Caladrius Biosciences Provides Corporate Update and Reports 2020 Third Quarter Financial Results

November 5, 2020

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

BASKING RIDGE, N.J. (November 5, 2020) – 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 nine months ended September 30, 2020.

"Amid the continuing global impact of COVID-19, our team continues to rise to the occasion, addressing a multitude of challenges tied to the pandemic," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius. "To date in 2020, we have extended our cash runway through the end of 2021, while continuing to deliver on a number of key initiatives in support of our clinical programs including the initiation of our study of CLBS119 for the treatment of COVID-19 induced lung damage and finalizing preparations for the start to our newly-named Phase 2b FREEDOM Study of CLBS16 in coronary microvascular dysfunction."

"We are excited about what lies ahead in 2020 and expect to build on this momentum as we continue to advance our clinical development pipeline and strive to achieve a number of important development milestones throughout the balance of the year," concluded Dr. Mazzo.

Product Development and Financing Highlights

HONEDRA® (formerly CLBS12) development in Japan continues to progress

The Company's open-label, registration-eligible study in Japan of HONEDRA® (formerly CLBS12), continues to progress toward enrollment completion, although enrollment has been slowed by the impact of the COVID-19 pandemic in Japan. HONEDRA® is a SAKIGAKE-designated product candidate for the treatment of critical limb ischemia ("CLI"); a disease with limited treatment options – most of which have minimal impact – and a higher combined incidence and mortality rate than all cancers but lung cancer. As previously reported, the Buerger's Disease (an "orphan-sized" type of CLI) cohort has concluded with 4 out of 7 (~60%) patients achieving a positive outcome, an outstandingly positive result for these patients who normally see continued progression leading to amputation. The Company remains encouraged by the patient pre-screening pipeline that has been identified for the arteriosclerosis obliterans ("ASO") cohort, which is the primary arm of the study, and anticipates trial enrollment to conclude in the first quarter of 2021, leading to top line data for the full study in late 2021 or early 2022.

CLBS14 remains poised to enter a single confirmatory phase 3 clinical trial

The Company's Phase 3 protocol for its RMAT-designated product candidate, CLBS14, for the treatment of no-option refractory angina ("NORDA") remains ready to initiate pending sufficient funding to run the program to completion. Based on an abundance of very strong data from previous Phase 1, 2, and 3 studies, Caladrius remains confident in the potential for clinical success once the program is executed.

CLBS16 to be studied in Phase 2b trial for the treatment of coronary microvascular dysfunction

Caladrius recently completed and announced the 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. Data from the Phase 2a trial showed a positive therapeutic effect with a statistically significant improvement in angina frequency, coronary flow reserve, Canadian Cardiovascular Society Angina Class and Seattle Questionnaire score, as well as an acceptable safety profile. The Company is committed to raising awareness of this growing women's health crisis and plans to initiate a rigorous Phase 2b FREEDOM trial, with the first patient expected to be enrolled by the end of 2020. The double-blind, randomized, placebo-controlled Phase 2b trial will evaluate the efficacy and safety of delivering autologous CD34+ cells (CLBS16) in subjects with CMD and without obstructive coronary artery disease.

CLBS119 for the repair of COVID-19-induced lung damage in COVID-19 survivors

Caladrius is committed to helping patients and communities combat the public health crisis of COVID-19 by leveraging its proprietary CD34+ cell technology to potentially repair COVID-19-induced lung damage. COVID-19 appears to damage the vasculature of the lungs and Caladrius believes the repair of that vasculature will prove necessary for patients to achieve a full recovery. Experience to date indicates that a large portion of COVID-19 survivors who required ventilatory support will suffer long-term, debilitating lung damage. While many developmental therapies responding to the COVID-19 pandemic are appropriately targeting the SARS-CoV-2 virus itself, or the manifestations of the acute phase of the illness, Caladrius is unaware of a therapy that has demonstrated the ability to repair COVID-19-induced lung damage. With consistent clinical and pre-clinical evidence that CD34+ cells can repair multiple organs, including models of severe lung inflammation, the Company sought and received FDA authorization for its investigational new drug ("IND") application for the study of CLBS119, a CD34+ cell therapy for the repair of COVID-19-induced lung damage. The planned 10-12-patient open-label, proof-of-concept clinical trial, is designed to evaluate the safety and efficacy of a single administration of CLBS119 for the treatment and repair of COVID-19-induced lung damage in adults. The study was recently initiated and patients who are experiencing hypoxia due to prior infection with SARS-CoV-2 and who require supplemental oxygen are now being screened for participation at NYU Langone Health.

Secures new capital to support cash runway through the end of 2021

As previously disclosed, in July 2020, Caladrius raised $2.0 million in a private placement priced at the market under Nasdaq rules. Caladrius has now successfully raised approximately $30 million in net proceeds year-to-date in 2020.

Third Quarter 2020 Financial Highlights

Research and development expenses were approximately $3.0 million for both the three months ended September 30, 2020 and the three months ended September 30, 2019. Research and development in both periods focused on the advancement of our ischemic repair platform. More specifically, R&D expense comprised (i) costs associated with investigational new drug application and planning for commencement of a pilot study of CLBS119, (ii) execution expenses for our ongoing registration-eligible study for CLBS12 in critical limb ischemia in Japan, and (iii) expenses for both the completion of our ESCaPE-CMD study of CLBS16 in coronary microvascular dysfunction and planning for the follow on Phase 2b study.

General and administrative expenses were approximately $2.3 million for the three months ended September 30, 2020, compared to $2.1 million for the three months ended September 30, 2019, representing an increase of 12%.

Overall, net losses were $5.3 million for the three months ended September 30, 2020, compared to $4.9 million for the three months ended September 30, 2019.

Balance Sheet Highlights

As of September 30, 2020, Caladrius had cash, cash equivalents and marketable securities of $40.3 million. Based on existing programs and projections, the Company remains confident that its current cash balances will fund its operations through 2021.

Conference Call

Caladrius will hold a conference call on Thursday, November 5, 2020, at 4:30 p.m. ET 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: +1-833-467-0024
International: 469-333-9553
Conference ID / Passcode: 5872349

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

For those unable to participate in the live conference call, a replay will be accessible approximately two hours after the call has concluded until November 12, 2020, by dialing 855-859-2056 (domestic) or 404-537-3406 (international) and referencing conference ID/passcode: 5872349. A webcast audio 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: HONEDRA® (formerly CLBS12), recipient of SAKIGAKE designation and eligible for early conditional approval in Japan for the treatment of critical limb ischemia ("CLI") based on the results of an ongoing clinical trial; CLBS14, a Regenerative Medicine Advanced Therapy ("RMAT") designated therapy for which the Company has finalized with the U.S. Food and Drug Administration (the "FDA") a protocol for a Phase 3 confirmatory trial in subjects with no-option refractory disabling angina ("NORDA"); CLBS16, the subject of a recently completed positive Phase 2a clinical trial in the U.S. for the treatment of coronary microvascular dysfunction ("CMD"); and CLBS119, an emergent CD34+ stem cell therapy responding to the COVID-19 pandemic and the potentially permanent damage the virus inflicts on the lungs of many patients. 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 intended use of net proceeds from financings 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; 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.

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– Tables to Follow –

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