



Caladrius Biosciences Reports First Quarter 2021 Financial Results and Provides Business Update

May 6, 2021

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

BASKING RIDGE, N.J., May 06, 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 months ended March 31, 2021.

"We are at a truly exciting point in our evolution with tremendous opportunities ahead of us. While the pandemic has impacted many companies, during the first quarter of 2021 we were able to both markedly strengthen our financial position and advance and expand our clinical pipeline," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius. To date, we are seeing good progress with site activation for our Phase 2b clinical trial of CLBS16 in the U.S., known as the FREEDOM Trial, for the treatment of coronary microvascular dysfunction as we continue to accelerate enrollment. Additionally, we remain optimistic that we soon will complete enrollment in our registration-eligible study of HONEDRA® in critical limb ischemia and Buerger's disease in Japan. However, enrollment for this program has been greatly impacted by the Japanese government-issued states of emergency tied to the pandemic. Lastly, we are working with the U.S. Food and Drug Administration ("FDA") to finalize the protocol design for our CLBS201 proof-of-concept study in diabetic kidney disease and have targeted initiation of that Phase 2 study in the third quarter of 2021."

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. Caladrius recently initiated, and is currently treating patients in, a rigorous 105-subject Phase 2b clinical trial (the FREEDOM Trial), which to our knowledge, is the first controlled regenerative medicine trial in CMD. The trial 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 to the hearts of subjects with 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 U.S. The study's enrollment continues to be slowed by the pandemic's impact in Japan, however, the Company is encouraged by the patient pre-screening pipeline and continues to make progress towards study completion, the exact date of which is impossible to predict given the continuing impact of COVID-19 on clinical trials in Japan. 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 that predicts continuing disease progression to amputation). In the U.S., the Company was pleased to report that the FDA granted orphan designation to CLBS12 as a treatment for Buerger's disease.

CLBS201 for the treatment of diabetic kidney disease

The Company's most recently proposed development program, CLBS201, is designed to assess the safety and efficacy of CD34+ cell therapy as a treatment for diabetic kidney disease 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 diabetic kidney disease. A Phase 2 proof of concept, randomized, placebo-controlled study is planned for initiation in the second half of 2021.

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

Caladrius 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. Caladrius remains in ongoing discussions with the FDA regarding the size and scope of an appropriate and practical 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.

Sufficient capital to fund operations beyond multiple key data readouts (>2023)

As previously disclosed, in January 2021, Caladrius raised \$25.0 million 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.

First Quarter 2021 Financial Summary

Research and development expenses for the three months ended March 31, 2021 were \$5.1 million, compared to \$1.5 million for the three months ended March 31, 2020. Research and development in the current year period focused on the advancement of our ischemic repair platform and related to:

- Ongoing expenses for HONEDRA® in critical limb ischemia and Buerger's disease in Japan for which we continue to focus spending on patient enrollment and Japanese NDA preparation; and
- Expenses associated with efforts to advance the FREEDOM Trial where the first patient was dosed in the first quarter of 2021; and
- Expenses associated with the planning and preparation of an IND and proof-of-concept protocol for CLBS201 as a treatment for diabetic kidney disease.

General and administrative expenses, which focus on general corporate related activities, were \$3.0 million for the three months ended March 31, 2021 compared to \$2.6 million for the three months ended March 31, 2020, representing an increase of 18%.

Overall, net losses were \$8.1 million and \$4.0 million for the years ended March 31, 2021 and 2020, respectively.

Balance Sheet Highlights

As of March 31, 2021, Caladrius had cash, cash equivalents and marketable securities of approximately \$111.5 million. 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 FREEDOM Trial, through the registration-eligible study completion for HONEDRA® and through the Phase 2 proof-of-concept study for CLBS201, while still providing capital to explore additional pipeline expansion opportunities.

Conference Call

Caladrius will hold a live conference call today, May 6, 2021, 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 "Events" in the Investors section of the Caladrius website, <https://www.caladrius.com/investors>, and will be available for replay for 90 days after the conclusion of the call.

Dial-in information:

U.S. Toll-Free: 866-595-8403

International: 706-758-9979

Conference ID / Access code: 6892792

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

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 13, 2021, by dialing 855-859-2056 (North America) or 404-537-3406 (International) and by entering the access code: 6892792.

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 orphan designation for Buerger's disease in the U.S. as well as 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 diabetic kidney disease; and OLOGO™ (CLBS14), a Regenerative Medicine Advanced Therapy ("RMAT") designated therapy for which the Company is in discussion with the FDA to finalize a Phase 3 protocol of appropriate and practical 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 February 25, 2021 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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Caladrius Biosciences, Inc.
Selected Financial Data
 (in thousands, except per share data)

	Three Months Ended Mar 31,	
	2021	2020
(in thousands, except per share data)	(unaudited)	(unaudited)
Statement of Operations Data:		
Research and development	\$ 5,076	\$ 1,499
General and administrative	3,010	2,558
Total operating expenses	8,086	4,057
Operating loss	(8,086)	(4,057)
Investment income, net	23	71
Net loss	(8,063)	(3,986)
Less - net income attributable to noncontrolling interests	-	4
Net loss attributable to Caladrius Biosciences, Inc. common stockholders	\$ (8,063)	\$ (3,990)
Basic and diluted loss per share attributable to Caladrius Biosciences, Inc. common stockholders	\$ (0.19)	\$ (0.38)
Weighted average common shares outstanding	42,117	10,623

	March 31, 2021	December 31, 2020
	(unaudited)	
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	\$ 111,511	\$ 34,573
Total assets	114,607	36,002
Total liabilities	4,593	3,760
Total equity	110,014	32,242



Source: Caladrius Biosciences, Inc.