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

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

February 6, 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

☐ 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.

Lisata Therapeutics, Inc. (the "Company") expects to report that it had cash, cash equivalents and marketable securities of approximately $69.2 million as of December 31, 2022. The estimated cash figure is preliminary and unaudited, represents a management estimate as of the date of this current report on Form 8-K and is subject to completion of the Company's financial closing procedures. The Company's independent registered public accounting firm has not conducted an audit or review of, and does not express an opinion or any other form of assurance with respect to, the estimated cash figure.

The information in this Item 2.02 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 7.01 Regulation FD Disclosure.

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 99.1 and is incorporated herein solely for purposes of this Item 7.01 disclosure.

The information in this Item 2.02, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

As previously disclosed, 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 diabetic kidney disease ("DKD"). 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. On February 6, 2023, the Company announced topline results which showed that the DKD patients in the LSTA201 study could tolerate mobilization, donation and administration of CD+34 cell therapy, but LSTA201 did not demonstrate consistent improvement in kidney function for all subjects of the study. Further clinical study would be required to determine therapeutic effectiveness. The Company will further evaluate the data and determine next steps with respect to LSTA201.

Item 9.01. Exhibits.

Exhibit No.	Description
99.1	Lisata Therapeutics, Inc. Corporate Presentation, February 6, 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: February 6, 2023

EXHIBIT 99.1

LISATA THERAPEUTICS

Targeted Therapy *Delivered*

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

Corporate Presentation | February 6, 2023
Nasdaq: LSTA

www.lisata.com

Forward-looking Statements Notice

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 22, 2022, and Exhibit 99.2 to Lisata's Amendment No. 1 to Current Report on Form 8-K filed on October 4, 2022, 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.

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; unaudited

Why Oncology? - Improved cancer treatment is a 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

Opportunity: solid tumors are a large & growing treatment 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	24,840	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%**

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: intratumoral drug exposure insufficient for ideal response

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

Solution: Lisata's CendR Platform®

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)
- Combats resistance by selectively depleting intratumoral immunosuppressive cells
- Platform extension possible to most drug modalities including nucleic acid-based drugs

LSTA1: CendR Platform® lead development candidate

LSTA1 is clinically advancing 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
- 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 $225 million to Lisata for milestones & tiered double-digit royalties on sales

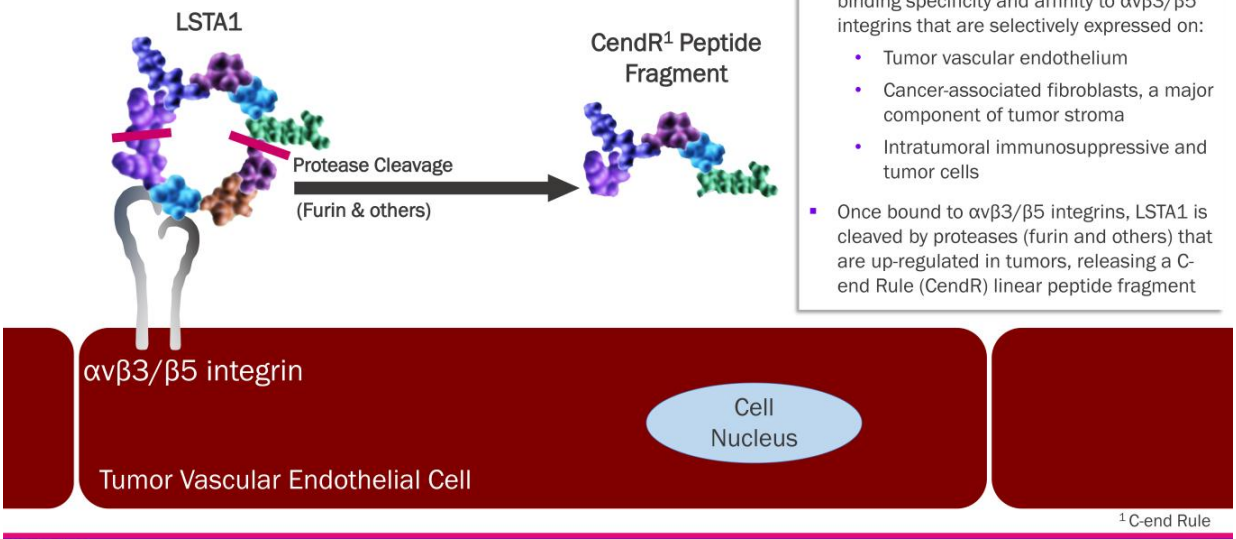
Clinical development collaboration with Roche in mPDAC

- LSTA1/gemcitabine/nab-paclitaxel treatment regimen ± atezolizumab as part of MORPHEUS trial

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


LSTA1
[formerly known as CEND-1]
Well-characterized Mechanism of Action with
Compelling Early Clinical Results

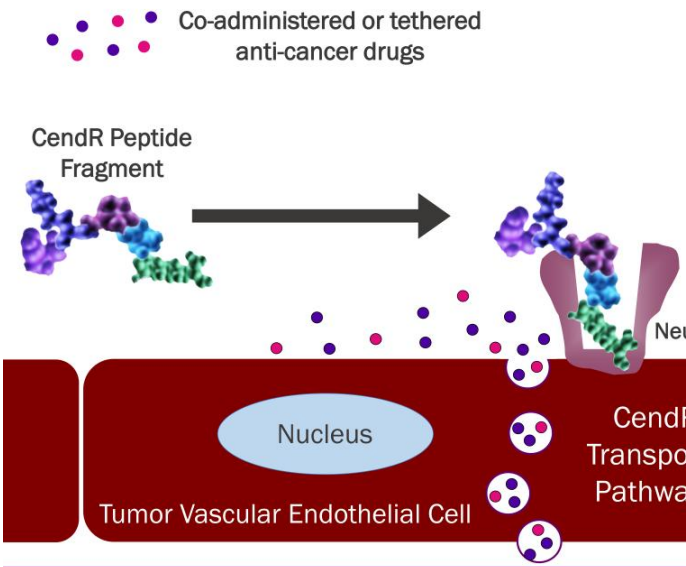
LSTA1: mechanism of action step one



- LSTA1: 9 amino acid cyclic peptide; high binding specificity and affinity to αvβ3/β5 integrins that are selectively expressed on:
  - Tumor vascular endothelium
  - Cancer-associated fibroblasts, a major component of tumor stroma
  - Intratumoral immunosuppressive and tumor cells
- Once bound to αvβ3/β5 integrins, LSTA1 is cleaved by proteases (furin and others) that are up-regulated in tumors, releasing a C-end Rule (CendR) linear peptide fragment

[1] C-end Rule

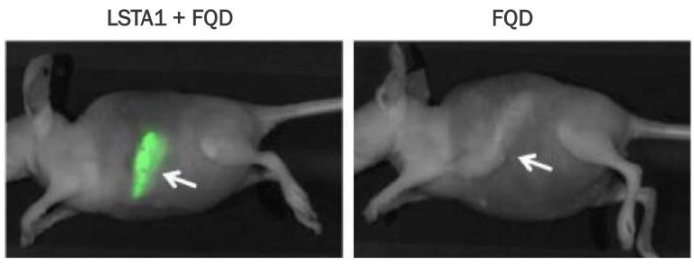
LSTA1: mechanism of action step two



- The CendR fragment then binds with high affinity to an adjacent receptor, neuropilin-1, activating the CendR transport pathway
  - Circulating moieties including 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

LSTA1 selectively and efficiently facilitates intratumoral penetration

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

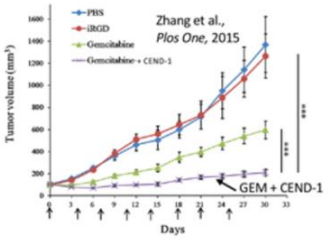


- Etching solution quenches fluorescence in circulation
- LSTA1 provides selective tumor penetration

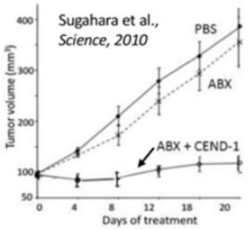
[1] Braun et al., Nature Mater. 2014.
[2] Liu, Braun et al., Nature Comm. 2017.

Increased tumor penetration enhances antitumor activity across various treatment modalities

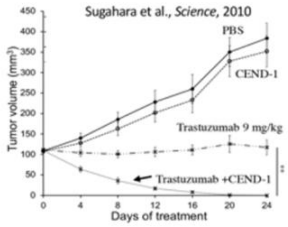
Lung cancer + gemcitabine + LSTA1



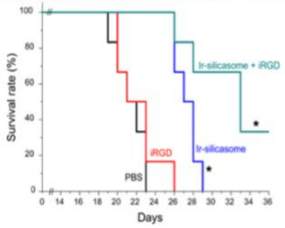
Breast cancer + nanoparticle Abraxane + LSTA1



Breast cancer + Herceptin® + LSTA1

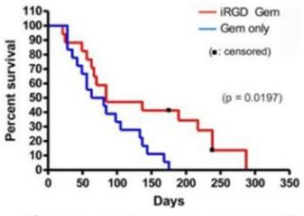


PDAC + irinotecan nanoparticles + LSTA1



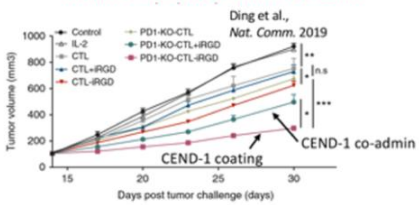
Orthotopically transplanted KPC PDAC tumors
CEND-1 + irinotecan nanoparticles (i.v. co-admin)

PDAC + gemcitabine + LSTA1



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 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.
[1] Dean A, et al., *The Lancet Gastroenterology & Hepatology*, 2022.


LSTA1
[formerly known as CEND-1]
Clinical Development Portfolio
Fast Track and Orphan Drug designated (PDAC) - USA

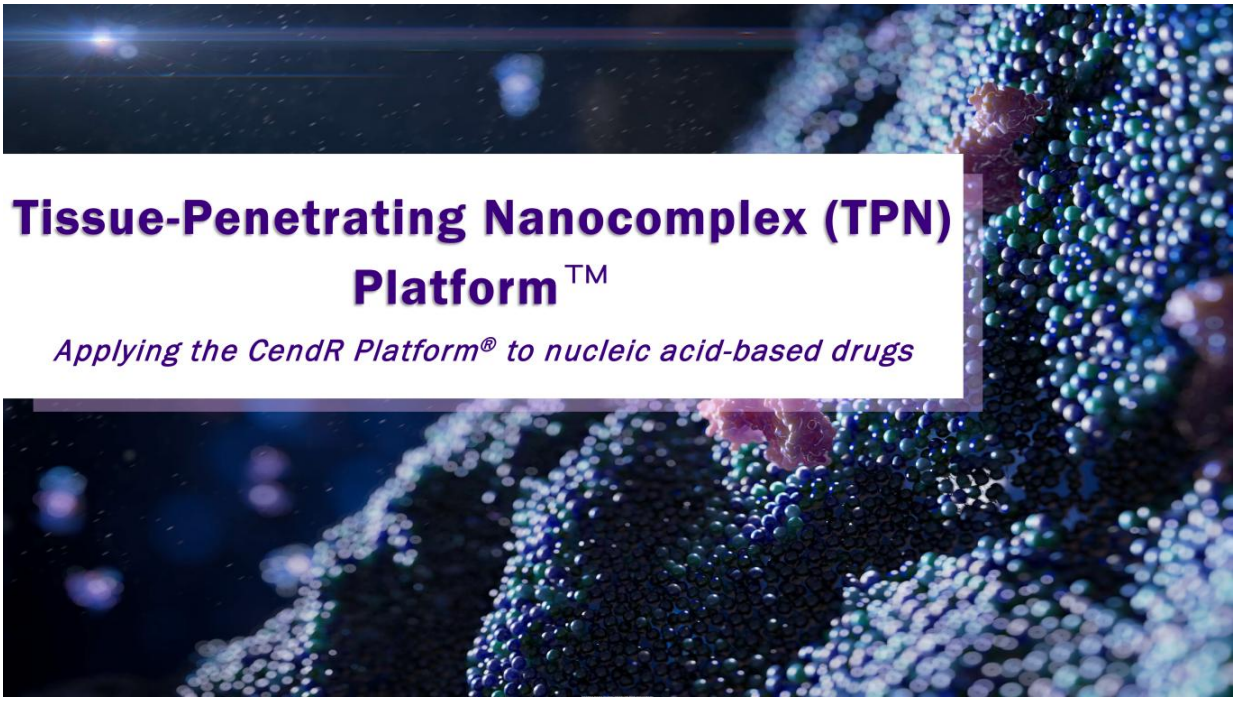
LSTA1 capital efficient development plan; shared costs & selective geography

Development Partner(s) [Development Venue]	Indication and Trial Product/Comparator	Stage of Development
Lisata/AGITG [Australia/New Zealand/Ireland]	First-line mPDAC; Gemcitabine/nab-paclitaxel with LSTA1 or placebo	Phase 2b (ASCEND)
Lisata [United States]	Various Solid Tumors; SoC with LSTA1 or placebo	Phase 2a (Basket Trial)
KUCC/Lisata [United States]	Pancreatic, Colon & Appendiceal Cancers; LSTA1 + FOLFIRINOX + panitumumab*	Phase 1b/2a (CENDIFOX)
Roche/Lisata [Multi-national]	First-line mPDAC; Gemcitabine/nab-paclitaxel/LSTA1 ± atezolizumab	Phase 1b/2 (MORPHEUS)
Qilu [China]	First-line mPDAC; Gemcitabine/nab-paclitaxel + LSTA1	Phase 1b/2a
Qilu [China]	First-line mPDAC; Gemcitabine/nab-paclitaxel + LSTA1	Phase 2b

*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
WARPNINE/Lisata [Australia]	Locally advanced resectable PDAC; Durvalumab/gemcitabine/nab-paclitaxel + LSTA1	Phase 1b/2a (iLSTA)
WARPNINE/Lisata [Australia]	Locally advanced resectable Gastroesophageal (GE) adenocarcinoma; Nivolumab + FFX + LSTA1	Phase 1b/2a (iGoLSTA)
Tartu University/Lisata [Estonia]	First-line Glioblastoma Multiforme; Temozolomide ± LSTA1	Phase 2a
UCSD/Columbia University/Lisata [United States]	Peritoneal Carcinomatosis LSTA+HIPEC intraoperatively	Phase 1b/2a


Tissue-Penetrating Nanocomplex (TPN) Platform™
Applying the CendR Platform® to nucleic acid-based drugs

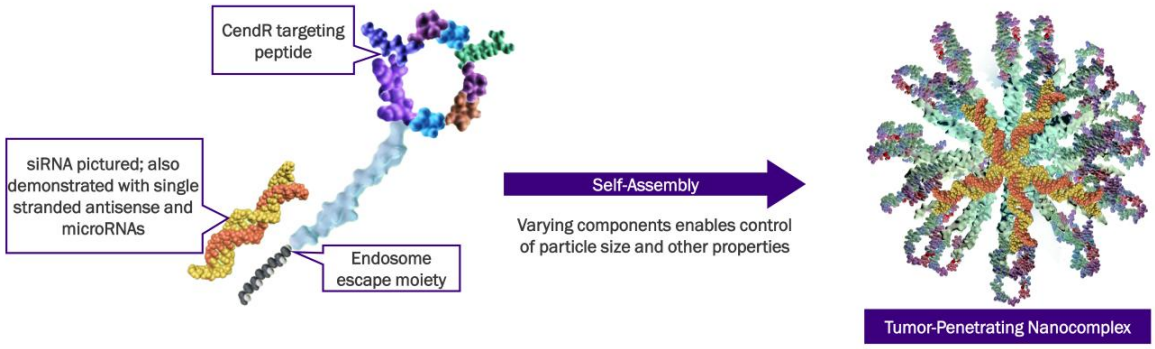
Anticancer applications of nucleic acid-based therapeutics

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
Lisata [United States]	Diabetic Kidney Disease; LSTA201	Phase 1b – Proof of Concept


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


LSTA201
(formerly known as CLBS201)
Diabetic Kidney Disease

LSTA201 in diabetic kidney disease (DKD)

Development Rationale

- CKD stages are determined by estimated glomerular filtration rate (eGFR), an indication of how well the kidneys are filtering blood[1]
- CKD is often associated with progressive microvasculature damage and loss[2,3]
- Preclinical studies show that microcirculation replenishment improves kidney function
- CD34+ cells are promoters of new capillary growth, improving the microvasculature
- A regenerative DKD therapy (i.e., reversing disease course) could represent a medical and pharmacoeconomic breakthrough
  - Therapies currently available and/or expected to be available over the next 5–10 years slow progression of CKD/DKD

Clinical Strategy

- To demonstrate that CD34+ cell mobilization, donation and administration can be tolerated by type 2 diabetes patients with CKD
- *To demonstrate that regeneration of the kidney microcirculation using CD34+ cell therapy improves kidney function*

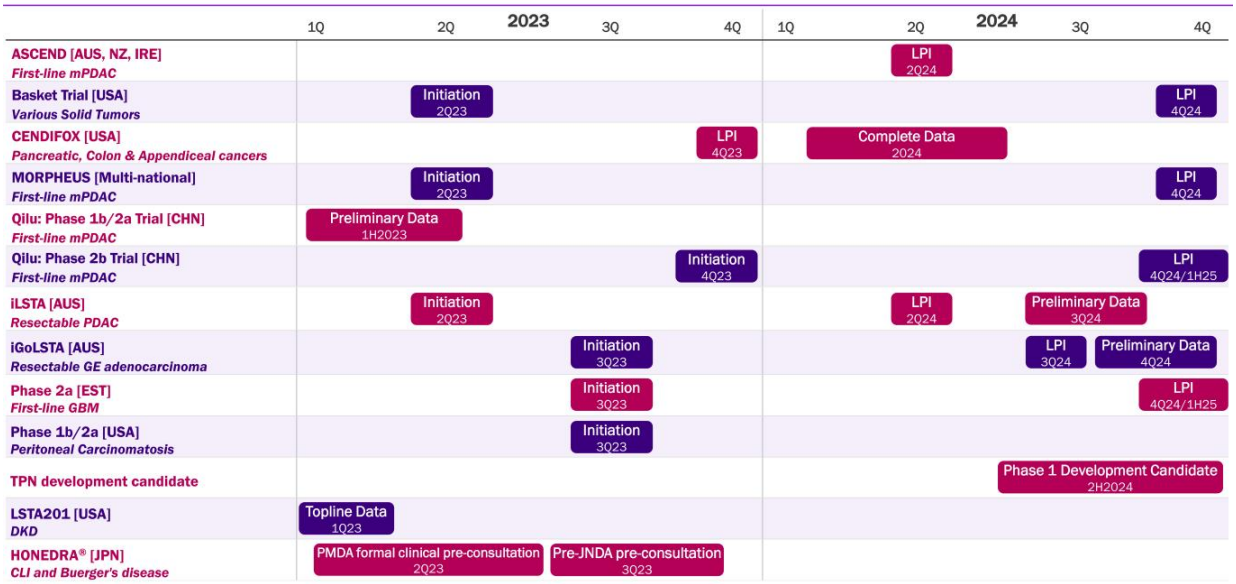
[1] 2020 Dallas Nephrology Associates.
[2] Chade AR. (2017) Small Vessels, Big Role: Renal Microcirculation and Progression of Renal Injury. Hypertension; 69(4):551-563.
[3] *Zuk, Anna & Bonventre, Joseph. (2016). Annual Review of Medicine. 67. 293-307. 10.1146/annurev-med-050214-013407.*

LSTA201 in diabetic kidney disease

Development Status

- Clinical trial completed
  - CKD patients can tolerate mobilization, donation and administration of CD34+ cell therapy
  - LSTA201 did not demonstrate consistent improvement kidney function in all subjects
- Further clinical study required to optimize therapeutic effect
- Next step of development by Lisata to be determined

A wealth of anticipated key milestones



Lisata Therapeutics: financial summary

Cash & Investments (12/31/2022)*	Debt	Projected Cash Runway
$69.2M	**$0**	**1H2025** *(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 shares[1]
Warrants Outstanding (12/31/2022): Weighted Average Exercise Price: $42.57	1.4 million shares

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

**unaudited*

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; unaudited

LISATA THERAPEUTICS

Targeted Therapy *Delivered*

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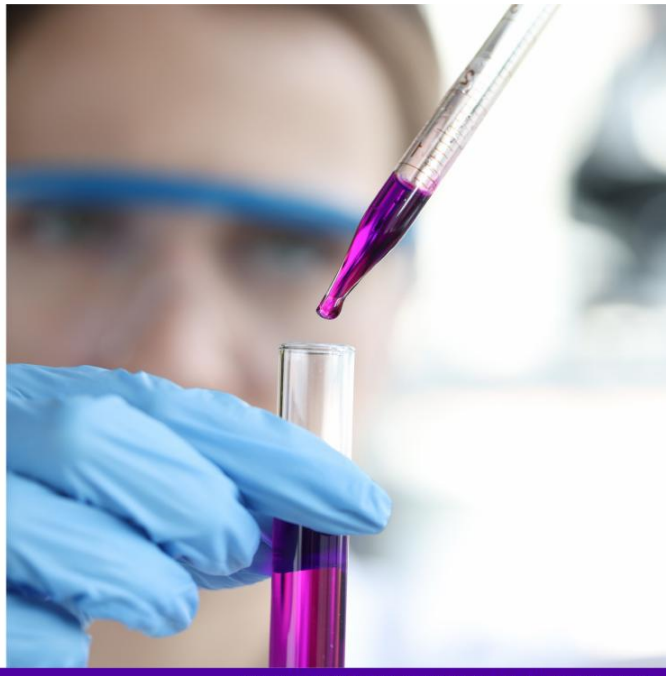


Appendix

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)
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)
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)
Qilu [China]	**First-line mPDAC;** Gemcitabine/nab-paclitaxel + LSTA1	**Phase 2b**	Continue development of LSTA1 in China (placebo controlled)

**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
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)
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)

CD34+ cell therapy current clinical trials

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

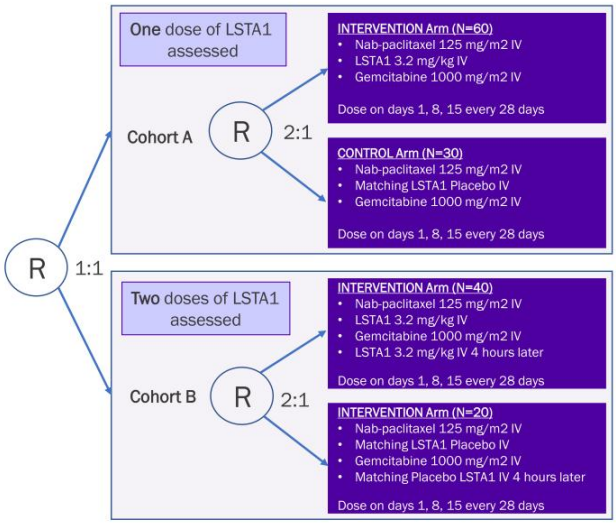
Sponsor [Development Venue]	Indication and Trial Product/Comparator	Stage of Development	Strategic Rationale
Lisata [Japan]	Critical Limb Ischemia & Buerger's Disease; HONEDRA® (LSTA12)	Registration Eligible	Assess safety and efficacy of LSTA12 in a controlled trial vs. SoC alone in the context of qualifying for approval in Japan under the accelerated regulatory pathway applicable to regenerative medicines
Lisata [United States]	Diabetic Kidney Disease; LSTA201	Phase 1b – Proof of Concept	Assess ability of LSTA201 to be administered to DKD patients safely and to increase eGFR (reverse disease progression)

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, New Zealand and Ireland)
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

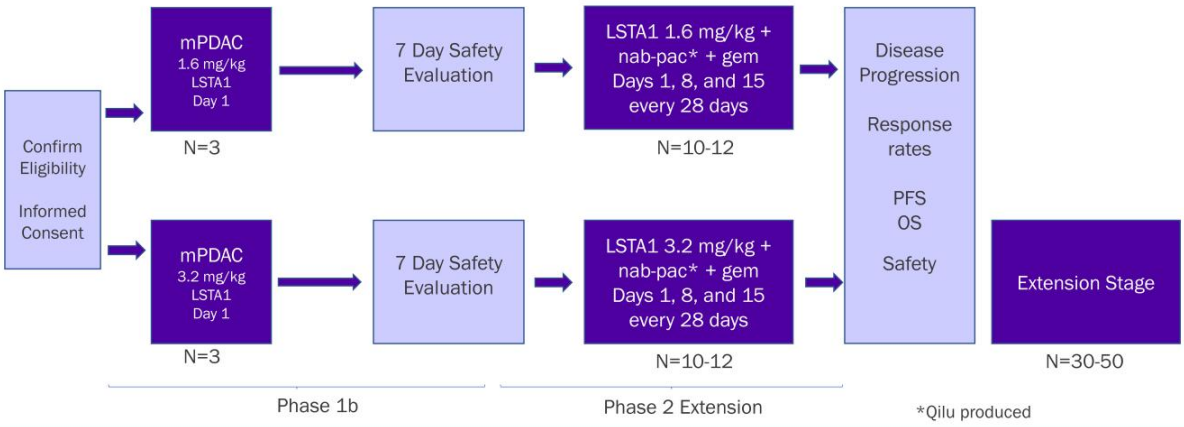
Phase 1b/2a open-label trial in mPDAC in China

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

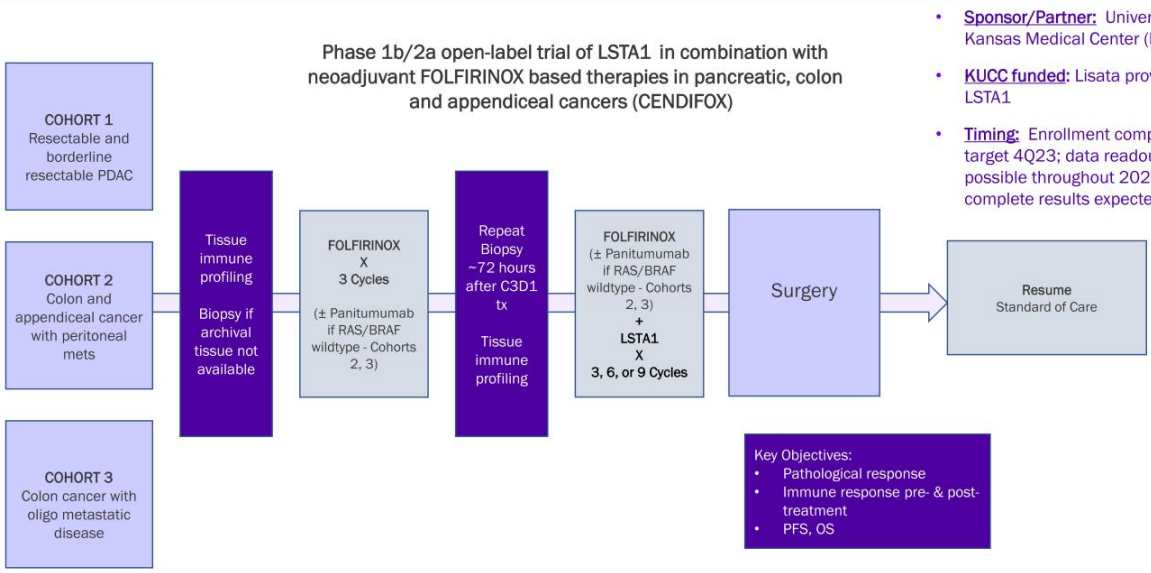


*Qilu produced

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

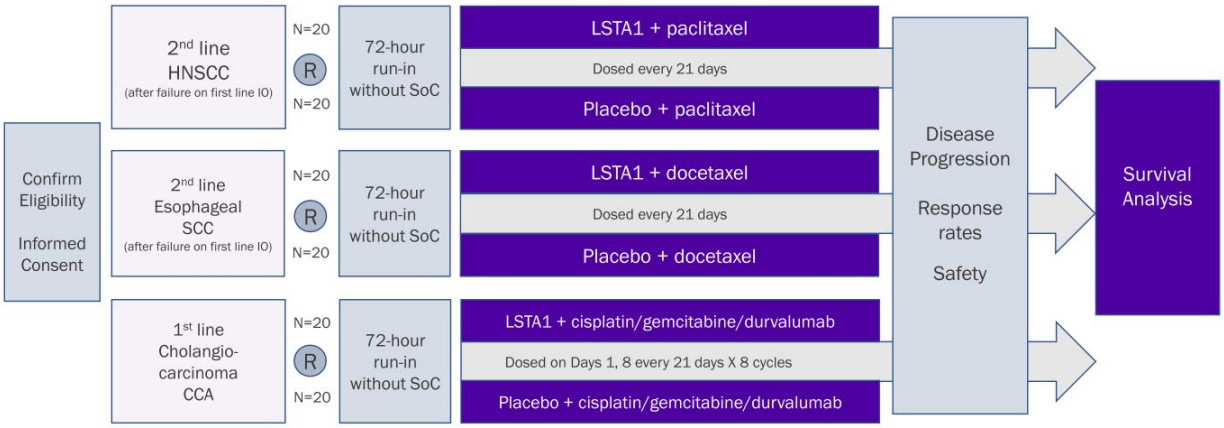
Basket: Phase 2 blinded, randomized PoC trial in various cancers

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	▪ 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



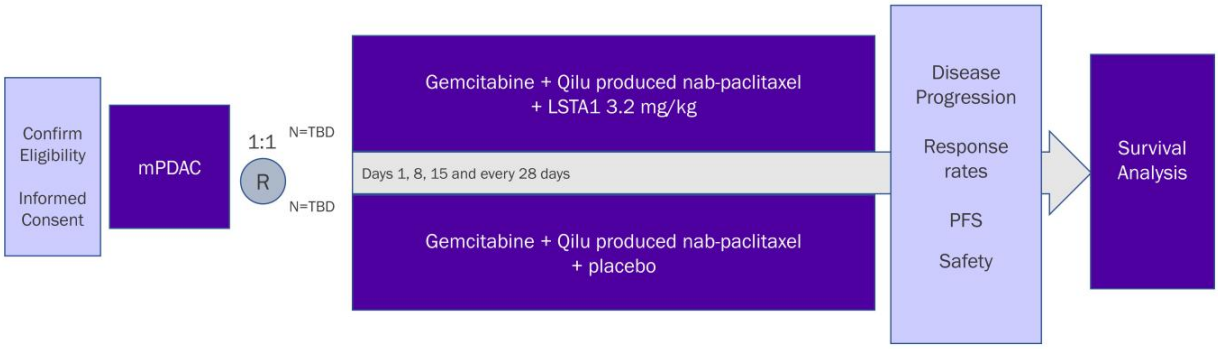
Phase 2b blinded, placebo-controlled trial in mPDAC in China

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 4Q23

Phase 2b 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



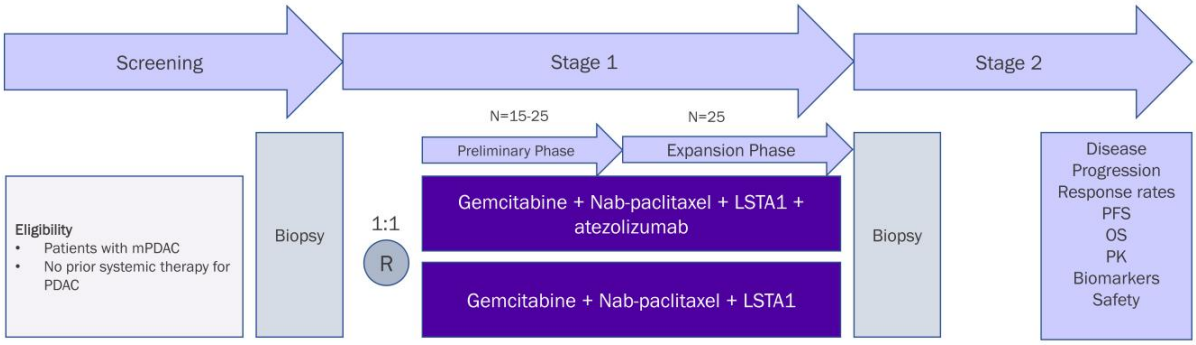
MORPHEUS: Phase 1b/2 mPDAC Umbrella trial

Sponsor/Partner	▪ Roche/Lisata co-funding trial; Roche operationalizing trial ▪ Roche supplying atezolizumab
Objective	▪ Evaluate safety and effectiveness of LSTA1 in combination with gemcitabine and nab-paclitaxel ± atezolizumab in mPDAC
Design	▪ Phase 1b/2, open-label, randomized umbrella study in patients with mPDAC evaluating the safety, PK and efficacy of immunotherapy-based treatment combinations in patients with mPDAC who have received no prior therapy
Study Size	▪ Preliminary phase: 12-25 ▪ Expansion phase: 25
Endpoints	▪ Objective response rate, progression free survival, overall survival, duration of response ▪ Safety, tolerability, PK, biomarkers
Timing	▪ Trial initiation target 2Q23

MORPHEUS: Phase 1b/2 mPDAC Umbrella trial

Phase 1b/2, open-label, randomized umbrella study in patients with mPDAC evaluating the safety, PK, and efficacy of immunotherapy-based treatment combinations in patients with mPDAC who have received no prior

- Sponsor/Partner: Roche Pharmaceuticals
- Roche/Lisata: co-fund trial; Roche operationalizes trial
- Timing: Trial initiation target 2Q23



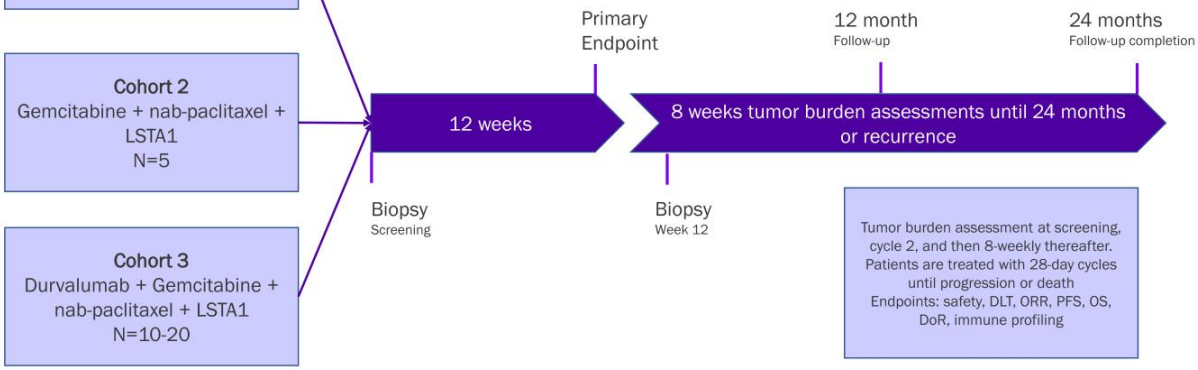
iLSTA: Phase 1b/2a trial in locally advanced PDAC with chemo & IO

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 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* 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	▪ 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

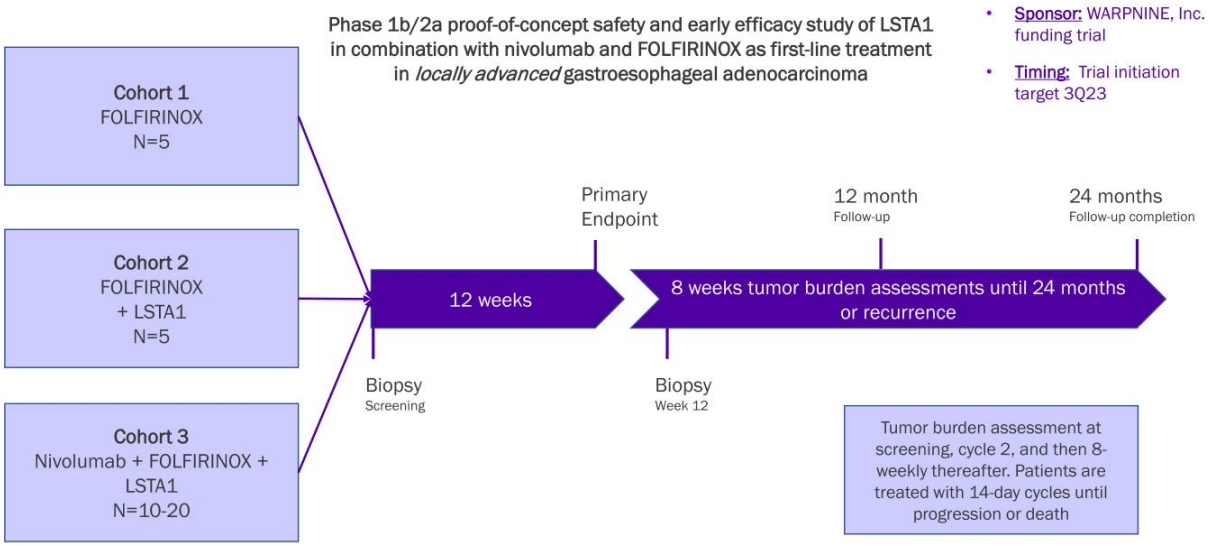


Tumor burden assessment at screening, cycle 2, and then 8-weekly thereafter. Patients are treated with 28-day cycles until progression or death
Endpoints: safety, DLT, ORR, PFS, OS, DoR, immune profiling

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 safety and therapeutic effect of LSTA1 in combination with IO & Chemo in locally advanced GE AdenoCa; 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* 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	▪ 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	▪ Tartu University Hospital (Investigator initiated trial in Estonia) ▪ Lisata providing study drug and funding trial
Objective	▪ Evaluate safety, tolerability, and therapeutic effect of LSTA1 in combination with standard-of-care (temozolomide) in patients with previously untreated Glioblastoma Multiforme
Design	▪ Phase 2a proof-of-concept, double-blind, placebo-controlled, randomized study evaluating LSTA1 when added to standard of care (temozolomide) versus SoC and placebo in subjects with newly diagnosed Glioblastoma Multiforme (GBM)
Study Size	▪ N=40
Endpoints	▪ Safety, tolerability ▪ ORR, PFS, OS, disease control rate
Timing	▪ Trial initiation target 3Q23

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

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

Sponsor/Partner	▪ Tsukuba Clinical Research & Development Organization (T-CReDO) ▪ Lisata providing study drug; AMED Grant funding trial in Japan
Objective	▪ Evaluate safety, pharmacokinetics and preliminary efficacy of various doses of LSTA1 added to SoC in Japanese patients with mPDAC
Design	▪ Phase 1b/2a open-label dose-ranging study in locally advanced and mPDAC patients of Japanese ethnicity testing SoC chemotherapy (gemcitabine + nab-paclitaxel) in combination with LSTA1
Study Size	▪ Up to 20 subjects
Endpoints	▪ Safety, tolerability ▪ ORR, PFS, OS, disease control rate
Timing	▪ Trial initiation target 4Q23