Caladrius Biosciences Reports 2019 Second Quarter and First Six Months Financial Results and Provides Corporate Update

August 8, 2019

Confirmatory Phase 3 Study Protocol Finalized for CLBS14 in No-Option Refractory Disabling Angina

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

BASKING RIDGE, N.J. (August 8, 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 six months ended June 30, 2019 and provides highlights of progress within the development pipeline.

"I am delighted to announce that, after close collaboration with the U.S. Food and Drug Administration, we have finalized the protocol design for a confirmatory Phase 3 trial of CLBS14 in no-option refractory disabling angina ("NORDA"). We now plan to initiate enrollment in this trial in early 2020," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius. "The protocol defines a prospective, randomized, double blind, ~400 total subject trial with a primary endpoint of total exercise time at the 6-month follow-up visit."

Dr. Mazzo continued, "We also recently announced that the European Medicines Agency granted CLBS12 the Advanced Therapy Medicinal Product classification for the treatment of critical limb ischemia ("CLI"). As a result, we now have the opportunity to work closely with the European regulators to define a path forward that would accelerate the approval of CLBS12's registration to treat CLI in Europe. Finally, the preliminary data from our clinical programs studying our CD34+ cell therapy platform for coronary microvascular dysfunction ("CMD") in the United States and CLI in Japan, continue to trend positively and we reiterate our expectations to report top-line data by the end of 2019 and early 2020, respectively."

Second Quarter Financial Highlights

Research and development expenses for the second quarter of 2019 were $3.0 million, a 41% increase compared with $2.1 million for the second 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 Phase 2 study of CLBS12 in CLI development program in Japan, (ii) expense associated with our ongoing Phase 2 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 $2.4 million for the second quarter of 2019, a 10% increase compared with $2.1 million for the second quarter of 2018.

The net loss for the second quarter of 2019 was $5.1 million, or $0.49 per share, compared with $4.1 million, or $0.42 per share, for the second quarter of 2018.

Six Month Financial Highlights

Research and development expenses for the first six months of 2019 were $5.0 million, a 15% increase compared with $4.4 million for the first six 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 study of CLBS12 in CLI development program in Japan, (ii) expense associated with our ongoing Phase 2 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 $4.9 million for the first six months of 2019, a 3% decrease compared with $5.0 million for the first six months of 2018.

The net loss for the first six months of 2019 was $9.5 million, or $0.93 per share, compared with $9.1 million, or $0.95 per share, for the first six months of 2018.

Balance Sheet Highlights

As of June 30, 2019, Caladrius had cash, cash equivalents and marketable securities of $33.7 million. Based on existing programs and projections, the Company remains confident that its cash balances will allow it to fund its current business plan through the second quarter of 2020.

Conference Call

Caladrius' management will host a conference call for the investment community beginning at 4:30 p.m. ET on Thursday, August 8, 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: 4491545. 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 August 15, 2019. To access the audio replay, dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and provide conference ID number: 4491545.

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, recipient of a RMAT designation in the U.S.A. and for which we are in preparation to commence a Phase 3 clinical trial in no option refractory disabling angina. 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.

Contact:

Investors:
Caladrius Biosciences, Inc.
John Menditto
Vice President, Investor Relations and Corporate Communications
Phone: +1-908-842-0084
Email: jmenditto@caladrius.com

– Tables to Follow –

Source: Caladrius Biosciences, Inc.