Caladrius Biosciences Reports 2018 Second Quarter and First Six Months Financial Results

August 9, 2018

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

BASKING RIDGE, N.J. (August 9, 2018) – Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company"), a development-stage biopharmaceutical company with multiple technology platforms targeting autoimmune and select cardiovascular indications, announces financial results for the three and six months ended June 30, 2018 and provides a business update.

Highlights of the 2018 second quarter and first six months include:

- Received regenerative medicine advanced therapy ("RMAT") designation from the U.S. Food and Drug Administration ("FDA") for the Company's late-stage CD34 cell therapy program CLBS14-RfA for the treatment of refractory angina, which is similar to breakthrough therapy designation, in that it provides increased agency meeting opportunities, the potential for accelerated approval and is reserved for therapies which treat a serious condition while showing preliminary evidence of addressing an unmet medical need;
- Received SAKIGAKE designation from the Japan Ministry of Health, Labour and Welfare ("MHLW") for the proprietary CD34 cell therapy CLBS12 for the treatment of no-option critical limb ischemia ("CLI"), which reflects MHLW's expectation of "prominent effectiveness" based on mechanism-of-action data from non-clinical and early clinical trials and provides an expedited path to potential conditional approval in Japan for products that show sufficient safety evidence and signals of efficacy in a Phase 2 study;
- Sold our ownership interest in a non-core development-stage counter-flow centrifugation system to Hitachi Chemical Advanced Therapeutics Solutions for $2.5 million;
- Continued enrollment in a Phase 2 clinical trial in Japan with CLBS12 for the treatment of no-option CLI;
- Continued enrollment in a Phase 2 clinical trial with the CD34 cell therapy CLBS14-CMD for the treatment of coronary microvascular dysfunction ("CMD"); and
- 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.

Management Commentary

"During the second quarter, we continued to advance our CD34 cell therapy programs. We took a major step forward as we reactivated the Investigational New Drug Application ("IND") for CLBS14-RfA as the sponsor and now have three development programs targeting three indications for our CD34 technology. Additionally, with receipt of RMAT designation for CLBS14-RfA, we are afforded an opportunity to work with the FDA to more rapidly and efficiently advance the development of a therapeutic candidate with the potential to impact a condition with no known effective treatment options and high morbidity. We also advanced our Phase 2 clinical trial in Japan that is evaluating CLBS12 for the treatment of no-option CLI, a condition for which we were granted SAKIGAKE designation from the MHLW in early April. As a result, we now have two potential nearer-term commercial opportunities," said Dr. David J. Mazzo, President and Chief Executive Officer of Caladrius.

"I am also pleased to report that enrollment in our Phase 2 study of CLBS14-CMD for the treatment of coronary microvascular dysfunction continues to progress as expected and that we remain on track to complete patient follow-up and primary endpoint analysis of The Sanford Project: T-Rex Study with anticipated top-line results reported in early 2019," Dr. Mazzo continued. "Finally, as a result of continued fiscal discipline, augmented by $2.5 million of non-dilutive funding received from the sale to Hitachi Chemical Advanced Therapeutics Solutions in June of our rights to a counter-flow centrifugation cell processing device, our cash position remains strong."

Second Quarter Financial Highlights

Research and development expenses for the second quarter of 2018 were $2.1 million, a 50% decrease compared with $4.3 million for the second quarter of 2017. The decline was due to significantly lower costs in our CLBS03 clinical program in type 1 diabetes upon the completion of enrollment in December 2017, which was partially offset by costs related to the initiation of clinical trials in late 2017 and early 2018 for CLBS12 in critical limb ischemia and CLBS14-CMD in coronary microvascular dysfunction, respectively.

General and administrative expenses for the second quarter of 2018 were $2.1 million, compared with $3.4 million for the second quarter of 2017. The decrease was due to 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 second quarter of 2018 was $4.1 million, or $0.42 per share, compared with $2.0 million, or $0.22 per share, for the second quarter of 2017.

Six Month Financial Highlights

Research and development expenses for the first six months of 2018 were $4.4 million, a 45% decrease compared with $8.0 million for the first six months of 2017. The decline was due to significantly lower costs in our CLBS03 clinical program in type 1 diabetes upon the completion of enrollment in December 2017, which was partially offset by costs related to the initiation of clinical trials in late 2017 and early 2018 for CLBS12 in critical limb ischemia and CLBS14-CMD in coronary microvascular dysfunction, respectively.

General and administrative expenses for the first six months of 2018 were $5.0 million, compared with $6.1 million for the first six months of 2017. The decrease was due to 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 first six months of 2018 was $9.1 million, or $0.95 per share, compared with $8.7 million, or $0.99 per share, for the first six months of 2017.

Balance Sheet Highlights

As of June 30, 2018, Caladrius had cash, cash equivalents and marketable securities of $50.3 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: 8899285. 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 August 15, 2018, and can be accessed by dialing (855) 859-2056 or (404) 537-3406. All listeners should provide the following replay access code: 8899285.

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

About Caladrius Biosciences

Caladrius is a clinical-stage 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 two clinical-stage 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; and CLBS14, in Phase 2 testing for the treatment of coronary microvascular dysfunction and in late-stage clinical 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.

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