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

September 22, 2022
Date of Report (date of earliest event reported)

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

Delaware	**001-33650**	**22-2343568**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

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

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

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

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

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

☐ Emerging growth company

o If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01. Regulation FD Disclosure.

A copy of a slide presentation that Lisata Therapeutics, Inc. (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 7.01, including Exhibit 99.1 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 Exhibit 99.1 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 8.01 Other Events.

As previously disclosed, in December 2020, the Company commenced enrollment in its Phase 2b FREEDOM Trial of XOWNA®, a double-blind, randomized, placebo-controlled clinical trial designed to further evaluate the efficacy and safety of intracoronary artery delivery of autologous CD34+ cells in subjects with Coronary Microvascular Dysfunction (CMD) and without obstructive coronary artery disease and was expected to complete enrollment in approximately 12 months. While early enrollment proceeded to plan with the first patient treated in January 2021, the COVID-19 pandemic resulted in insurmountable enrollment rate challenges and population heterogenicity. As a result, in May 2022, 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. Following the analysis of results of the FREEDOM Trial subjects completing 6-month follow-up along with Key Opinion Leaders' input, the Company's board of directors 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 without a strategic partner. 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. There can be no assurance that we will be able to identify such a partner and enter into an agreement with such partner on acceptable terms or at all.

Item 9.01 Exhibits.

Exhibit No.	Description
99.1	Lisata Therapeutics, Inc. Corporate Presentation, September 22, 2022

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.

CALADRIUS BIOSCIENCES, INC.

By: /s/ David J. Mazzo
Name: David J. Mazzo, PhD
Title: Chief Executive Officer

Dated: September 22, 2022

Exhibit 99.1


LISATA
THERAPEUTICS
Targeted Therapy Delivered
David J. Mazzo, Ph.D., Chief Executive Officer
September 22, 2022 | Nasdaq: LSTA | www.lisata.com

Forward-looking Statements

This presentation contains "forward-looking statements" that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this communication regarding strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management are forward-looking statements. In addition, when or if used in this communication, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" 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 22, 2022, and in the proxy statement/prospectus filed by Lisata with the Securities and Exchange Commission relating to the Merger. 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.

Investment highlights

| NOVEL INTRATUMORAL DELIVERY TECHNOLOGY TO IMPROVE THERAPEUTIC EFFICACY OF SoC* DRUGS |
| EXISTING CAPITAL EXPECTED TO FUND ANTICIPATED MILESTONES | EXISTING STRATEGIC PARTNERSHIPS |

- Nasdaq-listed with a focused mid-late-stage clinical development pipeline and a promising preclinical platform
- Stable finances: ~$76 million cash & investments as of 9/15/22; no debt
- Proprietary field-leading technology in underserved global indications backed by a strong IP portfolio
- Platform technology “validated” by strong existing partnerships with potential for many others
- Multiple potential value creating data and business development events projected in the next 12-24 months
- Seasoned management with domain expertise along with big pharma and emerging pharma experience

*SoC = standard-of-care

Proprietary platform technologies

CendR Platform™ - a targeted tissue penetration technology to enhance drug delivery to solid tumors

- Converts tumor stroma from barrier to conduit for efficient delivery of chemo-, targeted and immunotherapies
  - Delivery accomplished via co-administration or by tethering
- Selectively depletes intratumoral immunosuppressive cells
- Combination with many existing chemo- and immuno-therapeutics possible in a variety of indications

Tumor-Penetrating Nanocomplex (TPN) Platform™ - broad potential for delivery of nucleic acid-based therapies

- Designed to address challenges to ASO and siRNA delivery posed by stroma barrier and endosome sequestration
- Clinical development candidate identification expected in 2023

CD34+ Cell Therapy Platform - designed to address diseases and conditions caused by ischemia

- CD34+ cells repeatedly demonstrated vascular repair in multiple organs and have been clinically studied in a variety of ischemic diseases by numerous investigators across many sites and countries
  - Consistent results of rigorous clinical studies comprising >1,000 patients published in peer reviewed journals[1-4]
    - Single treatments elicited durable therapeutic effects
    - Treatment generally well-tolerated

[1] Povsic, T. et al. *JACC Cardiovasc Interv*, 2016, 9 (15) 1576-1585
[2] Losordo, D.W. et al. *Circ Cardiovasc Interv*, 2012; 5:821–830
[3] Velagapudi P, et al, *Cardiovas Revasc Med*, 2018, 20(3):215-219
[4] Henry T.D., et al, *European Heart Jour* 2018, 2208–2216

Clinical development pipeline with broad therapeutic reach

LSTA1 (formerly known as CEND-1), advancing in a variety of difficult-to-treat solid tumor applications

- Ongoing multiple studies in first-line, metastatic pancreatic ductal adenocarcinoma (mPDAC) in combination with standard-of-care (SoC) chemotherapy
- Basket trial initiation planned in 2023 expanding development to other solid tumors and additional anti-cancer drug combinations, including immunotherapies
- Granted Fast Track as well as Orphan Drug Designation by the U.S. FDA in PDAC

CD34+ autologous cell therapy development programs advancing to next development milestone

- XOWNA® development will continue if a partner is identified that can contribute the necessary capital
- HONEDRA® (SAKIGAKE designated) advancing through Japanese regulatory process toward JNDA
- CLBS201 proof-of-concept (PoC) results expected in 1Q23
- No additional capital outlay necessary to reach identified milestones

Therapeutic potential attracts strategic partners

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 in the licensed territories
- Potential for up to $225 million to Lisata for milestones and tiered double-digit royalties on potential sales
- $10 million payment due to Lisata for proceeding to Phase 3 in mPDAC in China

Clinical development collaboration with Roche in mPDAC

- LSTA1 tested in combination with atezolizumab in mPDAC as part of Morpheus trial

Additional partnership opportunities for broad applications of LSTA1 and the CendR Platform™

Ongoing discussions support goal to partner CD34+ programs

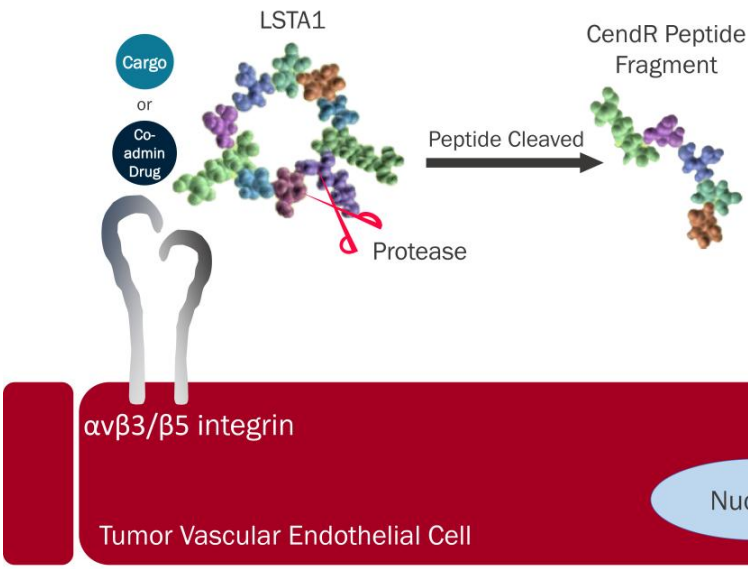
Robust portfolio of development candidates

Sponsor/Funding Partner	Trial Products	Indication	Development Stage	Next Development Milestone
CendR Platform™ Programs				
Lisata (Global)	Gemcitabine/nab-paclitaxel ± LSTA1	First-Line Metastatic Pancreatic Ductal Adenocarcinoma (mPDAC)	Phase 2/3 adaptive	FDA feedback 4Q22 Trial initiation planned 1Q/2Q23
AGITG (Australia/New Zealand)	Gemcitabine/nab-paclitaxel ± LSTA1		Phase 2b (ASCEND)	Enrollment completion target 4Q23 Data expected 2024
Qilu (China)	Gemcitabine/nab-paclitaxel ± LSTA1		Phase 1b/2	Preliminary data expected 2H23
Roche/Lisata (Multi-national)	LSTA1 + nab-paclitaxel + gemcitabine ± atezolizumab		Phase 1b/2	Trial initiation target 1Q23
KUCC - IIT (U.S.)	LSTA1 + FOLFIRINOX + panitumumab*	Pancreatic, Colon and Appendiceal Cancers	Phase 1b/2 (CENDIFOX)	Enrollment completion target 4Q23 Data expected 2024
Lisata (U.S.)	LSTA1 in combination with SoC	Various Solid Tumors	Phase 2a	Trial initiation planned 1Q/2Q23
Lisata (U.S.)	TPN development candidate		Preclinical	Development candidate ID target 2023 Phase 1 planned for 2024
CD34+ Platform Programs				
Lisata (U.S.)	XOWNA® (LSTA16)	Coronary Microvascular Dysfunction	Phase 2b (FREEDOM)	Partner sought to advance development
Lisata (Japan)	HONEDRA® (LSTA12)	Critical Limb Ischemia and Buerger's Disease	Phase 2	PMDA consultation underway
Lisata (U.S.)	LSTA201	Diabetic Kidney Disease	Phase 1b – PoC	Data expected 1Q23

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

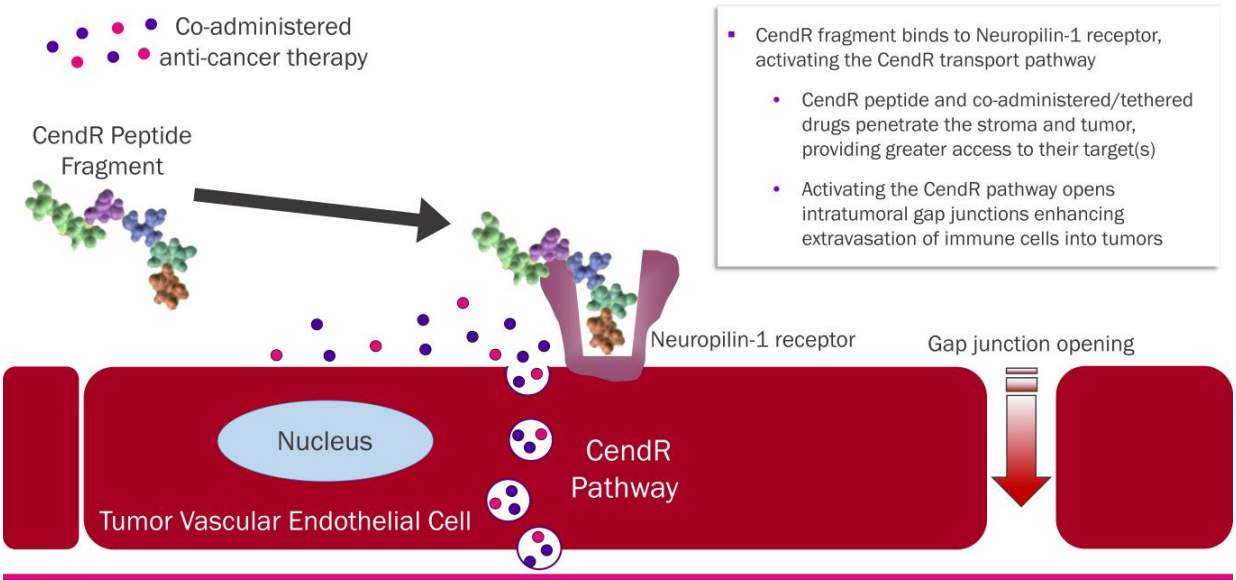

LSTA1
(formerly known as CEND-1)
CendR Platform™

LSTA1 mechanism of action (part 1)



- 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 cells
- Once bound to αvβ3/β5 integrins, LSTA1 is cleaved by proteases that are up-regulated in tumors, releasing a C-end Rule (CendR) linear peptide fragment

LSTA1 mechanism of action (part 2)



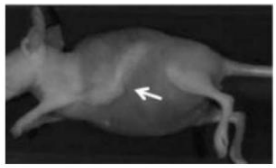
- CendR fragment binds to Neuropilin-1 receptor, activating the CendR transport pathway
  - CendR peptide and co-administered/tethered drugs penetrate the stroma and tumor, providing greater access to their target(s)
  - Activating the CendR pathway opens intratumoral gap junctions enhancing extravasation of immune cells into tumors

LSTA1 selectively and efficiently facilitates intratumoral delivery

Tumor-Targeting Penetration: In vivo

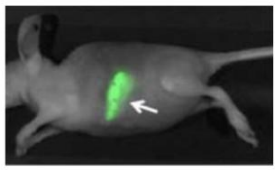
Imaging pancreatic ductal adenocarcinoma (PDAC) with LSTA1 + Fluorescent Quantum Dots (FQDs)

→ *+etch**



- FQD alone following etching solution to quench fluorescence in circulation

+LSTA1
→ *+etch**

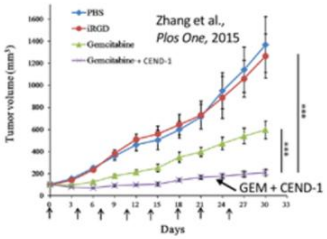


- FQD + LSTA1 followed by etching solution
  - FQDs show selective tumor penetration in the presence of LSTA1

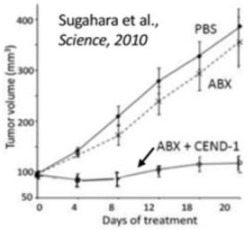
[1] Braun et al., Nature Mater. 2014.
[2] Liu, Braun et al., Nature Comm. 2017.

Increased tumor penetration enhances activity across treatment modalities

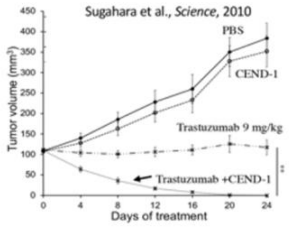
Lung cancer + gemcitabine



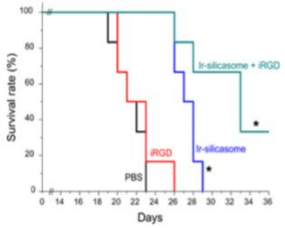
Breast cancer + nanoparticle Abraxane



Breast cancer + antibody (Herceptin®)

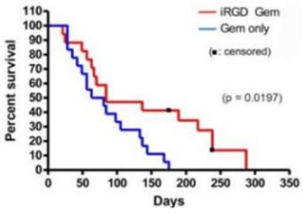


Pancreatic ductal adenocarcinoma



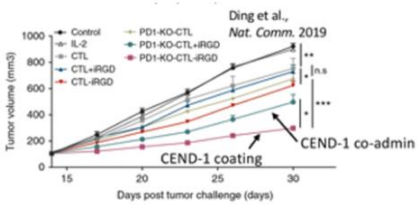
Orthotopically transplanted KPC PDAC tumors
CEND-1 + irinotecan nanoparticles (i.v. co-admin)

Pancreatic ductal adenocarcinoma



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

GI cancer + adoptive cell therapy



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

Treatment of solid tumors represents a large unmet clinical need

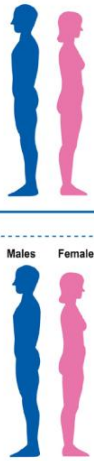
Estimated New Cancer Cases and Deaths in the United States, 2022[1]

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	29,240	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	11%	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	4%
Leukemia	14,020	4%	Uterine corpus	12,550	4%
Esophagus	13,250	4%	Liver & intrahepatic bile duct	10,100	4%
Urinary bladder	12,120	4%	Leukemia	9,980	3%
Non-Hodgkin lymphoma	11,700	4%	Non-Hodgkin lymphoma	8,550	3%
Brain & other nervous system	10,710	3%	Brain & other nervous system	7,570	3%
All Sites	**322,090**	**100%**	**All Sites**	**287,270**	**100%**



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

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

In the U.S. alone, over 90% of new cancer cases are solid tumors

An estimated 609,360 people will die from cancer in 2022, corresponding to ~1,700 deaths per day

Pancreatic cancer is one of the deadliest cancers in the U.S. with a five-year survival rate of only 11%, representing a high unmet medical need

Compelling Phase 1 clinical results of LSTA1

- Phase 1b: 31 subjects enrolled, 29 evaluable first-line, mPDAC patients from 3 sites in Australia [gemcitabine + nab-paclitaxel) with and without LSTA1
  - LSTA1 well-tolerated, no dose-limiting toxicities; safety with LSTA1 consistent with SoC alone
  - Favorable LSTA1 pharmacokinetic profile with median $T_{1/2}$ ~2 hours
  - Unprecedented improvement of SoC anti-tumor activity [1,2]
    - **Overall Response Rate** (PR+CR=ORR) 59% (vs. 23%) including Complete Response
    - **Disease Control Rate** at 16 weeks 79.3% (vs. 48%)
    - **CA19-9 circulating tumor biomarker reductions** in 96% of patients (vs. 61%)
    - **Median Progression-Free Survival** 9.7 months (vs. 5.5 months)
    - **Median Overall Survival** 13.2 months (vs. 8.5 months)

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

Ongoing & Planned LSTA1 Clinical Trials

ASCEND: Phase 2b randomized, double-blind trial in Aus and NZ

Sponsor/Partner	▪ Australasian Gastro-Intestinal Trials Group (AGITG) in collaboration with the NHMRC Clinical Trial Centre at the University of Sydney ▪ AGITG co-funded
Design	▪ Phase 2b randomized, double-blind study in mPDAC
Study Size	▪ 125 subjects (~40 sites in Australia and New Zealand)
Endpoints	▪ Primary: Progression Free Survival ▪ Secondary: AEs, SAEs, Overall Survival, Objective Tumor Response Rate
Control/Comparator	▪ SoC chemotherapy (gemcitabine/nab-paclitaxel) with LSTA1 or placebo
Objective	▪ Evaluate the effect of adding LSTA1, compared to placebo, to SoC chemotherapy in patients with untreated mPDAC
Timing	▪ Enrollment completion target 4Q23 ▪ Data expected 2024

LSTA1 Phase 1b/2 trial in China

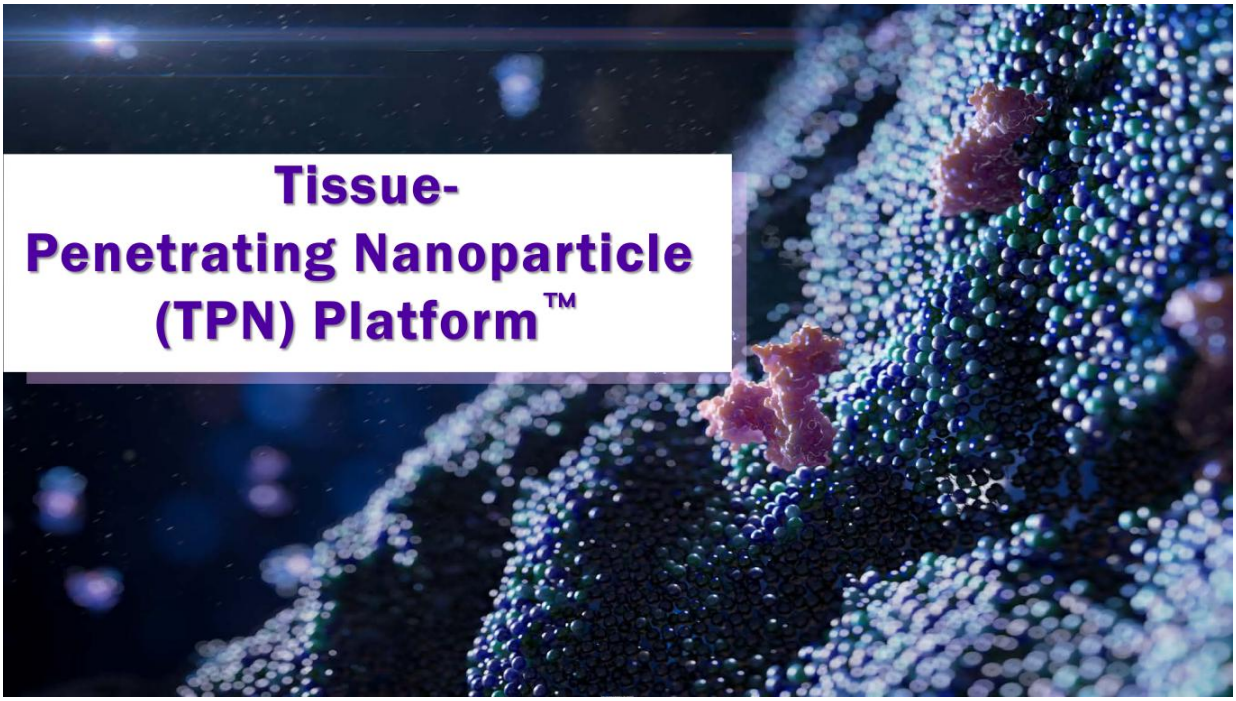
Sponsor/Partner	▪ QILU Pharmaceutical (provides all funding)
Design	▪ Phase 1b/2 open-label study in advanced mPDAC patients
Study Size	▪ 50 subjects (~15 sites; Chinese population)
Endpoints	▪ Primary: AEs, SAEs, Objective Response Rate, Duration Response Rate, Disease Control Rate, Overall Survival, and Progression Free Survival ▪ Secondary: Pharmacokinetic parameters
Control/Comparator	▪ SoC chemotherapy (gemcitabine/Qilu-produced nab-paclitaxel) with and without LSTA1
Objective	▪ Evaluate safety, pharmacokinetics and preliminary efficacy of LSTA1 added to SoC in Chinese patients with mPDAC
Timing	▪ Preliminary data expected 1H23; full data expected 2024

CENDIFOX: Phase 1b/2 trial in U.S.

Sponsor/Partner	▪ University of Kansas Medical Center (Investigator initiated trial)
Design	▪ Phase 1b/2 open-label study in pancreatic, colon and appendiceal cancers
Study Size	▪ 50 subjects
Endpoints	▪ Primary: Drug Safety ▪ Secondary: Overall Survival, Disease-free Survival, Overall Response Rate, RO Resection Rate, Pathological Response Rate
Control/Comparator	▪ SoC chemotherapy (neoadjuvant FOLFIRINOX-based therapies with LSTA1 or placebo
Objective	▪ Evaluate the safety of LSTA1 in combination with neoadjuvant FOLFIRINOX-based therapies for the treatment of pancreatic, colon, and appendiceal cancers
Timing	▪ Enrollment completion target 4Q23 ▪ Data expected 2024

Planned LSTA1 clinical trials

	PHASE 2/3 ADAPTIVE TRIAL IN mPDAC	PHASE 2A BASKET TRIAL IN MULTIPLE TUMOR TYPES
Sponsor	▪ Lisata	▪ Lisata
Design	▪ Phase 2/3, adaptive, double-blind, placebo-controlled, randomized trial in mPDAC (Global) - *pending FDA agreement*	▪ Phase 2, double-blind, placebo-controlled trial in multiple advanced solid tumor types (U.S.)
Study Size	▪ N=389	▪ N=120 (depending on number of arms in the "basket")
Endpoints	▪ Primary: OS ▪ Secondary: Safety, ORR, PFS	▪ Primary: OS ▪ Secondary: Safety, ORR, PFS
Control/Comparator	▪ Placebo; in combination with SoC chemo (gem/nab-paclitaxel)	▪ Placebo; in combination with tumor-type specific SoC chemo
Objective	▪ Evaluate the efficacy and safety of LSTA1 in subjects with previously untreated mPDAC (next step in development toward U.S. registration)	▪ Evaluate the preliminary efficacy, safety and tolerability of LSTA1 in combination with standards of care in subjects with advanced solid tumors
Timing	▪ FDA feedback: 4Q22 ▪ Trial initiation target: 1Q/2Q23	▪ Trial initiation target: 1Q/2Q23


Tissue-
Penetrating Nanoparticle
(TPN) Platform™

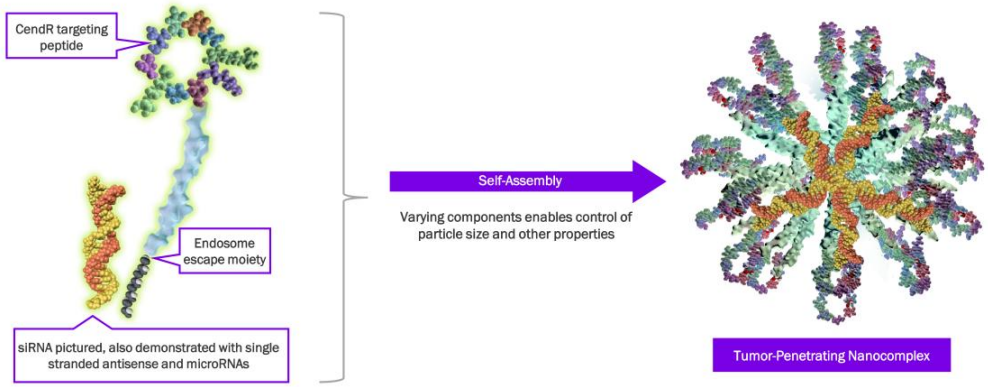
TPN Platform™ for nucleic acid medicine delivery in solid tumors

DELIVERY ISSUES LIMIT ANTICANCER APPLICATIONS OF RNA-BASED THERAPEUTICS

- RNA-based drugs have not been successful in the treatment of cancer despite advancement of candidates to multiple "undruggable" high-interest anticancer targets
- Early antisense oligonucleotide (ASO) and small interfering RNA (siRNA) anticancer programs failed to translate preclinical efficacy to clinical success
  - >95% of ASO and siRNA drugs sequestered in endosomes
  - Tumor stroma serves as primary impediment to effective delivery
  - High doses to drive intratumoral concentration resulted in on- and off-target side effects, including, but not limited to, clotting factors and renal toxicities
- Passive targeting (i.e., lipid nanoparticles) appears ineffective
- Non-targeted cell-/tissue-penetrating moieties can disrupt unintended tissues
- Moieties to target tumor increase bulk and may exacerbate problem of transiting stroma

Targeted approach to transit tumor stroma may enable effective solid tumor treatment

TPN Platform™ addresses nucleic acid tumor delivery challenges



- Peptides provide tumor and/or immune cell targeting
- Unique CendR pathway activation to penetrate stroma and deliver efficacious drug concentrations to all layers of solid tumors
- Technologies to evade endosome sequestration
- Targeted tissue penetration drives dose- and toxicity-sparing potency
- Ease of synthesis vs. biologics such as virus-like particles, Ab-conjugates or exosomes


CD34+ Cell Therapy
Platform Technology


XOWNA®
[LSTA16 (formerly known as CLBS16)]
Coronary Microvascular Dysfunction
(USA)

XOWNA® development status

Summary

- Coronary Microvascular Dysfunction (CMD) represents a large unmet medical need
  - Deficient heart microvasculature ***without large vessel obstructive disease*** causing frequent, severe angina
  - Not treatable by stents/bypass; responds poorly or not at all to available pharmacotherapies
  - U.S. CMD population potentially treatable by XOWNA® ranges from ~415,000 to ~1.6 million patients[1]
  - Compelling Phase 2a (published ESCaPE-CMD trial) results show the potential of XOWNA® to significantly improve symptoms of CMD
  - Phase 2b (FREEDOM) trial impacted directly and indirectly by COVID pandemic resulted in insurmountable enrollment rate challenges and population heterogenicity; trial enrollment suspended in May 2022 after ~1/3 of the intended subjects enrolled

Next Steps

- Analysis of results of FREEDOM Trial subjects completing 6-month follow-up along with KOL input suggests that execution of a redesigned FREEDOM-like trial is an appropriate next step
  - Cost of such trial is financially challenging in a "go-it-alone" strategy
- XOWNA® development will continue if a partner is identified that can contribute the necessary capital

[1] Marinescu MA, et al. JACC Cardiovasc Imaging. 2015;8:210-220


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

Indication: critical limb ischemia (CLI)

- Severe arterial obstruction impeding blood flow in the lower extremities
  - Includes severe rest pain and non-healing ulcers
- Buerger's disease (BD: inflammation in small and medium arteries) is a form of CLI associated with a history of heavy smoking (orphan population)
- Patients with no-option CLI have persistent symptoms even after bypass surgery, angioplasty, stenting and available pharmacotherapy
- CLI has been categorized as Rutherford Classification Stages[1]
  - Stages: 1-3 (mild to severe claudication); 4 (rest pain); 5 (minor tissue loss); 6 (major tissue loss)
  - CLI patients are at high risk of amputation and death with increasing Rutherford score
- Multi-million-dollar opportunity with an increasing prevalence of arteriosclerosis obliterans (ASO) and CLI in Japan
- Positive previously published Phase 2 results in Japan[3,4]

[1] Reinecke H., European Heart Journal, 2015 Apr 14;36(15):932-8
[3] Kinoshita et al, Atherosclerosis 224 (2012) 440-445
[4] Losordo, D.W. et al, Circulation 2012; 5(6):821-830

HONEDRA® registration-eligible study in Japan

Primary Endpoint	▪ Time to continuous CLI-free (2 consecutive monthly visits, adjudicated independently)
Target Study Size	▪ 35 subjects; recruited across 12 centers in Japan • 30 with no-option CLI (ASO) + 5 with BD; all Rutherford category 4 or 5
Dose	▪ Up to 10^6 cells/kg of HONEDRA® (LSTA12)
Control/Comparator	▪ SoC: wound care plus drugs approved in Japan • Including antimicrobials, antiplatelets, anticoagulants and vasodilators
Mode of Administration	▪ Intramuscular, 20 injections in affected lower limb in a single treatment
Objective	▪ Demonstrate a trend toward efficacy and acceptable safety to qualify for consideration of early conditional approval under Japan's Regenerative Medicine Development Guidelines

HONEDRA® development next steps

- Combined CLI and BD interim 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)
- Consultation process with the Pharmaceuticals & Medical Devices Agency (PDMA) is underway in support of the planned filing of a Japan New Drug Application


LSTA201
(formerly known as CLBS201)
Diabetic Kidney Disease

LSTA201 in diabetic kidney disease (DKD)

Development Rationale

- The stages of CKD are determined by GFR rate, 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
- Therapies currently available and/or expected to be available over the next 5–10 years will slow the progression of CKD/DKD
- A regenerative DKD therapy (i.e., one that reverses disease course) could represent a medical and pharmacoeconomic breakthrough

Clinical Strategy

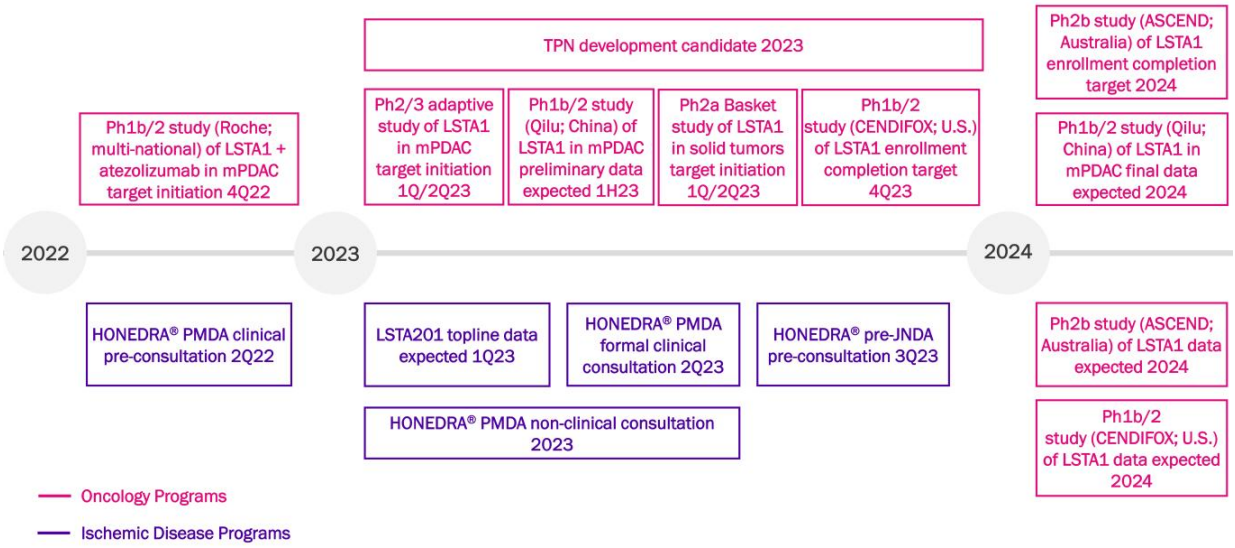
- To demonstrate that CD34+ cell mobilization, donation, and administration can be tolerated by patients with CKD and type 2 diabetes
- To demonstrate that regeneration of the kidney microcirculation using CD34+ cell therapy improves kidney function

[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: Phase 1b open-label, proof-of-concept study in U.S.

Endpoints	▪ Change in eGFR compared to baseline, assessed at 6 months ▪ Change in Urine albumin-to-creatinine ratio (UACR) and urine protein-to-creatinine ratio (UPCR) from baseline to 3 and 6 months
Study Size	▪ 6 patients (1 sentinel - unilateral inj., 1 sentinel - bilateral inj., 4 bilateral inj. patients)
Dose	▪ 1 x 10^6 – 300 x 10^6 cells administered as a one-time infusion
Patient Population	▪ Stage 3b DKD
Design	▪ Open-label, proof-of-concept Phase 1b study
Mode of Administration	▪ Intra-arterial injection into one or both renal arteries
Timing	▪ Top-line data target for all subjects: 1Q23

Anticipated milestones



Investment highlights

| NOVEL INTRATUMORAL DELIVERY TECHNOLOGY TO IMPROVE THERAPEUTIC EFFICACY OF SoC* DRUGS |
| EXISTING CAPITAL EXPECTED TO FUND ANTICIPATED MILESTONES | EXISTING STRATEGIC PARTNERSHIPS |

- Nasdaq-listed with a focused mid-late-stage clinical development pipeline and a promising preclinical platform
- Stable finances: ~$76 million cash & investments as of 9/15/22; no debt
- Proprietary field-leading technology in underserved global indications backed by a strong IP portfolio
- Platform technology “validated” by strong existing partnerships with potential for many others
- Multiple potential value creating data and business development events projected in the next 12-24 months
- Seasoned management with domain expertise along with big pharma and emerging pharma experience

*SoC = standard-of-care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