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

August 4, 2022

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

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

BASKING RIDGE, N.J., Aug. 04, 2022 (GLOBE NEWSWIRE) -- Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company"), a clinical-stage biopharmaceutical company developing innovative therapies designed to treat or reverse disease, today reported financial results for the three and six months ended June 30, 2022 and provided a business update.

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

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

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

Proposed Merger with Cend Therapeutics

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

Ongoing Development Portfolio Update

HONEDRA® (CLBS12) for the treatment of critical limb ischemia ("CLI")

HONEDRA® is the Company's SAKIGAKE-designated product candidate for the treatment of CLI and Buerger's disease in Japan which is now in the pre-consultation phase of the registration process with the Pharmaceuticals and Medical Devices Agency ("PMDA") in Japan. Data from the follow-up of all patients completed in the registration-eligible clinical trial in Japan has been compiled and will be reviewed by PMDA during the third quarter of 2022, after which the PMDA will provide important perspective to be considered in preparation for the formal consultation meetings which precede the Japanese new drug application. Concomitantly, the Company will focus its efforts to secure a Japanese partner to complete the remaining steps to produce registration in Japan.

XOWNA® (CLBS16) for the treatment of coronary microvascular dysfunction ("CMD")

XOWNA® is an experimental regenerative therapy for the treatment of CMD. It was the subject of a positive Phase 2a study (the "ESCaPE-CMD trial") reported in 2020 and is currently being evaluated in a U.S. Phase 2b study (the "FREEDOM Trial"). The FREEDOM Trial was originally designed as a 105-patient double-blind, randomized, placebo-controlled trial to further evaluate the efficacy and safety of intracoronary delivery of autologous CD34+ cells (XOWNA®) in subjects with CMD and without obstructive coronary artery disease and was expected to complete enrollment in approximately 12 months. As previously communicated, enrollment in the FREEDOM Trial initially proceeded as planned with the first patient treated in January 2021; however, the impact of the COVID-19 pandemic in the U.S., coupled with supply chain issues associated with the catheters used for diagnosis of CMD and/or administration of XOWNA®, as well as with a contrast agent typically used in many catheter laboratories, have made and continue to make

enrollment much slower than originally predicted and challenging to accelerate. As a result, and as previously disclosed, the Company has suspended further enrollment activities and is conducting an interim analysis of the data during the third quarter of 2022 to determine the next steps for the program, which may require a discussion with and guidance from FDA. The Company expects to have a decision on next steps for the program by the end of 2022.

CLBS201 for the treatment of diabetic kidney disease ("DKD")

Progressive kidney failure is associated with attrition of the microcirculation of the kidney. Preclinical studies in kidney disease and injury models have demonstrated that protection or replenishment of the microcirculation results in improved kidney function. Based on these observations, the Company recently initiated a Phase 1b, open-label, proof-of-concept trial evaluating CLBS201, a CD34+ regenerative cell therapy investigational product for intra-renal artery administration in patients with DKD. Patients selected for the study are in the pre-dialysis stage of kidney disease and exhibit rapidly progressing stage 3b disease. The protocol provides for a cohort of six patients overseen by an independent Data Safety Monitoring Board with the objective of determining the tolerance of intra-renal cell therapy injection in DKD patients as well as the ability of CLBS201 to regenerate kidney function. A key read-out of data will occur at the 6-month follow-up visit for all patients. The Company treated the first patient in April 2022 and completed treatment for all six subjects during the third quarter of 2022. Top-line data is anticipated from all subjects by the first quarter of 2023.

Second Quarter 2022 Financial Highlights

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

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

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

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

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

Balance Sheet Highlights

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

Conference Call Information

Caladrius will hold a live conference call today, August 4, 2022, at 4:30 p.m. (EDT) to discuss financial results, provide a business update and answer questions.

The Company is utilizing a new conference call service. Those wishing to participate must register for the conference call by way of the following link: CLICK HERE TO REGISTER. Registered participants will receive an email containing conference call details for dial-in options. To avoid delays, we encourage participants to dial into the conference call fifteen minutes ahead of the scheduled start time.

A live webcast of the call will also be accessible under the Investors & News section of the Caladrius website and will be available for replay beginning two hours after the conclusion of the call for 12 months.

About Caladrius Biosciences

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

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

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

Forward-Looking Statements

This communication contains “forward-looking statements” that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this communication regarding strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management are forward-looking statements. In addition, when or if used in this communication, the words “may,” “could,” “should,” “anticipate,” “believe,” “estimate,” “expect,” “intend,” “plan,” “predict”, “see” and similar expressions and their variants, as they relate to Caladrius, Cend or the management of either company, before or after the aforementioned merger, may identify forward-looking statements. Examples of forward-looking statements include, but are not limited to, statements relating to the timing and completion of the proposed merger; Caladrius’ continued listing on the Nasdaq Capital Market until closing of the proposed merger; the combined company’s listing on the Nasdaq Capital Market after closing of the proposed merger; expectations regarding the capitalization, resources and ownership structure of the combined company; the approach Cend is taking to discover and develop novel therapeutics; the adequacy of the combined company’s capital to support its future operations and its ability to successfully initiate and complete clinical trials; the difficulty in predicting the time and cost of development of Cend’s product candidates; the nature, strategy and focus of the combined company; the executive and board structure of the combined company; and expectations regarding voting by Caladrius’ and Cend’s stockholders. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: the risk that the conditions to the closing of the transaction are not satisfied, including the failure to timely or at all obtain stockholder approval for the transaction; uncertainties as to the timing of the consummation of the transaction and the ability of each of Caladrius and Cend to consummate the transaction; risks related to Caladrius’ ability to correctly estimate its operating expenses and its expenses associated with the transaction; the ability of Caladrius or Cend to protect their respective intellectual property rights; unexpected costs, charges or expenses resulting from the transaction; potential adverse reactions or changes to business relationships resulting from the announcement or completion of the transaction; and legislative, regulatory, political and economic developments. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in Caladrius’ Annual Report on Form 10-K filed with the SEC on March 22, 2022. Caladrius can give no assurance that the conditions to the transaction will be satisfied. Except as required by applicable law, Caladrius undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

No Offer or Solicitation

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

Important Additional Information Will be Filed with the SEC

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

Participants in the Solicitation

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

Contact:

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

- Tables to Follow –

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

	Three Months Ended Jun 30,		Six Months Ended Jun 30,	
	2022	2021	2022	2021
(in thousands, except per share data)	(unaudited)	(unaudited)	(unaudited)	(unaudited)

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

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