

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

March 30, 2023
Date of Report (date of earliest event reported)

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

Delaware
(State or other jurisdiction of incorporation or organization)

001-33650
(Commission File Number)

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

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

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

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

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

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

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

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

Emerging growth company

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 March 30, 2023, Lisata Therapeutics, Inc. (the "Company") issued a press release in connection with its financial results for the fiscal year ended December 31, 2022. 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 March 30, 2023
99.2	Lisata Therapeutics, Inc. Corporate Presentation, March 30, 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: Chief Executive Officer

Dated: March 30, 2023

Lisata Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

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

BASKING RIDGE, NJ (March 30, 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, provides a business update and reports financial results for the three and twelve months ended December 31, 2022.

“Last year (2022) was a year of major transformation, excitement and renewed energy for Lisata, allowing us to enter 2023 with growing momentum as we continue to build an enduring pharmaceutical company,” stated David J. Mazzo, Ph.D., Chief Executive Officer of Lisata. “We believe in the potential of our new development pipeline and take pride in the advancement of our clinical studies in oncology and other serious diseases. LSTA1, our lead investigational product candidate from the CendR Platform™, is the subject of multiple planned and ongoing clinical trials being conducted globally in a variety of solid tumor types and in combination with several anti-cancer agents. Based on substantial preclinical and, importantly, early human clinical data, we believe that LSTA1 has the potential to become an integral part of a revised standard-of-care therapy for many difficult to treat cancers.

Dr. Mazzo continued, “We are dedicated to continued efficient execution of our studies and, eventually, to producing definitive data hopefully confirming the promise of our clinical development pipeline. We anticipate that such execution and those data will result in increased shareholder value while prompting additional attractive partnering opportunities. I look forward to providing further updates on our progress in the coming weeks and months.”

Development Portfolio Update

LSTA1 (formerly CEND-1) 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 affected. LSTA1 also has the potential to modify the tumor microenvironment, with the objective of making tumors more susceptible to immunotherapies. We and our collaborators have amassed significant non-clinical data demonstrating enhanced delivery of a range of emerging anti-cancer therapies, including 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 Phase 1b/2a and 2b clinical studies being conducted globally in various solid tumors, including metastatic pancreatic ductal adenocarcinoma, in combination with a variety of anti-cancer regimens. The combination of LSTA1 with corresponding standards-of-care in other solid tumor indications is planned for clinical study in the first half of 2023.

HONEDRA® (LSTA12, formerly CLBS12) for the treatment of critical limb ischemia (“CLI”)

HONEDRA® is the Company’s SAKIGAKE-designated product candidate for the treatment of CLI and Buerger’s disease in Japan, which is now in the pre-consultation phase of the registration process with the Pharmaceuticals and Medical Devices Agency (“PMDA”) in Japan. Data from the follow-up of all patients completed in the registration-eligible clinical trial in Japan have been compiled and are being reviewed by the PMDA, after which the PMDA is expected to provide important perspective to be considered in preparation for the formal consultation meetings which precede the Japanese new drug application. If successful in the pre-consultation process, Lisata expects formal clinical consultation to occur during 2023. Concomitantly, the Company has reinforced its efforts to secure a Japanese partner to complete the remaining steps of registration as well as eventual commercialization in Japan.

XOWNA® (LSTA16, formerly CLBS16) for the treatment of coronary microvascular dysfunction (“CMD”)

XOWNA® is an experimental regenerative therapy for the treatment of CMD. It was the subject of a positive Phase 2a study (the “ESCaPE-CMD trial”) reported in 2020 as well as the FREEDOM Trial, a Phase 2b study conducted in the U.S. The FREEDOM Trial was originally designed as a 105-patient double-blind, randomized, placebo-controlled trial to further evaluate the efficacy and safety of intracoronary delivery of autologous CD34+ cells (XOWNA®) in subjects with CMD and without obstructive

coronary artery disease and was expected to complete enrollment in approximately 12 months. As previously disclosed, enrollment in the FREEDOM Trial initially proceeded as planned with the first patient treated in January 2021; however, the impact of the COVID-19 pandemic in the U.S., coupled with supply chain issues associated with the catheters used for diagnosis of CMD and/or administration of XOWNA®, as well as with a contrast agent typically used in many catheter laboratories, have made and continue to make enrollment much slower than originally predicted and challenging to accelerate. As a result, the Company announced that enrollment in the FREEDOM Trial had been suspended and that it intended to conduct an interim analysis of the data from not less than the first 20 patients enrolled using the 6-month follow-up data to evaluate the efficacy and safety of XOWNA® in subjects with CMD. Based on that and the input of Key Opinion Leaders, the Company determined that execution of a redesigned FREEDOM-like trial would be the appropriate next step, but the cost of such a trial would be prohibitively expensive to undergo alone. Accordingly, the Company's board of directors concluded that XOWNA® development will only be continued if a strategic partner that can contribute the necessary capital for a redesigned trial is identified and secured.

LSTA201 (formerly CLBS201) for the treatment of diabetic kidney disease ("DKD")

Progressive kidney failure is associated with attrition of the microcirculation of the kidney. Preclinical studies in kidney disease and injury models have demonstrated that protection or replenishment of the microcirculation results in improved kidney function. Based on these observations, the Company initiated a Phase 1b, open-label, proof-of-concept trial evaluating LSTA201, a CD34+ regenerative cell therapy investigational product for intra-renal artery administration in patients with DKD. Patients selected for the study were in the pre-dialysis stage of kidney disease and exhibited rapidly progressing stage 3b disease. The protocol provided for a cohort of six patients overseen by an independent Data Safety Monitoring Board with the objective of determining the tolerance of intra-renal cell therapy injection in DKD patients as well as the ability of LSTA201 to regenerate kidney function. The principal read-out of data was based on the 6-month follow-up visit for all patients. A key criterion for continued development of LSTA201 was determined, a priori, to be the ability of LSTA201 to demonstrate a therapeutic effect that will make it competitive in the field of DKD treatment, i.e., kidney function regeneration, as indicated by increased Glomerular Filtration Rate ("GFR"). The Company treated the first patient in the LSTA201 proof-of-concept study in April 2022 and completed treatment for all six subjects during the third quarter of 2022. Top line results, which were reported on February 6, 2023, showed that LSTA201 was safe and well-tolerated by patients with no serious adverse events related to the therapy. However, the study did not demonstrate a consistent improvement in kidney function among patients. Nevertheless, the Company, based on the encouragement of the study's principal investigator/key opinion leader, believes there may still be potential for use of CD34+ cell therapy for the treatment of DKD. However, it is expected that further development of LSTA201 would require significantly larger studies and capital investment. Thus, LSTA201 development will only be continued if a strategic partner that can contribute the necessary capital for future development is identified.

Fourth Quarter and Full Year 2022 Financial Highlights

Research and development expenses for the fourth quarter of 2022 were \$3.2 million, a 22% decrease compared with \$4.1 million for the fourth quarter of 2021, and \$13.1 million for the year ended December 31, 2022 compared to \$17.6 million for the year ended December 31, 2021, representing a decrease of approximately 26%. This was primarily due to a decrease in expenses associated with our XOWNA® Phase 2b study (the FREEDOM Trial) as a result of the suspension in enrollment which commenced in the second quarter of 2022 and study close out activities in the third quarter of 2022, a decrease in expenses associated with HONEDRA® in Japan related to study close out costs and one off recruiting expenses and interim chief medical officer consulting expenses in the prior year partially offset by the addition of manufacturing activities for LSTA1 and enrollment activities for the AGITG ASCEND study.

Research and development in both periods related to:

- Expenses associated with our XOWNA® Phase 2b study (the FREEDOM Trial);
- Expenses associated with our registration-eligible study for HONEDRA® in critical limb ischemia in Japan as well as corresponding regulatory discussions support expenses;
- Expenses associated with the preparation of our filing of an Investigational New Drug Application, as well as study execution expenses for the clinical study of LSTA201 for treatment of DKD; and
- Expenses associated with the addition of manufacturing activities for LSTA1, enrollment activities for the LSTA1 Phase 2b ASCEND study and preparatory activities associated with the design of a planned LSTA1 proof-of-concept basket trial in various solid tumors and in combination with the corresponding standards of care.

General and administrative expenses, which focus on general corporate related activities, were \$3.3 million for the three months ended December 31, 2022, representing an increase of 22% compared to \$2.7 million for the three months ended December 31, 2021, and \$14.1 million for the year ended December 31, 2022, representing an increase of 23% compared to \$11.5 million for the year ended December 31, 2021. This was primarily due to a one-time increase in fees associated with the review of potential strategic transactions and merger related costs, an increase in equity expense as a result of performance stock unit vesting, merger

option assumption expense and departing board member restricted stock unit vesting in addition to an increase in expenses associated with our annual stockholder meeting. Our general and administrative expenses are comprised of general corporate-related activities.

Overall, net losses were \$54.2 million (includes non-routine merger related in-process research and development expense of \$30.4 million) and \$27.5 million for the years ended December 31, 2022 and 2021, respectively.

Balance Sheet Highlights

As of December 31, 2022, the Company had cash, cash equivalents and marketable securities of approximately \$69.2 million. Current projections predict operating cash through the first half of 2025, encompassing anticipated data milestones from several ongoing and/or planned clinical studies.

Conference Call Information

Lisata will hold a live conference call today, March 30, 2023, at 4:30 p.m. Eastern time to discuss financial results, provide a business update and answer questions.

The Company is utilizing a new conference call service. 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 for 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 investigational product candidate, LSTA1 (formerly known as CEND-1), 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 affected. LSTA1 also has the potential to modify the tumor microenvironment, with the objective of making tumors more susceptible to immunotherapies LSTA1 has demonstrated favorable safety, tolerability, and activity in clinical trials to enhance delivery of standard-of-care chemotherapy for pancreatic cancer. Lisata and its collaborators have also amassed significant non-clinical data demonstrating enhanced delivery of a range of emerging anti-cancer therapies, including immunotherapies and RNA-based therapeutics. Lisata is exploring the potential of LSTA1 to enable a variety of treatment modalities to treat a range of solid tumors more effectively. In addition, Lisata has clinical development programs based on its autologous CD34+ cell therapy technology platform. 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, 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 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 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 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.

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 December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
(in thousands, except per share data)	(unaudited)	(unaudited)		
Statement of Operations Data:				
Research and development	\$ 3,219	\$ 4,127	\$ 13,067	\$ 17,576
In-process research and development	—	—	30,393	—
General and administrative	3,322	2,722	14,141	11,474
Total operating expenses	6,541	6,849	57,601	29,050
Operating loss	(6,541)	(6,849)	(57,601)	(29,050)
Investment income, net	556	40	1,052	151
Other expense, net	(6)	15	(155)	(75)
Net loss before benefit from income taxes and noncontrolling interests	(5,991)	(6,794)	(56,704)	(28,974)
Benefit from income taxes	—	—	(2,479)	(1,508)
Net loss	(5,991)	(6,794)	(54,225)	(27,466)
Less - net income (loss) attributable to noncontrolling interests	—	—	—	—
Net loss attributable to Lisata Therapeutics, Inc. common stockholders	\$ (5,991)	\$ (6,794)	\$ (54,225)	\$ (27,466)
Basic and diluted loss per share attributable to Lisata Therapeutics, Inc. common stockholders				
	\$ (0.76)	\$ (1.70)	\$ (10.47)	\$ (7.45)
Weighted average common shares outstanding	7,861	3,985	5,180	3,688

	December 31, 2022	December 31, 2021
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	\$69,226	\$94,970
Total assets	73,034	97,008
Total liabilities	6,710	5,008
Total equity	66,324	92,000

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Exhibit 99.1



Targeted Therapy *Delivered*

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

Corporate Presentation | March 30, 2023
Nasdaq: LSTA

www.lisata.com



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Forward-looking Statements Notice

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**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



Proprietary field-leading technology in underserved global indications backed by a strong IP portfolio



\$69.2 million cash and investments* - no debt; Highly capital efficient development plans funded through critical milestones



Multiple projected potential value creating product and business development events over the next 24 months



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



Seasoned management with successful drug development expertise as well as big and emerging pharma experience

* As of 12/31/2022

A light blue world map is centered in the background of the slide. The text is overlaid on the map.

**Cancer is a leading cause of death worldwide,
accounting for nearly 10 million deaths in 2020, or
nearly one in six deaths¹
– *World Health Organization***

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

Opportunity: solid tumors are a large & growing treatment market

Estimated New Cancer Cases and Deaths in the United States, 2022¹

Estimated New Cases

		Males	Females		
Prostate	268,490	27%		Breast	287,850
Lung & bronchus	117,910	12%		Lung & bronchus	118,830
Colon & rectum	80,690	8%		Colon & rectum	70,340
Urinary bladder	61,700	6%		Uterine corpus	65,950
Melanoma of the skin	57,180	6%		Melanoma of the skin	42,600
Kidney & renal pelvis	50,290	5%		Non-Hodgkin lymphoma	36,350
Non-Hodgkin lymphoma	44,120	4%		Thyroid	31,940
Oral cavity & pharynx	38,700	4%		Pancreas	29,710
Leukemia	35,610	4%		Kidney & renal pelvis	28,710
Pancreas	32,970	3%		Leukemia	28,640
All sites	983,160	100%		All sites	934,670

Estimated Deaths

		Males	Females		
Lung & bronchus	68,620	21%		Lung & bronchus	61,360
Prostate	34,500	15%		Breast	43,250
Colon & rectum	28,400	9%		Colon & rectum	24,180
Pancreas	25,970	8%		Pancreas	23,860
Liver & intrahepatic bile duct	20,420	6%		Ovary	12,810
Leukemia	14,020	4%		Uterine corpus	12,550
Esophagus	13,250	4%		Liver & intrahepatic bile duct	10,100
Urinary bladder	12,120	4%		Leukemia	9,980
Non-Hodgkin lymphoma	11,700	4%		Non-Hodgkin lymphoma	8,550
Brain & other nervous system	10,710	3%		Brain & other nervous system	7,570
All sites	322,090	100%		All sites	287,270

It is estimated that more than 1.9 million new cases of cancer will be diagnosed in 2022

In the U.S. alone, solid tumors account for over 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)

Challenge: tumor targeting & intratumoral penetration are inadequate

- **Tumor targeting and intratumoral penetration are inadequate**
 - Tumor stroma acts as an effective barrier to anti-cancer agent penetration
 - Tumor microenvironment immunosuppressive cells can lead to tumor resistance and/or metastases
 - Continued or escalating dosing of non-targeted anti-cancer therapy can lead to intolerable off-target side effects
- **Clinical response to many anti-cancer drugs is suboptimal**

Targeted penetration technology to enhance drug delivery to solid tumors

- Converts tumor stroma from *barrier to conduit* for penetration of anti-cancer treatments
 - Combination with many existing & emerging anti-cancer drugs possible in multiple indications
 - 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); product life cycle management
- Combats resistance by selectively depleting intratumoral immunosuppressive cells
- Platform extension possible to most drug modalities including nucleic acid-based drugs

LSTA1: lead clinical development candidate of the CendR Platform®

LSTA1 is being advanced in clinical trials in various difficult-to-treat solid tumor indications as part of a global registration strategy

- Multiple Phase 1b to 2b studies in *metastatic pancreatic ductal adenocarcinoma* (mPDAC) combined with standards-of-care (SoC) chemotherapy [i.e., (gemcitabine + nab-paclitaxel) or FOLFIRINOX]
 - **Granted Fast Track and Orphan Drug Designations by the U.S. FDA in PDAC**
 - Studies in combination with SoC plus immunotherapies targeted to begin in 1H23
- BOLSTER (basket) trial expanding development to *cholangiocarcinoma, head and neck squamous cell carcinoma and esophageal squamous cell carcinoma* with other anti-cancer drug combinations to initiate in 2Q23
- Phase 1b/2a trial start in *glioblastoma multiforme* in combination with temozolomide planned for 3Q23
- Phase 1/2a trial in *peritoneal carcinomatosis* targeted to begin in 3Q23

Broad applicability: noteworthy existing partnerships and beyond



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
- Potential for up to \$220 million to Lisata for milestones & tiered double-digit royalties on sales



Clinical development collaborations exploring combinations with immunotherapy

- LSTA1/gemcitabine/nab-paclitaxel treatment regimen ± durvalumab with **WARPNINE (AUS)**
- LSTA1/gemcitabine/nab-paclitaxel treatment regimen ± nivolumab with **WARPNINE (AUS)**
- LSTA1/gemcitabine/nab-paclitaxel treatment regimen ± atezolizumab with **ROCHE**



Additional partnership opportunities for the CendR Platform® in general and many combinations with LSTA1, specifically

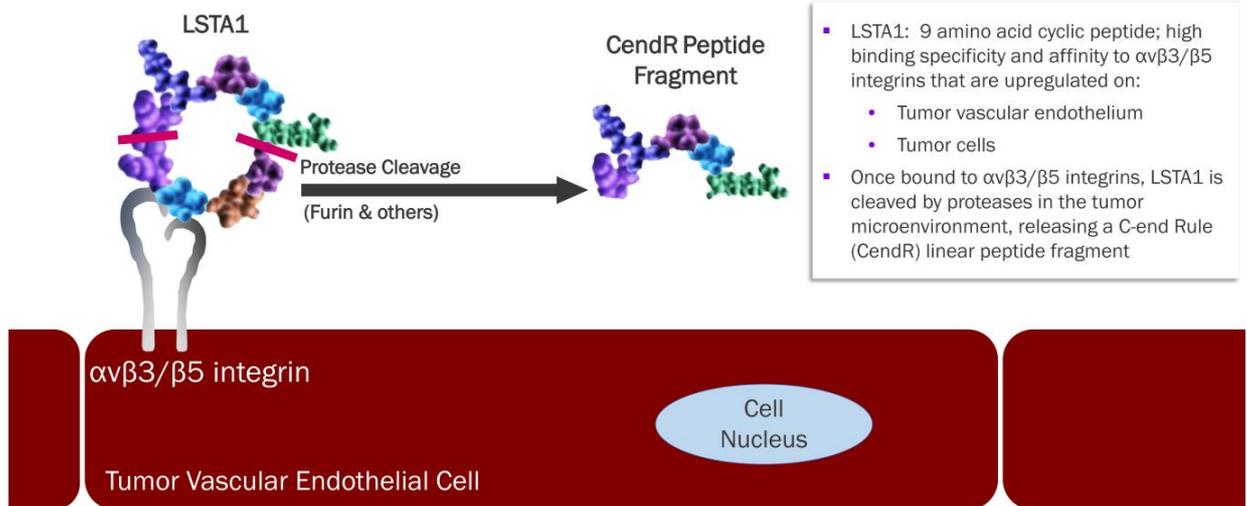
A 3D molecular model of the LSTA1 protein structure. The protein is depicted as a large, complex, blue-colored surface with numerous protrusions and indentations, resembling a virus or a highly branched molecule. Several smaller, purple-colored clusters are scattered around the main structure, some appearing to be bound to or near the surface. The background is a dark, gradient blue.

LSTA1

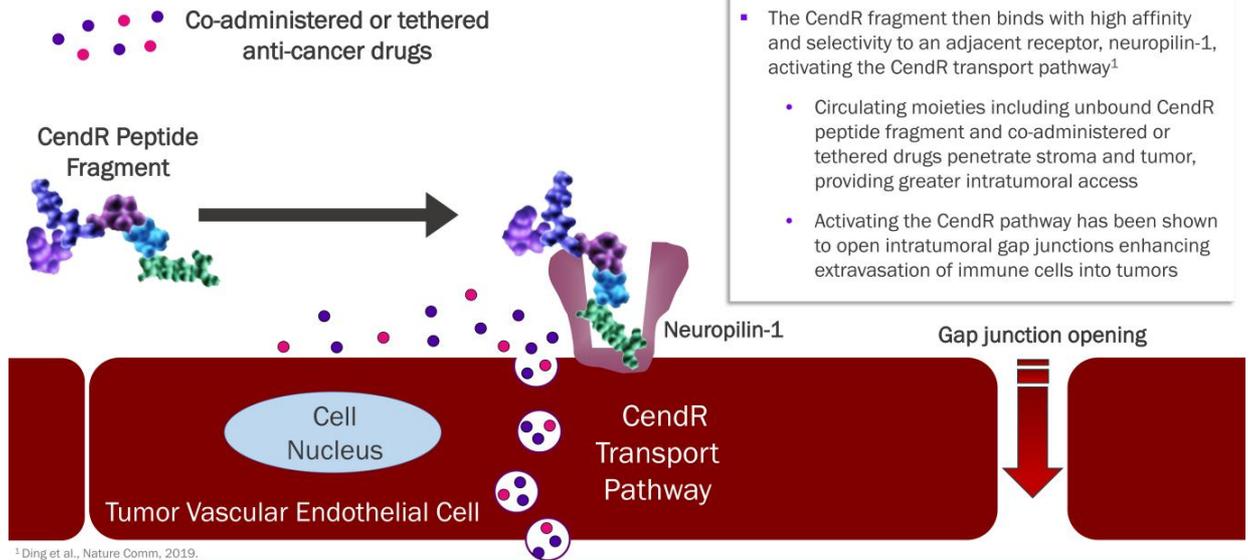
[formerly known as CEND-1]

*Well-characterized Mechanism of Action with
Compelling Early Clinical Results*

LSTA1 Mechanism of Action: Steps 1 & 2

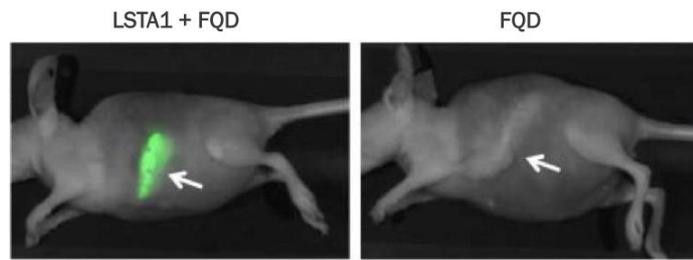


LSTA1 Mechanism of Action: Step 3



LSTA1 selectively and efficiently facilitates intratumoral penetration

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

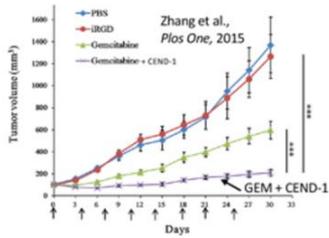


- Etching solution quenches fluorescence in circulation
- **LSTA1 provides selective tumor penetration**

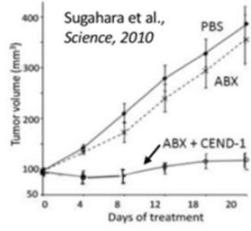
¹ Braun et al., Nature Mater. 2014.
² Liu, Braun et al., Nature Comm. 2017.

Increased tumor penetration enhances antitumor activity across various treatment modalities

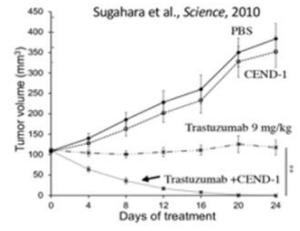
Lung cancer + gemcitabine + LSTA1



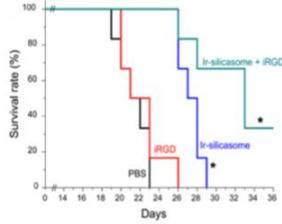
Breast cancer + nanoparticle Abraxane + LSTA1



Breast cancer + Herceptin® + LSTA1

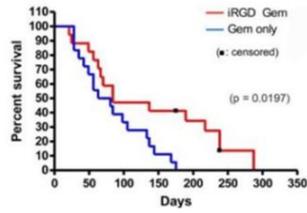


PDAC + irinotecan nanoparticles + LSTA1

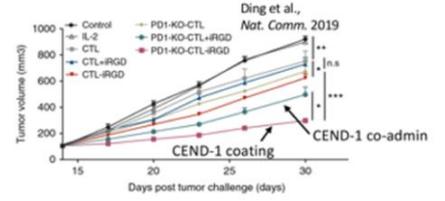


Orthotopically transplanted KPC PDAC tumors
CEND-1 + irinotecan nanoparticles (i.v. co-admin)

PDAC + gemcitabine + LSTA1



GI cancer + adoptive cell therapy + LSTA1



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

LSTA1 Phase 1b results reinforce promise of improving 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

Clinical Development Portfolio

Fast Track and Orphan Drug designated (PDAC) - USA

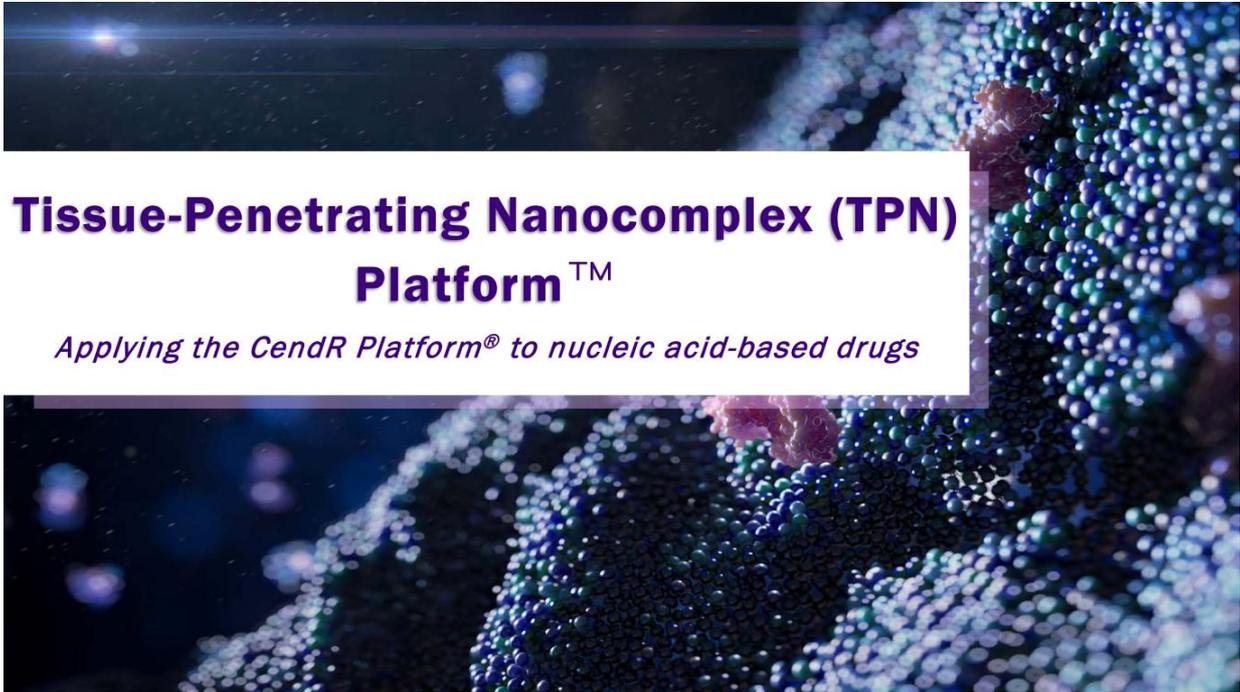
LSTA1 capital efficient development plan; shared costs & selective geography

Development Partner(s) [Development Venue]	Indication and Trial Product/Comparator	Stage of Development (Status)
Lisata/AGITG [Australia/New Zealand/Ireland]	First-line mPDAC; Gemcitabine/nab-paclitaxel with LSTA1 or placebo	Phase 2b (ASCEND) (Enrolling)
Lisata [United States]	Various Solid Tumors; SoC with LSTA1 or placebo	Phase 2a (BOLSTER) (Pending Initiation)
KUCC/Lisata [United States]	Pancreatic, Colon & Appendiceal Cancers; LSTA1 + FOLFIRINOX + panitumumab*	Phase 1b/2a (CENDIFOX) (Enrolling)
Qilu [China]	First-line mPDAC; Gemcitabine/nab-paclitaxel + LSTA1	Phase 1b/2a (Enrolling)
WARPNINE/Lisata [Australia]	Locally advanced resectable PDAC; Durvalumab/gemcitabine/nab-paclitaxel + LSTA1	Phase 1b/2a (iLSTA) (Enrolling)
WARPNINE/Lisata [Australia]	Locally advanced resectable Gastroesophageal (GE) adenocarcinoma; Nivolumab + FFX + LSTA1	Phase 1b/2a (iGoLSTA) (Pending Initiation)

*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 (Status)
Tartu University/Lisata [Estonia]	First-line Glioblastoma Multiforme; Temozolomide ± LSTA1	Phase 2a (Pending Initiation)
UCSD/Columbia University/Lisata [United States]	Peritoneal Carcinomatosis LSTA+HIPEC interoperative intraperitoneal lavage	Phase 1b/2a (Pending Initiation)
Qilu [China]	First-line mPDAC; Gemcitabine/nab-paclitaxel + LSTA1	Phase 2 (Pending Initiation)
Roche/Lisata [Multi-national]	First-line mPDAC; Gemcitabine/nab-paclitaxel/LSTA1 ± atezolizumab	Phase 1b/2 (MORPHEUS) (Pending Initiation)



**Tissue-Penetrating Nanocomplex (TPN)
Platform™**

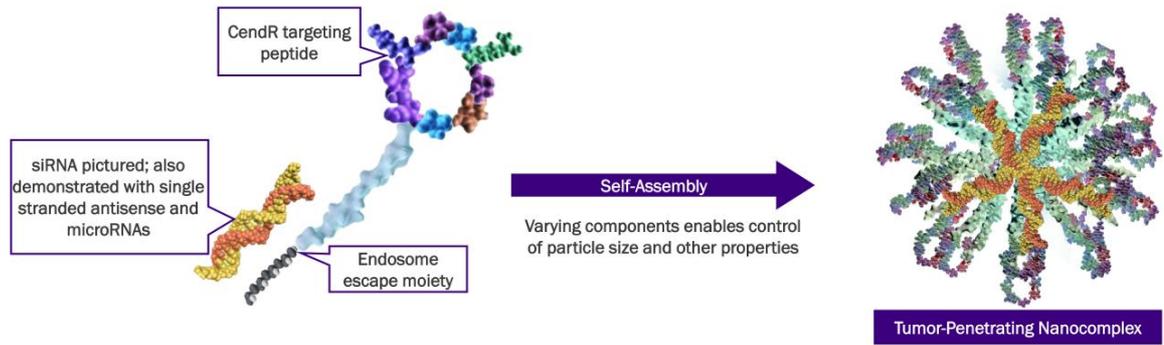
Applying the CendR Platform® to nucleic acid-based drugs

Anticancer applications of nucleic acid-based therapeutics

Tumor stroma serves as primary impediment to effective delivery of antisense oligonucleotides (ASO) and small interfering RNS (siRNA) drugs

- >95% of ASO and siRNA drugs sequestered in endosomes
- Passive targeting (i.e., lipid nanoparticles) appears ineffective
- Non-targeted cell-/tissue-penetrating moieties can disrupt unintended tissues
- A targeted approach to enhance tumor stroma penetration is needed
 - **TPN Platform™ - Applying the CendR Platform® to nucleic acid-based drugs**
 - Preclinical development underway

TPN Platform™ : applying CendR technology to nucleic acid delivery



- CendR peptides provide tumor and/or immune cell targeting with optimized tumor penetration
- Technologies to evade endosome sequestration
- Simpler synthesis vs. biologics such as virus-like particles, Ab-conjugates or exosomes
- Opportunities for a range of in-/out-licensing, collaboration or strategic deals



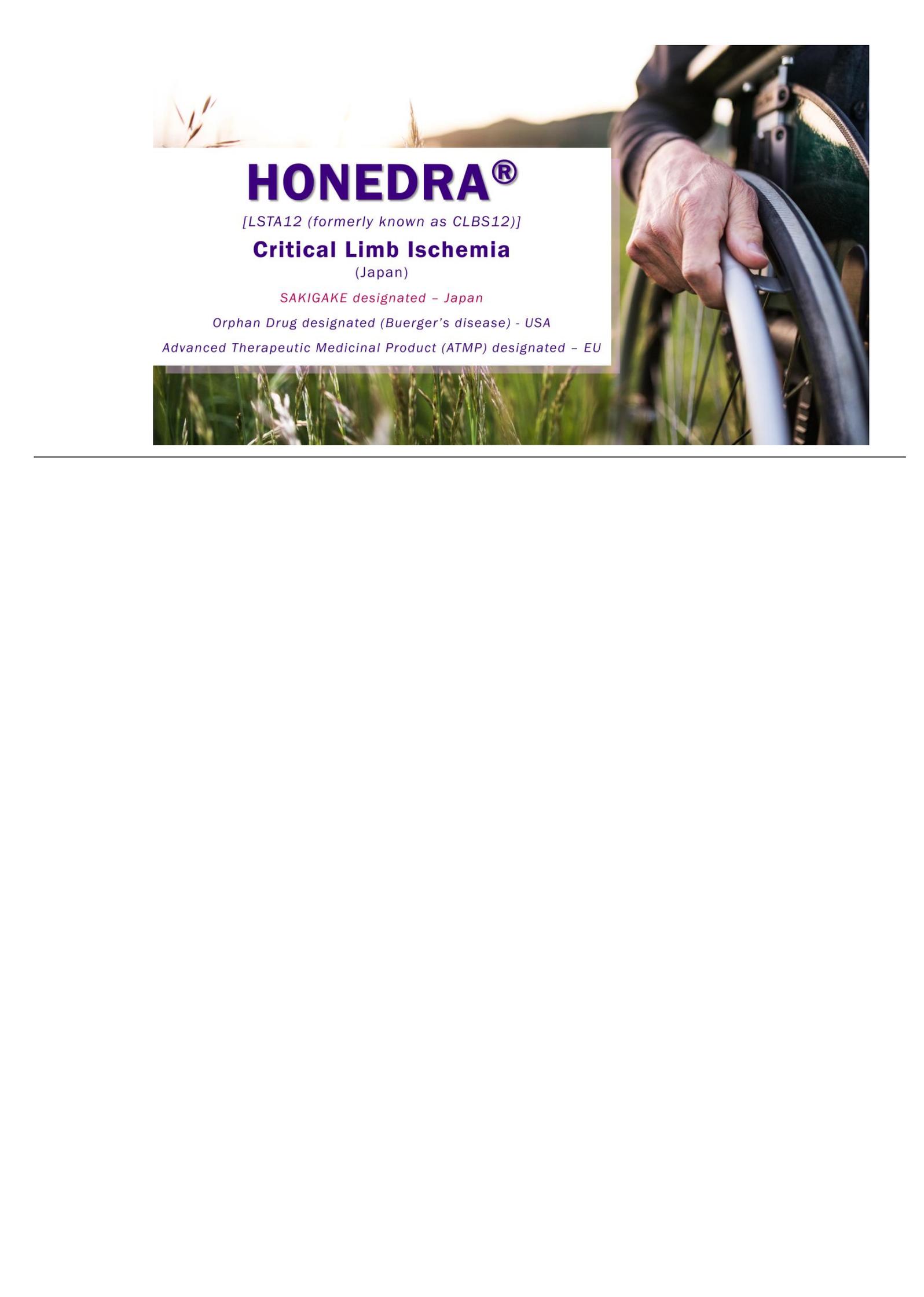
CD34+ Cell Therapy

Platform Technology

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
Lisata [Japan]	Critical Limb Ischemia & Buerger's Disease; HONEDRA® (LSTA12)	Registration Eligible



HONEDRA®

[LSTA12 (formerly known as CLBS12)]

Critical Limb Ischemia

(Japan)

SAKIGAKE designated - Japan

Orphan Drug designated (Buerger's disease) - USA

Advanced Therapeutic Medicinal Product (ATMP) designated - EU

HONEDRA®: autologous CD34+ cell therapy

Arteriosclerosis Obliterans (ASO); Critical Limb Ischemia (CLI)

- CLI is arterial obstruction impeding blood flow in the lower extremities with severe rest pain and non-healing ulcers
- Buerger's disease (BD); a subset of ASO is inflammation in small and medium arteries (orphan population)
- Current surgical intervention, angioplasty, stenting and pharmacotherapy) do not adequately treat CLI and BD
- Multi-million-dollar opportunity with an increasing prevalence of CLI in Japan
- Positive previously published Phase 2 results in Japan^{1,2}

Development Program

- Designed in conjunction with Japanese regulatory authorities (PDMA) under regenerative medicine regulations
- *Conditional approval can be based on a single trial showing an efficacy trend (non-statistical) and acceptable safety*

¹ Reinecke H., European Heart Journal, 2015 Apr 14;36(15):932-8
² Kinoshita et al, Atherosclerosis 224 (2012) 440-445

HONEDRA®: autologous CD34+ cell therapy

Development Status

- Registration eligible clinical trial completed
 - CLI and BD data suggest trend toward efficacy and acceptable safety
 - HONEDRA® was safe and well tolerated
 - Treatment group reached CLI-free status faster than SoC group (primary endpoint)

- PDMA consultation process underway as the normal next step for a planned filing of a Japan NDA

- Positive consultation process results expected to lead to acquisition of the product

A wealth of anticipated key milestones

	1Q	2Q	2023		3Q	4Q	1Q	2Q	2024		3Q	4Q
ASCEND [AUS, NZ, IRE] <i>First-line mPDAC</i>			Ongoing				LPI 2024					
BOLSTER Trial [USA] <i>Various Solid Tumors (Basket Trial)</i>		Initiation 2023										LPI 4Q24
CENDIFOX [USA] <i>Pancreatic, Colon & Appendiceal cancers</i>						LPI 4Q23		Complete Data 2024				
MORPHEUS [Multi-national] <i>First-line mPDAC</i>						Initiation TBD						
Qilu: Phase 1b/2a Trial [CHN] <i>First-line mPDAC</i>		Preliminary Data 1H2023										
Qilu: Phase 2 Trial [CHN] <i>First-line mPDAC</i>							Initiation 1Q24					
iLSTA [AUS] <i>Resectable PDAC</i>		Initiation 2023						LPI 2024				Preliminary Data 3Q24
iGoLSTA [AUS] <i>Resectable GE adenocarcinoma</i>					Initiation 3Q23						LPI 3Q24	
Phase 2a [EST] <i>First-line GBM</i>					Initiation 3Q23							LPI 4Q24/1H25
Phase 1b/2a [USA] <i>Peritoneal Carcinomatosis</i>					Initiation 3Q23							
LSTA201 [USA] <i>DKD</i>		Topline Data 1Q23										
HONEDRA® [JPN] <i>CLJ and Buerger's disease</i>		PMDA formal clinical pre-consultation 2023			Pre-JNDA pre-consultation 4Q23							

Lisata Therapeutics: financial summary

Cash & Investments

(12/31/2022)

\$69.2M

Debt

\$0

Projected Cash Runway Through

1H2025

(Funding through key development milestones)

Common Shares Outstanding (12/31/2022):

7.9 million shares

Options Outstanding (12/31/2022):

Exercise Price: \$0.02 - \$4.22 = 1,127,000 shares

Exercise Price: > \$4.22 = 264,000 shares

1.4 million shares¹

Warrants Outstanding (12/31/2022):

Weighted Average Exercise Price: \$42.57

1.4 million shares

¹Includes 1.2 million options assumed through the merger at a weighted average exercise price of \$3.77

Investment rationale



Proprietary field-leading technology in underserved global indications backed by a strong IP portfolio



\$69.2 million cash and investments* - no debt; Highly capital efficient development plans funded through critical milestones



Multiple projected potential value creating product and business development events over the next 24 months



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



Seasoned management with successful drug development expertise as well as big and emerging pharma experience

* As of 12/31/2022



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



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Appendix

LSTA1 capital efficient development plan

Development Partner(s) [Development Venue]	Indication and Trial Product/Comparator	Stage of Development	Strategic Rationale
Lisata/AGITG [Australia/New Zealand/Ireland]	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 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 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

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) in a 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*

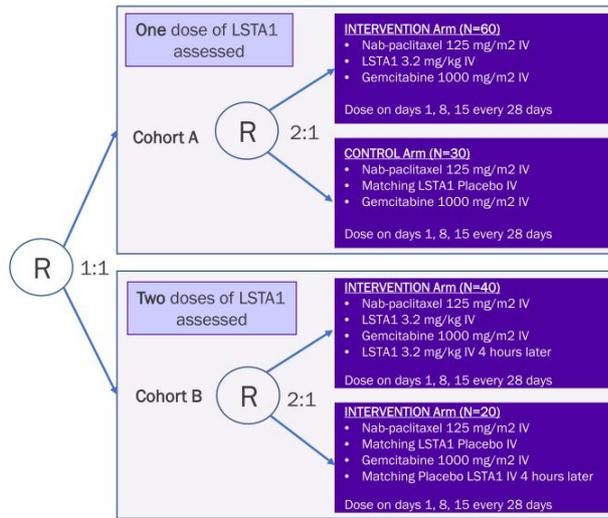
Sponsor [Development Venue]	Indication and Trial Product/Comparator	Stage of Development	Strategic Rationale
Lisata [Japan]	Critical Limb Ischemia & Buerger's Disease; HONEDRA® (LSTA12)	Registration Eligible	Assess safety and efficacy of LSTA12 in a controlled trial vs. SoC alone in the context of qualifying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

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

Sponsor/Partner	<ul style="list-style-type: none">▪ 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	<ul style="list-style-type: none">▪ Corroborate Phase 1b results in a placebo-controlled study▪ Determine if a second dose of LSTA1 further improves patient outcomes
Design	<ul style="list-style-type: none">▪ Phase 2b randomized, double-blind study in mPDAC testing gemcitabine + nab-paclitaxel SoC with one of two LSTA1 dose regimens or placebo
Study Size	<ul style="list-style-type: none">▪ ~150 subjects (~40 sites planned in Australia, New Zealand and Ireland)
Endpoints	<ul style="list-style-type: none">▪ Primary: Progression Free Survival▪ Secondary: AEs, SAEs, Overall Survival, Objective Tumor Response Rate
Timing	<ul style="list-style-type: none">▪ 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

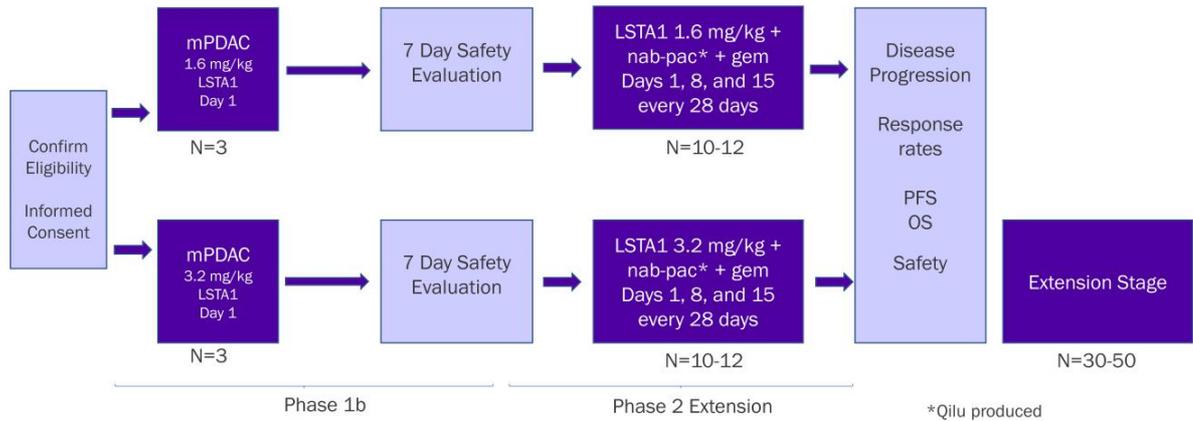
Phase 1b/2a open-label trial in mPDAC in China

Sponsor/Partner	<ul style="list-style-type: none">▪ Qilu Pharmaceutical (funds all development in China)
Objective	<ul style="list-style-type: none">▪ Evaluate safety, pharmacokinetics and preliminary efficacy of LSTA1 added to SoC in Chinese patients with mPDAC
Design	<ul style="list-style-type: none">▪ Phase 1b/2a open-label study in advanced mPDAC patients of Chinese ethnicity testing SoC chemotherapy (gemcitabine + Qilu-produced nab-paclitaxel) in combination with LSTA1
Study Size	<ul style="list-style-type: none">▪ 50 subjects (~15 sites)
Endpoints	<ul style="list-style-type: none">▪ Primary: AEs, SAEs, Objective Response Rate, Duration of Response, Disease Control Rate, Overall Survival, and Progression Free Survival▪ Secondary: Pharmacokinetic parameters
Timing	<ul style="list-style-type: none">▪ 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

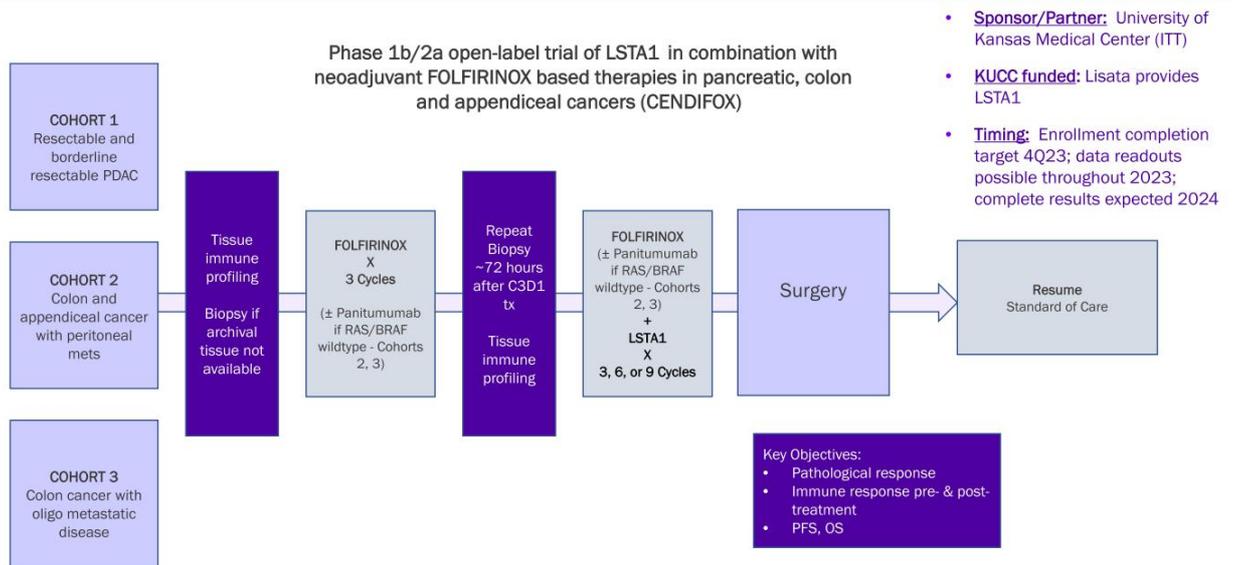
- **Sponsor/Partner:** Qilu Pharmaceutical (funds all development in China)
- **Timing:** Preliminary data expected 1H23



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

Sponsor/Partner	<ul style="list-style-type: none">University of Kansas Medical Center (Investigator initiated trial in U.S.)KUCC funded; Lisata provides LSTA1
Objective	<ul style="list-style-type: none">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	<ul style="list-style-type: none">Phase 1b/2a open-label study in resectable pancreatic, colon with oligo metastases and appendiceal with peritoneal metastases cancers testing SoC chemotherapy (neoadjuvant FOLFIRINOX-based therapies) with LSTA1 ± panitumumab
Study Size	<ul style="list-style-type: none">50 subjects (20 PDAC, 15 colon and 15 appendiceal)
Endpoints	<ul style="list-style-type: none">Primary: Drug SafetySecondary: Overall Survival, Disease-free Survival, Overall Response Rate, RO Resection Rate, Pathological Response Rate
Timing	<ul style="list-style-type: none">Enrollment completion target 4Q23Data readouts possible throughout 2023 with complete results expected 2024

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



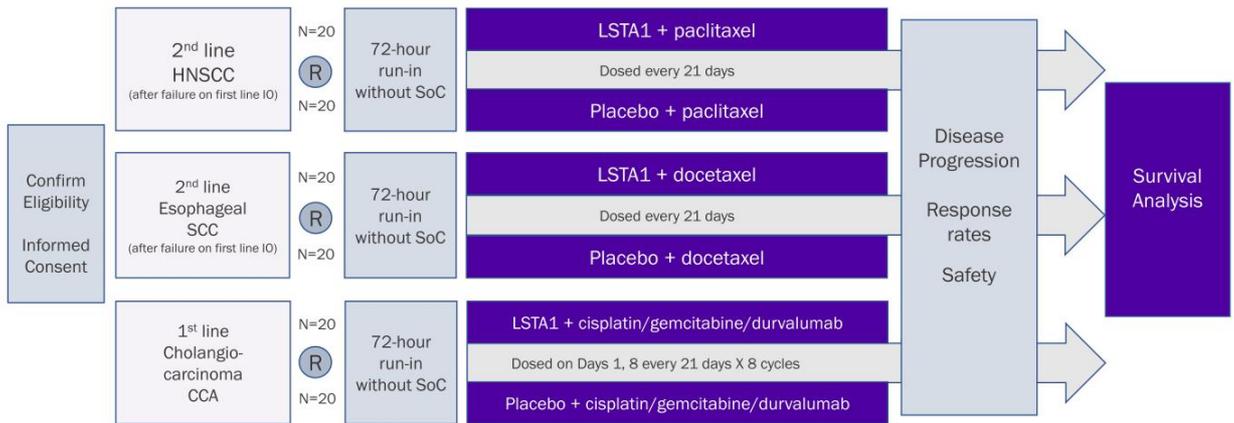
BOLSTER: Phase 2 blinded, randomized PoC trial in various cancers

Sponsor/Partner	<ul style="list-style-type: none">▪ Lisata (U.S.)
Objective	<ul style="list-style-type: none">▪ Evaluate the preliminary efficacy, safety and tolerability of LSTA1 in combination with standards of care in subjects with advanced solid tumors
Design	<ul style="list-style-type: none">▪ 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	<ul style="list-style-type: none">▪ 120 (40 per tumor type split 1:1 SoC + LSTA1 or SoC + placebo)
Endpoints	<ul style="list-style-type: none">▪ Primary: OS▪ Secondary: Safety, ORR, PFS
Objective	<ul style="list-style-type: none">▪ Evaluate the preliminary efficacy, safety and tolerability of LSTA1 in combination with standards of care in subjects with advanced solid tumors
Timing	<ul style="list-style-type: none">▪ Trial initiation target: 2Q23

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

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

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



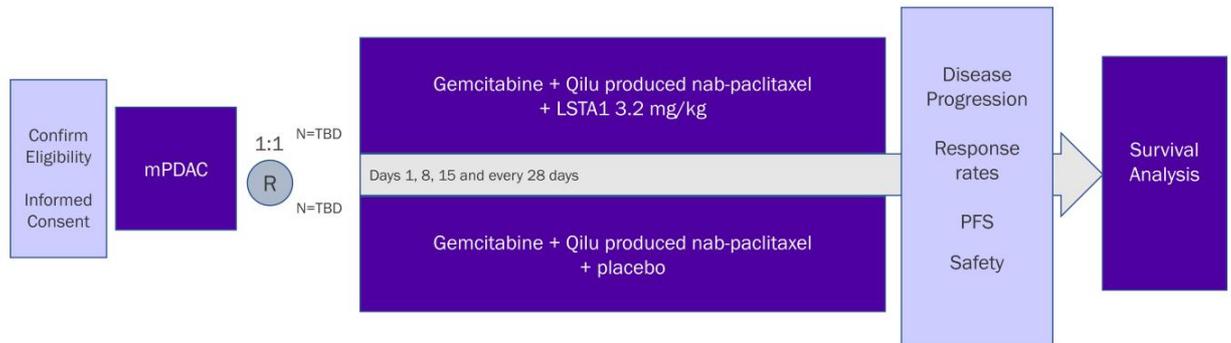
Phase 2 blinded, placebo-controlled trial in mPDAC in China

Sponsor/Partner	<ul style="list-style-type: none">▪ Qilu Pharmaceutical (funds all development in China)
Objective	<ul style="list-style-type: none">▪ Further evaluate safety and therapeutic efficacy of LSTA1 when added to SoC in Chinese patients with mPDAC
Design	<ul style="list-style-type: none">▪ Phase 2b, double-blind, placebo-controlled, randomized study evaluating LSTA1 + SoC (Qilu-produced nab-paclitaxel and gemcitabine) vs. placebo + SoC
Study Size	<ul style="list-style-type: none">▪ TBD
Endpoints	<ul style="list-style-type: none">▪ Objective response rate, progression free survival, overall survival▪ Safety
Timing	<ul style="list-style-type: none">▪ 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



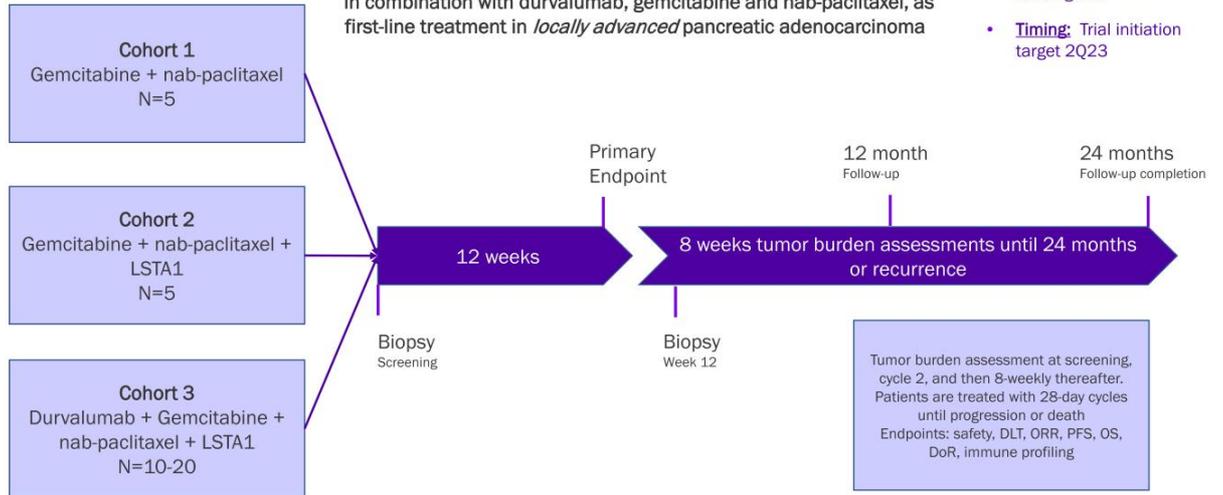
iLSTA: Phase 1b/2a trial in locally advanced PDAC with chemo & IO

Sponsor/Partner	<ul style="list-style-type: none">▪ WARPINE, Inc. (registered charity in Australia) is funding trial▪ Lisata providing study drug
Objective	<ul style="list-style-type: none">▪ Evaluate safety and therapeutic effect of LSTA1 in combination with IO & Chemo in locally advanced PDAC; determine if inoperable tumors can become operable
Design	<ul style="list-style-type: none">▪ Phase 1b/2a proof-of-concept safety and early efficacy study of LSTA1 in combination with durvalumab, gemcitabine and nab-paclitaxel, as first-line treatment in <i>locally advanced</i> pancreatic adenocarcinoma
Study Size	<ul style="list-style-type: none">▪ N=30
Endpoints	<ul style="list-style-type: none">▪ Safety and tolerability; 28-day DLTs▪ Objective response rate, PFS, OS, duration of response, immune cell infiltration
Timing	<ul style="list-style-type: none">▪ Trial initiation target 2Q23

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

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* pancreatic adenocarcinoma

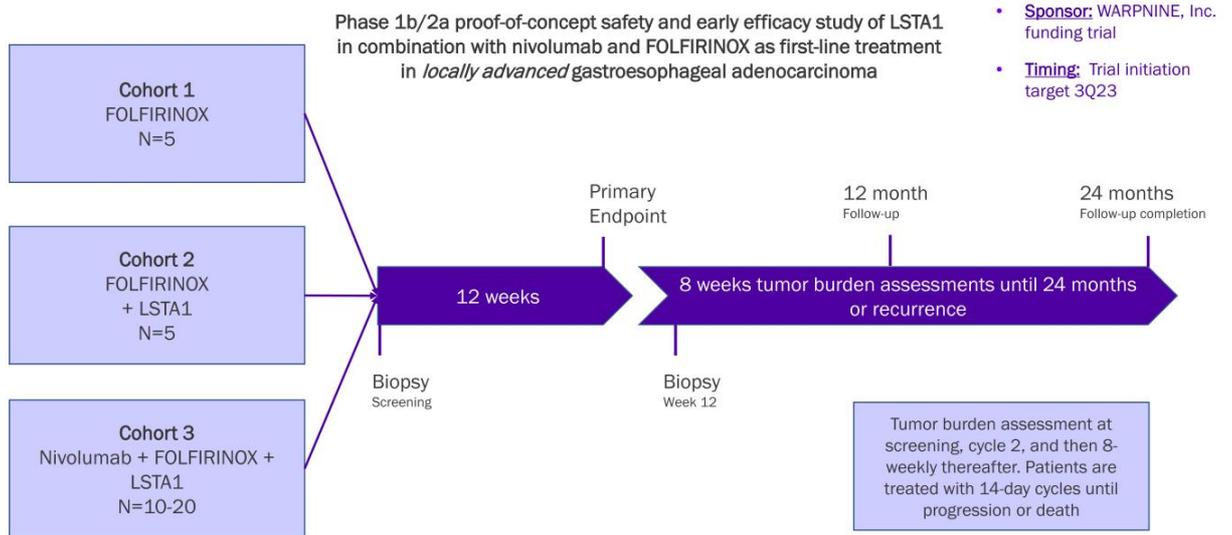
- **Sponsor:** WARPNINE, Inc. funding trial
- **Timing:** Trial initiation target 2Q23



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

Sponsor/Partner	<ul style="list-style-type: none">▪ WARPINE, Inc. (registered charity in Australia) is funding trial▪ Lisata providing study drug
Objective	<ul style="list-style-type: none">▪ Evaluate safety and therapeutic effect of LSTA1 in combination with IO & Chemo in locally advanced GE AdenoCa; determine if inoperable tumors can become operable
Design	<ul style="list-style-type: none">▪ Phase 1b/2a proof-of-concept, safety and early efficacy study of LSTA1 in combination with nivolumab and FOLFIRINOX, as first-line treatment in <i>locally advanced</i> gastroesophageal adenocarcinoma
Study Size	<ul style="list-style-type: none">▪ N=30
Endpoints	<ul style="list-style-type: none">▪ Safety and tolerability; 28-day DLTs▪ Objective response rate, PFS, OS, duration of response, immune cell infiltration
Timing	<ul style="list-style-type: none">▪ Trial initiation 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	<ul style="list-style-type: none">▪ Tartu University Hospital (Investigator initiated trial in Estonia)▪ Lisata providing study drug and funding trial
Objective	<ul style="list-style-type: none">▪ Evaluate safety, tolerability, and therapeutic effect of LSTA1 in combination with standard-of-care (temozolomide) in patients with previously untreated Glioblastoma Multiforme
Design	<ul style="list-style-type: none">▪ Phase 2a proof-of-concept, double-blind, placebo-controlled, randomized study evaluating LSTA1 when added to standard of care (temozolomide) versus SoC and placebo in subjects with newly diagnosed Glioblastoma Multiforme (GBM)
Study Size	<ul style="list-style-type: none">▪ N=40
Endpoints	<ul style="list-style-type: none">▪ Safety, tolerability▪ ORR, PFS, OS, disease control rate
Timing	<ul style="list-style-type: none">▪ Trial initiation target 3Q23

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

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

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



