

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

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

August 4, 2022
Date of Report (date of earliest event reported)

CALADRIUS BIOSCIENCES, 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

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	CLBS	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.

The information in Item 7.01 is incorporated by reference.

Item 7.01 Regulation FD Disclosure.

On August 4, 2022, Caladrius Biosciences, Inc. (the "Company") issued a press release in connection with its financial results for the second quarter ended June 30, 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.

The Company conducted a conference call to review its financial results on August 4, 2022 at 4:30 p.m. Eastern Time. A transcript of that conference call is furnished as Exhibit 99.2 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 99.3 and is incorporated herein solely for purposes of this Item 7.01 disclosure.

The information in this Item 7.01, including Exhibits 99.1, 99.2 and 99.3 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, 99.2 and 99.3 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
<u>99.1</u>	Press Release, dated August 4, 2022
<u>99.2</u>	Transcript of Earnings Release Conference Call, August 4, 2022
<u>99.3</u>	Caladrius Biosciences, Inc. Corporate Presentation, August 4, 2022

Pursuant to the requirements of the Securities Exchange Act of 1934, 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: President and Chief Executive Officer

Dated: August 5, 2022

Caladrius Biosciences Reports Second Quarter 2022 Financial Results and Provides Business Update

Merger with Cend Therapeutics remains on track to close in the third quarter of 2022, subject to stockholder approval, resulting in the formation of Lisata Therapeutics

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

BASKING RIDGE, N.J. (August 4, 2022) – Caladrius Biosciences, Inc. (Nasdaq: CLBS) (“Caladrius” or the “Company”), a clinical-stage biopharmaceutical company developing innovative therapies designed to treat or reverse disease, today reported financial results for the three and six months ended June 30, 2022 and provided a business update.

“The second quarter of 2022 was a transformative and energizing quarter for Caladrius with the announcement of our proposed merger with Cend Therapeutics (“Cend”). The merger process, which, when completed, will result in the change of our name to Lisata Therapeutics (“Lisata”), is progressing well and, subject to the approval by our stockholders, remains on track to close in the third quarter of 2022,” stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius. “Following the closing of the proposed merger, Lisata will focus on maximally exploiting the full potential of Cend’s CendR Platform™ technology in a range of solid tumor cancer settings while progressing Caladrius’ current product candidate development programs to their next development milestone. CEND-1, the lead product candidate from the CendR Platform™, has the potential to be combined with a myriad of chemo and immunotherapeutic agents that could become an integral part of a revised standard-of-care therapy for many difficult to treat cancers.”

“In June, Cend announced the first patient had been treated in the Phase 2b ASCEND study of CEND-1 in combination with gemcitabine and nab-paclitaxel for the treatment of first-line, metastatic pancreatic ductal adenocarcinoma (“mPDAC”). This 125-patient study is a double-blind, randomized, placebo-controlled clinical trial being conducted at up to 40 sites in Australia and New Zealand led by the Australasian Gastro-Intestinal Cancer Trials Group in collaboration with the NHMRC Clinical Trial Centre at the University of Sydney. In addition, *The Lancet Gastroenterology and Hepatology* recently published groundbreaking data from the Phase 1b study of CEND-1 in combination with gemcitabine and nab-paclitaxel for the treatment of first-line mPDAC.”

Dr. Mazzo continued, “While we continue to make progress on our current Caladrius programs, a tremendous amount of work already has been conducted under our collaboration agreement with Cend. This is an exciting time for the Company and the future Lisata. We look forward to providing additional updates in the coming weeks and months.”

Proposed Merger with Cend Therapeutics

As previously disclosed, the Company entered into a definitive merger agreement with Cend Therapeutics, Inc., a privately held, clinical-stage biotechnology company focused on a novel approach to enable more effective treatments for solid tumor cancers, under which Cend will merge with a wholly owned subsidiary of Caladrius in an all-stock approximate “merger of equals” transaction unanimously approved by the Boards of Directors of each company. Following closing, the combined company is expected to be renamed Lisata Therapeutics, Inc. and is expected to trade on the Nasdaq Capital Market under the ticker symbol “LSTA”. The merger is currently expected to close in the third quarter of 2022 subject to the approval of Caladrius and Cend stockholders as well as the satisfaction of certain other customary closing conditions and applicable approvals. In the interim, Caladrius has made an investment of \$10 million in Cend in connection with a collaboration agreement to maintain development momentum of the Cend pipeline.

Ongoing Development Portfolio Update

HONEDRA® (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 has been compiled and will be reviewed by PMDA during the third quarter of 2022, after which the PMDA will provide important perspective to be considered in preparation for the formal consultation meetings which precede the Japanese new drug application. Concomitantly, the Company will focus its efforts to secure a Japanese partner to complete the remaining steps to produce registration in Japan.

XOWNA® (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 and is currently being evaluated in a U.S. Phase 2b study (the “FREEDOM Trial”). 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 communicated, 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, and as previously disclosed, the Company has suspended further enrollment activities and is conducting an interim analysis of the data during the third quarter of 2022 to determine the next steps for the program, which may require a discussion with and guidance from FDA. The Company expects to have a decision on next steps for the program by the end of 2022.

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 recently initiated a Phase 1b, open-label, proof-of-concept trial evaluating CLBS201, a CD34+ regenerative cell therapy investigational product for intra-renal artery administration in patients with DKD. Patients selected for the study are in the pre-dialysis stage of kidney disease and exhibit rapidly progressing stage 3b disease. The protocol provides 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 CLBS201 to regenerate kidney function. A key read-out of data will occur at the 6-month follow-up visit for all patients. The Company treated the first patient in April 2022 and completed treatment for all six subjects during the third quarter of 2022. Top-line data is anticipated from all subjects by the first quarter of 2023.

Second Quarter 2022 Financial Highlights

Research and development expenses for the three months ended June 30, 2022 were \$3.2 million, compared to \$4.3 million for the three months ended June 30, 2021, representing a decrease of \$1.1 million or 25%. This decrease was primarily due to a decrease in expenses associated with HONEDRA® in Japan, revenue received from the collaboration agreement and one-off recruiting expenses in the prior year. Research and development activities in the current year period focused on the advancement of our ischemic repair platform and related to:

- execution of the FREEDOM Trial including preparation for an interim analysis;
- execution of the Phase 1b proof-of-concept trial of CLBS201 as a treatment for DKD, which commenced in the first quarter of 2022 with the first patient in the study treated in April 2022; and
- study close out activities and preparation for the pre-consultation meetings with the PMDA for HONEDRA® in CLI and Buerger’s disease in Japan.

General and administrative expenses, which focus on general corporate related activities, were \$3.5 million for the three months ended June 30, 2022, compared to \$2.8 million for the three months ended June 30, 2021, representing an increase of 24%. This increase was primarily due to an increase in professional fees associated with the proposed merger with Cend Therapeutics, Inc.

Overall, net losses were \$6.6 million and \$5.7 million for the three months ended June 30, 2022 and June 30, 2021, respectively.

In order to provide Cend with capital for its development programs prior to the closing of the merger, the Company made an investment of \$10 million in Cend in connection with a collaboration agreement to maintain development momentum of the Cend pipeline.

Balance Sheet Highlights

As of June 30, 2022, the Company had cash, cash equivalents and marketable securities of approximately \$73 million, which is net of our \$10 million investment in Cend and which we believe positions us well relative to the projected capital obligations for our existing development programs as well as our cash and investments balance target at the time of the closing of the merger with Cend.

Conference Call Information

Caladrius will hold a live conference call today, August 4, 2022, at 4:30 p.m. (EDT) 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:

<https://register.vevent.com/register/BI297a597797704e91a25bf5d05bdc7f98>. 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 (<https://ir.caladrius.com>) of the Caladrius website and will be available for replay beginning two hours after the conclusion of the call for 12 months.

About Caladrius Biosciences

Caladrius Biosciences, Inc. is a clinical-stage biopharmaceutical company dedicated to the development of innovative therapies designed to treat or reverse disease. We currently are developing first-in-class autologous cell therapy products based on the finely tuned mechanisms for self-repair that exist in the human body. Our technology leverages and enables these mechanisms in the form of specific cells, using formulations and modes of delivery unique to each medical indication.

The Company's current product candidates include: XOWNA® (CLBS16), the subject of both a recently completed positive Phase 2a study and an ongoing Phase 2b study (www.freedom-trial.com) in the U.S. for the treatment of coronary microvascular dysfunction ("CMD"); CLBS12 (HONEDRA® in Japan), recipient of a SAKIGAKE designation in Japan and eligible for early conditional approval for the treatment of critical limb ischemia ("CLI") and Buerger's disease based on the results of an ongoing clinical trial; and CLBS201, designed to assess the safety and efficacy of CD34+ cell therapy as a treatment for diabetic kidney disease ("DKD"). For more information on the Company, please visit www.caladrius.com.

The Company recently announced that it has signed a definitive merger agreement with Cend Therapeutics, Inc. (www.cendrx.com) to form Lisata Therapeutics. Upon closing, Lisata will be a publicly traded company with an advanced clinical development pipeline and strong balance sheet, which is expected to fund product candidates to their next development milestone. The merger is expected to close in the third quarter of 2022.

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,” “see” and similar expressions and their variants, as they relate to Caladrius, Cend or the management of either company, before or after the aforementioned merger, may identify forward-looking statements. Examples of forward-looking statements include, but are not limited to, statements relating to the timing and completion of the proposed merger; Caladrius’ continued listing on the Nasdaq Capital Market until closing of the proposed merger; the combined company’s listing on the Nasdaq Capital Market after closing of the proposed merger; expectations regarding the capitalization, resources and ownership structure of the combined company; the approach Cend is taking to discover and develop novel therapeutics; the adequacy of the combined company’s capital to support its future operations and its ability to successfully initiate and complete clinical trials; the difficulty in predicting the time and cost of development of Cend’s product candidates; the nature, strategy and focus of the combined company; the executive and board structure of the combined company; and expectations regarding voting by Caladrius’ and Cend’s stockholders. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: the risk that the conditions to the closing of the transaction are not satisfied, including the failure to timely or at all obtain stockholder approval for the transaction; uncertainties as to the timing of the consummation of the transaction and the ability of each of Caladrius and Cend to consummate the transaction; risks related to Caladrius’ ability to correctly estimate its operating expenses and its expenses associated with the transaction; the ability of Caladrius or Cend to protect their respective intellectual property rights; unexpected costs, charges or expenses resulting from the transaction; potential adverse reactions or changes to business relationships resulting from the announcement or completion of the transaction; 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 Caladrius’ Annual Report on Form 10-K filed with the SEC on March 22, 2022. Caladrius can give no assurance that the conditions to the transaction will be satisfied. Except as required by applicable law, Caladrius 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.

No Offer or Solicitation

This communication is not intended to and does not constitute an offer to sell or the solicitation of an offer to subscribe for or buy or an invitation to purchase or subscribe for any securities or the solicitation of any vote in any jurisdiction pursuant to the proposed transaction or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the United States Securities Act of 1933, as amended. Subject to certain exceptions to be approved by the relevant regulators or certain facts to be ascertained, the public offer will not be made directly or indirectly, in or into any jurisdiction where to do so would constitute a violation of the laws of such jurisdiction, or by use of the mails or by any means or instrumentality (including without limitation, facsimile transmission, telephone and the internet) of interstate or foreign commerce, or any facility of a national securities exchange, of any such jurisdiction.

Important Additional Information Will be Filed with the SEC

On June 15, 2022, Caladrius filed a Registration Statement on Form S-4 (File No. 333-265638) containing a proxy statement, prospectus and information statement with the SEC, in connection with the proposed transaction. **CALADRIUS URGES INVESTORS AND STOCKHOLDERS TO READ THESE MATERIALS CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT CALADRIUS, THE PROPOSED TRANSACTION AND RELATED MATTERS.** Investors and shareholders will be able to obtain free copies of the proxy statement, prospectus and other documents filed by Caladrius with the SEC through the website maintained by the SEC at www.sec.gov. In addition, investors and stockholders will be able to obtain free copies of the proxy statement, prospectus and other documents filed by Caladrius with the SEC by contacting Investor Relations by mail at Attn: Investor Relations, Caladrius Biosciences, Inc., 800 Westchester Avenue, Suite N341, Rye Brook, NY 10573. Investors and stockholders are urged to read the proxy statement, prospectus and the other relevant materials before making any voting or investment decision with respect to the proposed transaction.

Participants in the Solicitation

Caladrius and Cend, and each of their respective directors and executive officers and certain of their other members of management and employees, may be deemed to be participants in the solicitation of proxies in connection with the proposed transaction. Information about Caladrius' directors and executive officers is included in Caladrius' Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 22, 2022, and amended on April 21, 2022. Additional information regarding these persons and their interests in the transaction will be included in the proxy statement relating to the transaction when it is filed with the SEC. These documents can be obtained free of charge from the sources indicated below.

Contact:

Investors:
Caladrius Biosciences, Inc.
John Menditto
Vice President, Investor Relations and Corporate Communications
Phone: 908-842-0084
Email: jmenditto@caladrius.com

- Tables to Follow -

Caladrius Biosciences, Inc.
Selected Financial Data
(in thousands, except per share data)

(in thousands, except per share data)	Three Months Ended June 30,		Six Months Ended June 30,	
	2022 (unaudited)	2021 (unaudited)	2022 (unaudited)	2021 (unaudited)
Statement of Operations Data:				
Research and development	\$ 3,239	\$ 4,329	\$ 6,517	\$ 9,405
General and administrative	3,481	2,818	6,823	5,828
Total operating expenses	6,720	7,147	13,340	15,233
Operating loss	(6,720)	(7,147)	(13,340)	(15,233)
Investment income, net	94	47	158	70
Other expense, net	—	(90)	(149)	(90)
Net loss before benefit from income taxes and noncontrolling interests	(6,626)	(7,190)	(13,331)	(15,253)
Benefit from income taxes	—	(1,508)	(2,479)	(1,508)
Net loss attributable to Caladrius Biosciences, Inc. common stockholders	\$ (6,626)	\$ (5,682)	\$ (10,852)	\$ (13,745)
Basic and diluted loss per share attributable to Caladrius Biosciences, Inc. common stockholders	\$ (0.11)	\$ (0.10)	\$ (0.18)	\$ (0.27)
Weighted average common shares outstanding	60,533	59,510	60,546	50,862

	June 30, 2022 (unaudited)	December 31, 2021
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	\$72,991	\$94,970
Total assets	85,877	97,008
Total liabilities	3,740	5,008
Total equity	82,137	92,000

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Caladrius Biosciences Inc. (Q2 2022 Results)
August 04, 2022

Corporate Speakers:

- John Menditto; Caladrius Biosciences, Inc.; VP of IR & Corporate Communications
- David Mazzo; Caladrius Biosciences, Inc.; President, CEO
- James Nisco; Caladrius Biosciences, Inc.; VP of Finance & Treasury
- Kristen Buck; Caladrius Biosciences, Inc.; Executive VP of R&D and Chief Medical Officer

Participants:

- Kumaraguru Raja; Brookline Capital Markets, LLC; Research Division, Director & Senior Biotechnology Analyst
- Peter Enderlin; MAZ Capital Advisors, LLC; Portfolio Manager

PRESENTATION

Operator: Welcome to the Caladrius Biosciences' Second Quarter 2022 Financial Results and Business Update Conference Call. (Operator Instructions) As a reminder, this call is being recorded today, Thursday, August 4, 2022. I will now turn the call over to John Menditto, Vice President of Investor Relations and Corporate Communications at Caladrius. Please go ahead, sir.

John Menditto: Thank you, operator, and good afternoon, everyone. Welcome to Caladrius' second quarter 2022 conference call to discuss our financial results and provide a business update. Joining me today from our management team are Dr. David Mazzo, President and Chief Executive Officer; Dr. Kristen Buck, Executive Vice President of Research and Development and Chief Medical Officer; and James Nisco, Vice President of Finance and Treasury.

Shortly, before this call, we issued a press release announcing our second quarter 2022 financial results, which is available under the Investors and News section of the Company website, along with a webcast replay of this call. If you have not received this news release or you would like to be added to the Company's email distribution list, please email me at jmenditto@caladrius.com.

Before we begin, I will remind you that comments made by management during this conference call will contain forward-looking statements that involve risks and uncertainties regarding the operations and future results of Caladrius.

I encourage you to review the Company's filings with the Securities and Exchange Commission, including, without limitation, its Forms 10-Q, 8-K and 10-K, which identify specific risk factors that may cause actual results or events to differ materially from those described in the forward-looking statements.

Furthermore, the content of this conference call contains time-sensitive information that is accurate only as of the date of this live broadcast, Thursday, August 4, 2022. Caladrius Biosciences undertakes no obligation to revise or update any statements to reflect events or circumstances after the date of this conference call. With that, I will now turn the call over to Dr. Mazzo. Dave?

David Mazzo: Thank you, John, and good afternoon, everyone. Thank you for once again joining us today as we provide an overview of recent business highlights and discuss our second quarter 2022 financial results.

I can say to you with much enthusiasm and certainty that 2022 is proving to be an outstanding year of progress for Caladrius as the proposed merger with Cend Therapeutics remains on track to close in the third quarter of this year, subject to approval by our stockholders.

This transaction will be transformational for Caladrius, creating, upon closing, a financially sound Nasdaq-listed company with a diverse product development pipeline, strong existing partnership and the potential for future attractive partnerships.

The merged company will operate under the name Lisata Therapeutics, (“Lisata” for short) and will focus on maximally exploiting the full potential of Cend's CendR Platform™ technology in a range of solid tumor indications while progressing Caladrius' current CD34-positive technology-based product candidates to their next development milestone. CEND-1, the lead product candidate from the CendR Platform™, has the potential to be combined with myriad of chemo and immunotherapeutic agents and could become an integral part of a revised standard of care therapy for many difficult-to-treat cancers.

Coincident with the announcement of the signing of the definitive merger agreement back in April, we also announced that we had made a \$10 million investment in Cend in order to maintain the momentum of development of CEND-1 and to allow for immediate collaboration between the companies. Since then, a number of achievements have been announced regarding CEND-1. For example, in June, it was announced that the first patient had been treated in the Phase 2b ASCEND study of CEND-1 in combination with gemcitabine and nab-paclitaxel for the treatment of first-line metastatic pancreatic ductal adenocarcinoma (“mPDAC” for short). This 125-patient study is a double-blind, randomized, placebo-controlled clinical trial being conducted at up to 40 sites in Australia and New Zealand, led by the Australasian Gastro-Intestinal Cancer Trials Group, in collaboration with the National Health and Medical Research Council's Clinical Trial Centre at the University of Sydney. Additionally, groundbreaking data was recently published in The Lancet Gastroenterology and Hepatology journal from the Phase 1b study of CEND-1 in combination with gemcitabine and nab-paclitaxel for the treatment of first-line mPDAC. The results reinforce our belief that CEND-1 could become a transformative new medicine for the treatment of pancreatic cancer and other difficult-to-treat solid tumors. Imminently, we expect to announce the collaboration with a major pharmaceutical company regarding CEND-1 as well as advancement of our plans to initiate a registration-worthy study of

CEND-1 in mPDAC next year, along with a basket trial exploring the advantages of combining CEND-1 with current standard of care in a variety of other solid tumor types.

With that, I will now turn the call over to James Nisco, our VP of Finance and Treasury, to review and provide commentary on our second quarter 2022 financial results. James?

James Nisco: Thanks, Dave. I'm pleased to join today to present a summary of our second quarter 2022 financial results. Starting with operating expenses, research and development expenses for the three months ended June 30, 2022, were \$3.2 million compared to \$4.3 million for the three months ended June 30, 2021, representing a decrease of \$1.1 million or 25%.

This decrease was primarily due to a decrease in expenses associated with HONEDRA[®] in Japan, revenue received from the collaboration agreement and one-off recruiting expenses in the prior year. Research and development activities in the current year period focused on the advancement of our ischemic repair platform and related to:

- execution of the FREEDOM trial, including preparation for an interim analysis;
- execution of the Phase 1b proof-of-concept trial of CLBS201 as a treatment for Diabetic Kidney Disease, which commenced in the first quarter of 2022 with the first patient in the study treated in April 2022; and
- study closeout activities and preparation for the pre-consultation meetings with the Japanese Pharmaceuticals and Medical Devices Agency (or PMDA) and for HONEDRA[®] in Critical Limb Ischemia and Buerger's disease in Japan.

General and administrative expenses, which focused on general corporate-related activities were \$3.5 million for the three months ended June 30, 2022, compared to \$2.8 million for the 3 months ended June 30, 2021, representing an increase of 24%. This increase was primarily due to one-time professional fees associated with the proposed merger with Cend Therapeutics.

Overall, net losses were \$6.6 and \$5.7 million for the 3 months ended June 30, 2022 and June 30, 2021, respectively.

As previously communicated, Caladrius made an investment of \$10 million in Cend, in addition to entering into a collaboration agreement with Cend to maintain the development momentum of the Cend pipeline.

Turning now to our balance sheet and cash flow, as of June 30, 2022, the Company had cash, cash equivalents and marketable securities of approximately \$73 million, which is net of our \$10 million investment in Cend and which we believe positions us well relative to the projected capital obligations for our existing development programs as well as our cash and investments balance target at the time of closing of the merger with Cend.

That completes the financial overview. With that, I will now turn the call over to our Chief Medical Officer, Dr. Kristen Buck, for the review of our clinical development pipeline. Kristen?

Kristen Buck: Thank you, James, and good afternoon, everyone.

Before I provide an update on our current CD34 programs, I will reinforce what Dave had mentioned regarding our progress with Cend. Work under our collaboration agreement has been nothing short of seamless and the collaborative effort has already yielded great progress. We are excited about this opportunity and look forward to reporting more accomplishments in the coming weeks and months, including the final coalescence into a singular cohesive development team, post-merger closing.

Turning to our current pipeline. As you know, Caladrius' current development portfolio features autologous cellular therapies designed to treat or reverse disease. Our belief is that curative cell therapy products when applied to the right indication can restore human health and potentially improve quality of life with a single administration, as compared to a treatment that requires frequent re-administration.

I will now provide a summary of progress and status for each of Caladrius' clinical programs. Kicking off with CLBS12 (HONEDRA[®] in Japan), our product candidate for the treatment of Critical Limb Ischemia and Buerger's disease, HONEDRA[®] was awarded a SAKIGAKE designation from the Japanese regulatory authorities for the treatment of Critical Limb Ischemia and Buerger's disease, which is an orphan-sized subset of Critical Limb Ischemia.

The SAKIGAKE designation is akin to a Regenerative Medicine Advanced Therapy designation or an "RMAT" designation in the United States. SAKIGAKE designation affords the recipient prioritized regulatory consultation, a dedicated review system to support the development and review process, including the option of a rolling registration submission, as well as a reduced review time of six months for the registration application once filed. Additionally, under Japan's Regenerative Medicine Legislation, products such as HONEDRA[®] are eligible for early conditional approval and, possibly, full approval in Japan based on the assessment of the data from the trial or trials designed in direct collaboration with the Japanese Pharmaceuticals and Medical Devices Agency ("PMDA"). Note that conditional approval of a Regenerative Medicine product only requires a demonstration of a trend toward a therapeutic effect, together with acceptable safety. Further, the SAKIGAKE designation is a highly sought regulatory classification in Japan, and we hope that this, coupled with positively trending data from our trial will make HONEDRA[®] an attractive product for partnering to a Japanese pharmaceutical company.

The Company's study of HONEDRA[®] in Japan for the treatment of Critical Limb Ischemia and Buerger's disease has shown positive results to date. The responses observed in the subjects who have reached an endpoint in this study are consistent with our expectations of therapeutic effect and safety based on previously published clinical trial data generated in Japan and the United States. However, as discussed in prior quarters, enrollment in the ongoing study was suspended due to the impact of the global COVID-19 pandemic on recruitment, especially in Japan, to

minimize the operational and financial burden that we have incurred due to enrollment delays and lack of visibility on time to completion. Data from the follow-up of all patients completed in this registration-eligible clinical trial in Japan have been compiled and will be reviewed by the PMDA later this quarter. We are conducting an ongoing dialogue with the PMDA as to what needs to be considered in preparation for the formal consultation meetings which precede the Japanese new drug application. Simultaneously, the Company is focusing its efforts on securing a Japanese partner to complete the remaining steps to produce registration in Japan.

Turning now to XOWNA[®] or CLBS16 for the treatment of Coronary Microvascular Dysfunction, or CMD, Coronary Microvascular Dysfunction is a disease that continues to be underdiagnosed and potentially afflicts millions annually, a vast majority of whom are female, with no current treatment options. In May 2020, Caladrius announced the full data results from a Phase 2a ESCaPE-CMD trial, showing a highly statistically significant improvement in coronary flow reserve correlating with symptom relief for patients with CMD after a single intracoronary injection of XOWNA[®]. Subsequently, the Company initiated a rigorous Phase 2b clinical trial known as the FREEDOM trial, which, to our knowledge, is the first controlled regenerative medicine trial in CMD in the United States. The FREEDOM trial is a double-blind, randomized, placebo-controlled trial designed to corroborate the results of the ESCaPE-CMD trial, while assessing the efficacy and safety of delivering autologous CD34 cells, our XOWNA[®] product, to subjects with CMD and without obstructive coronary artery disease.

As previously communicated, 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. on patient and site availability, coupled with issues affecting all stages of the supply chain associated with patient qualification, product preparation and product administration, made enrollment much slower than originally predicted and challenging to accelerate. Despite multiple protocol amendments to address these obstacles, along with an increased number of sites in the study, the FREEDOM trial only had enrolled approximately one third of the targeted 105 patients by May of this year, and at this rate, more than four years would likely have been required to reach the primary endpoint follow-up at six months post-treatment for all subjects. As a result, the Company suspended further enrollment activities at that time and is in the process of conducting an interim analysis of the data to determine the next steps for the program, which may require a discussion with and guidance from the FDA. The Company expects to have a decision on next steps for the program by the end of 2022.

Lastly, our most recently proposed development program, CLBS201 for the treatment of Diabetic Kidney Disease, or DKD: the Company initiated a Phase 1b open-label, proof-of-concept trial evaluating CLBS201, a CD34-positive regenerative cell therapy investigational product for intrarenal artery administration, in patients with Diabetic Kidney Disease. This development program focuses on patients that exhibit rapidly progressing stage 3b/4 disease. The scientific rationale for the program is based on the association of progressive kidney disease with attrition of the microcirculation of the kidney. Pre-clinical studies in kidney disease and injury models have demonstrated that protection or replenishment of the microcirculation results in improved kidney function. Our proof-of-concept protocol provided for a staggered, sequentially dosed 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 Diabetic Kidney Disease patients as well as the ability of CLBS201 to regenerate kidney function. A key read-out of data will occur at the 6-month follow-up visit for all patients. The first patient treated in this study of CLBS201 was in April 2022, followed by completion of enrollment of all six subjects in July 2022, as recently announced. We continue to anticipate top-line data from all subjects by the first quarter of 2023. With that, I will now turn the call back to Dr. Mazzo. Dave?

David Mazzo: Thanks, Kristen. While we continue to make progress on our current Caladrius programs, a tremendous amount of work already has been conducted under our collaboration agreement with Cend. Over the next month or so, we will be working diligently with Cend and with you, our shareholders, to finalize the merger transaction and look forward to announcing the closing by our target of the end of September of this year. As I hope you appreciate, we are tremendously excited about and motivated by the prospects that this merger will bring for patients, our employees and our shareholders. We look forward to providing additional updates in the coming weeks and months.

With that, operator, we're ready to take questions.

QUESTIONS AND ANSWERS

Operator: (Operator Instructions) The first question comes from Kumaraguru Raja with Brookline Capital.

Kumar Raja: So first, with regard to the ASCEND trial, what is the expectation in terms of how soon these 40 sites can come on board? And also, when do you think potentially enrollment could be completed in that trial? And in terms of the merger process, what remains to be done so that it can be consummated?

David Mazzo: Thanks, Kumar. Appreciate your questions and I hope you're enjoying your summer. I'll take them in reverse order. So first, as far as the merger goes, things are working very well, going down the checklist of activities that are required to consummate the legal transaction.

What remains now is the final vote by shareholders of both companies and then the final legal transaction document signing that will occur once the shareholders approve the transaction. We collectively had filed the new proxy, the S-4 and a mailing of that document has gone out to all the Caladrius' shareholders. And beginning next week, we expect that shareholders will have the opportunity to begin to vote either online, by telephone or through the normal mail.

And we hope that we will accumulate a sufficient number of votes such that the voting will be completed, and we can announce an approval of all the resolutions at the currently scheduled special shareholder meeting for September 13. And then within 24 to 48 hours after that, assuming everything is approved, the legal documents will be completed, and we will be then officially Lisata Therapeutics trading under the ticker symbol LSTA on the NASDAQ.

Now going back to the ASCEND trial, the Phase 2b trial. This is a trial that's being run by the AGIGT -- I'm sorry AGITG in Australia. They just began enrolling patients a month or so ago. And the expectation is that it will take probably a couple of years to complete enrollment.

I don't have the specifics yet of when all 40 sites will be online, but we will expect to have some on our next conference call as Lisata Therapeutics. And at that point in time, not only will we have additional information and all the specifics about the CEND-1 programs, but we'll likely invite the CEO of Cend, who will then be the President and CBO of Lisata, to the call, and he'll be able to speak to some of these things as well.

Kumar Raja: Finally, as a follow-up, you alluded to something about a pharmaceutical collaboration. Anything additional you can share about it?

David Mazzo: The only thing, I can say is if everything goes well, watch the news wires for next week. That's all I can tell you.

Operator: (Operator Instructions) Our next question comes from Pete Enderlin with MAZ Partners.

Peter Enderlin: On XOWNA[®], your commentary was that you expect a decision on the next steps by the end of this year. And my simple question is whose decision are we talking about? I know it's sort of a collaborative process, but are you saying the FDA makes a decision, you make a decision and then go to them? Whose are we really talking about as the initial decision maker in that situation?

David Mazzo: Pete, thanks for your question. In these kinds of situations, the only types of decisions that FDA takes would be decisions related to safety and putting a company on clinical hold. Otherwise, it's up to the sponsor to take decisions about treating patients, conducting their trials and spending their money.

The decision to which I refer is a decision that will be a Caladrius decision or if it occurs post-merger, would be a Lisata decision, and it will be based upon an analysis of the data from the interim data analysis that's ongoing as well as any discussions that may be considered appropriate with the FDA. And so that's why we say we've given ourselves time to have those discussions with the agency should we need them. And that's why we project having the answer by the end of the year, but it could come much sooner than that.

Peter Enderlin: Okay. And there was a comment about some revenues from the collaborative agreement with Cend. I mean I know you gave them \$10 million, but what we are getting back must be fairly small because it was a factor in the reduction of R&D. But can you be a little more specific about that?

David Mazzo: I will. And this is really my apologies to James, our Vice President of Treasurer and to the Grant Thornton team, our auditors. But this is a bit of an accounting game, if you will.

As part of the collaboration agreement, we have allocated resources from Caladrius to help work on the Cend programs. And until we are a single company, we are accumulating a set of charges for the time spent by Caladrius employees working on the Cend program at some sort of flat rate.

So for the time being, those are being booked as a payable by Cend and a receivable by Caladrius, but also as part of the collaboration agreement as soon as the merger goes together and we combine the books from both they cancel each other out. So, it's really not something that anybody should spend any time on.

Peter Enderlin: Okay. And then the trial in Australia and New Zealand, is that because Cend had a historical relationship? Or is there some other specific reason to pick those particular venues?

David Mazzo: Well, there are a couple of reasons why that venue was chosen, but this is a program that was initiated by Cend Therapeutics, and it's based upon existing relationships that they had in Australia, but also with a particular lead investigator who was able to procure additional funding to help support the further development in that geographic area. So that's why it's being done in Australia and New Zealand.

Peter Enderlin: Are there differences in how to work with the regulatory agencies over there? Are they easier to work with? Or is it similar? Or are there any other significant differences?

David Mazzo: The Australian regulatory authorities have standards and practices that are similar to the FDA and the other Western European regulatory authorities.

I think the main reason why people choose to work in that venue, besides it being an interesting market for a product once it's ultimately approved, is that the Australian government offers an R&D credit for work done in Australia that makes it financially attractive to do research there. And for some indications, they have a higher prevalence of disease, which makes recruitment a little bit easier as well.

Peter Enderlin: Okay. I'll get on the queue to have maybe one more.

David Mazzo: Thanks, Pete.

Operator (Operator Instructions): This concludes the question-and-answer session. I will now turn the call back to Dr. Mazzo for closing remarks.

David Mazzo: Again, thank you all for participating in today's call. We look forward to speaking with you again during our next quarterly conference call, which we expect will be conducted under the banner of Lisata Therapeutics, to continue to provide updates on our achievements and progress. We remain grateful for your continued interest and support. Stay well. Have a good evening and enjoy the rest of your summer.

Operator: This concludes today's conference call. Thank you for participating. You may now disconnect.

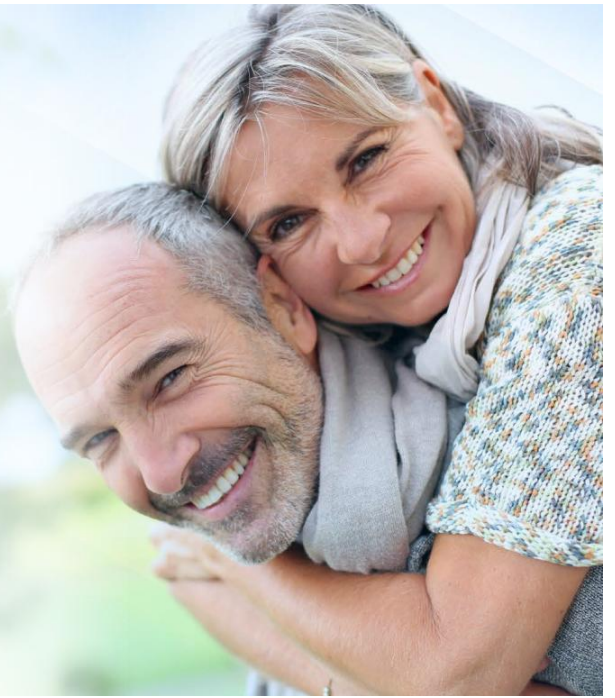
Exhibit 99.3

**caladrius**
BIOSCIENCES

*Developing Innovative Therapies
that Treat or Reverse Disease*

David J. Mazzo, PhD
President & Chief Executive Officer

August 4, 2022 | Nasdaq: CLBS



Information regarding disclosures

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 Caladrius, Cend or the management of either company, before or after the aforementioned merger, may identify forward-looking statements. Examples of forward-looking statements include, but are not limited to, statements relating to the timing and completion of the proposed merger; Caladrius’ continued listing on the Nasdaq Capital Market until closing of the proposed merger; the combined company’s listing on the Nasdaq Capital Market after closing of the proposed merger; expectations regarding the capitalization, resources and ownership structure of the combined company; the approach Cend is taking to discover and develop novel therapeutics; the adequacy of the combined company’s capital to support its future operations and its ability to successfully initiate and complete clinical trials; the difficulty in predicting the time and cost of development of Cend’s product candidates; the nature, strategy and focus of the combined company; the executive and board structure of the combined company; and expectations regarding voting by Caladrius’ and Cend’s stockholders. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: the risk that the conditions to the closing of the transaction are not satisfied, including the failure to timely or at all obtain stockholder approval for the transaction; uncertainties as to the timing of the consummation of the transaction and the ability of each of Caladrius and Cend to consummate the transaction; risks related to Caladrius’ ability to correctly estimate its operating expenses and its expenses associated with the transaction; the ability of Caladrius or Cend to protect their respective intellectual property rights; unexpected costs, charges or expenses resulting from the transaction; potential adverse reactions or changes to business relationships resulting from the announcement or completion of the transaction; 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 Caladrius’ Annual Report on Form 10-K filed with the SEC on March 22, 2022. Caladrius can give no assurance that the conditions to the transaction will be satisfied. Except as required by applicable law, Caladrius 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.

No Offer or Solicitation

This communication is not intended to and does not constitute an offer to sell or the solicitation of an offer to subscribe for or buy or an invitation to purchase or subscribe for any securities or the solicitation of any vote in any jurisdiction pursuant to the proposed transaction or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the United States Securities Act of 1933, as amended. Subject to certain exceptions to be approved by the relevant regulators or certain facts to be ascertained, the public offer will not be made directly or indirectly, in or into any jurisdiction where to do so would constitute a violation of the laws of such jurisdiction, or by use of the mails or by any means or instrumentality (including without limitation, facsimile transmission, telephone and the internet) of interstate or foreign commerce, or any facility of a national securities exchange, of any such jurisdiction.

Important Additional Information Will be Filed with the SEC

In connection with the proposed transaction between Caladrius and Cend, Caladrius filed a definitive proxy statement/prospectus/information statement with the SEC on July 29, 2022. **CALADRIUS URGES INVESTORS AND STOCKHOLDERS TO READ THESE MATERIALS CAREFULLY AND IN THEIR ENTIRETY BECAUSE THEY CONTAIN IMPORTANT INFORMATION ABOUT CALADRIUS, THE PROPOSED TRANSACTION AND RELATED MATTERS.** Investors and shareholders are able to obtain free copies of the proxy statement, prospectus and other documents filed by Caladrius with the SEC through the website maintained by the SEC at www.sec.gov. In addition, investors and stockholders will be able to obtain free copies of the proxy statement, prospectus and other documents filed by Caladrius with the SEC by contacting Investor Relations by mail at Attn: Investor Relations, Caladrius Biosciences, Inc., 110 Allen Road, 2nd floor, Basking Ridge, NJ 07920. Investors and stockholders are urged to read the proxy statement, prospectus and the other relevant materials before making any voting or investment decision with respect to the proposed transaction.

Participants in the Solicitation

Caladrius and Cend, and each of their respective directors and executive officers and certain of their other members of management and employees, may be deemed to be participants in the solicitation of proxies in connection with the proposed transaction. Information about Caladrius’ directors and executive officers is included in Caladrius’ Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 22, 2022, and amended on April 21, 2022. Additional information regarding these persons and their interests in the transaction are included in Caladrius’ definitive proxy statement, which was filed with the SEC on July 29, 2022. These documents can be obtained free of charge from the sources indicated above.

Caladrius investment highlights



Pending merger with Cend Therapeutics, creating Lisata Therapeutics, which we expect will be a financially sound publicly-traded company with clinical stage product candidates



Combination of Caladrius and Cend platforms expected to provide Lisata with a multi-product development pipeline



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



Potential value creating events in the next 12-24 months based on milestones across the pipeline



Strong balance sheet [\$73 million cash & investments* (as of 6/30/2022) - no debt]; well-positioned for current development programs' projected capital needs and cash balance target at merger closing



Seasoned management with domain expertise along with big pharma and emerging biotech experience

*Excludes \$10.0 million investment in Cend Therapeutics

Creating a new diversified therapeutics company, well-positioned for growth

caladrius
BIOSCIENCES

Cend
Therapeutics



- *Lisata* is derived from the Finnish for “augmented” or “enhanced”
- Public company with diverse development pipeline, strong existing & potential for future attractive partnerships
- Merger closing expected 3Q22 pending shareholder approvals and customary conditions
- Ownership divided as ~50% of outstanding shares owned by each of Caladrius and Cend shareholders
 - 4 Board appointees from each of Caladrius and Cend

Lisata Therapeutics overview

- Experienced Executive and Development Leadership with extensive domain-relevant expertise
 - David J. Mazzo, Ph.D. – Chief Executive Officer
 - David Slack, M.B.A. – President and Chief Business Officer
 - Kristen K. Buck, M.D. – Executive Vice President of R&D and Chief Medical Officer
- World-renowned Technical Advisor
 - Erkki Ruoslahti, M.D., Ph.D. – Scientific Founder of Cend technology
- Caladrius invested \$10 million in Cend which includes a resource collaboration to maintain pipeline momentum
- Full, capital-efficient development and public company operational infrastructure (~30 people)
- Combined pipeline of multiple clinical stage assets in a variety of indications with milestones over the next 2 years
- ~\$70 million in net cash* [no debt] projected as of transaction closing
- Existing Cend partnership with Qilu Pharmaceutical
 - Qilu has exclusive rights to CEND-1 in China, Taiwan, Hong Kong, and Macau and assumes all development and commercialization responsibilities in the licensed territories
 - Qilu will pay up to \$225 million in milestones and tiered double-digit royalties on product sales in the region, if any

*As defined in the Agreement and Plan of Merger and Reorganization dated as of April 26, 2022

Proprietary Platform Technologies

CendR Platform™ provides a targeted tissue penetration capability designed to specifically enhance drug delivery to solid tumors

- Converts tumor stroma from barrier to conduit for effective delivery via co-administration of a range of chemo-, targeted and immunotherapies
- Selectively depletes intratumoral immunosuppressive cells

Tumor-Penetrating Nanocomplex (TPN) Platform™ with broad potential to enable nucleic acid-based therapies to effectively treat solid tumor cancers

- Development candidate identification expected in 2023

Strong patent protection beyond 2030 with patent term extension eligibility

Robust Clinical Stage Pipeline with Broad Therapeutic Reach

Lead product candidate, CEND-1, advancing in a variety of difficult-to-treat solid tumor applications

- CEND-1 is currently in multiple studies in first-line, metastatic pancreatic ductal adenocarcinoma (mPDAC) in combination with standard-of-care chemotherapy
- CEND-1 development to expand to additional difficult-to-treat tumors (e.g., hepatocellular, gastric, breast cancers, etc.) and additional anti-cancer drug combinations, including immunotherapies
- CEND-1 has been granted Fast Track as well as Orphan Drug Designation by the U.S. FDA in mPDAC

Compelling Value Proposition

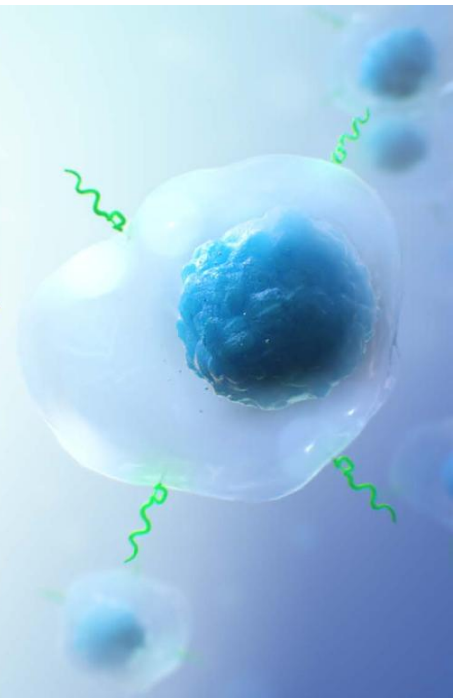
- Existing Cend strategic partnership in China with Qilu Pharmaceutical with non-dilutive milestone payments, development collaboration, and participation in downstream economics
 - Potential for up to \$225 million in milestones and royalties on potential sales in the region
 - \$10 million payment due for proceeding to Phase 3 in mPDAC (could be as soon as 2023)
- Additional partnership opportunities for broad applications of CEND-1 and the CendR Platform™
- Anticipated combined pipeline clinical & business development milestones over the next 24 months
- Experienced management team with extensive development expertise and leading scientific advisors

Lisata Therapeutics projected pipeline of novel product candidates

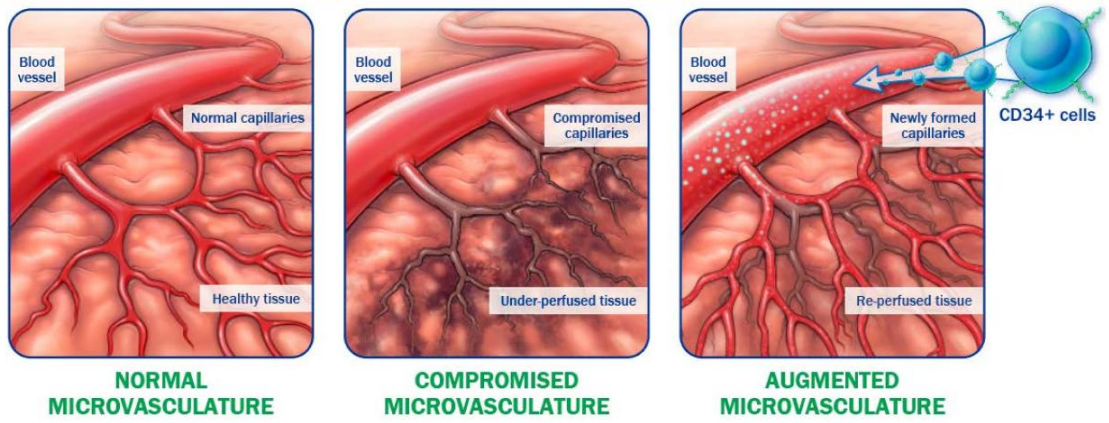
Sponsor/Funding Institution	Trial Products	Indication	Preclinical	Phase 1	Phase 2	Phase 3
CendR Programs						
Lisata (U.S.) Ph2/3 adaptive	Gemcitabine/nab-paclitaxel ± CEND-1	First-Line Metastatic Pancreatic Ductal Adenocarcinoma (mPDAC)	[Progress bar: Preclinical to Phase 2]			Trial initiation 1Q23
SWOG - NCI (U.S.) Ph2/3	FOLFIRINOX ± CEND-1		[Progress bar: Preclinical to Phase 2]			Trial initiation 1H23
AGITG (Aus) Ph2b	Gemcitabine/nab-paclitaxel ± CEND-1		[Progress bar: Preclinical to Phase 2]			Ongoing
Qilu (China) Ph1b/2	Gemcitabine/nab-paclitaxel ± CEND-1		[Progress bar: Preclinical to Phase 1]			Ongoing
Partner TBA/Lisata (Global) Ph1b/2	CEND-1 + Nab-paclitaxel + Gemcitabine ± anti-PD(L)1	Resectable PDAC Colon and High-Grade Appendiceal Cancers	[Progress bar: Preclinical to Phase 2]			Trial initiation 1Q23
KUCC - IIT (U.S.) Ph1b/2	CEND-1 + FOLFIRINOX CEND-1 + FOLFIRINOX + Panitumumab		[Progress bar: Preclinical to Phase 1]			Trial initiation 3Q22
Lisata (U.S.) Ph2a	CEND-1 in combination with SoC		[Progress bar: Preclinical to Phase 2]			Trial initiation 1Q23
Lisata (U.S.) Ph1	TPN development candidate	Various Solid Tumors	[Progress bar: Preclinical to Phase 1]			Trial initiation Late 2023/early 2024
CD34+ Programs						
Lisata (U.S.) Ph2b	XOWNA® (CLBS16)	Coronary Microvascular Dysfunction	[Progress bar: Preclinical to Phase 2]			Data expected 3Q22
Lisata (Japan) Ph2	HONEDRA® (CLBS12)	Critical Limb Ischemia and Buerger's Disease	[Progress bar: Preclinical to Phase 2]			Data expected 3Q22
Lisata (U.S.) Ph1	CLBS201	Diabetic Kidney Disease	[Progress bar: Preclinical to Phase 1]			Data expected 1Q23

CD34+ Cell Therapy

Technology Overview



CD34+ cells have a well characterized mechanism of action



- Naturally occurring endothelial progenitor cells that re-establish blood flow to under-perfused tissues^{1,2}
- Possess pre-programmed pro-angiogenic and anti-inflammatory tissue repair properties^{3,4}

¹Mackie, A.R. et al., *Tex Heart Inst J* 2011, 38(5), 474-485
²Kocher, A.A. et al., *Nat Med* 2001, 440-436

³Abd-Allah et al., *Cytotherapy* 2015, 17: 443-53
⁴Lo, B.C. et al., *Am J Respir Cell Mol Biol* 2017, 57: 651-61

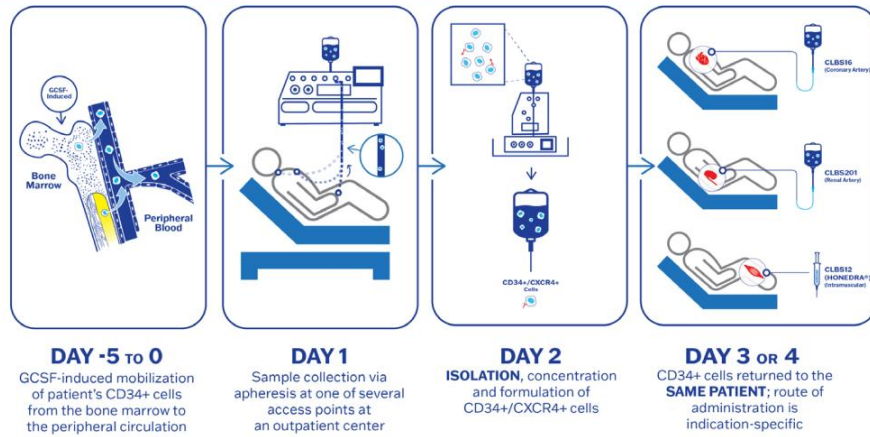
CD34+ autologous cell therapy is extensively studied/clinically validated

- CD34+ cells have been studied clinically in a variety of ischemic disease indications by numerous investigators across many sites and countries
- CD34+ cells repeatedly demonstrated vascular repair in multiple organs
- Consistent and compelling results of rigorous clinical studies comprising >1,000 patients have been published in peer reviewed journals¹⁻⁴
 - Single treatments elicited durable therapeutic effects
 - Treatment generally well-tolerated
- Strong patent protection beyond 2031 with 9 U.S. patents and 28 foreign patents granted
 - Key patent claims:
 - Pharmaceutical composition of non-expanded CD34+/CXCR4+ cells
 - Therapeutic concentration range
 - Stabilizing serum
 - Repair of injury caused by vascular insufficiency

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. *Cardiovasc Revasc Med.* 2018; 20(3):215-219
⁴ Henry T.D., et al. *European Heart Jour* 2018; 2208-2216

Caladrius' autologous CD34+ cell process is rapid/economical/scaled



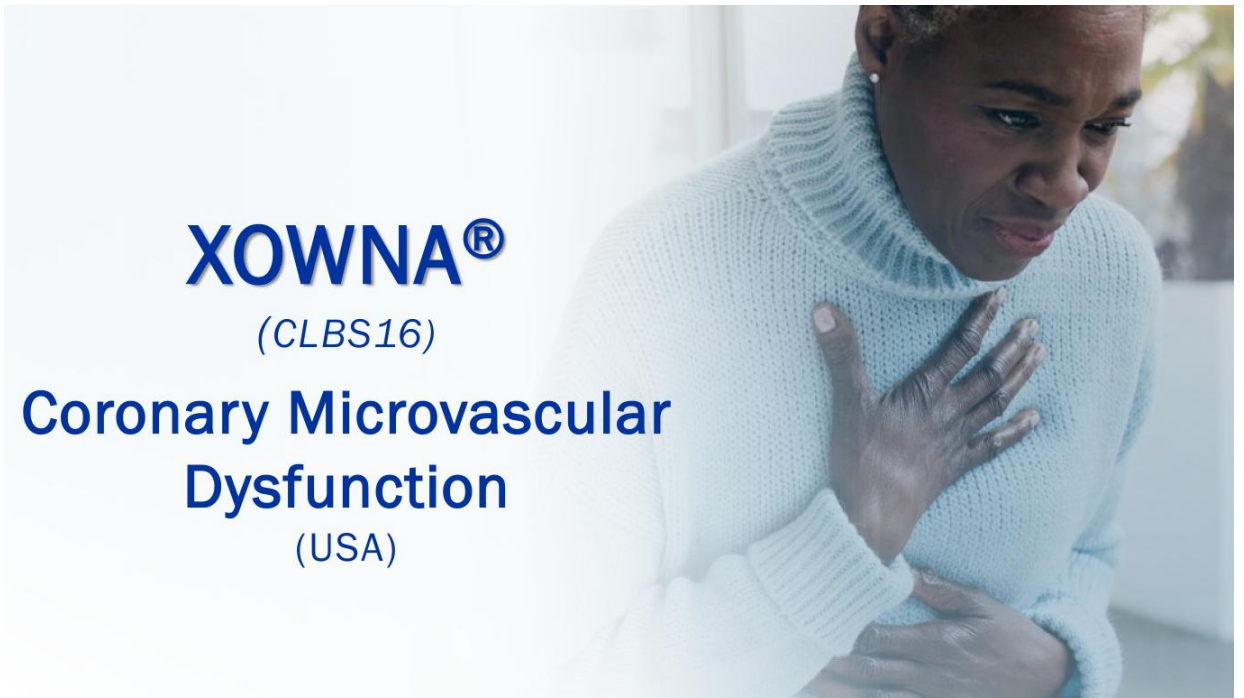
- Drug induced mobilization eliminates need for surgical bone marrow aspiration
- No genetic manipulation or *ex vivo* expansion of cells
- Four days or less from donation to treatment

XOWNA®

(CLBS16)

**Coronary Microvascular
Dysfunction**

(USA)



Indication: Coronary microvascular dysfunction (CMD)

- Deficient heart microvasculature *without large vessel obstructive disease*
- Causes frequent, debilitating chest pain; not treatable by stents or bypass; responds poorly or not at all to available pharmacotherapies
- Afflicts women more frequently (2:1 to 3:1), especially younger women^{1,2}
- Results in poor prognosis for patients³
 - Significantly elevated risk of all-cause mortality⁴
- Clinically diagnosed based on symptoms *and* demonstrated absence of large vessel obstructive disease
- Quantitatively diagnosed using Coronary Flow Reserve (CFR)⁵ and image-techniques (cPET and cMRI)
- 50% - 65% of patients with angina without obstructive coronary artery disease (CAD) are believed to have CMD⁶
- Applicable CMD population in the U.S. potentially treatable by XOWNA[®] ranges from ~415,000 to ~1.6 million patients⁷

¹ Coronary Microvascular Disease. (2015, July 31). In American Heart Association

² R. David Anderson, John W. Petersen, Puja K. Mehta, et al., *Journal of Interventional Cardiology*, 2019; 8

³ Loffler and Bourque, *Curr Cardiol Rep*. 2016 Jan; 18(1): 1

⁴ Kenkre, T.S. et al., *Circ: CV Qual & Outcomes* 2017, 10(12) 1-9

⁵ Collins, P., *British heart journal* (1993) 69(4), 279-281

⁶ Marinescu MA, et al. *JACC Cardiovasc Imaging*. 2015;8:210-220

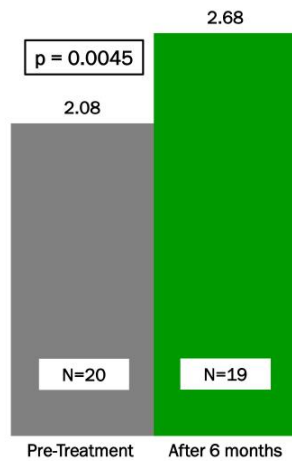
⁷ Tunstall-Pedoe H, (ed.) WHO, Geneva, 2003, pp. 244, Swiss Fr 45, ISBN: 92-4-156223-4

ESCaPE-CMD: Phase 2a interventional, proof-of-concept trial completed

Endpoints	<ul style="list-style-type: none">▪ Therapeutic effect and the evaluation of adverse events; including changes from baseline to 6 months for coronary flow reserve, angina frequency, CCS angina class, quality of life
Study Size	<ul style="list-style-type: none">▪ 20 subjects (U.S. centers - Cedars Sinai, Los Angeles & Mayo Clinic, Rochester)
Dose	<ul style="list-style-type: none">▪ Up to 300×10^6 CD34+ cells
Mode of Administration	<ul style="list-style-type: none">▪ Single intracoronary infusion
Objective	<ul style="list-style-type: none">▪ Demonstrate proof-of-concept of CD34+ cell therapy in CMD patients▪ Data reported at AHA 2019 and SCAI 2020

ESCaPE-CMD: Durable, physiologic coronary vasculature improvement

Coronary Flow Reserve ¹



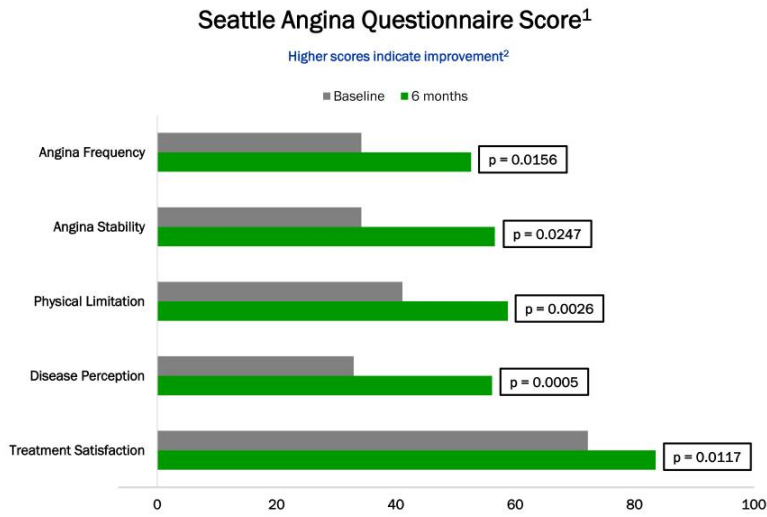
Key Points:

- Evaluated subjects with CFR ≤ 2.5 (diagnosed as CMD)
- CFR = 2 correlates with a 3-4x increase in major adverse cardiac events (MACE) at 3 years¹
- A single intracoronary XOWNA[®] infusion significantly increased CFR to normal values (i.e., ≥ 2.5) for at least 6 months (period of patient follow-up)
 - First therapy to potentially reverse CMD
 - Treatment generally well-tolerated
- Intracoronary XOWNA[®] infusion may ultimately correlate with a reduction in MACE

¹ Murthy et al. Circulation. 2014

² Henry, T. D., Bairey Merz, C. N., et al. (2022). Cardiovascular interventions.

ESCaPE-CMD: Durable, symptomatic anginal relief

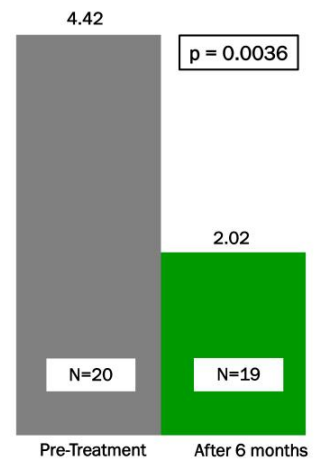


¹ Henry, D. T., SCAI 2020 Scientific Sessions

² Spertus, J.A. et al, JACC Vol. 25, No. 2 February 1995: 333-341

³ Henry, T. D., Bairey Merz, C. N., et al. (2022), Cardiovascular interventions.

Daily Angina Frequency²



FREEDOM trial: Phase 2b double-blind, placebo-controlled

Endpoints	<ul style="list-style-type: none">▪ Change from baseline in angina frequency [Baseline to 3 and 6 months]▪ Change from baseline in total exercise time [Baseline to 6 months]▪ Change from baseline in health-related quality of life [Baseline to 3 and 6 months]▪ Change from baseline in peak coronary flow reserve [Baseline to 6 months]
Study Size	<ul style="list-style-type: none">▪ 105 subjects (~15 sites in the USA)
Dose	<ul style="list-style-type: none">▪ 1 x 10⁶ to 300 x 10⁶ CD34+ cells (XOWNA®) or placebo
Mode of Administration	<ul style="list-style-type: none">▪ Single intracoronary infusion
Objective	<ul style="list-style-type: none">▪ Confirm ESCaPE-CMD safety and efficacy results in a controlled trial (possible basis for RMAT application)▪ Estimate magnitude of effect size for endpoint(s) likely required in a registration trial▪ Characterize patient flow and diagnoses using “real world” criteria

XOWNA®/FREEDOM Trial status update

- Enrollment discontinued at ~1/3 of 105 originally stipulated patients due to COVID-19 pandemic related delays and other challenges, including:
 - Restricted accessibility of subjects to investigational sites
 - Reduced availability of staff at the clinical sites
 - Unexpected discontinuation of the catheter originally specified for the diagnosis of CMD
 - Subjects testing positive for COVID-19 prior to treatment
 - Competition for available apheresis resources
 - Supply chain (i.e., out-of-stock) issues for some catheters FDA cleared for administration of XOWNA®
 - Discontinuation of catheters cleared by FDA for administration of XOWNA®
 - Supply chain (i.e., out-of-stock) issues associated with Omnipaque, a commonly used contrast agent
 - Financial pressures of dramatically increased costs of personnel, materials and manufacturing

XOWNA®/FREEDOM Trial status update (cont.)

- Additional clinical data are not particularly useful for future regulatory and/or commercial use
- Revised projected recruitment timeline of >4 years to trial primary endpoint readout not viable for financial and commercial reasons
- Planned interim analysis of data from not fewer than 20 patients with 6-month follow up to address study objectives; results expected in the third quarter of 2022
- Next development steps will be based on interim analysis results, discussions with FDA, as appropriate, and a review of the cost and timeline of a revised development plan
 - Decision expected by year-end 2022



HONEDRA®
(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
 - Often found as a co-morbidity in diabetes patients
 - Includes severe rest pain and non-healing ulcers
- Buerger's disease (BD = inflammation in small and medium arteries) 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 patients are at high risk of amputation and death
- Multi-hundred-million-dollar opportunity in Japan

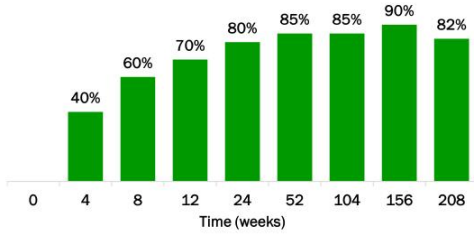
Single treatment of CD34+ cells reversed CLI (Phase 2 data)

Actual CLI Patient Laser Doppler Image

Pre-treatment Post-treatment (week 12)

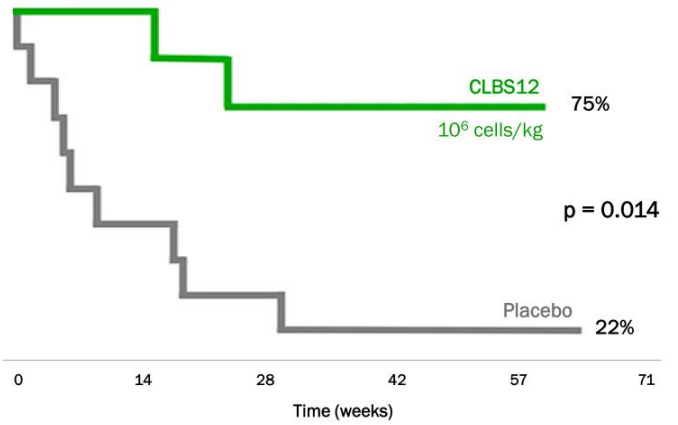


% of Patients (CLI + BD) Achieving CLI-free Status (Japan; n=27)¹



~80% of patients achieved sustainable remission within 6 months of a single treatment; durable for at least 4 years

Probability of Amputation-Free Survival (USA; n=28)²



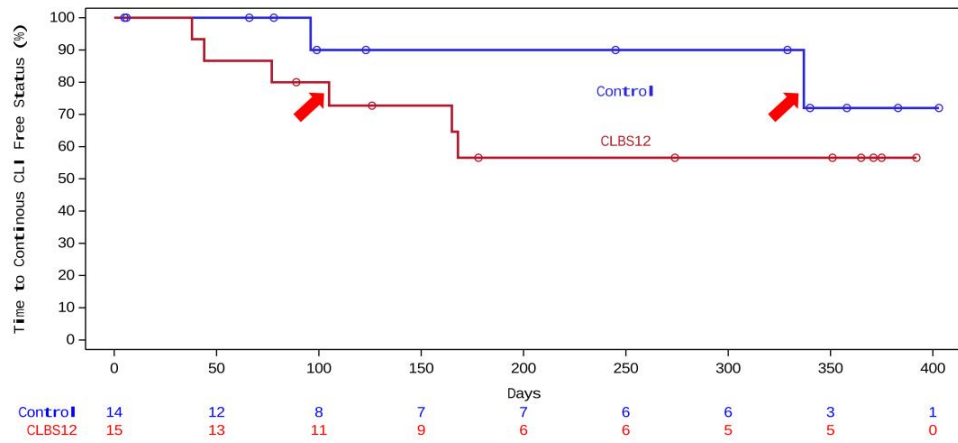
¹ Kinoshita et al, Atherosclerosis 224 (2012) 440-445
² Losordo, D.W. et al, Circulation 2012; 5(6):821-830

HONEDRA® registration-eligible study (CLBS12-P01, Japan)

Primary Endpoint	<ul style="list-style-type: none">▪ Time to continuous CLI-free (2 consecutive monthly visits, adjudicated independently)
Target Study Size	<ul style="list-style-type: none">▪ 35 (30 subjects with no-option CLI (ASO) + 5 Buerger's disease (BD) pts.); all Rutherford category 4 or 5; recruited across 12 centers in Japan
Dose	<ul style="list-style-type: none">▪ Up to 10⁶ cells/kg of HONEDRA® (CLBS12)
Control/Comparator	<ul style="list-style-type: none">▪ Standard of Care: wound care plus drugs approved in Japan<ul style="list-style-type: none">▪ Including antimicrobials, antiplatelets, anticoagulants and vasodilators
Mode of Administration	<ul style="list-style-type: none">▪ Intramuscular, 20 injections in affected lower limb in a single treatment
Objective	<ul style="list-style-type: none">▪ Demonstrate a trend toward efficacy and acceptable safety to qualify for consideration of early conditional approval under Japan's Regenerative Medicine Development Guidelines

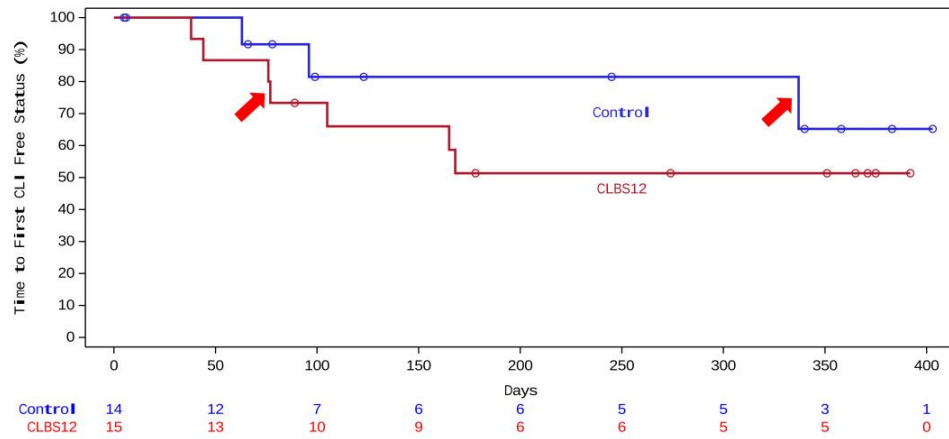
CLBS12-P01: Treated subjects reach primary endpoint sooner

25% of CLBS12-treated subjects (ASO+BD) reached **CONTINUOUS CLI-free status**
 ~232 days sooner than 25% of subjects in the control arm



CLBS12-P01: Treated subjects hit secondary endpoint sooner

25% of CLBS12-treated subjects (ASO+BD) reached **FIRST CLI-free status**
 ~260 days sooner than 25% of subjects in the control arm



HONEDRA® development next steps

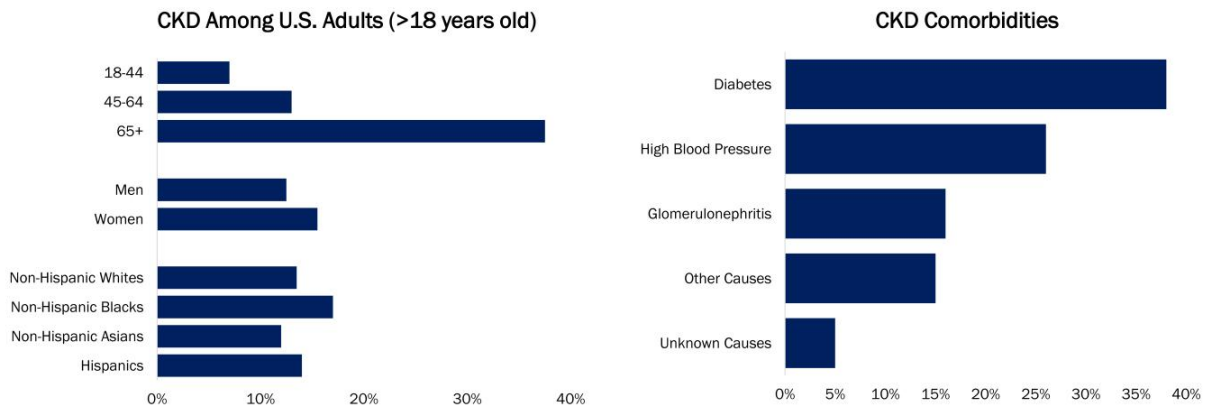
- HONEDRA® study enrollment was significantly curtailed by the impact of COVID-19 (States of Emergency in Japan between ~February 2020 and October 2021)
 - Total enrolled to date: 33 (26 ASO pts. + 7 BD pts. vs. planned 30 ASO pts. + 5 BD pts.)
- Combined CLI and BD interim data suggest trend toward efficacy and acceptable safety
 - Further enrollment paused as a result of substantial continued operational & financial burden due to enrollment delays and unpredictability of completion timing
- Presentation of CLBS12-P01 topline results to the Pharmaceuticals & Medical Devices Agency (PDMA) in a pre-consultation meeting; feedback will provide important perspective for preparation for formal consultation meetings which precede the Japanese new drug application
- Primary focus in Japan is to secure a local partner to explore submitting the existing data to the PMDA under the SAKIGAKE designation

CLBS201
Diabetic Kidney
Disease
(USA)



Chronic kidney disease: Risk factors and comorbidities

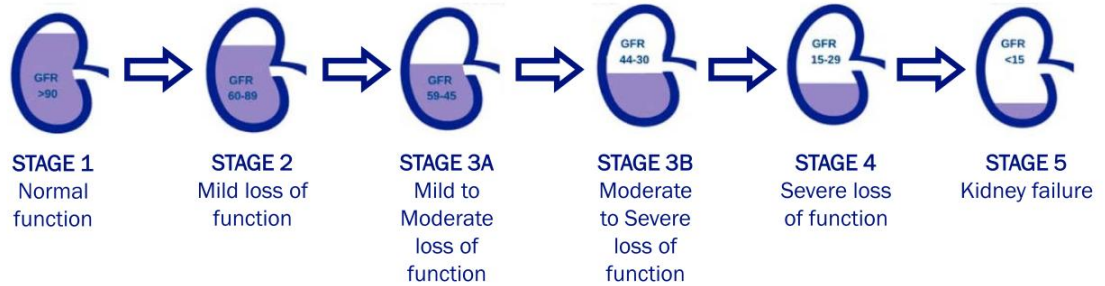
- Advancing age is a risk factor for chronic kidney disease (CKD). Type 2 diabetes and hypertension are common comorbidities
 - 1 in 3 adults are type 2 diabetic and 1 in 5 adults are hypertensive¹



¹ Centers for Disease Control and Prevention. Chronic Kidney Disease in the United States, 2019. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2019.

CKD: Multiple stages progressing toward kidney failure

- The stages of CKD are determined by glomerular filtration rate (GFR)¹
- GFR is measured to determine how well the kidneys are filtering blood
- As kidney function worsens, the level of creatinine increases and GFR decreases
- In 2015-2016, 14%-15% of U.S. adults had evidence of CKD stages 1-4; of these, ~15 to 18 million had evidence of CKD stage 3 or 4²



¹ 2020 Dallas Nephrology Associates

² Centers for Disease Control and Prevention. Chronic Kidney Disease Surveillance System—United States.

Development rationale for CLBS201

- CKD is often associated with progressive microvasculature damage and loss^{1,2}
- 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/diabetic kidney disease (DKD)
- An effective regenerative DKD therapy (i.e., one that *reverses* the course of the disease) could represent a medical and pharmacoeconomic breakthrough

CLBS201 clinical strategy

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

¹ Chade AR. (2017) Small Vessels, Big Role: Renal Microcirculation and Progression of Renal Injury. *Hypertension*; 69(4):551-563.

² Zuk, Anna & Borventre, Joseph. (2016). *Annual Review of Medicine*. 67. 293-307. [10.1146/annurev-med-050214-013407](https://doi.org/10.1146/annurev-med-050214-013407).

CLBS201: Phase 1 proof-of-concept study

Endpoints	<ul style="list-style-type: none">▪ 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	<ul style="list-style-type: none">▪ 6 patients (1 sentinel - unilateral inj., 1 sentinel - bilateral inj., 4 bilateral inj. patients)
Dose	<ul style="list-style-type: none">▪ 1×10^6 – 300×10^6 cells administered as a one-time infusion
Patient Population	<ul style="list-style-type: none">▪ Stage 3b DKD
Design	<ul style="list-style-type: none">▪ Open-label
Mode of Administration	<ul style="list-style-type: none">▪ Intra-arterial injection into one or both renal arteries
Timing	<ul style="list-style-type: none">▪ Enrollment completed 3Q2022; Top-line data target for all subjects: 1Q2023

LISATA

THERAPEUTICS

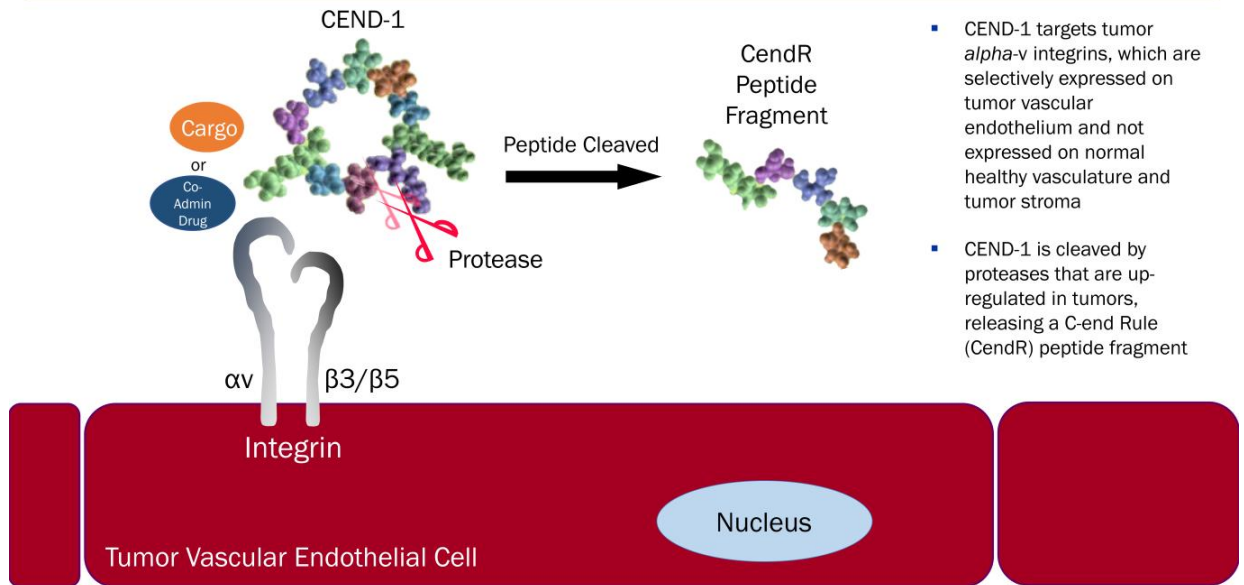
Emphasizing the development of more effective
treatments for solid tumors



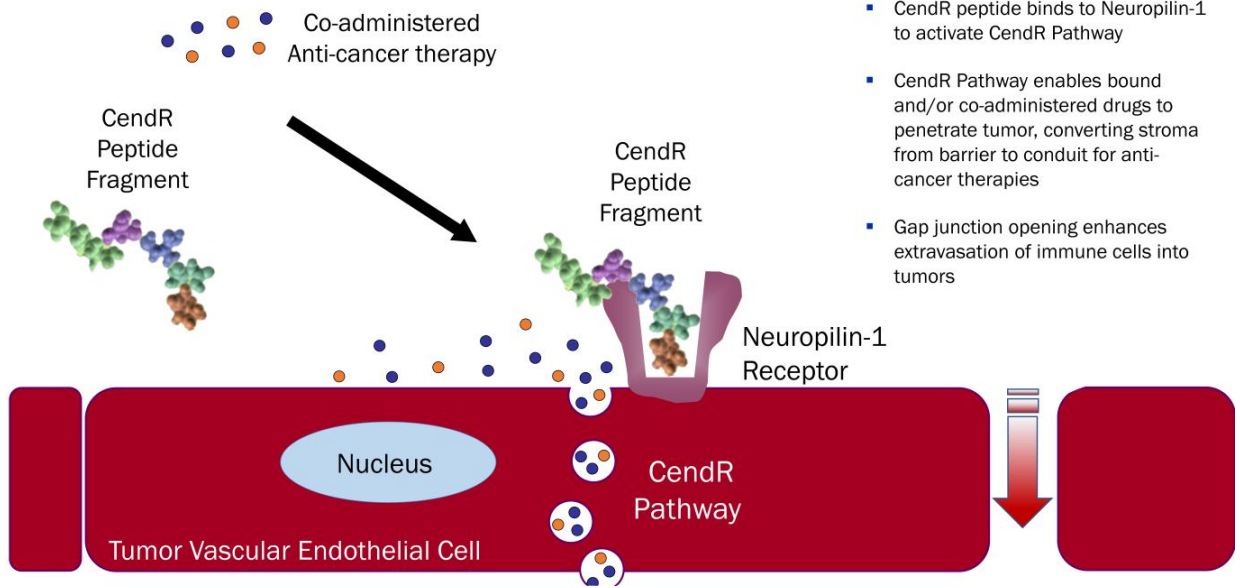
CEND-1 (iRGD) mechanism of action

- CEND-1, a cyclic peptide, targets tumors by binding to *alpha-v* (“ αv ”) integrins, which are selectively expressed on tumor vascular endothelium and not expressed on normal healthy vasculature
 - αv integrins are also expressed on:
 - Cancer-associated fibroblasts, a major component of tumor stroma, and on tumor cells themselves
 - Intratumoral immunosuppressive cells which contribute to an immunotherapy-refractory or “cold” tumor microenvironment evident in pancreatic and other cancers
- Once bound to these integrins, CEND-1 is cleaved by proteases that are up-regulated in tumors, releasing a C-end Rule (CendR) linear peptide fragment
- The CendR fragment then binds to a second receptor, Neuropilin-1, to trigger activation of the CendR Pathway, a novel active transport pathway
 - The CendR Pathway allows co-administered and/or bound drugs to penetrate the tumor, essentially converting the tumor stroma from a barrier to a conduit to reach tumor cell targets

CEND-1 (iRGD) mechanism of action: part 1



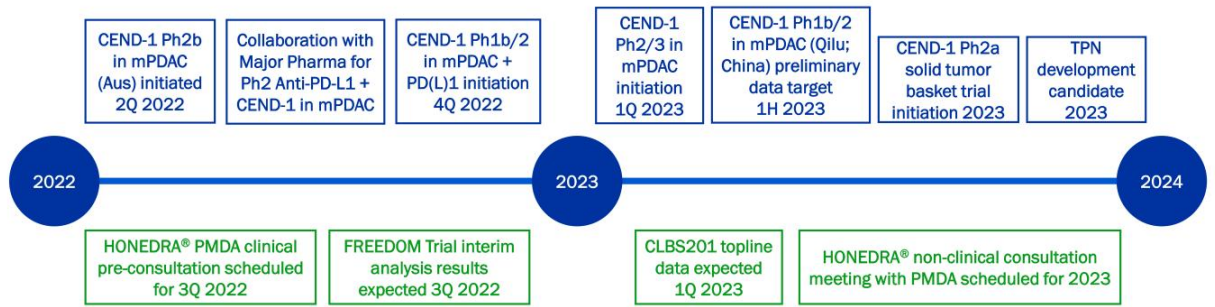
CEND-1 (iRGD) mechanism of action: part 2



Lisata Therapeutics projected pipeline of novel product candidates

Sponsor/Funding Institution	Trial Products	Indication	Preclinical	Phase 1	Phase 2	Phase 3
CendR Programs						
Lisata (U.S.) Ph2/3 adaptive	Gemcitabine/nab-paclitaxel ± CEND-1	First-Line Metastatic Pancreatic Ductal Adenocarcinoma (mPDAC)	[Progress bar: Preclinical, Phase 1, Phase 2]			Trial initiation 1Q23
SWOG - NCI (U.S.) Ph2/3	FOLFIRINOX ± CEND-1		[Progress bar: Preclinical, Phase 1, Phase 2]			Trial initiation 1H23
AGITG (Aus) Ph2b	Gemcitabine/nab-paclitaxel ± CEND-1		[Progress bar: Preclinical, Phase 1, Phase 2]			Ongoing
Qilu (China) Ph1b/2	Gemcitabine/nab-paclitaxel ± CEND-1		[Progress bar: Preclinical, Phase 1]			Ongoing
Partner TBA/Lisata (Global) Ph1b/2	CEND-1 + Nab-paclitaxel + Gemcitabine ± anti-PD(L)1	Resectable PDAC Colon and High-Grade Appendiceal Cancers	[Progress bar: Preclinical, Phase 1, Phase 2]			Trial initiation 1Q23
KUCC - IIT (U.S.) Ph1b/2	CEND-1 + FOLFIRINOX CEND-1 + FOLFIRINOX + Panitumumab		[Progress bar: Preclinical, Phase 1, Phase 2]			Trial initiation 3Q22
Lisata (U.S.) Ph2a	CEND-1 in combination with SoC		[Progress bar: Preclinical, Phase 1, Phase 2]			Trial initiation 1Q23
Lisata (U.S.) Ph1	TPN development candidate	Various Solid Tumors	[Progress bar: Preclinical, Phase 1]			Trial initiation Late 2023/early 2024
CD34+ Programs						
Lisata (U.S.) Ph2b	XOWNA® (CLBS16)	Coronary Microvascular Dysfunction	[Progress bar: Preclinical, Phase 1, Phase 2]			Data expected 3Q22
Lisata (Japan) Ph2	HONEDRA® (CLBS12)	Critical Limb Ischemia and Buerger's Disease	[Progress bar: Preclinical, Phase 1, Phase 2]			Data expected 3Q22
Lisata (U.S.) Ph1	CLBS201	Diabetic Kidney Disease	[Progress bar: Preclinical, Phase 1]			Data expected 1Q23

Lisata Therapeutics anticipated milestones



Caladrius key financial information

Cash & Investments ¹ : As of June 30, 2022	\$73.0 million
Six months ended June 30, 2022, Operating Cash Burn ² :	\$13.0 million
Cash Runway Based on Current Plan:	Sufficient capital for existing programs as well as our balance target at expected closing of merger with Cend in 3Q'22
Debt as of June 30, 2022:	\$0
Common Shares Outstanding: As of June 30, 2022	60.6 million shares
Options Outstanding as of June 30, 2022: Exercise Price: \$0.46 - \$3.28 = 1,988,000 shares Exercise Price: > \$3.28 = 624,000 shares	2.6 million shares
Warrants Outstanding as of June 30, 2022: Weighted Average Exercise Price: \$2.84	21.4 million shares

¹ Excludes \$10.0 million investment in Cend Therapeutics

² Excludes \$2.3 million in net proceeds from sale of New Jersey NOLs

Caladrius investment highlights



Pending merger with Cend Therapeutics, creating Lisata Therapeutics, which we expect will be a financially sound publicly-traded company with clinical stage product candidates



Combination of Caladrius and Cend platforms expected to provide Lisata with a multi-product development pipeline



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



Potential value creating events in the next 12-24 months based on milestones across the pipeline



Strong balance sheet [\$73 million cash & investments* (as of 6/30/2022) - no debt]; well-positioned for current development programs' projected capital needs and cash balance target at merger closing



Seasoned management with domain expertise along with big pharma and emerging biotech experience

*Excludes \$10.0 million investment in Cend Therapeutics

A photograph of a middle-aged couple smiling and embracing each other outdoors. The woman is leaning her head on the man's shoulder. They are both looking towards the camera with warm expressions.

caladrius

BIOSCIENCES

*Developing Innovative Therapies
that Treat or Reverse Disease*

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August 4, 2022 | Nasdaq: CLBS
