Caladrius Biosciences Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Business Update

February 25, 2021

Company demonstrates resilience despite COVID-19 challenges: Financial situation secure and development programs progressing

Conference call begins today at 4:30 p.m. (ET)

BASKING RIDGE, N.J., Feb. 25, 2021 (GLOBE NEWSWIRE) -- Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company"), a clinical-stage biopharmaceutical company dedicated to the development of cellular therapies designed to reverse disease, provides a corporate update and reports financial results for the three and twelve months ended December 31, 2020.

"Despite the continued headwinds of the global pandemic, we are pleased to report continued progress of our development programs as well as an improved financial situation during the fourth quarter and full year of 2020, which reflect the resiliency, creativity and strength of our team and the growing optimism associated with our CD34+ cell technology-based clinical programs," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius. "We ended 2020 in a strong financial and strategic position and have set the stage for key clinical enrollment milestones this year.

"Importantly, we have continued the operational momentum into 2021 with an even further strengthened balance sheet, giving us the confidence and means to expand program development and execute on our business priorities," Dr. Mazzo concluded.

Product Development and Financing Highlights

CLBS16 for the treatment of coronary microvascular dysfunction

Caladrius reported in May 2020 the compelling positive results of its ESCaPE-CMD Phase 2a study of CLBS16 for the treatment of coronary microvascular dysfunction ("CMD"), a disease that continues to be underdiagnosed and potentially afflicts millions annually - a vast majority of whom are female - with no current treatment options. The Company is committed to raising awareness of this growing women's health crisis and finding an effective treatment for it. Consequently, Caladrius recently initiated a rigorous 105-subject Phase 2b clinical trial (the FREEDOM trial), which, to our knowledge, is the first controlled regenerative medicine trial in CMD, and, which is currently recruiting and treating patients and is targeted to complete enrollment by the end of 2021 with top line data anticipated for the third quarter of 2022. This double-blind, randomized, placebo-controlled Phase 2b trial will evaluate the efficacy and safety of delivering autologous CD34+ cells in subjects with CMD and without obstructive coronary artery disease. In support of the FREEDOM trial, the Company is engaging with the American Heart Association for a variety of initiatives around Heart Health Month (February) and the "Go Red for Women" campaign to help raise awareness of CMD.

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

The Company's open-label, registration-eligible study of SAKIGAKE-designated HONEDRA® in Japan for the treatment of critical limb ischemia ("CLI") and Buerger's Disease (an orphan-sized subset of CLI) has shown strong results to date. The initial responses observed in the subjects who have reached an endpoint in this study are consistent with a therapeutic effect and safety profile reported by previously published clinical trials in Japan and the USA. Although the study's enrollment has been slowed by the pandemic's impact in Japan, the Company is encouraged by the patient pre-screening pipeline and hopes to conclude trial enrollment during the second quarter of 2021. While the final outcome of the trial will depend on all data from all subjects, the data to date is very encouraging (~60% of subjects in the completed Buerger's Disease cohort have reached a positive "CLI-free" endpoint, despite a natural history of such patients predicting continuing disease progression to amputation).

CLBS201 for the treatment of pre-dialysis chronic kidney disease

Our most recently proposed development program, CLBS201, is designed to assess the safety and efficacy of CD34+ cell therapy as a treatment for chronic kidney disease ("CKD") in patients not yet requiring dialysis. Based on a wealth of published preclinical and early clinical data, it appears that the innate ability of CD34+ cells to promote the growth of new microvasculature could be a means to attenuate the progression of the disease or even reverse the course of CKD. Caladrius plans to file an IND for this program in the second quarter of 2021 and to initiate a Phase 1/2 proof-of-concept study of CLBS201 in a moderate to severe CKD population shortly thereafter. Chronic Kidney Disease remains a largely unmet medical need, especially as the general population ages and the incidence of diabetes and hypertension increases.

OLOGO™ for the treatment of no option refractory disabling angina ("NORDA")

We acquired the rights to data and regulatory filings for a CD34+ cell therapy program for NORDA that had been advanced to Phase 3 by a previous sponsor. Based on the clinical evidence from the completed studies that a single administration of OLOGO™ reduces mortality, improves angina and increases exercise capacity in patients with otherwise untreatable angina, this product received Regenerative Medicine Advanced Therapy ("RMAT") designation from the FDA. We remain in discussion with the FDA regarding the size and scope of a phase 3 trial which, in combination with previously filed Phase 1, 2 and 3 data, will be considered for the registration of OLOGO™. Notably, the RMAT designation affords the product a 6-month review time for a biologics license application ("BLA"), once submitted.

Closed on an additional $90.0 million in funding

In January 2021, the Company announced that it had closed on a $25.0 million capital raise through the sale of its common stock to several institutional and accredited investors in a private placement priced at-the-market under Nasdaq rules. In February 2021, the Company announced that

it closed a $65.0 million capital raise through the sale of its common stock to several institutional and accredited investors in two registered direct offerings priced at-the-market under Nasdaq rules.

Fourth Quarter and Full Year 2020 Financial Highlights

Research and development expenses for the fourth quarter of 2020 were $2.9 million, a 5% increase compared with $2.8 million for the fourth quarter of 2019, and $9.3 million for the year ended December 31, 2020 compared to $10.8 million for the year ended December 31, 2019, representing a decrease of approximately 14%. Research and development in both the current year and prior year periods focused on the advancement of our ischemic repair platform and related to:

- Expenses associated with exploration of our concept program, CLBS119, a CD34+ cell therapy for repair of COVID-19 induced lung damage targeting patients with severe SARS-CoV-2 infection that required ventilatory support due to respiratory failure (this program has since been indefinitely postponed due to the continuous evolution of the targeted patient population);
- Ongoing expenses for HONEDRA® in critical limb ischemia in Japan, whereby we continue to focus spending on patient enrollment and Japanese NDA preparation (enrollment completion is now targeted for 2Q21 based on the impact of the COVID-19 pandemic in Japan);
- Expenses associated with the proof-of-concept study for CLBS16 in coronary microvascular dysfunction, for which study enrollment was completed in the second quarter of 2019 and full results reported in May 2020 and continuing efforts to advance CLBS16 into a Phase 2b study (the FREEDOM trial) in the second half of 2020; and
- Expenses associated with the ongoing dialogue with FDA regarding design and execution of confirmatory Phase 3 study of OLOGO™ in NORDA.

General and administrative expenses, which focus on general corporate related activities, were $2.5 million for the three months ended December 31, 2020, compared to $2.3 million for the three months ended December 31, 2019, and $9.9 million for the year ended December 31, 2020, compared to $9.3 million for the year ended December 31, 2019, representing an increase of 6%.

Overall, net losses were $8.1 million and $19.4 million for the years ended December 31, 2020 and 2019, respectively.

Balance Sheet Highlights

As of December 31, 2020, Caladrius had cash, cash equivalents and marketable securities of $34.6 million and, following the previously mentioned capital raises in January and February 2021, the Company has cash, cash equivalents and marketable securities of approximately $116 million as of February 25, 2021. Based on existing programs and projections, the Company remains confident that its current cash balances will fund its operations for the next several years, notably, through study completion for the Phase 2b for CLBS16, through the registration-eligible study completion for HONEDRA® and through the Phase 1/2 Proof-of-Concept study for CLBS201 while still providing capital to explore additional pipeline expansion opportunities.

Conference Call

Caladrius will hold a conference call on Thursday, February 25, 2021, at 4:30 p.m. Eastern time to discuss the financial results, provide a business update and answer questions. To join the conference call, please refer to the dial-in information provided below. The conference call will also be webcast live under the Investors section on the Company's website at www.caladrius.com.

Dial-in information:
U.S. Toll-Free: 866-595-8403
International: 706-758-9979
Conference ID / Passcode: 7372695

Please dial-in at least 10 minutes before the conference call starts.

For those unable to participate in the live conference call, an audio replay will be available approximately two hours after the call has concluded until March 4, 2021, by dialing 855-859-2056 (domestic) or 404-537-3406 (international) and referencing conference ID / passcode: 7372695. A webcast recording of the call will also be archived for 90 days under the Investors section of the Company's website at www.caladrius.com.

About Caladrius Biosciences

Caladrius Biosciences, Inc. is a clinical-stage biopharmaceutical company dedicated to the development of cellular therapies designed to reverse disease. We are developing first-in-class 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: CLBS16, the subject of both a recently completed positive Phase 2a study and a newly initiated Phase 2b study in the U.S. for the treatment of coronary microvascular dysfunction ("CMD"); HONEDRA® (CLBS12), recipient of SAKIGAKE designation and eligible for early conditional approval in Japan for the treatment of critical limb ischemia ("CLI") and Buerger's Disease based on the results of an ongoing clinical trial; CLBS201, designed to assess the safety and efficacy of CD34+ cell therapy as a treatment for chronic kidney disease ("CKD") and OLOGO™ (CLBS14), a Regenerative Medicine Advanced Therapy ("RMAT") designated therapy for which the Company is in discussion with the U.S. Food and Drug Administration (the "FDA") to finalize a Phase 3 protocol of reduced size and scope for a confirmatory trial in subjects with no-option refractory disabling angina ("NORDA"). 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, all statements related to the completion of the private placement, the satisfaction of customary closing conditions related to the private placement and the intended use of net proceeds from the private placement as well as 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 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 5, 2020 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: +1-908-842-0084
Email: jmenditto@caladrius.com

Media:
W2O Group
Christiana Pascale
Phone: +1-212-257-6722
Email: cpascale@w2ogroup.com

- 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,	
	2020	2019	2020	2019
(in thousands, except per share data)	(unaudited)	(unaudited)		
Statement of Operations Data:				
Research and development	$ 2,907	$ 2,767	$ 9,253	$ 10,797
General and administrative	2,539	2,316	9,892	9,295
Total operating expenses	**5,446**	**5,083**	**19,145**	**20,092**
Operating loss	**(5,446)**	**(5,083)**	**(19,145)**	**(20,092)**
Investment income, net	15	129	132	740
Net loss before benefit from income taxes and noncontrolling interests	**(5,431)**	**(4,954)**	**(19,013)**	**(19,352)**
Benefit from income taxes	-	-	(10,872)	-
Net loss	**(5,431)**	**(4,954)**	**(8,141)**	**(19,352)**
Less - net (loss) income attributable to noncontrolling interests	(1)	3	9	9
Net loss attributable to Caladrius Biosciences, Inc. common shareholders	**$ (5,430)**	**$ (4,957)**	**$ (8,150)**	**$ (19,361)**
Basic and diluted loss per share attributable to Caladrius Biosciences, Inc. common shareholders	**$ (0.28)**	**$ (0.47)**	**$ (0.53)**	**$ (1.88)**
Weighted average common shares outstanding	**19,396**	**10,460**	**15,440**	**10,325**

	December 31, 2020	December 31, 2019
Balance Sheet Data:		

Cash, cash equivalents and marketable securities	$ 34,573	$ 25,157
Total assets	36,002	27,153
Total liabilities	3,760	6,600
Total equity	32,242	20,553

Source: Caladrius Biosciences, Inc.