Caladrius Biosciences Provides Corporate Update and Reports 2020 Second Quarter Financial Results

August 13, 2020

Clinical programs advanced and expanded with strengthened cash position

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

BASKING RIDGE, N.J. (August 13, 2020) – Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company"), a clinical-stage biopharmaceutical company dedicated to the development of cellular therapies designed to reverse, not manage, disease, provides a corporate update and reports financial results for the three and six months ended June 30, 2020.

Product Development and Financing Highlights

CLBS119 clinical trial targeting the repair of COVID-19 induced lung damage to be initiated in 3Q 2020

Caladrius is committed to helping patients and communities combat the public health crisis of COVID-19 by leveraging its proprietary CD34+ cell technology to potentially repair COVID-19 induced lung damage. Experience to date indicates that a large portion of COVID-19 survivors who required ventilatory support will suffer long-term, debilitating lung damage.[1] Scientists learned in the aftermath of the first SARS epidemic that the coronavirus targets cells that express CD34.[2] Depletion of that cell population generally is thought to be connected to the lung's inability to repair itself.[2] Early reports from the COVID-19 pandemic indicate that the endothelial cells that line the microvasculature of the lung are targeted by the virus and that the destruction of the lung microcirculation may be a critical factor in the inability of the lung to repair itself even after the virus has been eliminated.[3] Clinical trials and preclinical models have shown that CD34+ cells act in a restorative and regenerative capacity in multiple organs, including models of severe lung inflammation.[4] Research has also shown that a deficiency in vascular CD34+ cells can result in a predisposition to injury in the lungs.[5] Based on this accumulated evidence, Caladrius is excited to launch the pilot study of CLBS119 to evaluate its autologous CD34+ cell therapy for the repair of COVID-19 induced lung damage in patients who have suffered respiratory failure. The trial is planned to initiate by late August with the first patient expected to be treated in September.

CLBS12 development in Japan continues to yield promising results

The Company's open-label, registration-eligible study in Japan of CLBS12, its SAKIGAKE-designated product candidate for the treatment of critical limb ischemia ("CLI"), a disease with no currently available approved therapy [6] and a higher mortality rate than all cancers except that of lung cancer,[7] has shown positive results to date. The Buerger's Disease cohort has concluded with 4 out of 7 (57%) patients achieving a positive outcome, an outstandingly positive result for these patients who normally see continued progression leading to amputation. Despite the global impact of COVID-19, which has caused the deceleration of clinical trial enrollment globally, the Company remains encouraged by the patient pre-screening pipeline that has been identified and targets to complete trial enrollment by the end of 2020 and report top line data for the full study in late 2021 or early 2022. Based on the data from the concluded Buerger's Disease cohort and the data to date in the no-option CLI cohort, the Company maintains its expectation of the study's ultimate success.

CLBS16 to be studied in Phase 2b trial for the treatment of coronary microvascular dysfunction

Caladrius recently completed and announced the results of its ESCaPE-CMD Phase 2 study of CLBS16 for the treatment of coronary microvascular dysfunction ("CMD"), a disease that continues to be underdiagnosed and potentially afflicts millions annually – a vast majority of whom are female – with no current treatment options. Data from the Phase 2 trial showed highly statistically significant improvement in coronary flow reserve correlating with symptom relief for patients with CMD after a single intracoronary injection of CLBS16. The Company is committed to raising awareness of this growing women's health crisis as it initiates a rigorous Phase 2b clinical trial of CLBS16 with the first patient expected to be enrolled by late 2020. The double-blind, randomized, placebo-controlled trial will evaluate the efficacy and safety of delivering autologous CD34+ cells (CLBS16) in subjects with coronary microvascular dysfunction and without obstructive coronary artery disease.

CLBS14 remains poised to enter a single confirmatory Phase 3 clinical trial

The Company's Phase 3 protocol for its RMAT-designated product candidate, CLBS14, for the treatment of no-option refractory angina ("NORDA") remains ready to initiate pending sufficient funding to run the program to completion. Based on an abundance of very strong data from previous Phase 1, 2, and 3 studies, Caladrius remains confident in the potential for clinical success once the program is executed.

Caladrius secures almost $30 million in new capital year-to-date and extends cash runway through the end of 2021

In April 2020, Caladrius generated $10.9 million in non-dilutive funding through the sale of a portion of its qualified New Jersey net operating losses. Throughout the remainder of the second quarter, the Company executed two registered direct offerings priced at the market under Nasdaq rules raising an additional aggregate $9.3 million. In July 2020, Caladrius raised $2.0 million in a private placement priced at the market under Nasdaq rules. In addition, Caladrius opportunistically raised $8.3 million through its Common Stock At-the-Market Sales Agreement with H.C. Wainwright & Co. year-to-date.

“Despite COVID-19’s unprecedented global impact, we continue to deliver on a number of key initiatives that we believe position the Company for success in the quarters ahead,” stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius. “To date in 2020, we successfully raised enough capital to extend our cash runway through the end of 2021, continued activities in support of our existing and newly initiated clinical programs and strengthened our Board with the previously announced addition of Dr. Michael Davidson.”

“We are excited about what lies ahead through the balance of 2020 and into 2021 with a number of key milestones expected, including the commencement of our pilot study of CLBS119 in COVID-19 induced lung damage, the completion of enrollment in our Phase 2 study of CLBS12 for critical limb ischemia and the initiation of our Phase 2b study of CLBS16 in coronary microvascular dysfunction,” concluded Dr. Mazzo.

Second Quarter 2020 Financial Highlights

Research and development expenses for the second quarter of 2020 were $1.8 million, a 39% decrease compared with $3.0 million for the second quarter of 2019. Research and development in both periods focused on the advancement of our ischemic repair platform. More specifically, R&D expense comprised (i) costs associated with investigational new drug application and planning for commencement of a pilot study of CLBS119, (ii) execution expenses for our ongoing registration-eligible study for CLBS12 in critical limb ischemia in Japan, and (iii) expenses for both the completion of our ESCaPE-CMD clinical study for CLBS16 in coronary microvascular dysfunction and planning for the follow on Phase 2b study.

General and administrative expenses for the second quarter of 2020 were $2.5 million, compared with $2.4 million for the second quarter of 2019.

Overall, net income was $6.6 million for the second quarter of 2020, which included a $10.9 million income tax benefit from the sale of qualified New Jersey net operating losses, compared to a net loss of $5.1 million for the second quarter of 2019.

Balance Sheet Highlights

As of June 30, 2020, Caladrius had cash, cash equivalents and marketable securities of $34.9 million. Based on existing programs and projections, the Company remains confident that its current cash balances will fund its operations through 2021.

Conference Call

Caladrius management will host a conference call for investors beginning at 4:30 p.m. ET on Thursday, August 13, 2020 to discuss the financial results, provide a business 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) and referencing conference ID number 2093833. The conference call will also be webcast live under the Investors section on the Company’s website at www.caladrius.com.

For those unable to participate in the live conference call, a replay will be accessible approximately two hours after its completion through August 20, 2020, by dialing 855-859-2056 (domestic) or 404-537-3406 (international) and referencing conference ID number 2093833. A webcast audio recording of the call will also be archived for 90 days under the Investors section of the Company’s website at www.caladrius.com.

About Caladrius Biosciences

Caladrius Biosciences, Inc. is a clinical-stage biopharmaceutical company dedicated to the development of cellular therapies designed to reverse, not manage, disease. We are developing a first- in-class cell therapy product that is based on the notion that our body contains finely tuned mechanisms for self-repair. Our technology leverages and enables these mechanisms in the form of specific cells, using formulations and modes of delivery unique to each medical indication.

The Company’s current product candidates include CLBS119, a CD34+ cell therapy product candidate for the repair of lung damage found in patients with severe COVID-19 infection who experienced respiratory failure, for which the Company plans to initiate a clinical trial in the coming months as well as three developmental treatments for ischemic diseases based on its CD34+ cell therapy platform: CLBS12, recipient of SAKIGAKE designation and eligible for early conditional approval in Japan for the treatment of critical limb ischemia (“CLI”) based on the results of an ongoing clinical trial; CLBS16, the subject of a recently completed positive Phase 2 clinical trial in the U.S. for the treatment of coronary microvascular dysfunction (“CMD”); and CLBS14, a Regenerative Medicine Advanced Therapy (“RMAT”) designated therapy for which the Company has finalized with the U.S. Food and Drug Administration (the “FDA”) a protocol for a Phase 3 confirmatory trial in subjects with no-option refractory disabling angina (“NORDA”). For more information on the company, please visit www.caladrius.com.

[1]Yuhui Wang, et al, *Radiology*, March 19, 2020

[2]Chen Y, Chan VS, Zheng B, et al. A novel subset of putative stem/progenitor CD34+Oct-4+ cells is the major target for SARS coronavirus in human lung. J Exp Med. 2007;204(11):2529-2536. doi:10.1084/jem.20070462

[3]Varga Z, Flammer AJ, Steiger P, et al. Endothelial cell infection and endotheliitis in COVID-19. Lancet. 2020;395(10234):1417-1418. doi:10.1016/S0140-6736(20)30937-5

[4]Abd-Allah, et al, Cytotherapy, 2015;17(4):443-53

[5]Lo, Gold, Scheer, et al.: CD34 Maintains Lung Vascular Integrity after Injury

[6]Cacione DG, et al, Pharm. treatment of Buerger’s Disease, Cochrane Database of Systematic Reviews, 2016, (3) CD011033

[7]Mustapha, J. A., Katzen, B. T., et al. (2019, May). Endovascular Today, 18(5), 80-82

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 the intended use of net proceeds from financings as well as 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 5, 2020 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, except as required by law.

Contact:

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

Media:
W2O Group
Christiana Pascale
Phone: +1-212-257-6722
Email: cpascale@w2ogroup.com

– Tables to Follow –

Source: Caladrius Biosciences, Inc.