Caladrius Biosciences Provides Corporate Update and Reports 2021 Third Quarter Financial Results

November 4, 2021

Company Reports Strong Cash Position as it Prepares to Initiate a CD34+ Cell Therapy Study in Diabetic Kidney Disease

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

BASKING RIDGE, N.J., Nov. 04, 2021 (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 corporate update and reports financial results for the three and nine months ended September 30, 2021.

"Caladrius continued to advance and optimize its development programs in the third quarter despite the ongoing challenges to clinical development posed by the global COVID-19 pandemic. A cash position of approximately $100 million, coupled with continued prudent cash management, enabled the Company to focus on refining and executing its development plans while identifying and evaluating attractive strategic corporate development opportunities," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius. "Additionally, Caladrius strengthened and further diversified its operations and management team with the addition of several highly qualified and experienced personnel, including the appointment of veteran drug developer, Kristen K. Buck, M.D., as Executive VP of R&D and Chief Medical Officer. Dr. Buck will play a key role in defining, optimizing, and implementing development strategies that maximize the probability of clinical and commercial success of existing programs. She will also contribute to one of our corporate priorities of adding promising new assets to our development portfolio by leading our technical evaluation efforts."

Product Development and Financing Highlights

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

With respect to HONEDRA®, the Company's SAKIGAKE-designated product candidate for the treatment of CLI and Buerger's disease in Japan, the headwinds to enrollment in the ongoing registration-eligible trial, as discussed in prior quarters, have persisted. The multiple states of emergency declared by the Japanese government over the past 18 months due to the COVID-19 pandemic have made incremental enrollment exceedingly challenging, prompting Caladrius to consider alternate approaches to achieving development success. 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 has decided to suspend enrollment activities in favor of focusing efforts in Japan on securing a partner to complete study enrollment with four remaining patients, if necessary, and/or to explore the possibility of submitting the existing data to the Japanese Regulatory Authorities under the SAKIGAKE designation. This decision is 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.

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 recently reported positive Phase 2a study (the "ESCaPE-CMD trial") and is currently being evaluated in a U.S. Phase 2b study (the "FREEDOM Trial"). The FREEDOM Trial is a double-blind, randomized, placebo-controlled trial designed to assess the efficacy and safety of delivering autologous CD34+ cells (XOWNA®) to subjects with CMD and without obstructive coronary artery disease. Early enrollment in the FREEDOM Trial proceeded as planned with the first patient treated in January 2021, however, the impact of the COVID-19 pandemic in the U.S. since then has contributed to a general slowing of enrollment. Caladrius has taken steps to accelerate enrollment by expanding the number of participating investigational sites and modifying the study protocol. These protocol amendments were implemented in the latter part of the quarter after agreement with the U.S. Food and Drug Administration, and we will assess their impact on enrollment in the coming months, at which time the Company expects to be in a better position to provide an informed estimate for enrollment feasibility and completion. Final data from the study are expected approximately 6 months after last patient/last visit in the study.

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 plans to initiate 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 pre-dialysis, these patients exhibit rapidly progressing stage 3b disease. The protocol, pending final approval from the Institutional Review Board, will be 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 and 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 projects enrollment of this study to begin in the first quarter of 2022 with data from all subjects expected by the first quarter of 2023.

Third Quarter 2021 Financial Summary

Research and development expenses were approximately $4.1 million for the three months ended September 30, 2021, compared to $3.0 million for the three months ended September 30, 2020, representing an increase of 36%. Research and development in both 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 and preparation of an IND and Phase 1 proof-of-concept protocol 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 were approximately $2.8 million for the three months ended September 30, 2021, compared to $2.3 million for the three months ended September 30, 2020, representing an increase of 22%. This increase was primarily due to an increase in directors and officers insurance premiums and strategic consulting expenses.

Overall, net losses were $6.9 million for the three months ended September 30, 2021, compared to $5.3 million for the three months ended September 30, 2020.

Balance Sheet Highlights

As of September 30, 2021, we had cash, cash equivalents and marketable securities of approximately $100.1 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. Based on this favorable cash position, the Company continues its concerted efforts to identify and acquire additional development assets to diversify our portfolio of product candidates and to enhance the opportunity for near-term shareholder value creation.

Conference Call

Caladrius will hold a live conference call today, November 4, 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 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: 8378269
U.S. Toll-Free: 866-595-8403
International: 706-758-9979

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 November 11, 2021, by dialing 855-859-2056 (U.S. Toll-Free) or 404-537-3406 (International) and by entering the replay passcode: 8378269.

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 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: XOWNA ® (CLBS16), the subject of both a recently completed positive Phase 2a study and a newly initiated 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 orphan designation for Buerger's Disease in the U.S. and, in Japan, recipient of a SAKIGAKE designation and eligible for early conditional approval for the treatment of 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 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 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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- Tables to Follow -

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

	Three Months Ended Sept 30,		Nine Months Ended Sept 30,	
	2021	2020	2021	2020
(in thousands, except per share data)	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Statement of Operations Data:				
Research and development	$ 4,125	$ 3,029	$ 13,530	$ 6,346
General and administrative	2,843	2,321	8,671	7,353
Total operating expenses	**6,968**	**5,350**	**22,201**	**13,699**
Operating loss	**(6,968)**	**(5,350)**	**(22,201)**	**(13,699)**
Investment income, net	41	25	111	118
Other expense, net	-	-	(90)	-
Net loss before benefit from income taxes and noncontrolling interests	**(6,927)**	**(5,325)**	**(22,180)**	**(13,581)**
Benefit from income taxes	-	-	(1,508)	(10,872)
Net loss	**(6,927)**	**(5,325)**	**(20,672)**	**(2,709)**
Less - net income attributable to noncontrolling interests	-	2	-	10
Net loss attributable to Caladrius Biosciences, Inc. common stockholders	**$ (6,927)**	**$ (5,327)**	**$ (20,672)**	**$ (2,719)**
Basic and diluted loss per share attributable to Caladrius Biosciences, Inc. common stockholders	**$ (0.12)**	**$ (0.29)**	**$ (0.38)**	**$ (0.19)**
Weighted average common shares outstanding	**59,614**	**18,597**	**53,811**	**14,116**

	Sept 30, 2021	December 31, 2020
	(unaudited)	
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 100,149	$ 34,573
Total assets	102,538	36,002
Total liabilities	4,125	3,760
Total equity	98,413	32,242