**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**

May 5, 2022
Date of Report (date of earliest event reported)

**CALADRIUS BIOSCIENCES, 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

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

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

**Item 2.02 Results of Operations and Financial Condition.**

The information in Item 7.01 is incorporated by reference.

**Item 7.01 Regulation FD Disclosure.**

On May 5, 2022, Caladrius Biosciences, Inc. (the "Company") issued a press release in connection with its financial results for the first quarter ended March 31, 2022. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 7.01 by reference.

The Company will conduct a conference call to review its financial results on May 5, 2022 at 4:30 p.m. Eastern Time.

A copy of a slide presentation that the Company will use at investor and industry conferences and presentations is attached to this Current Report as Exhibit 99.2 and is incorporated herein solely for purposes of this Item 7.01 disclosure.

The information in this Item 7.01, including Exhibits 99.1 and 99.2 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Item 7.01, including Exhibits 99.1 and 99.2 attached hereto, shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, except as otherwise expressly stated in such filing.

**Item 9.01. Financial Statement and Exhibits.**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release, dated May 5, 2022 |
| 99.2 | Caladrius Biosciences, Inc. Corporate Presentation, May 5, 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: May 5, 2022

**Exhibit 99.1**

# Caladrius Biosciences Reports First Quarter 2022 Financial Results and Provides Business Update

*Signs definitive merger agreement with Cend Therapeutics along with immediate investment and collaboration agreements*

*Maintains strong financial position while advancing and expanding development portfolio*

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

**BASKING RIDGE, N.J. (May 5, 2022)** – Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company"), a clinical-stage biopharmaceutical company dedicated to the development of innovative therapies designed to treat or reverse disease, today reported financial results for the three months ended March 31, 2022 and provided a business update.

"During the quarter, we continued to advance our CD34+ cell therapy development pipeline with the initiation of the proof-of-concept study for CLBS201 in diabetic kidney disease. However, the most important achievement was the culmination, after the close of the quarter, of our efforts to diversify and expand our development portfolio, which resulted in the recently announced signing of a merger agreement with Cend Therapeutics," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius. "This transaction will be transformational for Caladrius, creating, upon closing, a financially sound Nasdaq-listed company with a diverse product development pipeline, strong existing partnerships and potential for future attractive collaborations. The merged company will operate under the name of Lisata Therapeutics ("Lisata") with a primary focus on exploiting the full potential of Cend's CendR Platform™ technology in a range of solid tumor oncology indications. CEND-1, the lead product candidate from the CendR Platform™, has the potential to be combined with a myriad of chemo and immunotherapeutic agents and nanoparticle technology that could become an integral part of a revised standard of care therapy for many difficult to treat cancers. The collaboration with Cend will allow the Caladrius team to leverage its broad development expertise and experience, specifically in oncology, with the goal of rapidly progressing Lisata's product development candidates toward global registrations. We couldn't be more excited and motivated about the prospects that this merger will bring for patients and shareholders."

**Business, Product Development and Financing Highlights**

Subsequent to the close of the first quarter of 2022, the Company announced that it has entered into a definitive agreement to merge with Cend Therapeutics, Inc. ("Cend"), 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 will be renamed Lisata Therapeutics, Inc. ("Lisata") 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 development collaboration agreement to maintain development momentum of the Cend pipeline.

***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 for which, as previously announced, the Company suspended enrollment of its registration eligible trial, CLBS12-P01, and turned its focus to securing a Japanese partner to either complete study enrollment of

the four remaining patients, if necessary, and/or to explore the possibility of submitting the existing data to the Japanese Regulatory Authorities for registration review. This decision was motivated by the Company's desire to minimize additional operational and financial burden caused by enrollment delays and the lack of visibility on time to completion of the current study. The Company expects to receive guidance from the Pharmaceuticals and Medical Devices Agency ("PMDA") in Japan during the second or third quarter of 2022 on the next steps of development. In an upcoming clinical pre-consultation meeting, topline results from the CLBS12-P01 study will be presented and discussed with the PMDA. The outcome of this meeting will provide important perspective to be considered in preparation for the formal consultation meetings which precede the Japanese new drug application.

***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 the U.S. Phase 2b FREEDOM Trial. The FREEDOM Trial is a double-blind, randomized, placebo-controlled study designed to assess the efficacy and safety of delivering autologous CD34+ cells 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., coupled with supply chain issues associated with the catheters used for diagnosis of CMD and/or administration of XOWNA® have made and continue to make enrollment much slower than originally predicted and challenging to accelerate. Notwithstanding the obstacles, Caladrius has taken steps to accelerate enrollment by expanding the number of participating investigational sites as well as modifying the study protocol to make study inclusion criteria more flexible. Caladrius continues to monitor the progress of the study and will consider additional future protocol and/or execution changes, as appropriate.

***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 1, 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 will be in the pre-dialysis stage of kidney disease and will exhibit rapidly progressing stage 3b disease. The protocol provides 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 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. As previously announced, the first patient was treated in this Phase 1b study of CLBS201 in April 2022 leading to top-line data from all subjects expected by the first quarter of 2023.

**First Quarter 2022 Financial Highlights**

Research and development expenses for the three months ended March 31, 2022, were $3.3 million, compared to $5.1 million for the three months ended March 31, 2021. Research and development activities in the current year period focused on the advancement of our ischemic repair platform and related to:

- Expenses associated with efforts to continue execution and acceleration of enrollment of the FREEDOM Trial;
- Expenses associated with the planning, preparation and initiation of the Phase 1b proof-of-concept trial for CLBS201 as a treatment for DKD; and
- Ongoing expenses for HONEDRA® in CLI and Buerger's disease in Japan associated with study close out activities and preparation for the pre-consultation meetings with the PMDA.

General and administrative expenses, which focus on general corporate related activities, were $3.3 million for the three months ended March 31, 2022, compared to $3.0 million for the three months ended March 31, 2021, representing an increase of 11%. This increase was primarily due to an increase in fees associated with the review of potential strategic transactions.

Overall, net losses were $4.2 million and $8.1 million for the three months ended March 31, 2022 and March 31, 2021, respectively.

**Balance Sheet Highlights**

As of March 31, 2022, the Company had cash, cash equivalents and marketable securities of approximately $88.5 million, which 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**

Caladrius will hold a live conference call today May 5, 2022, at 4:30 p.m. (ET) to discuss financial results, provide a business update and answer questions. To join the conference call, please refer to the dial-in information provided below. A live webcast of the call will also be available under the Investors & News section of the Caladrius website (https://ir.caladrius.com/) and will be available for replay for 90 days after the conclusion of the call.

Dial-in information:
**Conference ID:** 7129748
**U.S. Toll-Free:** 866-595-8403
**International:** 706-758-9979

*Please dial-in 10 minutes before the start of the conference call.*

For those unable to participate on the live conference call, an audio replay will be available that day starting at 7:30 p.m. (ET) until May 12, 2022, by dialing 855-859-2056 (U.S. Toll-Free) or 404-537-3406 (International) and by entering the replay passcode: 7129748.

**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). The merger is expected to close in the third quarter of 2022.

**Safe Harbor for Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements reflect management's current expectations, as of the date of this press release, and involve certain risks and uncertainties. All statements other than statements of historical fact contained in this press release are forward-looking statements including, without limitation, any expectations of revenues, expenses, cash flows, earnings or losses from operations, cash required to maintain current and planned operations, capital or other financial items; any statements of the plans, strategies and objectives of management for future operations; market and other conditions; any plans or expectations with respect to product research, development and commercialization, including regulatory approvals; any plans or expectations to complete strategic transactions to diversify the Company's pipeline of development product candidates; statements relating to the timing and completion 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's and Cend's stockholders; and any other statements of expectations, plans, intentions or beliefs; and any statements of assumptions underlying any of the foregoing. Without limiting the foregoing, the words "plan," "project," "forecast," "outlook," "intend," "may," "will," "expect," "likely," "believe," "could," "anticipate," "estimate," "continue" or similar expressions or other variations or comparable terminology are intended to identify such forward-looking statements, although some forward-looking statements are expressed differently. 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's 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" described in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 22, 2022, and in the Company's other periodic filings with the SEC. The Company's further development is highly dependent on, among other things, future medical and research developments, and market acceptance, which are outside of its control. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this Press Release. Caladrius does not intend, and disclaims any obligation, to update or revise any forward-looking information contained in this Press Release or with respect to the matters described herein, except as required by law.

**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 intends to file relevant materials with the SEC, including a registration statement that will contain a proxy statement and prospectus. **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 (when they become available) 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, Second Floor, Basking Ridge NJ 07920. Investors and stockholders are urged to read the proxy statement, prospectus and the

other relevant materials when they become available 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's directors and executive officers is included in Caladrius's 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)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2022** | **2021** |
| (in thousands, except per share data) | **(unaudited)** | **(unaudited)** |
| **Statement of Operations Data:** | | |
| Research and development | $ 3,278 | $ 5,076 |
| General and administrative | 3,342 | 3,010 |
| **Total operating expenses** | **6,620** | **8,086** |
| **Operating loss** | **(6,620)** | **(8,086)** |
| Investment income, net | 63 | 23 |
| Other expense, net | (148) | — |
| **Net loss before benefit from income taxes** | **(6,705)** | **(8,063)** |
| Benefit from income taxes | (2,479) | — |
| **Net loss attributable to Caladrius Biosciences, Inc. common stockholders** | **$ (4,226)** | **$ (8,063)** |
| | | |
| **Basic and diluted loss per share attributable to Caladrius Biosciences, Inc. common stockholders** | **$ (0.07)** | **$ (0.19)** |
| **Weighted average common shares outstanding** | **60,560** | **42,117** |

| | **March 31, 2022** | **December 31, 2021** |
|---|---|---|
| | **(unaudited)** | |
| **Balance Sheet Data:** | | |
| Cash, cash equivalents and marketable securities | $88,519 | $94,970 |
| Total assets | 91,463 | 97,008 |
| Total liabilities | 3,222 | 5,008 |
| Total equity | 88,241 | 92,000 |

# # #

Exhibit 99.2

caladrius
BIOSCIENCES

*Developing Innovative Therapies that Treat or Reverse Disease*

David J. Mazzo, PhD
*President & Chief Executive Officer*

May 5, 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's 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's 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's 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's 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 intends to file relevant materials with the SEC, including a registration statement that will contain a proxy statement and prospectus. **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 (when they become available) 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 when they become available before making any voting or investment decision with respect to the proposed transaction.

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## **Caladrius** investment highlights

- Signed a merger agreement with Cend Therapeutics, creating Lisata Therapeutics, which will be a public company with a diverse pipeline of clinical stage product candidates in multiple indications
- CD34+ cell therapy platform yielding a multi-product development pipeline with 2 clinical programs having regenerative medicine “breakthrough” designation
- 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 [$88.5 million cash & investments (as of 3/31) - no debt]; well-positioned relative to projected capital needs for current development programs and cash balance target at merger closing
- Seasoned management with noteworthy domain expertise along with big pharma and emerging biotech experience

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

caladrius BIOSCIENCES

*Caladrius is focused on the discovery, development and commercialization of therapies designed to reverse disease and promote the regeneration of damaged tissue.*

Cend Therapeutics

*Cend Therapeutics is focused on the development and commercialization of a novel approach to provide more effective treatments for solid tumor cancer patients.*

**Lisata Therapeutics**

(Nasdaq: LSTA)

- *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 + 1 jointly agreed new director

# 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
- Immediate $10 million Caladrius investment in Cend + resource collaboration to maintain Cend 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 double-digit royalties on product sales in the region, if any

# Lisata Therapeutics strategic rationale

## Proprietary Platform Technology

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

- Converts tumor stroma from barrier to a conduit for effective delivery via co-administration of a range of chemo- 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
- Strong patent protection beyond 2030 with patent term extension eligibility

# Lisata Therapeutics strategic rationale

## Robust Clinical Stage Pipeline with Broad Therapeutic Reach

*Focused on advancing lead product candidate, CEND-1, in a variety of difficult-to-treat solid tumor applications*

- CEND-1 is currently in multiple studies in first-line, metastatic pancreatic ductal adenocarcinoma (PDAC) in combination with standard-of-care chemotherapy
- CEND-1 development to expand to additional difficult to treat tumors (e.g., hepatocellular, gastric, breast cancers) 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 PDAC

# Lisata Therapeutics strategic rationale

## 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 PDAC (could be as soon as 2023)
- Additional partnership opportunities for broad applications of CEND-1 and the CendR Platform™
- Anticipated clinical data and business development milestones across the consolidated pipeline over the next 24 months
- Experienced management team with extensive development expertise and leading scientific advisors

# Lisata Therapeutics

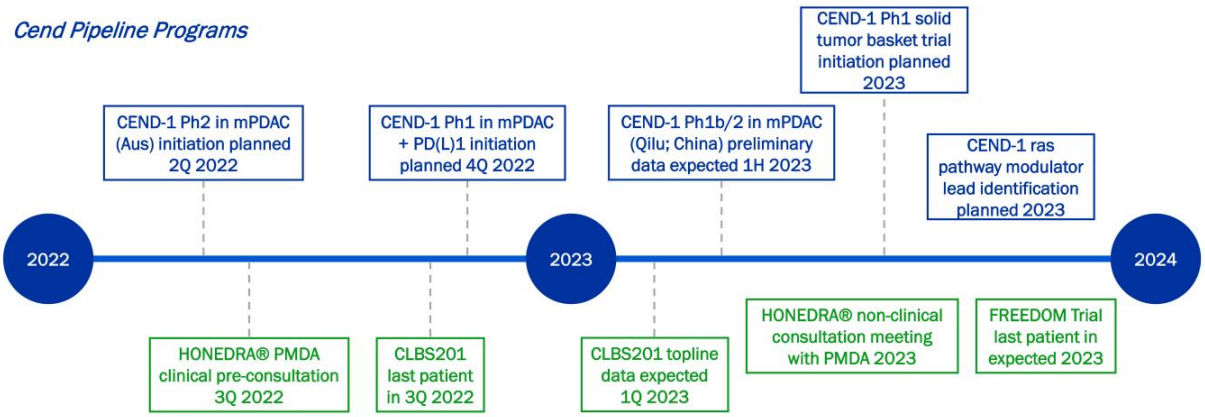
## Combined Pipeline

# Lisata Therapeutics projected pipeline of novel product candidates

| Product | Indication | Preclinical | Phase 1 | Phase 2 | Phase 3 |
|---|---|---|---|---|---|
| **Cend Pipeline** | | | | | |
| CEND-1 + gemcitabine/nab-paclitaxel | First-Line mPDAC (Metastatic Pancreatic Ductal Adenocarcinoma) | | | | |
| CEND-1 + SoC chemo + anti-PD(L)1 | | | | | |
| CEND-1 + FOLFIRINOX | PDAC (Resectable & Borderline Resectable) | | | | |
| CEND-1 + FOLFIRINOX + panitumumab | Colon and High-Grade Appendiceal Cancers | | | | |
| CEND-1 + SoC | Solid Tumor Basket Trial | | | | |
| Ras pathway modulator TPN | PDAC + Other Ras-Driven Solid Tumors | | | | |
| **Caladrius Pipeline** | | | | | |
| XOWNA® (CLBS16) | Coronary Microvascular Dysfunction | | | | |
| HONEDRA® (CLBS12) | Critical Limb Ischemia and Buerger's Disease | | | | |
| CLBS201 | Diabetic Kidney Disease | | | | |

# Lisata Therapeutics anticipated milestones

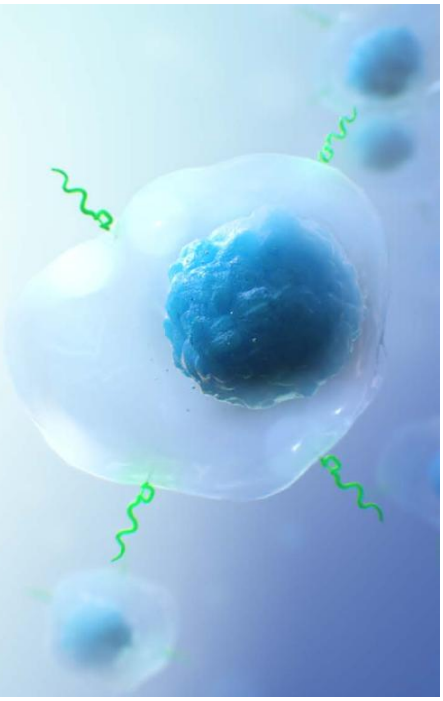
*Cend Pipeline Programs*



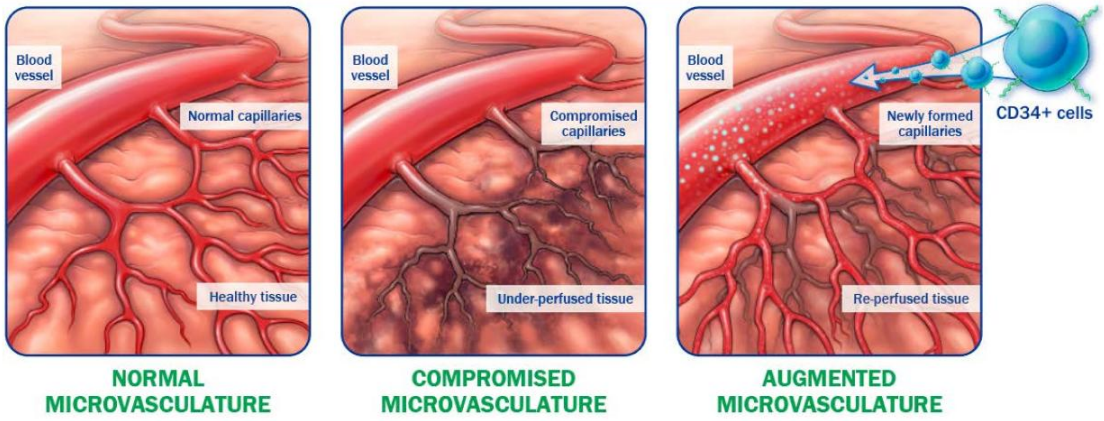

*Caladrius Pipeline Programs*

# 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]

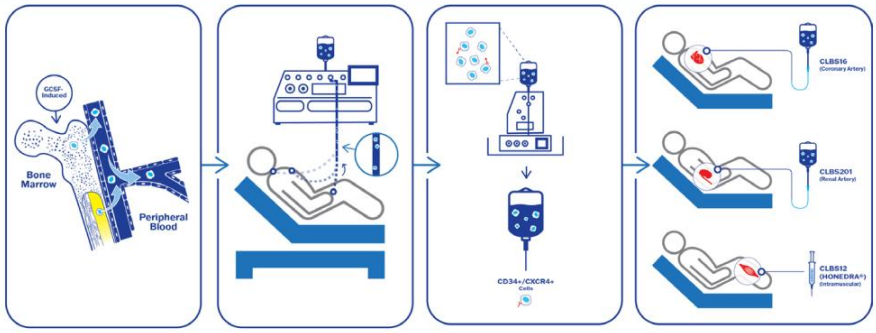
[1]Mackie, A.R. et al., *Tex Heart Inst J* 2011, 38(5), 474-485
[2]Kocher, A.A. et al., *Nat Med* 2001, 440-436
[3]Abd-Allah et al., *Cytotherapy 2015*, 17: 443-53
[4]Lo , B.C. et al., *Am J Respir Cell Mol Biol* 2017, 57: 651-61

# 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 journals[1-4]
  - 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, *Cardiovas 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



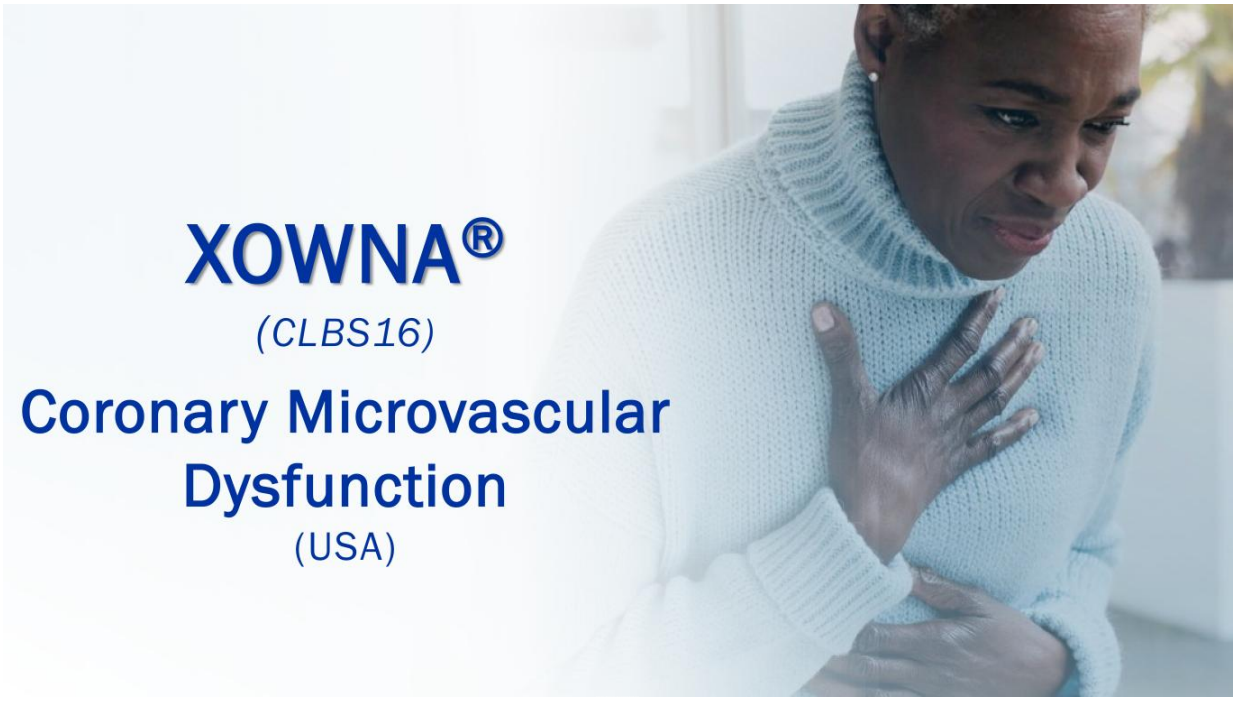

**DAY -5 TO 0**
GCSF-induced mobilization of patient's CD34+ cells from the bone marrow to the peripheral circulation

**DAY 1**
Sample collection via apheresis at one of several access points at an outpatient center

**DAY 2**
**ISOLATION**, concentration and formulation of CD34+/CXCR4+ cells

**DAY 3 OR 4**
CD34+ cells returned to the **SAME PATIENT**; route of administration is indication-specific

- 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 patients[3]
  - Significantly elevated risk of all-cause mortality[4]
- 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 CMD[6]
- Applicable CMD population in the U.S. potentially treatable by XOWNA® ranges from ~415,000 to ~1.6 million patients[7]

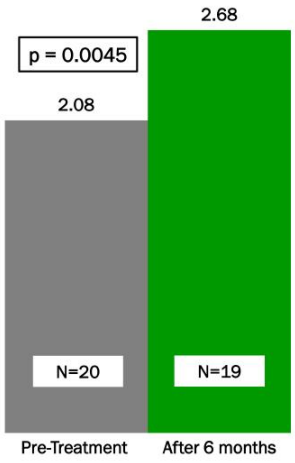
[1] Coronary Microvascular Disease. (2015, July 31). In American Heart Association
[2] R. David Anderson, John W. Petersen, Puja K. Mehta, et al., Journal of Interventional Cardiology, 2019: 8
[3] Loffler and Bourque, Curr Cardiol Rep. 2016 Jan; 18(1): 1
[4] Kenkre, T.S. et al., Circ: CV Qual & Outcomes 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** | ▪ 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** | ▪ 20 subjects (U.S. centers - Cedars Sinai, Los Angeles & Mayo Clinic, Rochester) |
| **Dose** | ▪ Up to 300 x $10^6$ CD34+ cells |
| **Mode of Administration** | ▪ Single intracoronary infusion |
| **Objective** | ▪ Demonstrate proof-of-concept of CD34+ cell therapy in CMD patients<br>▪ Data reported at AHA 2019 and SCAI 2020 |

# ESCaPE-CMD: Durable, physiologic coronary vasculature improvement

**Coronary Flow Reserve** [1]

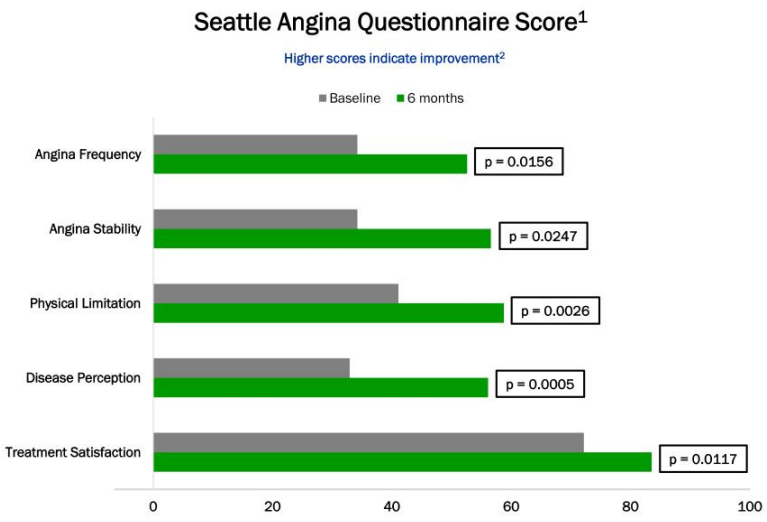


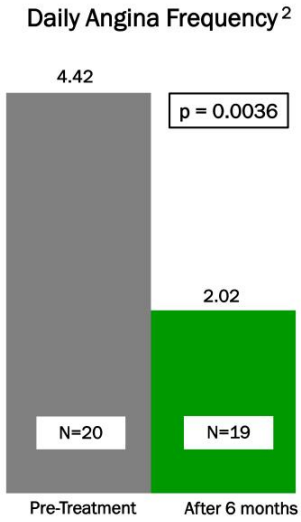

**Key Points:**

- 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 years[1]
- 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.

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

| | |
|---|---|
| **Endpoints** | ▪ Change from baseline in angina frequency [Baseline to 3 and 6 months]<br>▪ Change from baseline in total exercise time [Baseline to 6 months]<br>▪ Change from baseline in health-related quality of life [Baseline to 3 and 6 months]<br>▪ Change from baseline in peak coronary flow reserve [Baseline to 6 months] |
| **Study Size** | ▪ 105 subjects (~15 sites in the USA) |
| **Dose** | ▪ 1 x $10^6$ to 300 x $10^6$ CD34+ cells (XOWNA®) or placebo |
| **Mode of Administration** | ▪ Single intracoronary infusion |
| **Objective** | ▪ Confirm ESCaPE-CMD safety and efficacy results in a controlled trial (possible basis for RMAT application)<br>▪ Estimate effect size for endpoint(s) likely required in a registration trial<br>▪ Characterize patient flow and diagnoses using “real world” criteria |


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

# HONEDRA® targets patients based on the Rutherford Scale

**CLI amputation rates increase with increasing Rutherford score (disease severity)[1]**

**Rutherford ("R") scale**

**R 6:** Functional foot no longer salvageable

**R 5:** Minor tissue loss non-healing ulcer; focal gangrene with diffuse pedal ischemia

**R 4:** Debilitating rest pain

**R 1-3:** Mild to severe claudication

HONEDRA® targets patients with **R4** or **R5** disease

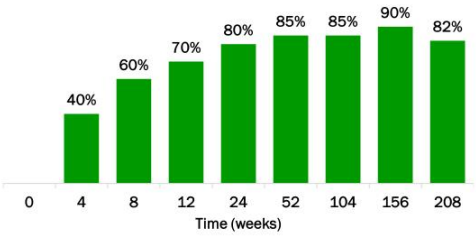
[1] Reinecke H., European Heart Journal, 2015 Apr 14;36(15):932-8

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

**Actual CLI Patient Laser Doppler Image**

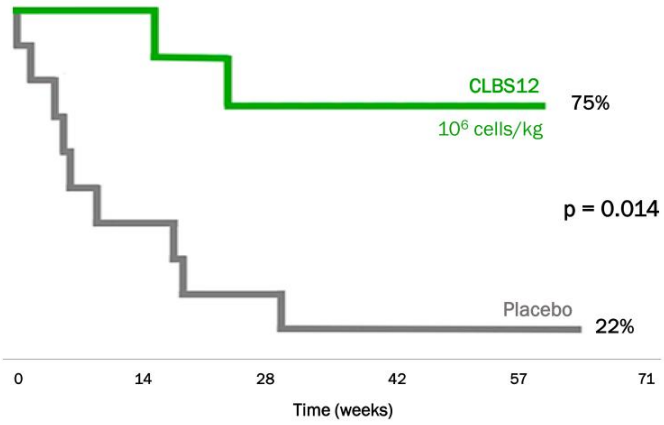
Pre-treatment Post-treatment (week 12)

**% 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]**



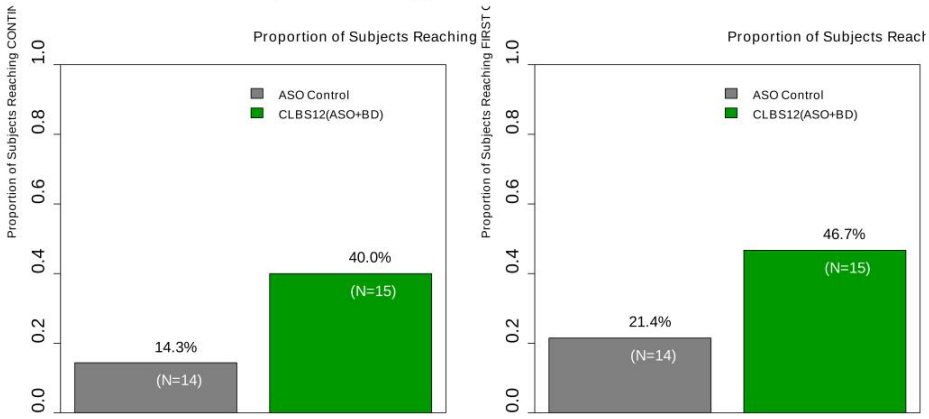

[1] Kinoshita et al, Atherosclerosis 224 (2012) 440-445
[2] Losordo, D.W. et al, Circulation 2012; 5(6):821-830

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

| | |
|---|---|
| **Primary Endpoint** | ▪ Time to continuous CLI-free (2 consecutive monthly visits, adjudicated independently) |
| **Target Study Size** | ▪ 35 (30 subjects with no-option CLI + 5 Buerger's disease pts.); all Rutherford category 4 or 5; recruited across 12 centers in Japan |
| **Dose** | ▪ Up to $10^6$ cells/kg of HONEDRA® (CLBS12) |
| **Control/Comparator** | ▪ Standard of Care: wound care plus drugs approved in Japan<br>  ▪ 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 |

# CLBS12-P01 "full analysis set" efficacy trends positively

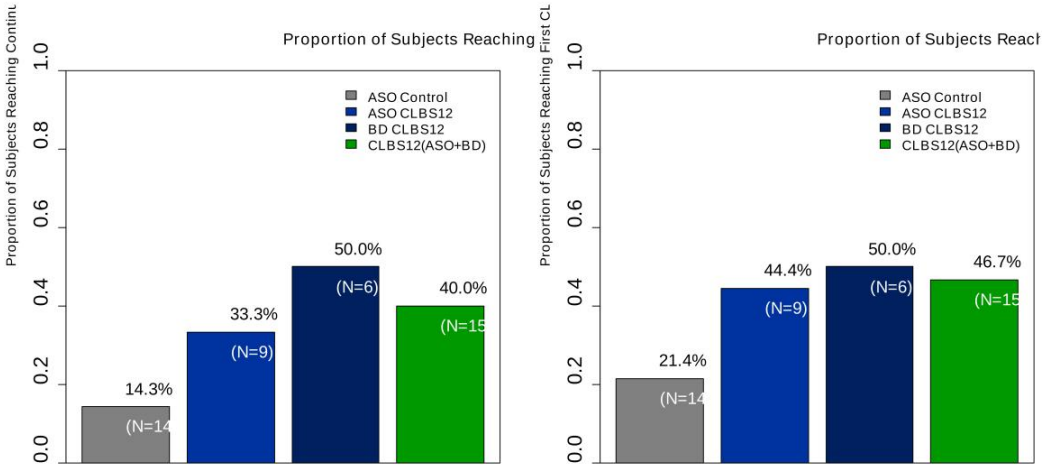
- Proportion of CLBS12-treated subjects reaching **CONTINUOUS** CLI-free status **MORE THAN DOUBLE** control arm
- Proportion of CLBS12-treated subjects reaching **FIRST** CLI-free status **MORE THAN DOUBLE** control arm




FAS: Full Analysis Set as defined by Japanese Regulators (PMDA)

# CLBS12-P01 efficacy trends positively for both ASO and BD individually

Efficacy trends are consistent across both populations




FAS: Full Analysis Set as defined by Japanese Regulators (PMDA)

# 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 no-option CLI pts. + 7 Buerger's disease 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
- Priority for Caladrius in Japan is securing a local partner to explore submitting the existing data to the Pharmaceuticals & Medical Devices Agency (PMDA) under the SAKIGAKE designation
- In an upcoming clinical pre-consultation meeting with the PMDA, topline results from the CLBS12-P01 study will be presented and discussed, which will provide important perspective to be considered in preparation for the formal consultation meetings which precede the Japanese new drug application

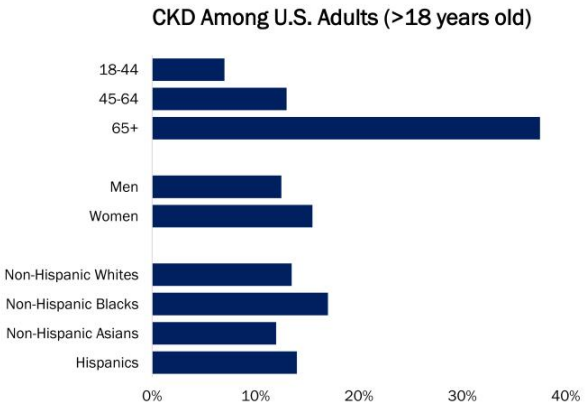
# CLBS201

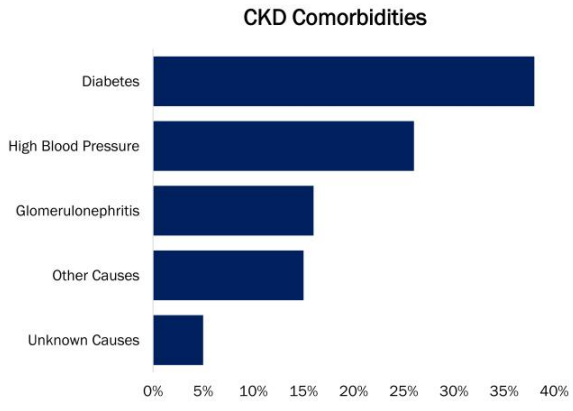
## Diabetic Kidney Disease

(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 hypertensive[1]

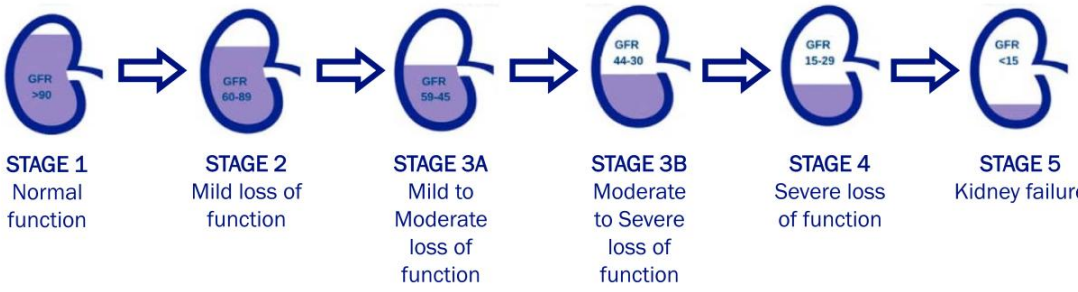



[1] Centers for Disease Control and Prevention. Chronic Kidney Disease in the United States, 2019. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2019.

## **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 4[2]




**STAGE 1** Normal function

**STAGE 2** Mild loss of function

**STAGE 3A** Mild to Moderate loss of function

**STAGE 3B** Moderate to Severe loss of function

**STAGE 4** Severe loss of function

**STAGE 5** Kidney failure

[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 & Bonventre, Joseph. (2016). Annual Review of Medicine. 67. 293-307. 10.1146/annurev-med-050214-013407.*

# CLBS201: Planned Phase 1 proof-of-concept study

| | |
|---|---|
| **Endpoints** | ▪ Change in eGFR compared to baseline, assessed at 6 months<br>▪ 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 |
| **Mode of Administration** | ▪ Intra-arterial injection into one or both renal arteries |
| **Timing** | ▪ Top-line data target for all subjects: 1Q2023 |

# Caladrius key financial information

| | |
|---|---|
| Cash & Investments:<br>As of March 31, 2022 | $88.5 million |
| Three months ended March 31, 2022 Operating Cash Burn[1]: | $8.0 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 March 31, 2022: | $0 |
| Common Shares Outstanding:<br>As of March 31, 2022 | 60.5 million shares |
| Options Outstanding as of March 31, 2022:<br>Exercise Price: $0.76 - $3.28 = 2,000,000 shares<br>Exercise Price: > $3.28 = 640,000 shares | 2.6 million shares |
| Warrants Outstanding as of March 31, 2022:<br>Weighted Average Exercise Price: $2.84 | 21.4 million shares |

[1] Excludes $2.3 million in net proceeds from sale of New Jersey NOLs

## **Caladrius** investment highlights

- Signed a merger agreement with Cend Therapeutics, creating Lisata Therapeutics, which will be a public company with a diverse pipeline of clinical stage product candidates in multiple indications
- CD34+ cell therapy platform yielding a multi-product development pipeline with 2 clinical programs having regenerative medicine “breakthrough” designation
- 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 [$88.5 million cash & investments (as of 3/31) - no debt]; well-positioned relative to projected capital needs for current development programs and cash balance target at merger closing
- Seasoned management with noteworthy domain expertise along with big pharma and emerging biotech experience

caladrius
BIOSCIENCES

*Developing Innovative Therapies that Treat or Reverse Disease*

**Investor Relations Contact:**
*John D. Menditto*
Tel: (908) 842-0084
jmenditto@caladrius.com

May 5, 2022| Nasdaq: CLBS