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

August 5, 2021

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

BASKING RIDGE, N.J., Aug. 05, 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 six months ended June 30, 2021.

"The second quarter and first six months of 2021 have proven to be operationally and financially positive for Caladrius. Despite the continuing challenges presented by the COVID-19 pandemic, we continued to advance and expand our clinical pipeline while also adding a large amount of additional capital to our balance sheet," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius. "Most notably, we are seeing steady progress with site activation for our Phase 2b FREEDOM Trial of CLBS16 for the treatment of coronary microvascular dysfunction, as we continue to increase outreach activities to potential subjects in order to accelerate enrollment. In addition, a Phase 2 proof-of-concept clinical trial of CLBS201, designed to assess the safety and efficacy of CD34+ cell therapy as a treatment for patients with pre-dialysis diabetic kidney disease, is on track for a planned initiation in the second half of 2021. Lastly, even though our registration-eligible study of HONEDRA® in critical limb ischemia and Buerger's disease continues to be greatly impacted by the Japanese government-issued states of emergency tied to the COVID-19 pandemic, we have managed to treat patients and remain optimistic that the few remaining patients needed to complete enrollment will be treated by year end."

Product Development and Financing Highlights

CLBS16 for the treatment of coronary microvascular dysfunction

Caladrius reported in May 2020 the compelling 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. To this end, we have partnered with the American Heart Association on a number of activities designed to educate people about CMD and to encourage them to discuss the condition with their physician. 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.

Investigator and subject response to the FREEDOM Trial has been favorable and early enrollment proceeded according to plan. However, the continued impact of the COVID-19 pandemic, including the resurgence of cases occurring in select areas throughout the United States, has contributed to a general slowing of enrollment. In addition, further work with investigators and prospective subject feedback led the Company to propose to the FDA amendments to the FREEDOM Trial protocol to enhance the breadth and speed of subject enrollment. These changes included expanding the techniques that are acceptable for diagnosing CMD. Nevertheless, given the uncertainty that persists surrounding the future impact of the COVID-19 pandemic on potential patient recruitment and the accessibility of investigator sites, the Company now projects enrollment completion for the FREEDOM Trial to occur in the third quarter of 2022 with final data (based on the 6 month assessment of all subjects) expected by the second quarter of 2023.

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 positive therapeutic effect and safety profile reported by previously published clinical trials in Japan and the U.S. The study's enrollment continues to be almost stopped by the pandemic's impact in Japan, however, the Company is encouraged that less than a handful of patients are needed to reach 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 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 U.S. Food and Drug Administration ("FDA") granted orphan designation to CLBS12 as a treatment for Buerger's disease, however, any decisions regarding potential development in the U.S. will be made after further discussion with FDA on the requirements for registration.

CLBS201 for the treatment of diabetic kidney disease

The Company has prepared an initial development plan for the clinical study of CLBS201, a CD34+ investigational product for administration via the renal arteries to slow the deterioration, or, ideally, reverse the decline of renal function in patients with diabetic kidney disease ("DKD") who, although still pre-dialysis, exhibit rapidly progressing stage 3b disease. 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. A Phase 2 proof of concept, randomized, placebo-controlled study for the stage 3b chronic kidney disease patient population is planned to initiate in the second half of 2021. The protocol, pending final central institutional review board approval, calls for a six-subject open-label treatment run-in arm in which patients will be treated sequentially, to be completed, evaluated and cleared for continuation by the study's data safety monitoring board prior to initiating the 40-patient randomized, placebo-controlled, double blinded portion of the trial. The Company is projecting that safety data from the six-subject run-in arm will be completed by the end of the second quarter of 2022.

OLOGO™ for the treatment of no option refractory disabling angina

Caladrius acquired the rights to data and regulatory filings for a CD34+ cell therapy program for no option refractory disabling angina ("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. Discussions with the FDA have resulted in a rejection of the Company's efforts to reduce the FDA requirement of a 400-patient Phase 3 study for registration (including an arm of 50 standard of care patients and an arm of 150 placebo patients), despite data showing that the NORDA population is orphan in size. Because enrollment of a study of this magnitude and design is projected to take many years, if executable at all, the Company has decided not to pursue a Phase 3 program for OLOGO™ on its own, but will continue to seek a partner to execute the study and advance the program.

Sufficient capital to fund operations beyond multiple key data readouts anticipated in 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 and warrants to several institutional and accredited investors in two registered direct offerings priced at-the-market under Nasdaq rules. In addition, in May 2021, the Company received $1.4 million in non-dilutive funding as an approved participant of the Technology Business Tax Certificate Transfer Program (the "Program") sponsored by the New Jersey Economic Development Authority (NJEDA). The Program enables qualifying New Jersey-based biotechnology or technology companies to sell a percentage of their New Jersey net operating losses ("NOLs") and research and development tax credits to unrelated qualifying corporations.

Second Quarter 2021 Financial Summary

Research and development expenses were approximately $4.3 million for the three months ended June 30, 2021, compared to $1.8 million for the three months ended June 30, 2020, representing an increase of 138%. Research and development in both periods focused on the advancement of our ischemic repair platform and related to:

- Expenses associated with efforts to advance the FREEDOM Trial where the first patient was dosed in the first quarter of 2021;
- Expenses associated with the planning and preparation of an IND and Phase 2 proof-of-concept protocol for CLBS201 as a treatment for diabetic kidney disease; and
- 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.

General and administrative expenses were approximately $2.8 million for the three months ended June 30, 2021, compared to $2.5 million for the three months ended June 30, 2020, representing an increase of 14%.

Overall, net losses were $5.7 million for the three months ended June 30, 2021, compared to net income of $6.6 million for the three months ended June 30, 2020.

Balance Sheet Highlights

As of June 30, 2021, we had cash, cash equivalents and marketable securities of approximately $106.1 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, 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 potentially providing capital to explore additional pipeline expansion opportunities.

Conference Call

Caladrius will hold a live conference call today, August 5, 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:
U.S. Toll-Free: 844-369-8774
International: 862-298-0844

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 August 19, 2021, by dialing 877-481-4010 (U.S. Toll-Free) or 919-882-2331 (International) and by entering the replay passcode: 42180.

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 (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 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 (“DKD”); and OLOGO™ (CLBS14), a Regenerative Medicine Advanced Therapy (“RMAT”) designated phase 3 ready therapy for 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, 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 Jun 30,		Six Months Ended Jun 30,	
	2021	2020	2021	2020
(in thousands, except per share data)	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Statement of Operations Data:				
Research and development	$ 4,329	$ 1,818	$ 9,405	$ 3,317
General and administrative	2,818	2,474	5,828	5,032
Total operating expenses	**7,147**	**4,292**	**15,233**	**8,349**
Operating loss	**(7,147)**	**(4,292)**	**(15,233)**	**(8,349)**
Investment income, net	47	22	70	93
Other expense, net	(90)	-	(90)	-
Net loss before benefit from income taxes and noncontrolling interests	**(7,190)**	**(4,270)**	**(15,253)**	**(8,256)**
Benefit from income taxes	(1,508)	(10,872)	(1,508)	(10,872)
Net (loss) income	**(5,682)**	**6,602**	**(13,745)**	**2,616**
Less - net income attributable to noncontrolling interests	-	4	-	8
Net (loss) income attributable to Caladrius Biosciences, Inc. common stockholders	**$ (5,682)**	**$ 6,598**	**$ (13,745)**	**$ 2,608**
Basic and diluted (loss) income per share attributable to Caladrius Biosciences, Inc. common stockholders	**$ (0.10)**	**$ 0.50**	**$ (0.27)**	**$ 0.22**
Weighted average common shares outstanding	**59,510**	**13,151**	**50,862**	**11,880**

	June 30, 2021 (unaudited)	December 31, 2020
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 106,090	$ 34,573
Total assets	108,614	36,002
Total liabilities	3,935	3,760
Total equity	104,679	32,242