Caladrius Biosciences Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Business Update

March 22, 2022

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

BASKING RIDGE, N.J., March 22, 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, provides a business update and reports financial results for the three and twelve months ended December 31, 2021.

"Caladrius made significant progress in 2021 that we believe has positioned us well to achieve several important milestones in 2022," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius. "Highlights from 2021 include the initiation of our ongoing Phase 2b FREEDOM Trial of XOWNA® for the treatment of coronary microvascular dysfunction; the appointment of Kristen K. Buck, M.D., as Executive Vice President of Research & Development and Chief Medical Officer; and the strengthening of our balance sheet with approximately $95 million in capital that will serve as a foundation for our next phase of growth. The Company remains focused on refining and executing its development plans in 2022 and is already off to a strong start with the initiation of our Phase 1 study of CLBS201 in diabetic kidney disease where we anticipate the first patient to be treated early in the second quarter. In parallel, the Company continues to identify and evaluate strategic development opportunities with the aim of consummating transactions that will deliver additional value to our shareholders beyond our current development pipeline."

Product Development and Financing Highlights

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. As discussed in previous quarters, enrollment in the ongoing registration-eligible trial has been severely impeded by the multiple states of emergency declared by the Japanese government during 2020 and 2021 as a result of the COVID-19 pandemic. This has made even incremental enrollment exceedingly challenging. Since the trial continues to demonstrate positive trends in both safety and efficacy, the key criteria for consideration of conditional approval in Japan under the SAKIGAKE designation, the Company suspended enrollment and turned its focus to securing a Japanese partner either to 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 has had numerous conversations with the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan regarding the best path forward and anticipates having clarity on next steps during the second quarter of 2022.

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. has contributed to a general slowing of enrollment that continues to this day. 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. At this time, the Company is unable to give guidance on when enrollment will be completed but expects the study to run into 2023, if continued as planned. Final data from the study is expected approximately six months after last patient/last visit in the study. Caladrius continues to monitor the progress of the study and will consider additional future protocol and/or execution changes, as appropriate, to accelerate completion.

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

Progressive kidney failure is associated with attrition of the microcirculation of the kidney. Pre-clinical studies in kidney disease and injury models have demonstrated that protection or replenishment of the microcirculation results in improved kidney function. 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. Although still in the pre-dialysis stage of kidney disease, the selected patients 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 (DSMB) 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 Company anticipates the first patient to be treated in this study early in the second quarter of 2022 with top-line data from all subjects expected by the first quarter of 2023.

Fourth Quarter and Full Year 2021 Financial Highlights

Research and development expenses for the fourth quarter of 2021 were $4.2 million, a 43% increase compared with $2.9 million for the fourth quarter of 2020, and $17.7 million for the year ended December 31, 2021 compared to $9.3 million for the year ended December 31, 2020, representing an increase of approximately 91%. Research and development activities in both the current year and prior year periods 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 1 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 maintenance of manufacturing facility and personnel qualification as well as Contract Research Organization engagement despite no subject treatment execution due to the COVID-19 imposed state of emergency in Japan.

General and administrative expenses, which focus on general corporate related activities, were $2.7 million for the three months ended December 31, 2021, representing an increase of 6% compared to $2.5 million for the three months ended December 31, 2020, and $11.4 million for the year ended December 31, 2021, representing an increase of 15% compared to $9.9 million for the year ended December 31, 2020. This increase was primarily due to an increase in directors and officers liability insurance premiums and strategic consulting expenses.

Overall, net losses were $27.5 million and $8.1 million for the years ended December 31, 2021, and 2020, respectively.

Balance Sheet Highlights

As of December 31, 2021, we had cash, cash equivalents and marketable securities of approximately $95.0 million. Based on existing development programs, the Company projects that its current cash balance will fund operations for the next several years. Based on this favorable cash position, the Company will continue its concerted efforts to identify and acquire additional development assets to diversify its portfolio of product candidates and to enhance the opportunity for shareholder value creation.

Conference Call

Caladrius will hold a live conference call today March 22, 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: 5066195
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 March 29, 2022, by dialing 855-859-2056 (U.S. Toll-Free) or 404-537-3406 (International) and by entering the replay passcode: 5066195.

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.

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 our pipeline of development product candidates; 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. Factors that could cause future results to differ materially from the recent results or those projected in forward-looking statements include 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.

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- Tables to Follow -

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

	Three Months Ended Dec 31,		Twelve Months Ended Dec 31,	
	2021	2020	2021	2020
(in thousands, except per share data)	(unaudited)	(unaudited)		
Statement of Operations Data:				
Research and development	$ 4,150	$ 2,907	$ 17,680	$ 9,253
General and administrative	2,699	2,539	11,370	9,892
Total operating expenses	**6,849**	**5,446**	**29,050**	**19,145**
Operating loss	**(6,849)**	**(5,446)**	**(29,050)**	**(19,145)**
Investment income, net	40	15	151	132
Other expense, net	15	-	(75)	-
Net loss before benefit from income taxes and noncontrolling interests	**(6,794)**	**(5,431)**	**(28,974)**	**(19,013)**
Benefit from income taxes	-	-	(1,508)	(10,872)
Net loss	**(6,794)**	**(5,431)**	**(27,466)**	**(8,141)**
Less - net (loss) income attributable to noncontrolling interests	-	(1)	-	9
Net loss attributable to Caladrius Biosciences, Inc. common stockholders	**$ (6,794)**	**$ (5,430)**	**$ (27,466)**	**$ (8,150)**
Basic and diluted loss per share attributable to Caladrius Biosciences, Inc. common stockholders	**$ (0.11)**	**$ (0.28)**	**$ (0.50)**	**$ (0.53)**
Weighted average common shares outstanding	**59,775**	**19,396**	**55,313**	**15,440**

	December 31, 2021	December 31, 2020
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 94,970	$ 34,573
Total assets	97,008	36,002
Total liabilities	5,008	3,760
Total equity	92,000	32,242