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 23, 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 7.01 Regulation FD Disclosure.

On May 23, 2022, Caladrius Biosciences, Inc. (the "Company") issued a press release in connection with the status of its XOWNA®/FREEDOM Trial. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K and is incorporated into this Item 7.01 by reference.

The Company will conduct a conference call to review the XOWNA®/FREEDOM Trial status on May 24, 2022 at 8:15 a.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 23, 2022
99.2	Caladrius Biosciences, Inc. Corporate Presentation, May 23, 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 23, 2022

Exhibit 99.1

Caladrius Biosciences Provides Update on Phase 2b FREEDOM Trial of XOWNA® in Coronary Microvascular Dysfunction

Interim analysis to be conducted following enrollment suspension in the double-blind, randomized, placebo-controlled clinical trial

Next development steps for XOWNA® to be announced by year-end 2022 following regulatory and business review

Caladrius Management will host a conference call tomorrow, May 24th at 8:15 a.m. EDT

BASKING RIDGE, N.J. (May 23, 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 announced that the Company has suspended patient enrollment in its Phase 2b study of XOWNA®, known as the FREEDOM Trial, for the treatment of coronary microvascular dysfunction ("CMD"). The Company intends to conduct an interim analysis of the data from not less than the first 20 patients enrolled using the 6-month follow-up data to evaluate the efficacy and safety of XOWNA® in subjects with CMD and corroborate the ESCaPE-CMD study results. Additionally, the data from the analysis is expected to provide an indication of the magnitude of the XOWNA® effect size on the clinical endpoints likely to be required by the FDA in a future pivotal study. Per good clinical practice, Caladrius will continue to assess and follow all treated subjects according to protocol through completion of follow-up. The interim analysis is expected to be completed in August 2022 and the next steps in development of XOWNA® will subsequently be determined after appropriate regulatory and business review, expected to be announced prior to year-end 2022.

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. The primary objectives of the FREEDOM Trial were to corroborate, in a controlled trial, the results of the ESCaPE-CMD trial, a Phase 2a open-label, proof-of-concept study in CMD patients, to get a better estimation of the treatment effect size of XOWNA® on clinical endpoints likely to be required by the FDA in a pivotal trial, and to assess the impact of XOWNA® on a patient population more broadly representative of the intended commercial population. 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. Despite the multiple protocol amendments to address these obstacles, along with an increased number of sites in the study, the FREEDOM Trial has only enrolled approximately one third of the targeted 105 patients, and at this rate, more than four years would likely be required to reach the primary endpoint follow-up at 6 months post-treatment for all subjects. The Company believes that this revised timeline is not viable for financial and commercial reasons and an alternative development plan must be considered. As a result, the Company has suspended further enrollment activities and will conduct an interim analysis of the data to determine the next steps for the program.

"We have concluded that it is in the Company's best interest to suspend enrollment in the FREEDOM Trial and complete an interim analysis of the data from the subjects enrolled to date, which we expect will provide meaningful insight on the best future clinical development pathway of the program," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius. "Since the inception of the FREEDOM Trial, new technology has been

introduced and validated for the diagnosis of CMD, yet these new techniques are not widely available nor are the associated diagnostic parameters widely accepted. Further compounding the situation is the discontinuation by the manufacturer of the diagnostic equipment that was originally specified in the trial to qualify patients for the study, discontinuation and/or supply shortages of catheters qualified for XOWNA® administration and supply shortages of a contrast agent commonly employed in many catheter laboratories. These complications, coupled with the impact of the COVID-19 pandemic in the U.S., have made incremental enrollment exceedingly challenging, despite our efforts 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. Consequently, we have halted enrollment in the study to alleviate the operational and financial burden due to enrollment delays and the lack of visibility on the time to completion. We will consider additional protocol and/or executional changes based on the results of the interim analysis, which are expected in August 2022."

For more information on this study, please visit clinicaltrials.gov (identifier: NCT04614467).

About Coronary Microvascular Dysfunction

CMD is a type of non-obstructive coronary artery disease that causes decreased blood flow to the heart muscle that affects approximately 8.3 million people in the U.S.[1,2] With common symptoms that include recurring, debilitating chest pain, tiredness, and shortness of breath, many CMD patients are undiagnosed because of the absence of large vessel obstruction. Due to an under appreciation of the disease, patients, the majority of whom are women, often go years without proper treatment. When a diagnosis of CMD is missed, patients are untreated and remain at high risk of heart attack and/or cardiovascular-related death.

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[1] Mittal, S.R.; Indian Heart Journal, Volume 66, 2014, Pages 678–681
[2] Cleveland Clinic/AHA (American Heart Association)

Conference Call Details:

Date: Tuesday, May 24, 2022
Time: 8:15 a.m. Eastern time
Toll-free Dial-in Number: (866) 595-8403
International Dial-in Number: (706) 758-9979
Conference ID: 7729348

A live webcast will be available on the Events & Presentations page (https://ir.caladrius.com/news-events/events-presentations) under the Investors & News section of the Caladrius website.

A telephone replay will also be available through May 27, 2022. To access replay, please dial (855) 859-2056 (Domestic) or (404) 537-3406 (International). At the system prompt, please enter the code 7729348 followed by the # sign.

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, our expectations with respect to the interim analysis of the data from the FREEDOM trial, 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 with Cend; the combined company's listing on the Nasdaq Capital Market after closing of the proposed merger; 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 merger with Cend 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; the uncertainties inherent in the clinical and preclinical development process; the ability of Caladrius to protect its intellectual property rights; 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 the Company's Quarterly Report on Form 10-Q filed with the SEC on May 5, 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.

Contact:

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

# # #

Exhibit 99.2

caladrius
BIOSCIENCES

Developing Innovative Therapies to Treat or Reverse Disease

David J. Mazzo, PhD
President & Chief Executive Officer

May 23, 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.

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.

Caladrius investment highlights

- Pending merger with Cend Therapeutics, creating Lisata Therapeutics, which will be a financially sound publicly-traded company with clinical stage product candidates
- Combination of Caladrius and Cend platforms provides 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 [$88.5 million cash & investments (as of 3/31/2022) - 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

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

caladrius BIOSCIENCES

Focused on the development of therapies that reverse cardiovascular disease

Cend Therapeutics

Focused on the development of more effective treatments for solid tumor cancers

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
- 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

Lisata Therapeutics strategic rationale

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

Lisata Therapeutics strategic rationale

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 (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

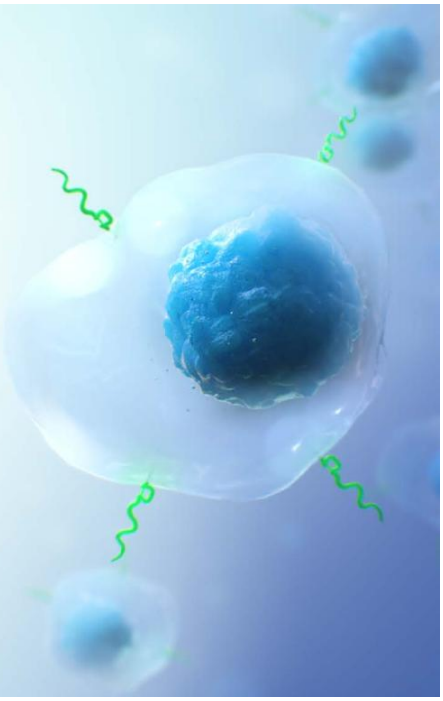
- Existing Cend strategic partnership in China with Qilu Pharmaceutical with non-dilutive milestone payments, development collaboration and participation in downstream economics
  - Potential for up to $225 million in milestones and royalties on potential sales in the region
  - $10 million payment due 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 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

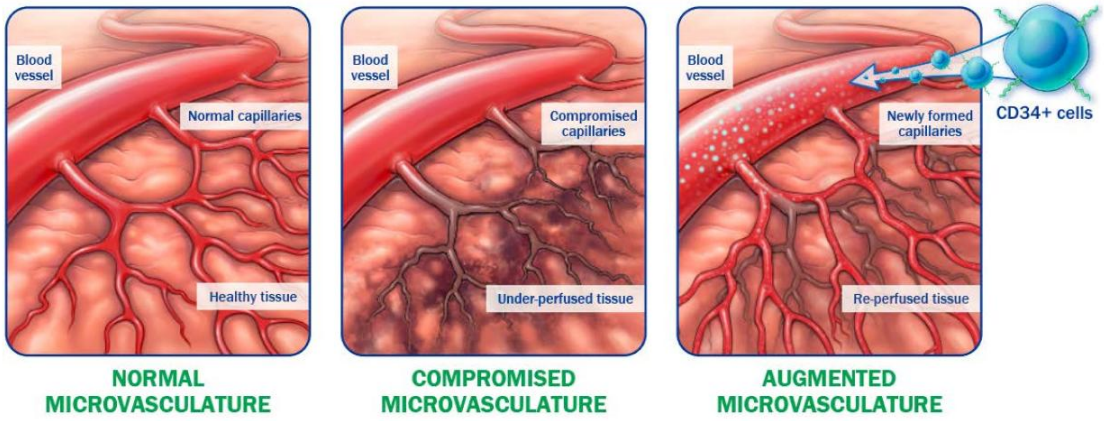
Product	Indication	Preclinical	Phase 1	Phase 2	Phase 3
Cend Pipeline					
CEND-1 + gemcitabine/nab-paclitaxel	First-Line mPDAC (Metastatic Pancreatic Ductal Adenocarcinoma)				
CEND-1 + SoC chemo + anti-PD(L)1					
CEND-1 + FOLFIRINOX	PDAC (Resectable & Borderline Resectable)				
CEND-1 + FOLFIRINOX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

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]

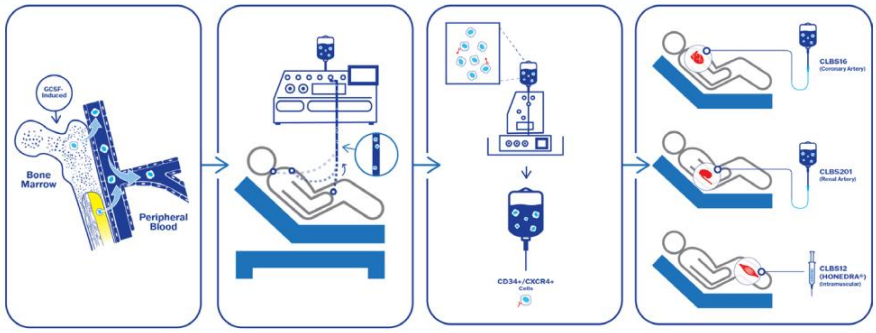
[1]Mackie, A.R. et al., *Tex Heart Inst J* 2011, 38(5), 474-485
[2]Kocher, A.A. et al., *Nat Med* 2001, 440-436
[3]Abd-Allah et al., *Cytotherapy 2015*, 17: 443-53
[4]Lo , B.C. et al., *Am J Respir Cell Mol Biol* 2017, 57: 651-61

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



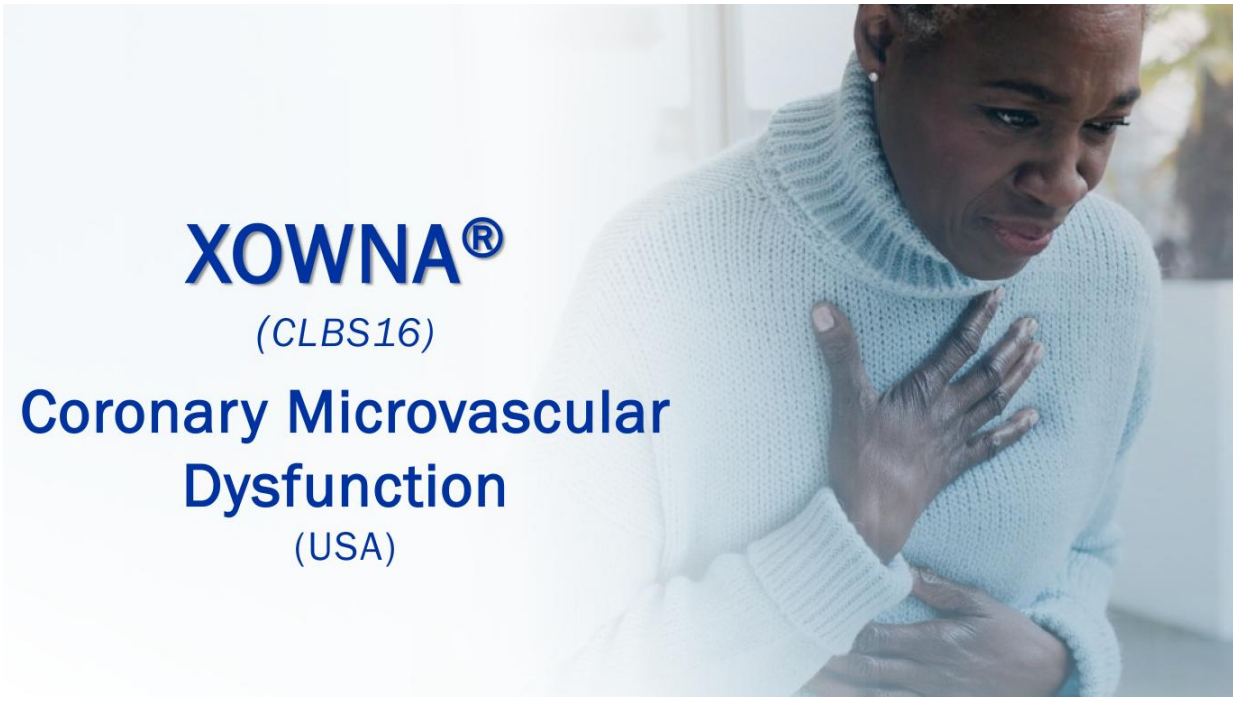
DAY -5 TO 0
GCSF-induced mobilization of patient's CD34+ cells from the bone marrow to the peripheral circulation

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]

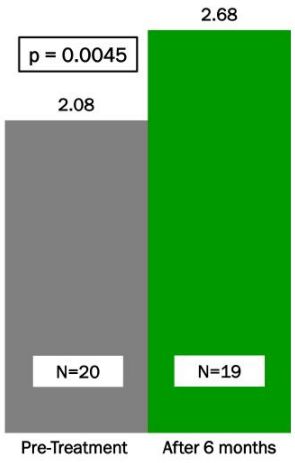
[1] Coronary Microvascular Disease. (2015, July 31). In American Heart Association
[2] R. David Anderson, John W. Petersen, Puja K. Mehta, et al., Journal of Interventional Cardiology, 2019: 8
[3] Loffler and Bourque, Curr Cardiol Rep. 2016 Jan; 18(1): 1
[4] Kenkre, T.S. et al., Circ: CV Qual & Outcomes 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 ▪ Data reported at AHA 2019 and SCAI 2020

ESCaPE-CMD: Durable, physiologic coronary vasculature improvement

Coronary Flow Reserve [1]

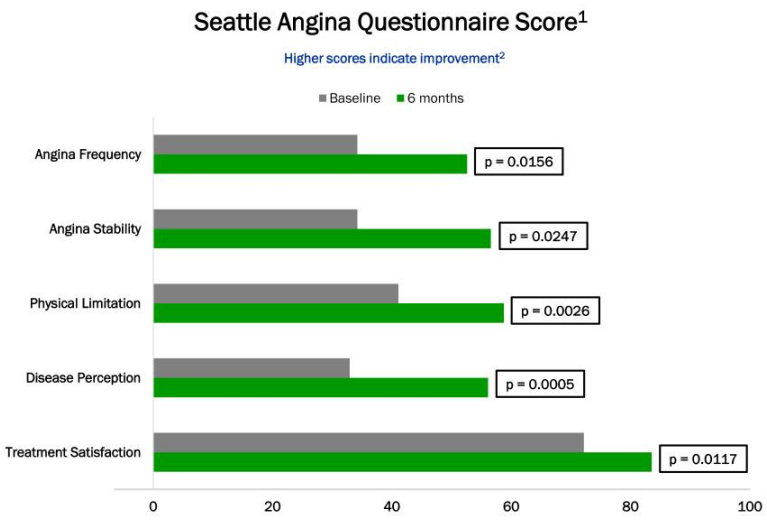


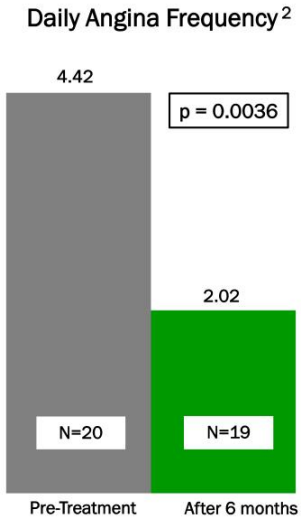
Key Points:

- 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] ▪ 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	▪ 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) ▪ 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
  - 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

- Additional clinical data is 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 August 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)

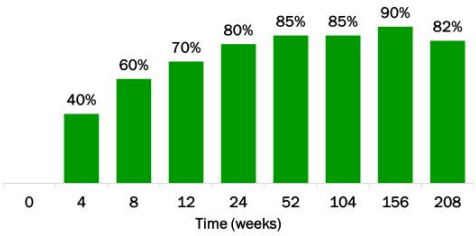
- Severe arterial obstruction impeding blood flow in the lower extremities
  - Often found as a co-morbidity in diabetes patients
  - Includes severe rest pain and non-healing ulcers
- Buerger's disease (BD = inflammation in small and medium arteries) a form of CLI associated with a history of heavy 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

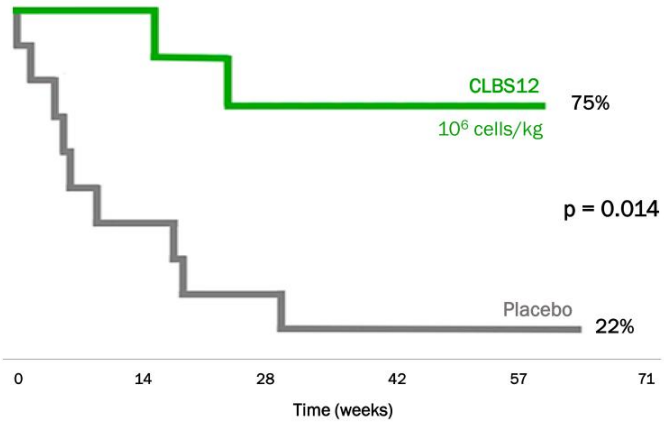
Pre-treatment Post-treatment (week 12)

% 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]



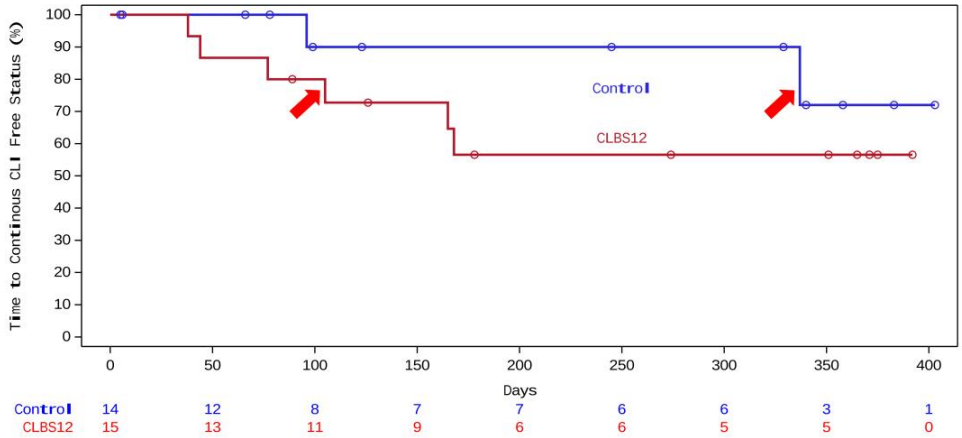
[1] Kinoshita et al, Atherosclerosis 224 (2012) 440-445
[2] Losordo, D.W. et al, Circulation 2012; 5(6):821-830

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

Primary Endpoint	▪ Time to continuous CLI-free (2 consecutive monthly visits, adjudicated independently)
Target Study Size	▪ 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	▪ Up to 10^6 cells/kg of HONEDRA® (CLBS12)
Control/Comparator	▪ Standard of Care: wound care plus drugs approved in Japan ▪ Including antimicrobials, antiplatelets, anticoagulants and vasodilators
Mode of Administration	▪ Intramuscular, 20 injections in affected lower limb in a single treatment
Objective	▪ Demonstrate a trend toward efficacy and acceptable safety to qualify for consideration of early conditional approval under Japan's Regenerative Medicine Development Guidelines

CLBS12-P01: Treated subjects reach primary endpoint sooner

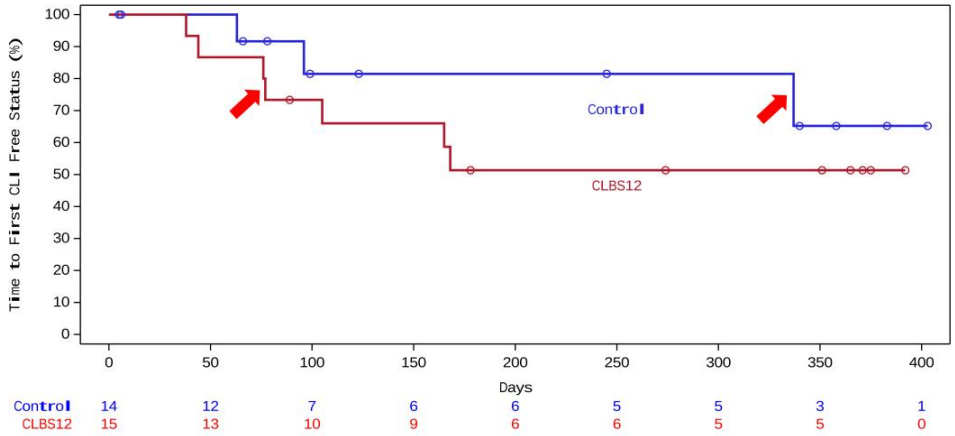
25% of CLBS12-treated subjects (ASO+BD) reached **CONTINUOUS CLI-free status**
~232 days sooner than 25% of subjects in the control arm



Control	14	12	8	7	7	6	6	3	1
CLBS12	15	13	11	9	6	6	5	5	0

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



Control	14	12	7	6	6	5	5	3	1
CLBS12	15	13	10	9	6	6	5	5	0

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
- Focus in Japan is to secure a local partner to explore submitting the existing data to the PMDA under the SAKIGAKE designation

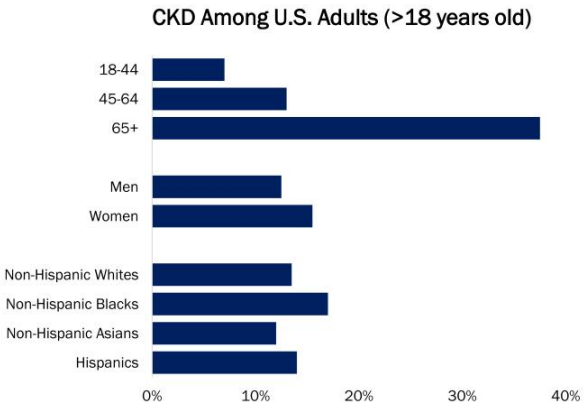
CLBS201

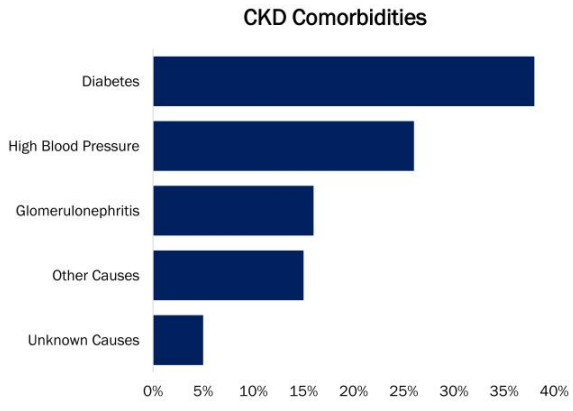
Diabetic Kidney Disease

(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 hypertensive[1]

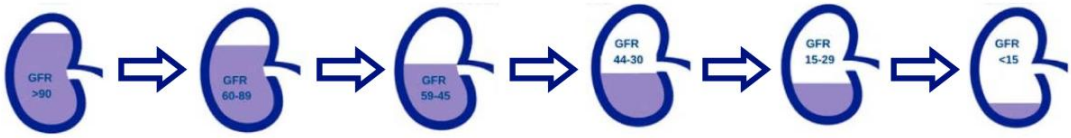




[1] Centers for Disease Control and Prevention. Chronic Kidney Disease in the United States, 2019. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2019.

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: Phase 1 proof-of-concept study

Endpoints	▪ Change in eGFR compared to baseline, assessed at 6 months ▪ Change in Urine albumin-to-creatinine ratio (UACR) and urine protein-to-creatinine ratio (UPCR) from baseline to 3 and 6 months
Study Size	▪ 6 patients (1 sentinel - unilateral inj., 1 sentinel - bilateral inj., 4 bilateral inj. patients)
Dose	▪ 1 x 10^6 – 300 x 10^6 cells administered as a one-time infusion
Patient Population	▪ Stage 3b DKD
Design	▪ Open-label
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: 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: As of March 31, 2022	60.5 million shares
Options Outstanding as of March 31, 2022: Exercise Price: $0.76 - $3.28 = 2,000,000 shares Exercise Price: > $3.28 = 640,000 shares	2.6 million shares
Warrants Outstanding as of March 31, 2022: Weighted Average Exercise Price: $2.84	21.4 million shares

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

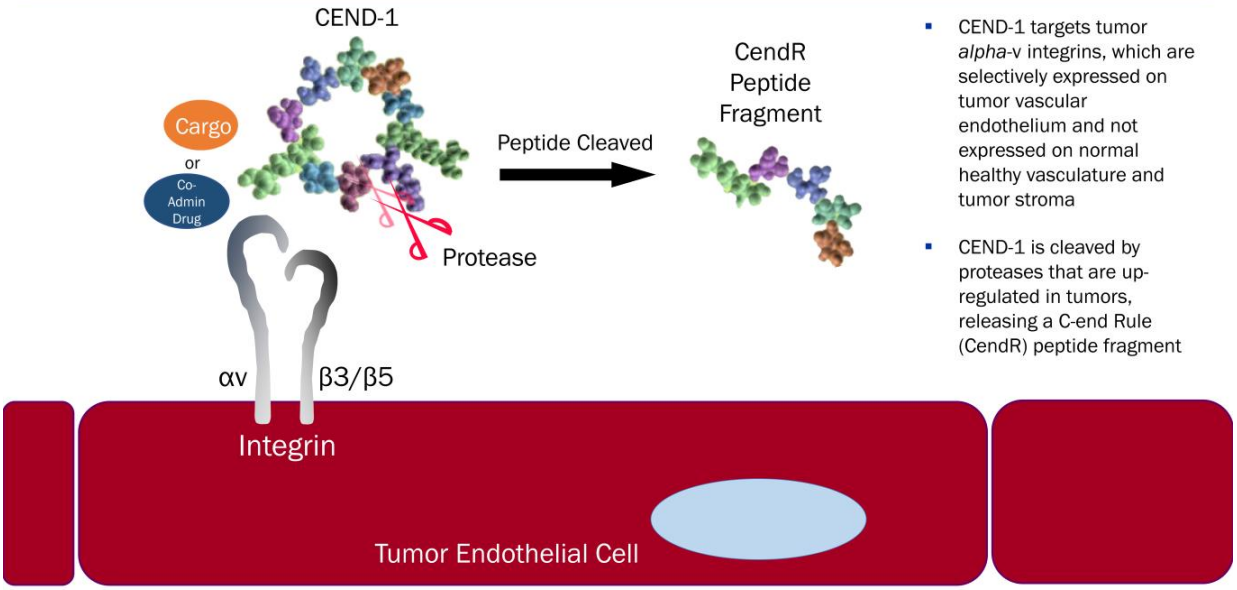
Lisata Therapeutics

Emphasizing the development of more effective treatments for solid tumor cancers

CEND-1 (iRGD) mechanism of action

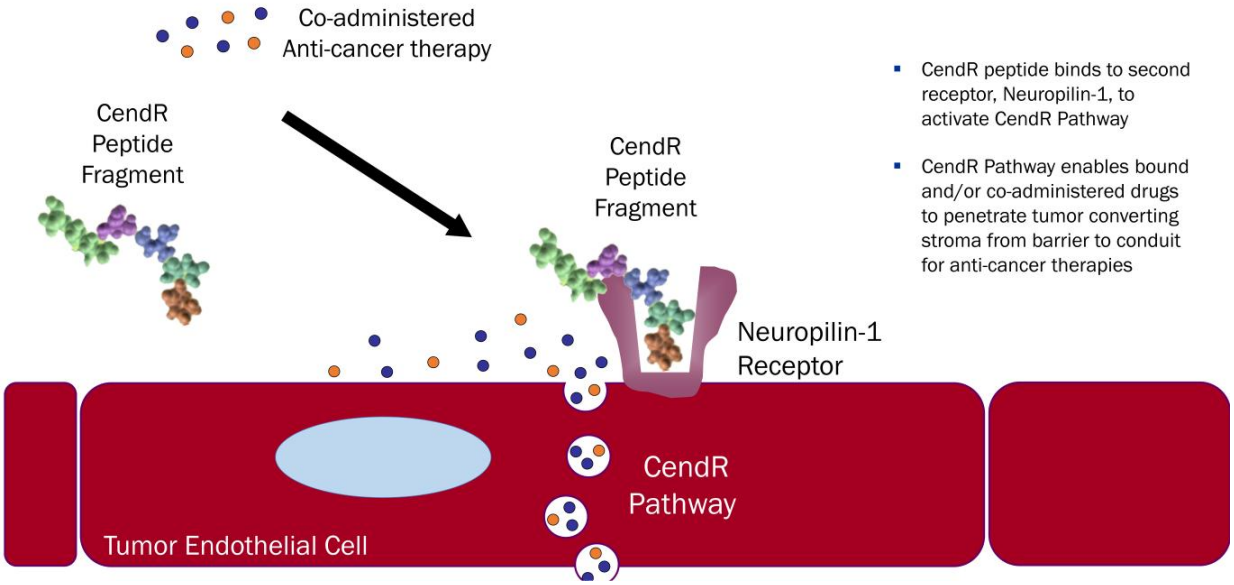
- CEND-1, a cyclic peptide, targets tumors by binding to *alpha*-v ("αv") integrins, which are selectively expressed on tumor vascular endothelium and not expressed on normal healthy vasculature
  - αv integrins are also expressed on:
    - Cancer-associated fibroblasts, a major component of tumor stroma, 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
  - Enables the CendR peptide and 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 targets tumor *alpha*-v integrins, which are selectively expressed on tumor vascular endothelium and not expressed on normal healthy vasculature and tumor stroma
- CEND-1 is cleaved by proteases that are up-regulated in tumors, releasing a C-end Rule (CendR) peptide fragment

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



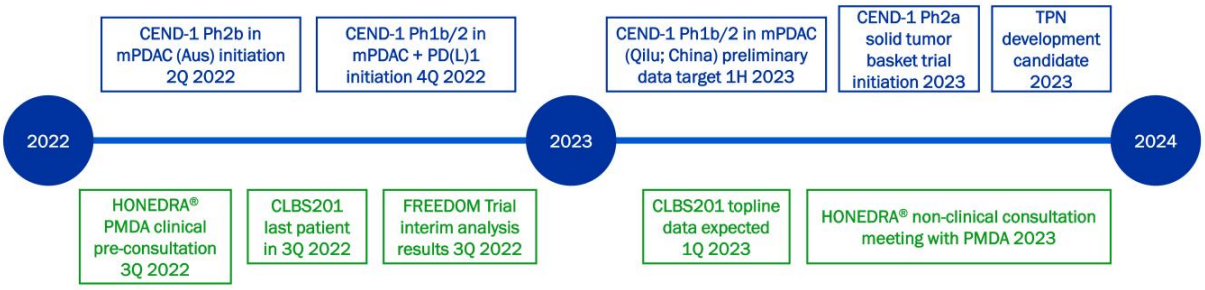
- CendR peptide binds to second receptor, Neuropilin-1, to activate CendR Pathway
- CendR Pathway enables bound and/or co-administered drugs to penetrate tumor converting stroma from barrier to conduit for anti-cancer therapies

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				
TPN development candidate	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

Caladrius investment highlights

- Pending merger with Cend Therapeutics, creating Lisata Therapeutics, which will be a financially sound publicly-traded company with clinical stage product candidates
- Combination of Caladrius and Cend platforms provides 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 [$88.5 million cash & investments (as of 3/31/2022) - 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

caladrius

BIOSCIENCES

Developing Innovative Therapies that Treat or Reverse Disease

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