

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 10, 2018

CALADRIUS BIOSCIENCES, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-33650
(Commission
File Number)

22-2343568
(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:

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

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).

Emerging growth company

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 10, 2018, Caladrius Biosciences, Inc. (the "Company") issued a press release in connection with its 2018 First Quarter Financial Results. 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 10, 2018 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
<u>99.1</u>	Press release, dated May 10, 2018

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 10, 2018

Caladrius Biosciences Reports 2018 First Quarter Financial Results

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

BASKING RIDGE, N.J. (May 10, 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 months ended March 31, 2018 and provides a business update.

Highlights of the 2018 first quarter and recent weeks include:

- Reported results from the predetermined interim analysis in The Sanford Project: T-Rex Study, which concluded that the treatment is well-tolerated and non-futile for therapeutic effect;
- Dosed the first patient in a Phase 2 clinical trial in Japan with Caladrius’ proprietary CD34 cell therapy (CLBS12) for the treatment of no-option critical limb ischemia (“CLI”);
- Received SAKIGAKE designation from the Japan Ministry of Health, Labour and Welfare (the “MHLW”) for CLBS12 for the treatment of CLI, which reflects MHLW’s expectation of “prominent effectiveness” based on data of mechanism of action from non-clinical and early phase of 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;
- Acquired an exclusive worldwide license to data and regulatory filings from Shire plc (LSE: SHP, NASDAQ: SHPG) for a late-stage CD34 cell therapy program for the treatment of chronic myocardial ischemia targeting refractory angina;
- Reactivated the investigational new drug application (“IND”) with the U.S. Food and Drug Administration (“FDA”) for the program licensed from Shire treating chronic myocardial ischemia targeting refractory angina; and
- Enrolled the first patient in the study of CD34 cell therapy (CLBS14-CMD) for the treatment of coronary microvascular dysfunction.

Management Commentary

“Our CD34 cell therapy program continues to progress with the initiation of a Phase 2 clinical trial in Japan evaluating CLBS12 for the treatment of no-option CLI. Most-recently, we received exciting news from Japan’s MHLW that CLBS12 was assigned SAKIGAKE designation - a regulatory status similar to breakthrough designation awarded by FDA in the USA. This designation reflects MHLW’s assessment of early evidence of “prominent effectiveness” and affords CLBS12 the associated regulatory advantages of prioritized consultation, a dedicated review system to support the development and review process, as well as a reduced review timeline. The combination of the SAKIGAKE designation and, pending a successful outcome, the consideration for early conditional approval that is possible in Japan for CLBS12 for CLI, provide us with the possibility of an exciting and potentially nearer-term commercial opportunity,” added Dr. Mazzo. “We are also pleased to announce that we have recently opened a Phase 2 clinical study of CLBS14 for the treatment of CMD and have enrolled the first patient. We expect to announce the dosing of that patient in the coming weeks.”

“When we completed the transition to a pure clinical development company last year, we committed to identifying opportunities with robust and synergistic potential. The license of the Shire CD34 data in refractory angina in the first quarter reinforces that commitment. This program, for which we have now re-activated the IND, offers the potential for a late-stage clinical opportunity that fits well within our corporate strategy and provides us with another opportunity to expand our development portfolio,” concluded Dr. Mazzo.

First Quarter Financial Highlights

Research and development expenses for the first quarter of 2018 were \$2.3 million, a 39% decrease compared with \$3.7 million for the first quarter of 2017, with the decline due to the completion of enrollment in our CLBS03 clinical study.

General and administrative expenses for the first quarter of 2018 were \$2.9 million, compared with \$2.7 million for the first quarter of 2017, with the slight increase due to higher corporate development activity.

The net loss from continuing operations for the first quarter of 2018 was \$5.0 million, or \$0.52 per share, compared with \$6.6 million, or \$0.78 per share, for the first quarter of 2017.

Balance Sheet Highlights

As of March 31, 2018, Caladrius had cash, cash equivalents, restricted cash and marketable securities of \$53.6 million, compared with \$60.1 million as of December 31, 2017. Based on existing programs and projections, the Company is 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 9763239. 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 in the live conference call or webcast, a replay will be available beginning May 10, 2018 two hours after the close of the conference call. To access the replay, dial (855) 859-2056 or (404) 537-3406. The replay passcode is 9763239.

The webcast will be archived on the Company's website for 90 days.

About Caladrius Biosciences

Caladrius Biosciences, Inc. is a clinical stage biopharmaceutical company with multiple technology platforms targeting select cardiovascular indications and autoimmune diseases. The Company is developing CLBS14, a CD34 cell therapy intended as a treatment for coronary microvascular dysfunction (CLBS14-CMD) and refractory angina (CLBS14-RfA). CLBS14 is Caladrius' proprietary and patent protected formulation of CD34 cells designed specifically to enhance the potency of the CD34 cells for repair and regeneration of cardiovascular tissue. CLBS14-CMD is the subject of an ongoing phase 2 proof-of-principal study being conducted in the USA at Cedars-Sinai (Los Angeles) and the Mayo Clinic (Minneapolis). A companion product, CLBS12, is formulated specifically for intramuscular administration for the treatment of lower extremity ischemia. A phase 2 study of CLBS12 as a treatment for critical limb ischemia is being conducted in Japan, a successful outcome of which will, based on discussion with the Japanese regulatory authorities, qualify the program for consideration of early conditional approval as provided for under Japan's progressive regenerative medicine regulations. CLBS12 has been granted SAKIGAKE designation in Japan for the CLI indication, a designation similar to "Breakthrough Therapy Designation" granted by FDA in the USA. Additionally, the Company is investigating its CLBS03 product candidate, an ex vivo expanded polyclonal T regulatory cell therapy for the treatment of recent-onset type 1 diabetes, in an ongoing Phase 2 trial for which top-line data is expected in early 2019. CLBS03 has been granted Fast Track and orphan drug designations from the U.S. Food and Drug Administration ("FDA") as well as Advanced Therapeutic Medicinal Product ("ATMP") classification from the European Medicines Agency ("EMA"). For more information about Caladrius 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 materially differ 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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- Tables to Follow -

Caladrius Biosciences, Inc.
Selected Financial Data (unaudited)

(in thousands, except per share data)	Three Months Ended March 31,	
	2018	2017
Statement of Operations Data:		
Research and development	\$ 2,262	\$ 3,726
General and administrative	2,896	2,706
Total operating expenses	5,159	6,433
Operating loss	(5,159)	(6,433)
Other income (expense), net	178	(44)
Interest expense	(3)	(159)
Loss before income taxes and noncontrolling interests	(4,984)	(6,636)
Benefit from income taxes	—	—
Net loss from continuing operations	(4,984)	(6,636)
Discontinued operations	—	(3,157)
Net loss	(4,984)	(9,793)
Less - net loss from continuing operations attributable to noncontrolling interests	(2)	(65)
Less - net loss from discontinued operations attributable to noncontrolling interests	—	(369)
Net loss attributable to Caladrius Biosciences, Inc. common stockholders	\$ (4,982)	\$ (9,359)
Basic and diluted loss per share attributable to Caladrius Biosciences, Inc. common stockholders		
Continuing operations	\$ (0.52)	\$ (0.78)
Discontinued operations	\$ —	\$ (0.33)
Caladrius Biosciences, Inc. common stockholders	\$ (0.52)	\$ (1.12)
Weighted average common shares outstanding	9,557	8,387

	March 31, 2018	December 31, 2017
	Balance Sheet Data:	
Cash, cash equivalents and marketable securities	\$ 53,592	\$ 60,085
Total assets	56,717	63,376
Total liabilities	11,401	13,186
Total equity	45,316	50,190

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