Caladrius Biosciences Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Business Update

March 5, 2020

CLBS16 ESCaPE-CMD data presented at American Heart Association 2019 Scientific Sessions demonstrated highly statistically significant improvement in coronary flow reserve and angina symptoms

CLBS12 registration eligible trial in Japan targeted to complete enrollment in 1H2020; Data to date continues to corroborate previously published positive results

CLBS14 is poised to commence a single confirmatory phase 3 study as agreed with FDA pending finalization of funding

Existing capital provides runway through 2Q 2021

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

BASKING RIDGE, N.J. (March 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, not manage, cardiovascular disease, announces financial results for the three and twelve months ended December 31, 2019.

"I am pleased with the Company's many achievements throughout 2019 as we made significant progress advancing our CD34+ technology-based clinical programs while maintaining strict financial controls," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius. "Notably, in November at the American Heart Association Scientific Sessions 2019, we reported the data for those patients (17 of 20) who, at that time, had completed their six-month follow-up visit in our ESCaPE-CMD study of CLBS16. The results showed highly statistically significant improvement in coronary flow reserve ("CFR") correlating with angina symptom relief for patients with coronary microvascular dysfunction ("CMD") after a single administration of CLBS16. To our knowledge, this is the first therapy to show the ability to durably increase CFR and potentially reverse CMD after a single administration. We look forward to reporting the full study data in the first half of 2020 in an appropriate forum. In Japan, enrollment continues to progress for the study of CLBS12 in critical limb ischemia ("CLI"), and we anticipate completing enrollment in the first half of 2020. Current data in both the no-option CLI and Buerger's Disease cohorts of that study (the latter cohort has been fully enrolled and data are available in our corporate presentation) remain corroborative of previously published results, which we believe are an indication of a high probability of clinical success of the trial. We continue to anticipate top line data for the full study in early 2021 leading to an earliest possible approval in Japan in late 2021 or early 2022. Finally, we have completed all preparatory measures for the initiation of the single confirmatory phase 3 study agreed with U.S. Food and Drug Administration (the "FDA") to conclude development of CLBS14 in no-option refractory disabling angina (NORDA) and are awaiting finalization of a funding plan before commencing the trial.

"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.

Fourth Quarter and Full Year 2019 Financial Highlights

Research and development expenses for the fourth quarter of 2019 were $2.8 million, an 84% increase compared with $1.5 million for the fourth quarter of 2018, and $10.8 million for 2019, a 42% increase compared with $7.6 million for 2018. Research and development in both the current year and prior year periods focused on the advancement of our ischemic repair platform and related to:

- ongoing registration-eligible study expenses for CLBS12 in critical limb ischemia in Japan, whereby we continue to focus spending on our patient enrollment;
- ongoing Phase 2 proof-of-concept study expenses for CLBS16 in coronary microvascular dysfunction, for which study enrollment was completed in the second quarter of 2019; and
- expenses associated with preparation of our confirmatory Phase 3 study of CLBS14 in NORDA. In late 2019, we projected that the Phase 3 study would cost approximately $70 million in external expenses over the next several years to complete, and as a result, we elected to postpone the initiation of the study until we have confidence that we can access sufficient capital to allow us to complete the study uninterrupted

General and administrative expenses, which focus on general corporate related activities, were approximately $2.3 million for both the fourth quarters of 2019 and 2018, and $9.3 million for 2019, a slight decline compared to $9.4 million in 2018.

The net loss for the fourth quarter of 2019 was $5.0 million, or $0.47 per share, compared with $3.6 million, or $0.36 per share, for the fourth quarter of 2018. The net loss for 2019 was $19.4 million, or $1.88 per share, compared with $16.2 million, or $1.67 per share, for 2018.

Balance Sheet Highlights

As of December 31, 2019, Caladrius had cash, cash equivalents and marketable securities of $25.2 million. Based on existing programs and projections, the Company remains confident that its cash balances will fund its operations through at least the second quarter of 2021.

Conference Call

Caladrius' management will host a conference call for the investment community later today, March 5, 2020, at 4:30 p.m. (ET) to discuss the financial results, provide a company update and answer questions.

Shareholders and other interested parties may participate on the conference call by dialing (866) 595-8403 (U.S.) or (706) 758-9979 (International), using the conference ID code: 4155934. The live webcast will be accessible via the Events page listed under the Investor section of the Company's website at www.caladrius.com/investors/news-events/events.

For those unable to participate on the live conference call, an audio replay will be available approximately two hours after the conclusion of the call until 11:59 p.m. ET on March 12, 2020. To access the replay, please dial (855) 859-2056 (U.S.) or (404) 537-3406 (International) and provide the conference ID code: 4155934.

A webcast replay of the conference call will remain available on the Company's website for 90 days.

About Caladrius Biosciences

Caladrius Biosciences, Inc. is a clinical-stage biopharmaceutical company dedicated to the development of cellular therapies designed to reverse, not manage, cardiovascular disease. We are developing a first in-class cell therapy product that is based on the notion that our body contains finely tuned mechanisms for self-repair. Our technology leverages and enables these mechanisms in the form of specific cells, using formulations and modes of delivery unique to each medical indication.

Our leadership team collectively has decades of biopharmaceutical development experience and world-recognized scientific achievement in the field of cardiovascular disease, among other fields. Our goal is to build a broad portfolio of novel and versatile products that address important unmet medical needs and bring these products to market to benefit patients, the medical community and our shareholders. Our current product candidates include three developmental treatments for ischemic diseases based on our CD34+ cell therapy platform: CLBS12, recipient of SAKIGAKE designation (a Japanese regulatory status that is similar in certain respects to "breakthrough therapy" designation granted by the U.S. Food and Drug Administration (the "FDA") to eligible investigational treatments) 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; CLBS16, in a Phase 2 proof-of-concept clinical trial in the U.S. for the treatment of coronary microvascular dysfunction ("CMD"); and CLBS14, an RMAT designated therapy for which we have finalized with the FDA a protocol for a Phase 3 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 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, 2019 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.

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— Tables to Follow –

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