Caladrius Biosciences Reports 2018 Third Quarter Financial Results

November 8, 2018

Development programs remain on track accompanied by continued strong fiscal management.
Conference call begins today at 4:30 p.m. Eastern time

BASKING RIDGE, N.J. (November 8, 2018) – Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company"), a late-stage therapeutics development biopharmaceutical company with multiple technology platforms targeting select cardiovascular indications and autoimmune disease, announces financial results for the three ended September 30, 2018, and provides a business update.

Highlights of the 2018 third quarter and early fourth quarter include:

- Continued enrollment in a Phase 2 (SAKIGAKE designated and eligible for early conditional approval) clinical trial in Japan of CLBS12 for the treatment of no-option critical limb ischemia ("CLI"), including completion of enrollment of the five patient Buerger's disease cohort;
- Continued enrollment in a Phase 2 clinical trial using the CD34 cell therapy CLBS14-CMD for the treatment of coronary microvascular dysfunction ("CMD");
- Continued follow-up analysis of The Sanford Project: T-Rex Study Phase 2 clinical trial of CLBS03 in type 1 diabetes after completing enrollment and reporting six-month results on 50% of trial subjects in the first quarter of 2018 that concluded the treatment is well-tolerated and non-futile for therapeutic effect; and
- Conducted a Type B meeting with the US Food and Drug Administration ("FDA") under the provisions of the RMAT designation for CLBS14-RfA for the treatment of refractory angina to define remaining steps to registration.

"We are pleased with the advancement of our clinical programs during the third quarter. We maintain our previous guidance regarding development milestones and continue to demonstrate efficient management of cash spend," stated Dr. David J. Mazzo, President and CEO. "The fully-enrolled T-Rex Study of CLBS03 in type 1 diabetes remains on track for top-line data in early 2019. Our programs studying our CD34 cell therapy platform for CMD here in the United States and CLI in Japan continue to enroll with a target for top-line data in the second half of 2019 and early 2020, respectively.

"We are also pleased to announce that we recently completed our Type B meeting with the FDA pertaining to CLBS14-RfA for the treatment of refractory angina. This meeting was conducted to obtain FDA guidance and to define the remaining requirements for registration of this product under the terms of its RMAT designation. We believe that the meeting was both collaborative and positive and our assessment of the conversation is that FDA is demonstrating maximum flexibility afforded under the RMAT designation as we work together to establish the development steps necessary to bring this product to registration. We will be working with FDA to finalize the next development steps and to formalize the minutes of the meeting. We look forward to providing further information once these actions are completed."

Third Quarter Financial Highlights

Research and development expenses for the third quarter of 2018 were $1.7 million, a 47% decrease compared with $3.2 million for the third quarter of 2017. The current quarter expenses were principally comprised of costs in our ischemic repair programs for CLBS12 and CLBS14-CMD, as well as initial planning for our CLBS14-RfA program. Conversely, the prior year quarter expenses were primarily focused on our T-Rex study for CLBS03, which completed enrollment in December 2017 and is now in the follow-up phase of the study.

General and administrative expenses for the third quarter of 2018 were $2.1 million, a 30% decrease compared with $2.9 million for the third quarter of 2017, due to lower general and administrative headcount and corporate-related activities compared with the prior year period.

The net loss from continuing operations for the third quarter of 2018 was $3.5 million, or $0.36 per share, compared with $3.5 million, or $0.38 per share, for the third quarter of 2017.

Nine Month Financial Highlights

Research and development expenses for the nine months ended September 30, 2018 were $6.1 million, a 46% decrease compared with $11.2 million for the nine months of 2017. The current year expenses were principally comprised of costs in our ischemic repair programs for CLBS12 and CLBS14-CMD as well as initial planning for our CLBS14-RfA program. Conversely, the prior year expenses were primarily focused on our T-Rex study for CLBS03, which completed enrollment in December 2017 and is now in the follow-up phase of the study.

General and administrative expenses for the nine months ended September 30, 2018 were $7.1 million, a 22% decrease compared with $9.1 million for the nine months of 2017. The decrease was due to lower general and administrative headcount and corporate-related activities compared with the prior year period, along with the sale of our counter-flow centrifugation system to Hitachi in the second quarter of 2018, which resulted in a one-time $1.4 million gain included in general and administrative expenses.

The net loss from continuing operations for the nine months ended September 30, 2018 was $12.6 million, or $1.31 per share, compared with $25.8 million, or $1.37 per share, for the nine months of 2017.

Balance Sheet Highlights

As of September 30, 2018, Caladrius had cash, cash equivalents and marketable securities of $46.1 million, compared with $60.1 million as of December 31, 2017. Based on existing programs and projections, the Company continues to remain confident that its cash balances and additional grant funding, along with continued disciplined expense management, will allow it to fund its current business plan beyond 2019.

Conference Call

Caladrius management will host a conference call for the investment community today beginning at 4:30 p.m. Eastern time to review financial results, provide a Company update and answer questions.

Stockholders and other interested parties may participate in the conference call by dialing (866) 595-8403 (domestic), or (706) 758-9979 (international), and providing conference ID: 9490459. The call will also be broadcast live on the Internet via the Company's website at www.caladrius.com/investors/news-events.

For those unable to participate on the live conference call, a replay will be available through November 15, 2018, and can be accessed by dialing (855) 859-2056 or (404) 537-3406. All listeners should provide the following replay access code: 9490459.

The webcast replay will be archived on the Company's website for 90 days at www.caladrius.com.

About Caladrius Biosciences

Caladrius is a late-stage therapeutics development biopharmaceutical company committed to the development of innovative products that have the potential to restore the health of people with chronic illnesses. 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. The Company's goal is to build a broad portfolio of novel and versatile products that address important unmet medical needs. Our current product candidates include three developmental treatments for cardiovascular diseases based on our CD34 cell therapy platform: CLBS12, recipient of SAKIGAKE designation, in Phase 2 testing in Japan and eligible for early conditional approval for the treatment of critical limb ischemia; CLBS14-CMD, in Phase 2 testing for the treatment of coronary microvascular dysfunction and CLBS14-RfA in late-stage development for refractory angina for which it has received RMAT designation. Caladrius' autoimmune product candidate in Phase 2 testing, CLBS03, is an *ex vivo* expanded polyclonal T regulatory cell therapy for the treatment of recent-onset type 1 diabetes. CLBS03 has been awarded Fast Track and Orphan designations by the FDA. 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. The Company's actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors. 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 22, 2018, as subsequently amended on April 2, 2018, 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.

Contacts:

Caladrius Biosciences, Inc.

John Menditto
Executive Director, Investor Relations and Corporate Communications
Phone: +1-908-842-0084
Email: jmenditto@caladrius.com

– Tables to Follow –

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