UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 7, 2020

CALADRIUS BIOSCIENCES, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware	001-33650	22-2343568
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

110 Allen Road, Second Floor, Basking Ridge, NJ 07920
(Address of Principal Executive Offices)(Zip Code)

(908) 842-0100
Registrant's Telephone Number

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	CLBS	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

o Emerging growth company

o If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

The information in Item 7.01 is incorporated by reference.

Item 7.01 Regulation FD Disclosure.

On May 7, 2020, Caladrius Biosciences, Inc. (the "Company") issued a press release in connection with its financial results for the first quarter ended March 31, 2020. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 7.01 by reference.

The Company will conduct a conference call to review its financial results on May 7, 2020 at 4:30 p.m. Eastern Time.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Item 7.01, including Exhibit 99.1 attached hereto, shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, except as otherwise expressly stated in such filing.

Item 9.01. Financial Statement and Exhibits.

Exhibit No.	Description
99.1	Press release, dated May 7, 2020

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CALADRIUS BIOSCIENCES, INC.

By: /s/ David J. Mazzo
Name: David J. Mazzo, PhD
Title: President and Chief Executive Officer

Dated: May 7, 2020

Exhibit 99.1

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

Company initiates development of CLBS119 for the repair of COVID-19 induced lung damage and expands its proprietary CD34+ cell therapy portfolio

Adds ~$16 million in funding bringing current cash to ~$34 million

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

BASKING RIDGE, N.J. (May 7, 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 announces financial results for the three months ended March 31, 2020.

Product Development and Financing Highlights

Caladrius initiates development of CLBS119, a CD34+ cell therapy specifically intended to repair COVID-19 induced lung damage

For thousands of COVID-19 survivors leaving hospitals around the world, vestiges of the virus will return home with them in the form of debilitating lung damage. Many companies are searching for treatments for the acute effects of the virus or for a vaccine that thwarts infection altogether. Caladrius, however, has taken a leadership position in helping those patients who have beaten the virus but have suffered potentially permanent lung damage in the battle. Initial evidence indicates that a large portion of the survivors of COVID-19 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] Caladrius has opened an Investigational New Drug ("IND") application, agreed with the Food and Drug Administration ("FDA") on a protocol and has begun manufacturing preparation with the intention of initiating a clinical trial as soon as possible to evaluate CLBS119 as a treatment to restore lung function specifically in patients who experienced severe SARS-CoV-2 infection and required ventilatory support due to respiratory failure.

CLBS12 development in Japan continues to yield promising results

The Company's open-label, registration-eligible study of CLBS12, its SAKIGAKE-designated product candidate, in Japan 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. Although the study enrollment, which had been targeted for completion this year, has been slowed by the impact of the COVID-19 pandemic in Japan, the Company is encouraged by the patient pre-screening pipeline that has been identified and hopes to conclude the trial enrollment rapidly once the coronavirus abates and physicians are again

able to treat non-COVID-19 patients. Based on the data from the concluded Buerger's Disease cohort and the data to date in the no-option CLI cohort, the Company affirms its expectation of the study's ultimate success.

CLBS16 demonstrates ability to improve coronary flow reserve in patients and potentially reverse coronary microvascular dysfunction

Caladrius reported that it has concluded its ESCaPE-CMD study of CLBS16 for the treatment of coronary microvascular dysfunction ("CMD"), a disease that potentially afflicts millions annually with no current treatment options. The full data from that study will be presented at the SCAI 2020 Scientific Sessions Virtual Conference on May 14th and is expected to corroborate the positive partial results presented at the American Heart Association Scientific Sessions in November 2019. The Company is already taking steps necessary to initiate the next trial in CLBS16 development, a Phase 2b study, in the fall of 2020.

CLBS14 remains poised to enter a single confirmatory phase 3 clinical trial pending finalization of funding

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 substantial data from previous Phase 1, 2, and 3 studies, Caladrius remains confident in the potential for clinical success once the program is executed.

An additional ~$16 million of capital (~$11 million of which is non-dilutive) added to balance sheet

Notwithstanding the challenging financial macro-environment, Caladrius recently announced that it secured approximately $10.9 million of non-dilutive capital from the sale of its New Jersey net operating losses ("NJ NOLs") through the New Jersey Technology Business Tax Certificate Transfer Program. Soon thereafter it raised an additional $5.0 million pursuant to a registered direct institutional offering priced at-the-market under Nasdaq rules. This infusion of capital at this time once again demonstrates the Company's ability to acquire non-dilutive capital. The successful completion of the registered direct offering during the COVID-19 pandemic also reinforces the attractiveness of the Company, its progress and the potential of its programs to the capital markets. The collected funds will, among other things, support the continued advancement of its ongoing CD34+ technology-based clinical programs.

"Throughout this extraordinary time, we remain steadfast in our commitment to advance our CD34+ cell technology-based clinical development programs, even as the global COVID-19 pandemic provokes unprecedented challenges for product development," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius. "In fact, we have rallied to address the challenges of the pandemic and responded by defining and quickly moving to development CLBS119. We've done this while further securing our financial situation at a time when other companies are being forced to take draconian measures just to survive financially.

"Despite the global uncertainty brought about by the coronavirus, we are excited about what lies ahead in 2020 and expect to build on the momentum we generated during the first quarter," concluded Dr. Mazzo.

First Quarter 2020 Financial Highlights

Research and development expenses for the first quarter of 2020 were $1.5 million, a 26% decrease compared with $2.0 million for the first quarter of 2019. Research and development in both periods focused on the advancement of our ischemic repair platform. More specifically, R&D expense was incurred as a result of our ongoing registration-eligible study for CLBS12 in critical limb ischemia in Japan, along with the concluding expenses for our ESCaPE-CMD clinical study for CLBS16 in coronary microvascular dysfunction. Note that the majority of costs associated with the ESCaPE-CMD clinical trial were covered by a grant from the National Institutes of Health.

General and administrative expenses, which focus on general corporate related activities, remain constant and were approximately $2.6 million for both the first quarters of 2020 and 2019.

The net loss for the first quarter of 2020 was $4.0 million, or $0.38 per share, compared with $4.4 million, or $0.44 per share, for the first quarter of 2019.

Balance Sheet Highlights

As of March 31, 2020, Caladrius had cash and cash equivalents of $20.7 million. Together with the combined net proceeds from the sale of the NJ NOLs and the registered direct offering in April 2020, our cash and cash equivalents today are approximately $34 million. Based on existing programs and projections, the Company remains confident that its current cash balances will fund its operations into the second half of 2021.

Conference Call

Caladrius management will host a conference call for investors beginning at 4:30 p.m. ET on Thursday, May 7, 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 8869677. The conference call will also be webcast live under the Investors section of 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 May 14, 2020, by dialing 855-859-2056 (domestic) or 404-537-3406 (international) and referencing conference ID number 8869677. A webcast 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, cardiovascular 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 the registered direct offering and the sale of NJ NOLs 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.

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- Tables to Follow -

Caladrius Biosciences, Inc.
Selected Financial Data
(in thousands, except per share data)

(in thousands, except per share data)	Three Months Ended March 31, 2020 (unaudited)	Three Months Ended March 31, 2019 (unaudited)
Statement of Operations Data:		
Research and development	$ 1,499	$ 2,038
General and administrative	2,558	2,554
Total operating expenses	**4,057**	**4,592**
Operating loss	**(4,057)**	**(4,592)**
Investment income, net	71	227
Net loss	**(3,986)**	**(4,365)**
Less - net income (loss) attributable to noncontrolling interests	4	2
Net loss attributable to Caladrius Biosciences, Inc. common stockholders	**$ (3,990)**	**$ (4,367)**
Basic and diluted loss per share attributable to Caladrius Biosciences, Inc. common stockholders	**$ (0.38)**	**$ (0.44)**
Weighted average common shares outstanding	**10,623**	**10,027**

	March 31, 2020 (unaudited)	December 31, 2019
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 20,745	$ 25,157
Total assets	22,140	27,153
Total liabilities	5,156	6,600
Total equity	16,984	20,553

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