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

May 5, 2022

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 05, 2022 (GLOBE NEWSWIRE) -- 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:

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- Tables to Follow -

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

	Three Months Ended Mar 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 (unaudited)		December 31, 2021
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