# Caladrius Biosciences Reports 2019 Third Quarter and Nine Month Financial Results and Provides Corporate Update

November 6, 2019

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

**BASKING RIDGE, N.J. (November 6, 2019)** – Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company"), a late-stage therapeutics development biopharmaceutical company pioneering advancements of cell therapies in select cardiovascular and autoimmune diseases, announces financial results for the three and nine months ended September 30, 2019.

"I am pleased with our third quarter performance as we continued to advance our ongoing CD34+ technology-based clinical programs for which the data continues to trend positively. Enrollment in Japan for the study of CLBS12 in critical limb ischemia ("CLI") is ongoing and we anticipate completion in the first half of 2020, with top line data targeted for late 2020 or early in 2021. We remain on track for an earliest possible approval in Japan during 2021 based on the accelerated review afforded by CLBS12's SAKIGAKE designation. The 6-month follow-up from all subjects in our ESCaPE-CMD study of CLBS16 in coronary microvascular dysfunction ("CMD") will be completed by the end of this year and we are very excited to have the latest data from the study presented by Dr. C. Noel Bairey Merz at the upcoming American Heart Association Scientific Sessions 2019 on November 16th. Assuming that the full data set corroborates previously reported results, we are planning to advance the program to its next clinical development step as expeditiously as possible," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius.

"Lastly, we substantially completed the preparatory work for the initiation of a confirmatory Phase 3 trial of CLBS14 in no-option refractory disabling angina ("NORDA"); however, we will not commence enrolling patients until sufficient capital resources are identified that would give us confidence that the study could be funded through completion," Dr. Mazzo continued. "As a result, and after eliminating CLBS14 study costs from our 2020 operating budget, our projected cash runway will now bring us into early 2021."

**Third Quarter Financial Highlights**

Research and development expenses for the third quarter of 2019 were $3.0 million, a 77% increase compared with $1.7 million for the third quarter of 2018. Research and development in both periods focused on the advancement of our ischemic repair platform and related to (i) expenses associated with our ongoing registration-eligible Phase 2 clinical study in Japan for CLBS12 in CLI, (ii) expense associated with our ESCaPE-CMD clinical study for CLBS16 in CMD, and (iii) expenses associated with the planning and preparation for Phase 3 enrollment initiation of our CLBS14 program in NORDA.

General and administrative expenses, which focus on general corporate related activities, were $2.1 million for both the third quarters of 2019 and 2018.

The net loss for the third quarter of 2019 was $4.9 million, or $0.47 per share, compared with $3.5 million, or $0.36 per share, for the third quarter of 2018.

**Nine Month Financial Highlights**

Research and development expenses for the first nine months of 2019 were $8.0 million, a 32% increase compared with $6.1 million for the first nine months of 2018. Research and development in both periods focused on the advancement of our ischemic repair platform and related to (i) expenses associated with our ongoing Phase 2 clinical study in Japan for CLBS12 in CLI, (ii) expense associated with our ESCaPE-CMD clinical study for CLBS16 in CMD, and (iii) expenses associated with the planning and preparation for Phase 3 enrollment initiation of our CLBS14 program in NORDA.

General and administrative expenses, which focus on general corporate related activities, were $7.0 million for the first nine months of 2019, a 2% decrease compared with $7.1 million for the first nine months of 2018.

The net loss for the first nine months of 2019 was $14.4 million, or $1.40 per share, compared with $12.6 million, or $1.31 per share, for the first nine months of 2018.

**Balance Sheet Highlights**

As of September 30, 2019, Caladrius had cash, cash equivalents and marketable securities of $29.2 million. Based on existing programs and projections, the Company remains confident that its cash balances will allow it to fund its current business plan until early 2021.

**Conference Call**

Caladrius' management will host a conference call for the investment community beginning at 4:30 p.m. ET on Wednesday, November 6, 2019 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 (domestic) or (706) 758-9979 (international), using the conference ID number: 9091688. The conference call will also be webcast live and can be accessed from the Company's website at www.caladrius.com/investors/news-events.

For those unable to participate in the live conference call or webcast, an audio recording will be available for replay approximately two hours after the

conclusion of the call until 11:59 p.m. ET on November 13, 2019. To access the audio replay, dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and provide conference ID number: 9091688.

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

**About Caladrius Biosciences**

Caladrius is a late-stage therapeutics development biopharmaceutical company pioneering advancements of cell therapies for select cardiovascular and autoimmune diseases. Our leadership team collectively has decades of biopharmaceutical development experience and world-recognized scientific achievement in the fields of cardiovascular and autoimmune disease, among other areas. Our current product candidates include three developmental treatments for cardiovascular diseases based on our CD34+ cell therapy platform: CLBS12, recipient of a SAKIGAKE designation in Japan and advanced therapy medicinal product classification (ATMP) in Europe, eligible for early conditional approval for the treatment of critical limb ischemia in Japan based on an ongoing clinical trial; CLBS16, subject of the proof-of-concept ESCaPE-CMD clinical trial in the U.S.A. for the treatment of coronary microvascular dysfunction; and CLBS14, a Phase 3 ready clinical program in no option refractory disabling angina and recipient of a RMAT designation in the U.S.A. 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 14, 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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Source: Caladrius Biosciences, Inc.