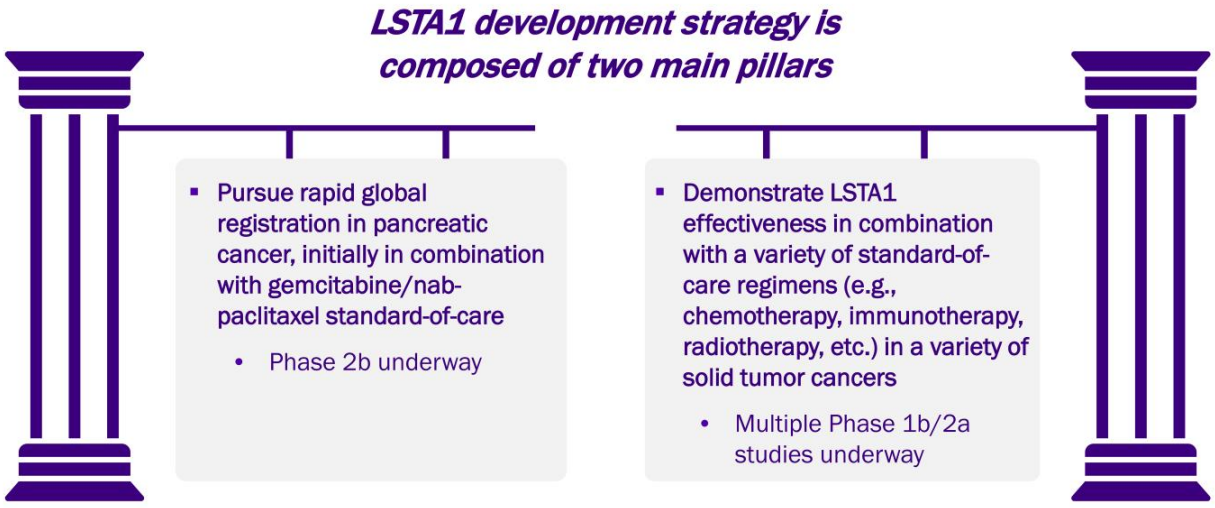
- **Tumor targeting and intratumoral penetration are suboptimal**
  - Tumor stroma acts as an effective barrier to anti-cancer agents
  - Tumor microenvironment immunosuppressive cells contribute to tumor resistance and/or metastases
  - Continued or escalated dosing of non-targeted anti-cancer therapy can lead to intolerable off-target side effects

Lisata's CendR Platform® promises optimized solid tumor treatment

Targeted penetration technology enhances drug delivery to solid tumors

- Converts tumor stroma from *barrier to conduit*
  - Combination possible with most anti-cancer drugs
    - LSTA1 effectiveness agnostic to co-administered drug modality
  - Mechanism effective with co-administered or tethered anti-cancer therapies
    - Co-administration presents a streamlined development path to registration
    - Tethering provides for prolonged compound exclusivity (NCE)
- Resistance combated by selective depletion of intratumoral immunosuppressive cells

LSTA1: lead clinical development candidate of the CendR Platform®




Partnerships
Noteworthy existing relationships with the 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*

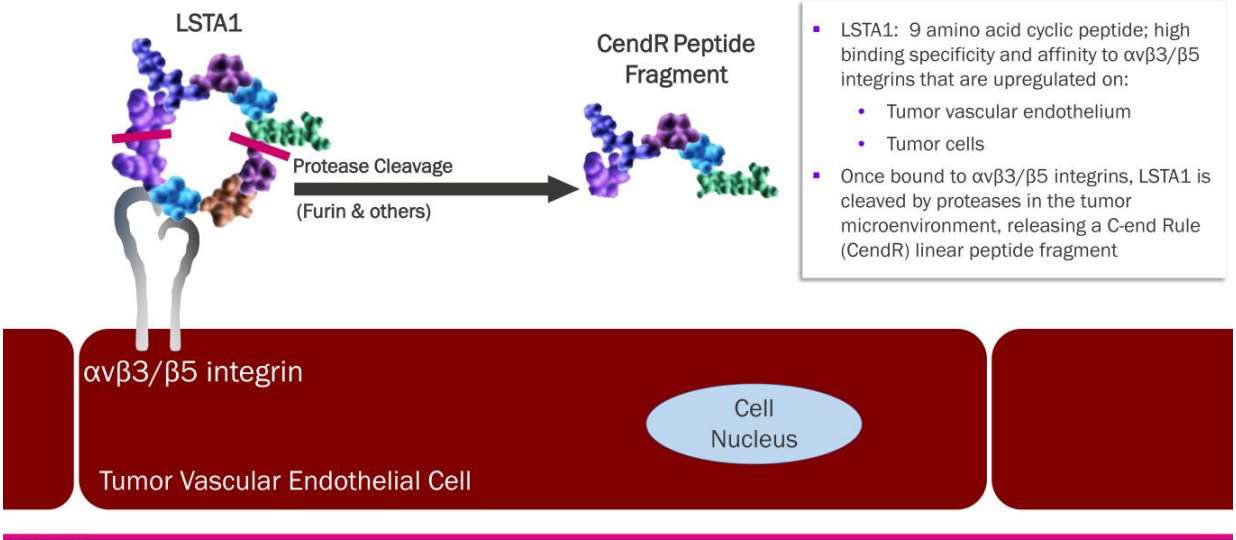
Strategic partnership in China with Qilu Pharmaceutical

- 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

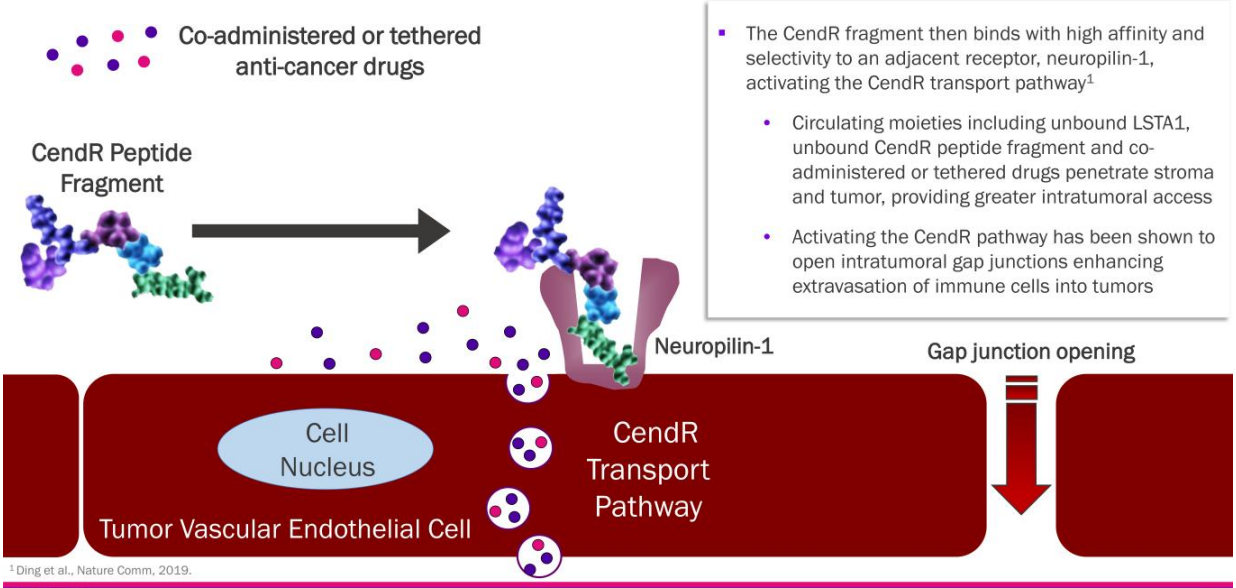

LSTA1
Strong Scientific Foundation and Rationale

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



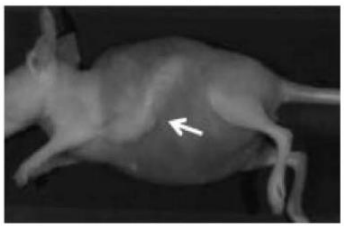
- The CendR fragment then binds with high affinity and selectivity to an adjacent receptor, neuropilin-1, activating the CendR transport pathway[1]
  - Circulating moieties including unbound LSTA1, unbound CendR peptide fragment and co-administered or tethered drugs penetrate stroma and tumor, providing 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.

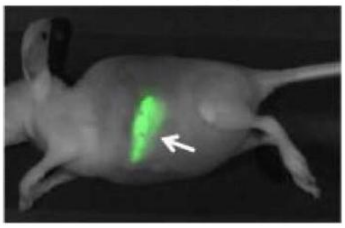
LSTA1 selectively and efficiently facilitates intratumoral penetration

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



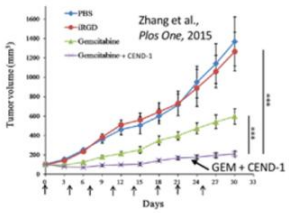
- Etching solution quenches fluorescence in circulation
- LSTA1 provides selective tumor penetration

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

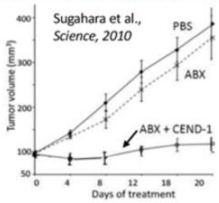
Large body of work shows consistent LSTA1 activity/broad applicability

Sampling of >225 scientific publications showing LSTA1 augmentation effects

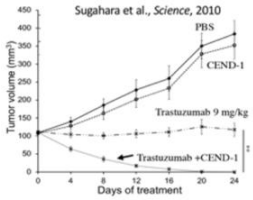
Lung cancer + gemcitabine + LSTA1



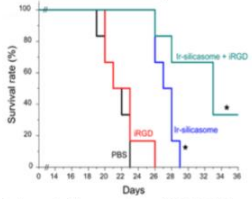
Breast cancer + nanoparticle Abraxane + LSTA1



Breast cancer + Herceptin® + LSTA1

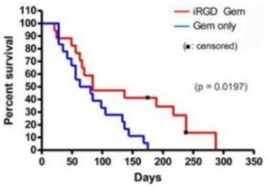


PDAC + irinotecan nanoparticles + LSTA1



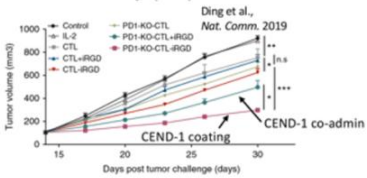
Orthotopically transplanted KPC PDAC tumors
CEND-1 + irinotecan nanoparticles (i.v. co-admin)

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

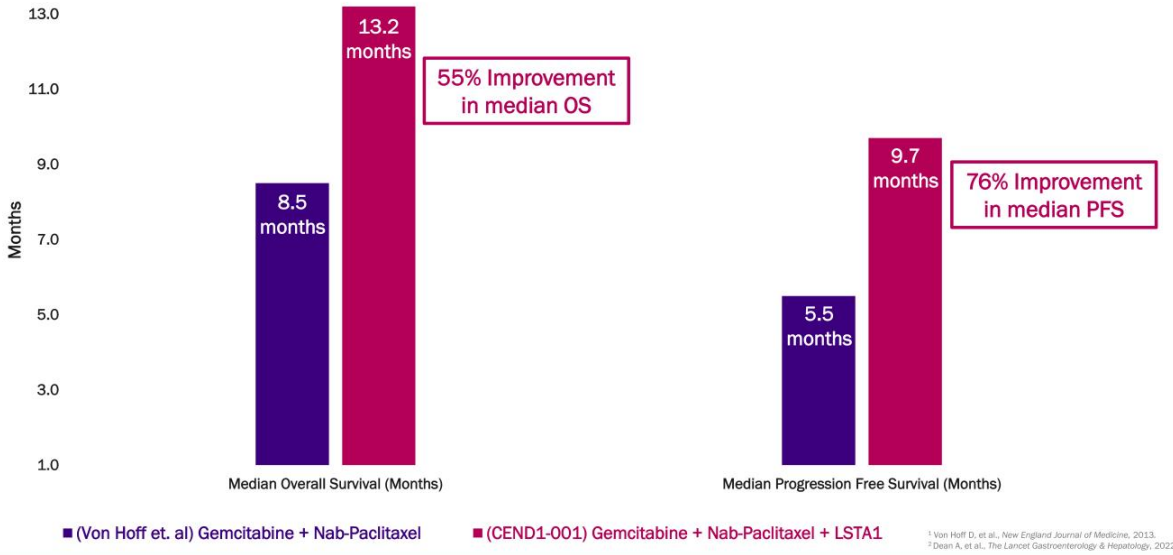
Endpoints	Gemcitabine[1]	Gemcitabine + Nab-paclitaxel[2]	LSTA1 + Gemcitabine + Nab-paclitaxel[3]
N= # of study participants	N=171	N=431	**N=31**
Median Overall Survival	6.8 mos.	8.5 mos.	**13.2 mos.**
Median Progression-Free Survival	3.3 mos.	5.5 mos.	**9.7 mos.**
Objective Response Rate	9.4% (16)	23% (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

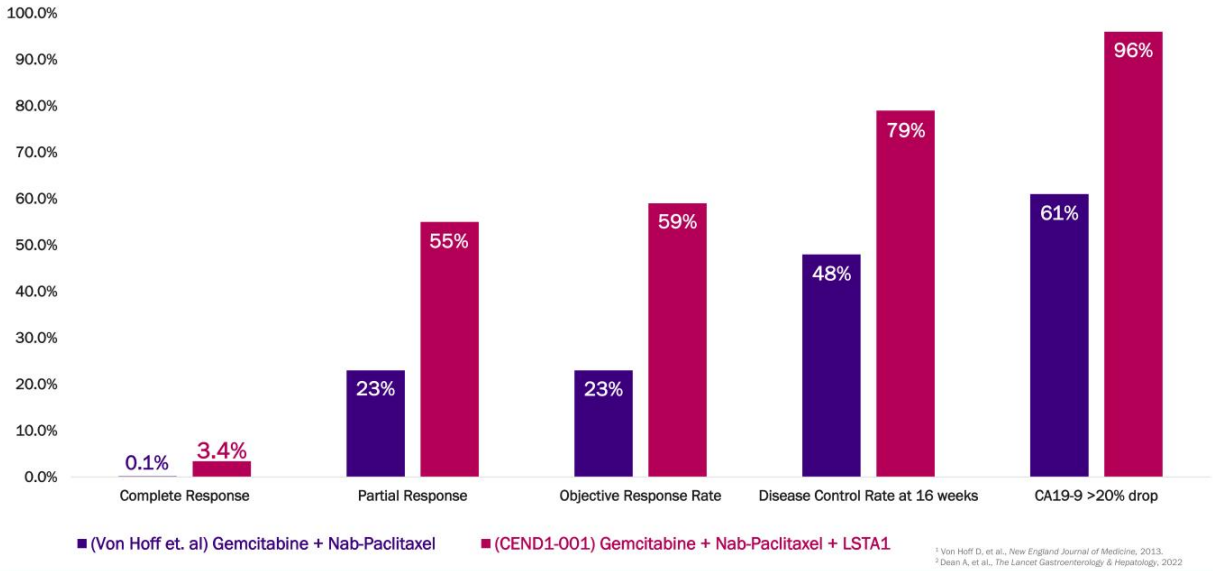
[1] Conroy T, et al., *New England Journal of Medicine*, 2011.
[2] Von Hoff D, et al., *New England Journal of Medicine*, 2013.
[3] Dean A, et al., *The Lancet Gastroenterology & Hepatology*, 2022.

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 and Orphan Drug designated (PDAC) - USA

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	**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*
WARPNINE/Lisata	Australia	**Locally advanced, non-resectable Gastroesophageal Adenocarcinoma** Nivolumab/FOLFIRINOX + LSTA1	Phase 1b/2a (**iGoLSTA**) Open-label *Pending initiation*

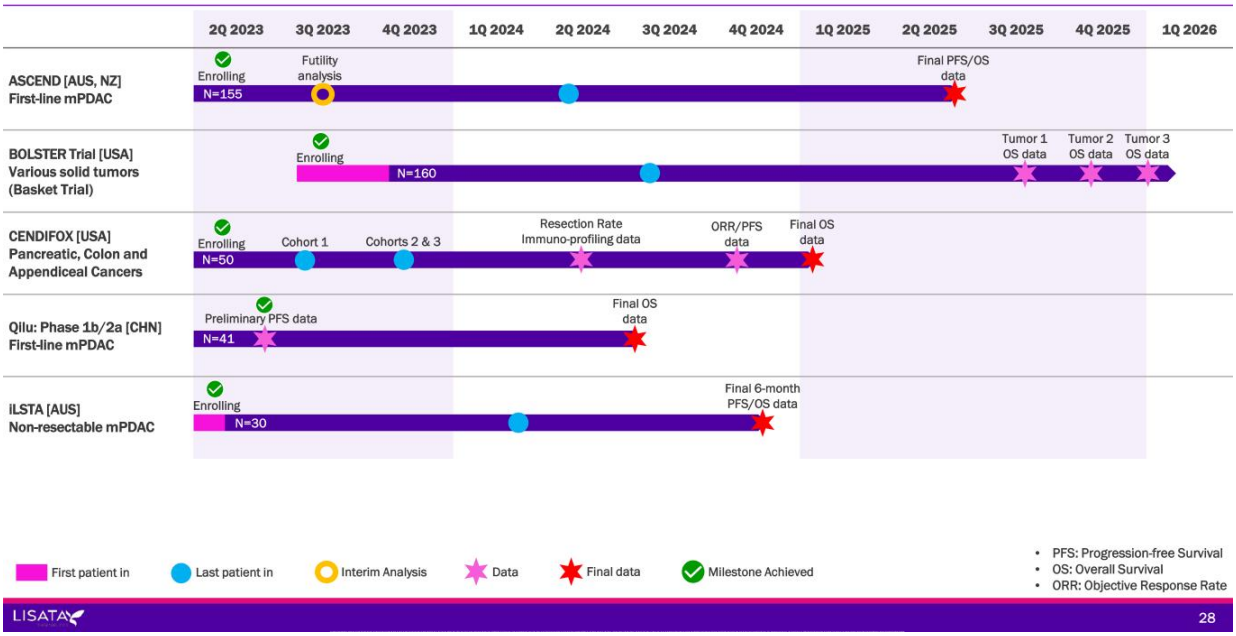
**Panitumumab may be added for colorectal or appendiceal patients without Ras mutation*

LSTA1 capital efficient development plan; shared costs & selective geography

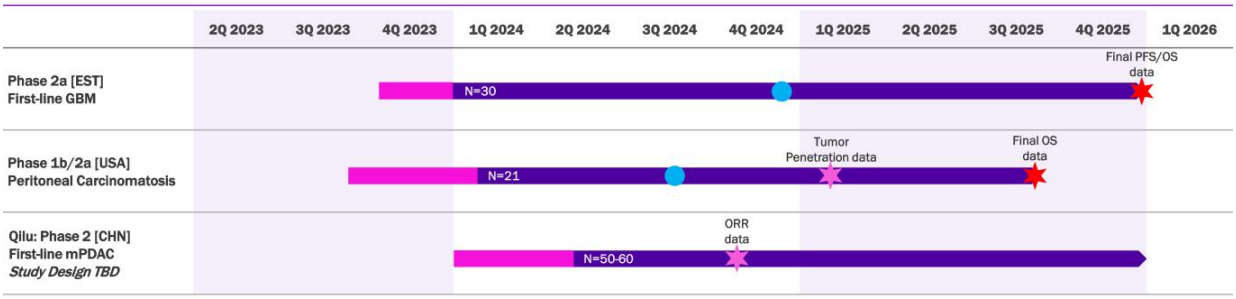
Partners	Region	Indication and Test Articles	Status
Tartu University Lisata	Estonia & Latvia	**First-line Glioblastoma Multiforme (GBM)** Temozolomide +/- LSTA1	Phase 2a Placebo-controlled *Pending initiation*
UCSD/Columbia University/Lisata	USA	**Peritoneal Carcinomatosis (Colon & Ovarian)** LSTA1 +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


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

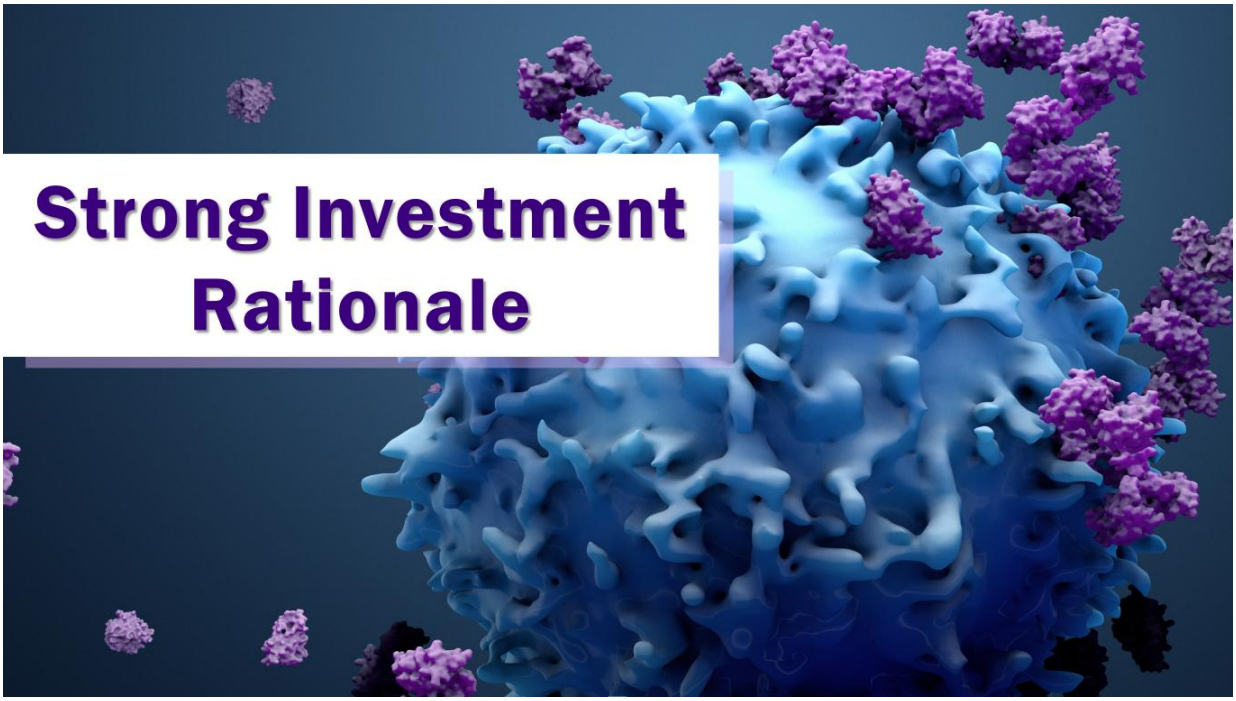
- PFS: Progression-free Survival
- OS: Overall Survival
- ORR: Objective Response Rate


Financial
Highlights

Lisata projects available capital to fund all clinical data milestones

Cash & Investments *As of 6/30/2023*	Debt	Projected Cash Runway Into
$57.6M	**$0**	**1Q2026**

Common Shares Outstanding (6/30/2023):	8.1 million shares
Options Outstanding (6/30/2023): Exercise Price: $0.02 - $4.22 = 1,078,000 shares Exercise Price: > $4.22 = 261,000 shares	1.3 million shares
Warrants Outstanding (6/30/2023): Weighted Average Exercise Price: $42.51	1.4 million shares


Strong Investment
Rationale

Investment rationale – key company differentiation

Seasoned management with successful drug development experience and expertise

Proprietary field-leading technology in underserved global indications

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

Multiple projected product and business milestones over the next 24 months

$57.6 million cash*- no debt; Development funded through critical milestones

* As of 6/30/2023; 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

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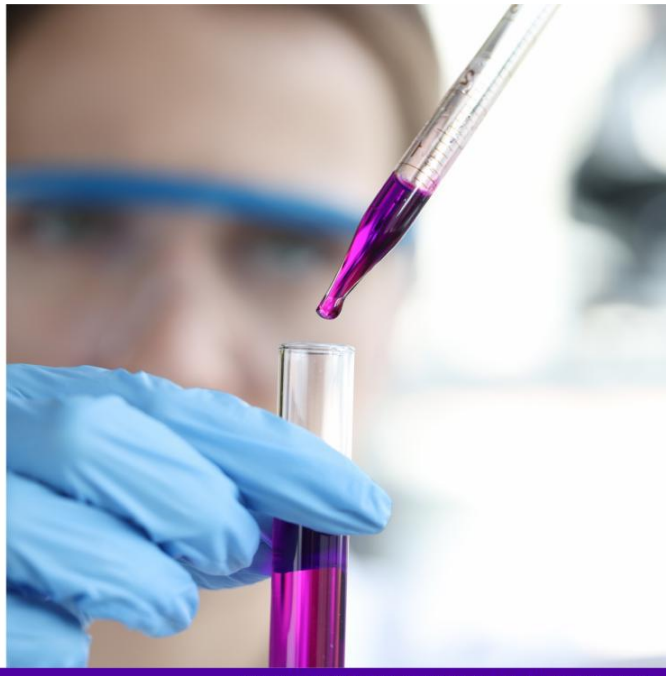
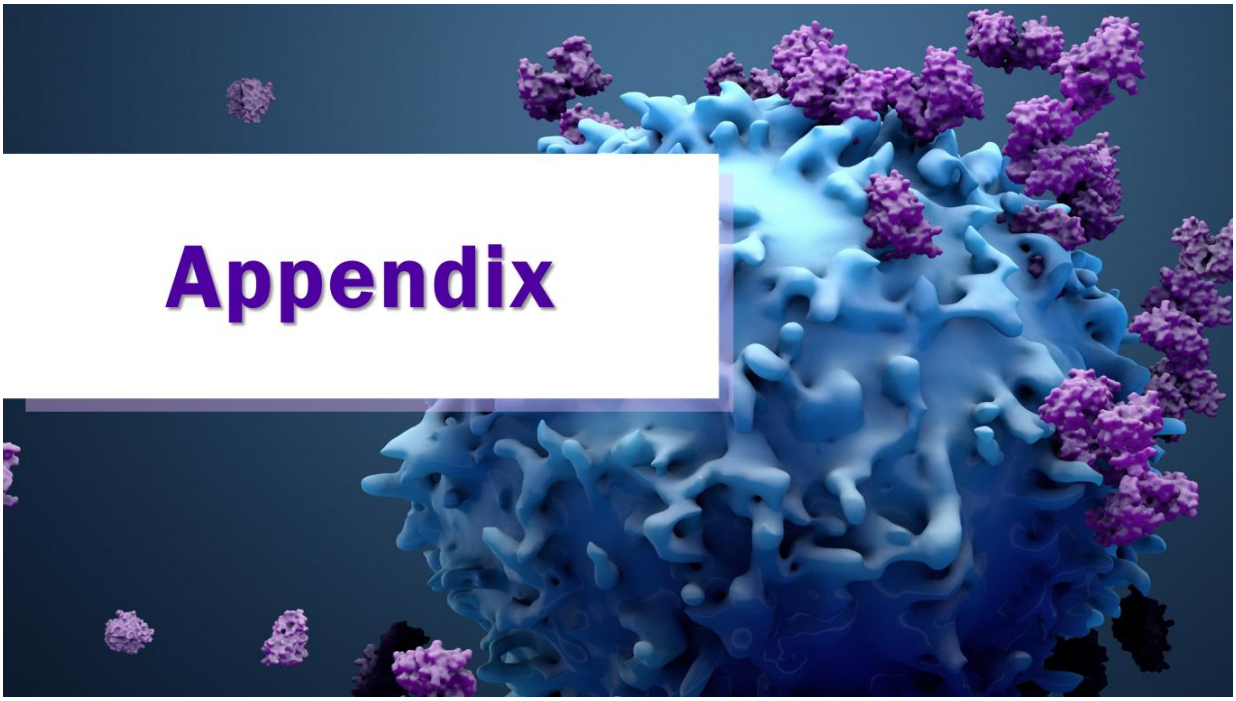




Appendix

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 (Basket Trial)**	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)

CD34+ cell therapy current clinical trials

*Legacy development programs provide potential value upside with **no** further capital outlay*

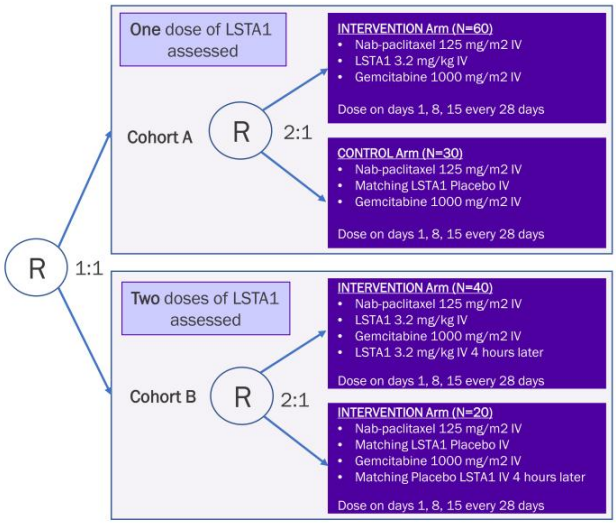
Sponsor [Development Venue]	Indication and Trial Product/Comparator	Stage of Development	Strategic Rationale
Lisata [Japan]	Critical Limb Ischemia & Buerger's Disease; HONEDRA® (LSTA12)	Registration Eligible	Assess safety and efficacy of LSTA12 in a controlled trial vs. SoC alone in the context of qualifying for approval in Japan under the accelerated regulatory pathway applicable to regenerative medicines

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

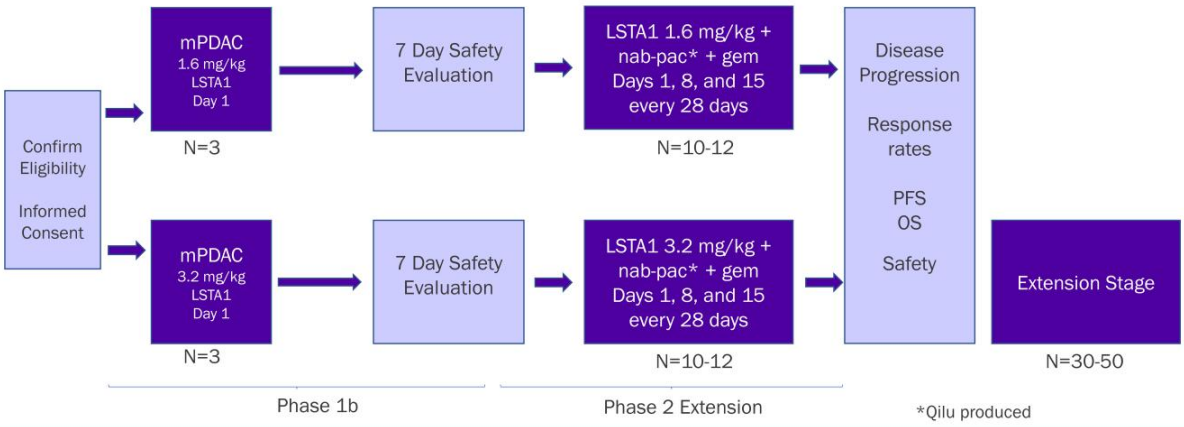
Phase 1b/2a open-label trial in mPDAC in China

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

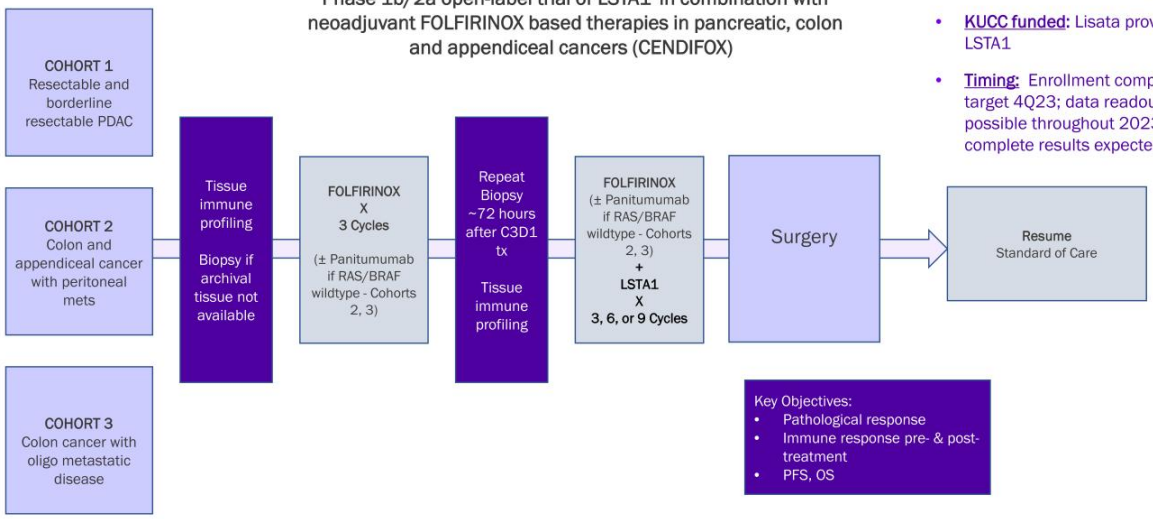


*Qilu produced

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

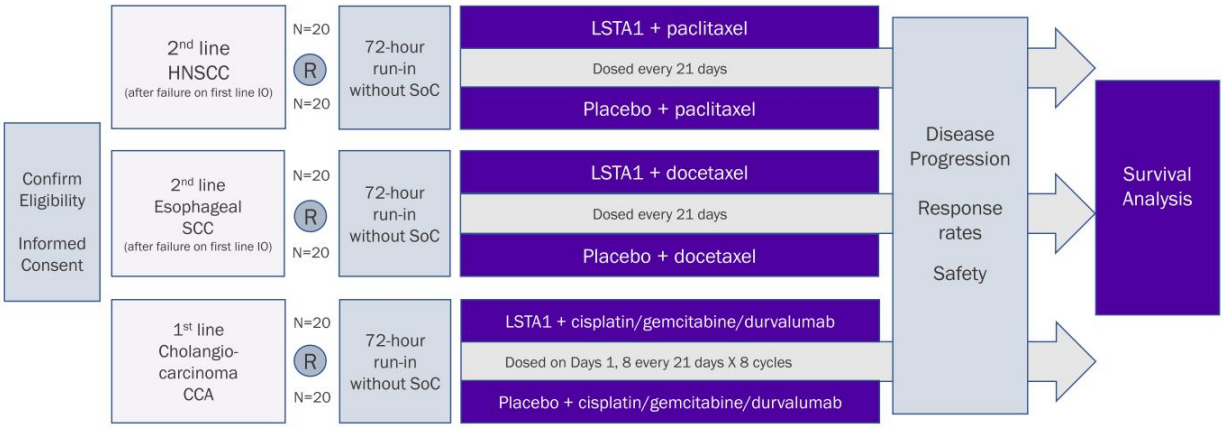
BOLSTER: Phase 2 blinded, randomized PoC trial in various cancers

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



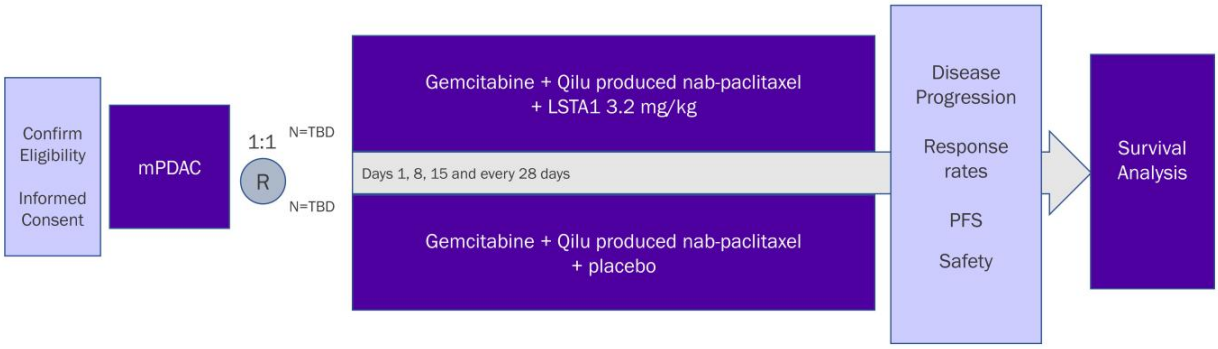
Phase 2 blinded, placebo-controlled trial in mPDAC in China

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

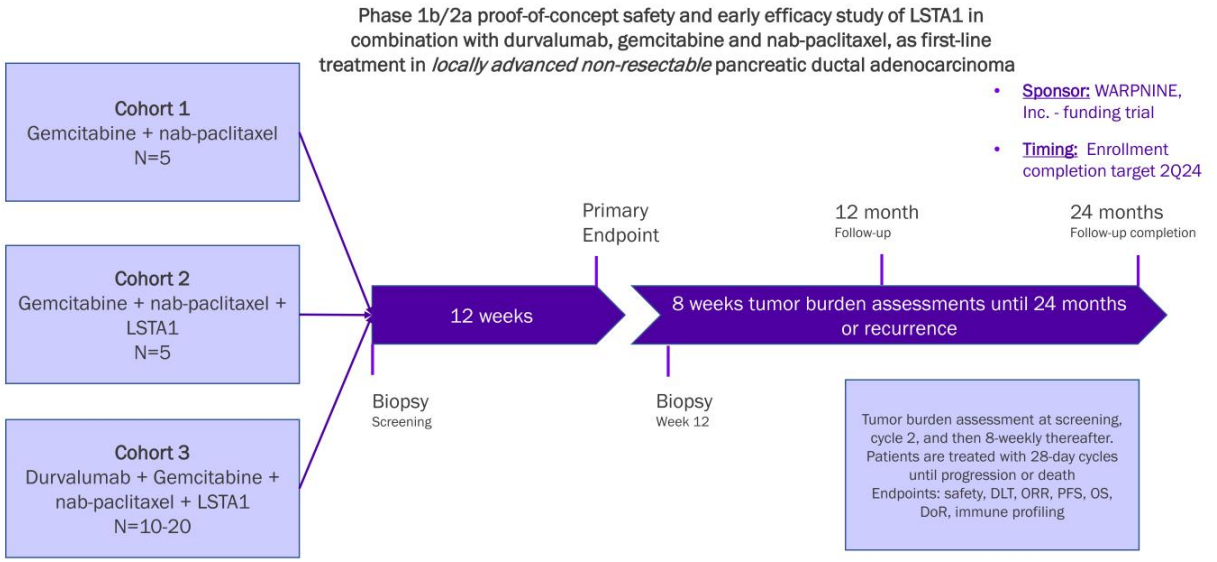
- Sponsor/Partner: Qilu Pharmaceutical (funds all development in China)
- Timing: Trial initiation target 4Q23



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

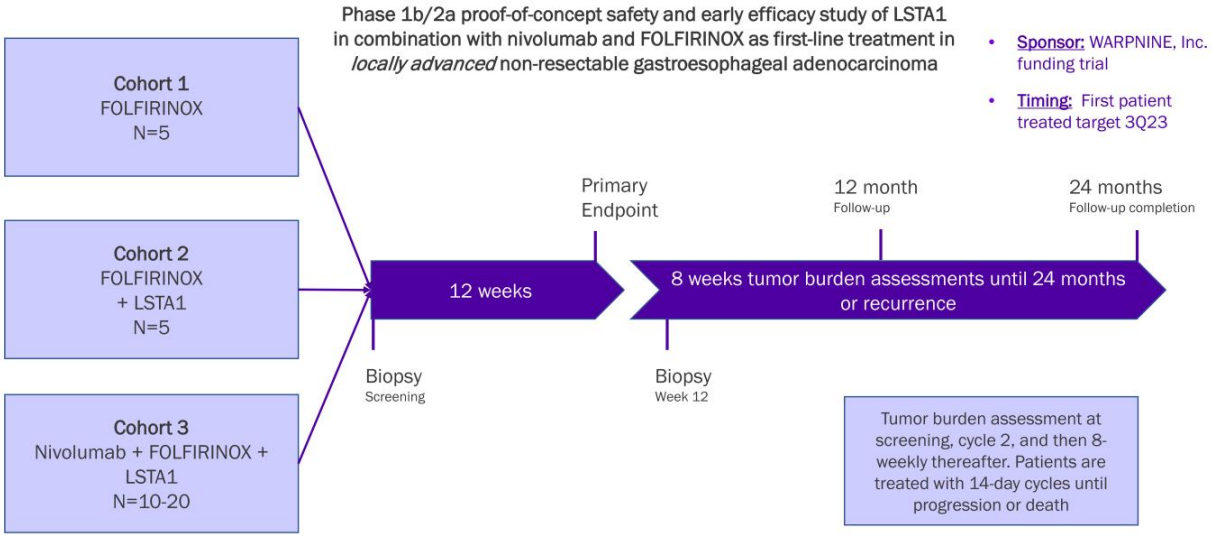
iLSTA: Phase 1b/2a trial in locally advanced PDAC with chemo & IO



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