Caladrius Biosciences Reports 2018 Fourth Quarter and Year End Financial Results

March 14, 2019

BASKING RIDGE, N.J. (March 14, 2019) – Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company"), 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 and with a focus on select cardiovascular indications, announces financial results for the three and twelve months ended December 31, 2018.

"2018 was an exciting and productive year for Caladrius, featuring a number of significant developments. Specifically, we made great progress advancing and expanding our clinical CD34+ cell technology platform while maintaining strong fiscal prudence," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius. "Notably, we initiated the ESCaPE-CMD phase 2 study in the U.S. for CLBS14-CMD and subsequently acquired a data license for our no-option refractory disabling angina program, CLBS14-NORDA, for which we plan to initiate a phase 3 trial in the fall of this year pending finalization of the protocol with the U.S Food and Drug Administration. We continue to expect to report top-line data in the ESCaPE-CMD trial by the end of 2019 or early 2020, and we continue to enroll in our CLI study in Japan for CLBS12 for which we expect to report topline data in the first half of 2020.

"We are excited about what lies ahead in 2019 and expect the momentum to continue as we advance our clinical development pipeline and achieve a number of important development milestones throughout the balance of the year," concluded Dr. Mazzo.

Fourth Quarter Financial Highlights

Research and development expenses for the fourth quarter of 2018 were $1.5 million, a 68% decrease compared with $4.7 million for the fourth quarter of 2017. Expenses in the fourth quarter of 2018 principally comprised costs in our ischemic repair programs for CLBS12 and CLBS14-CMD and preparation for our CLBS14-NORDA program. Conversely, the prior year quarter expenses were focused primarily on our T-Rex study for CLBS03, which completed enrollment in December 2017.

General and administrative expenses for the fourth quarter of 2018 were $2.3 million, a 14% decrease compared with $2.7 million for the fourth quarter of 2017, due to lower corporate-related activities compared with the prior year period.

The net loss from continuing operations for the fourth quarter of 2018 was $3.6 million, or $0.36 per share, compared with $4.0 million, or $0.40 per share, for the fourth quarter of 2017.

2018 Financial Highlights

Research and development expenses for 2018 were $7.6 million, a 52% decrease compared with $15.8 million for 2017. The current year expenses were principally comprised of costs related to our ischemic repair programs for CLBS12 and CLBS14-CMD as well as initial preparation for our CLBS14-NORDA program. Conversely, the prior year expenses were focused primarily on our T-Rex study for CLBS03, which trial completed enrollment in December 2017.

General and administrative expenses for 2018 were $9.4 million, a 20% decrease compared with $11.8 million for 2017. The decrease was due to lower 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.

Net loss from continuing operations for the twelve months ended December 31, 2018 was $16.2 million, or $1.67 per share, compared with $16.2 million, or $1.78 per share, for the same period of 2017.

Balance Sheet Highlights

As of December 31, 2018, Caladrius had cash, cash equivalents and marketable securities of $43.1 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 mid-2020.

Conference Call

Caladrius' management will host a conference call for the investment community beginning at 4:30 p.m. ET on Thursday, March 14, 2019 to discuss the financial results, provide a company update and answer questions.

Shareholders and other interested parties may participate in the conference call by dialing (866) 595-8403 (domestic) or (706) 758-9979 (international), using the conference ID number: 2168777. 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 of the call will be available for replay approximately two hours after the conclusion of the call until 11:59 p.m. ET on March 21, 2019. To access the audio replay, dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and provide conference ID number: 2168777.

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 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-NORDA (formerly CLBS14-RfA) in late-stage development for no option refractory disabling angina for which it has received RMAT designation. 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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