

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): November 7, 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 5.02 Departure of Directors or Principal Officers; Election of Officers; Appointment of Principal Officers; Compensatory Arrangements of Certain Officers

(d) On November 7, 2018, the board of directors (the "Board") of Caladrius Biosciences, Inc. (the "Company") appointed Ms. Cynthia Schwalm as a Class I member of the Company's Board effective immediately. Ms. Schwalm will serve as a member of the Audit Committee of the Board and as a member of the Science and Technology Committee of the Board.

Ms. Schwalm was the President and Chief Executive Officer for Ipsen North America, and, prior to Ipsen, she served as President of Eisai Pharmaceuticals, where she oversaw commercial operations, medical affairs and services, alliance management and other functions. She has also held leadership roles at Amgen, Inc. and Johnson & Johnson. Ms. Schwalm has held positions on numerous corporate and non-profit boards, including the Women's Leadership Advisory Board for the John F. Kennedy School of Government at Harvard University and the board of directors for the Sarah Cannon Oncology Research Institute. She currently serves as a Wharton Business School Leadership Advisor. Ms. Schwalm holds an MBA from the Wharton School of the University of Pennsylvania and a B.S.N. from the University of Delaware.

As a non-employee director, Ms. Schwalm is entitled to receive cash compensation and grants of stock options or other equity awards in accordance with the arrangements in effect for non-employee directors of the Company and its committees. In connection with her appointment to the Company's Board and the Audit Committee and the Science and Technology Committee of the Board, Ms. Schwalm will receive a grant of restricted stock units of the Company's common stock, with a value of \$60,000, with one-third of the shares vesting annually on each of the first, second and third anniversaries of the grant date.

There are no arrangements or understandings between Ms. Schwalm and any other person pursuant to which she was selected as a member of the Board. The Company is not aware of any transaction in which Ms. Schwalm has an interest requiring disclosure under Item 404(a) of Regulation S-K. On November 8, 2018, the Company issued a press release announcing the appointment of Ms. Schwalm to the Board. A copy of this press release is filed as Exhibit 99.2 to this current report.

Item 7.01 Regulation FD Disclosure.

On November 8, 2018, Caladrius Biosciences, Inc. (the "Company") issued a press release in connection with its 2018 Third 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 November 8, 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
99.1	Press release, dated November 8, 2018
99.2	Press release, dated November 8, 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: November 8, 2018

Caladrius Biosciences Reports 2018 Third Quarter Financial Results

*Development programs remain on track accompanied by
continued strong fiscal management*

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

BASKING RIDGE, N.J. (November 8, 2018) - Caladrius Biosciences, Inc. (Nasdaq: CLBS) (“Caladrius” or the “Company”), a late-stage therapeutics development biopharmaceutical company with multiple technology platforms targeting select cardiovascular indications and autoimmune disease, announces financial results for the three ended September 30, 2018, and provides a business update.

Highlights of the 2018 third quarter and early fourth quarter include:

- Continued enrollment in a Phase 2 (SAKIGAKE designated and eligible for early conditional approval) clinical trial in Japan of CLBS12 for the treatment of no-option critical limb ischemia (“CLI”), including completion of enrollment of the five patient Buerger’s disease cohort;
- Continued enrollment in a Phase 2 clinical trial using the CD34 cell therapy CLBS14-CMD for the treatment of coronary microvascular dysfunction (“CMD”);
- 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; and
- Conducted a Type B meeting with the US Food and Drug Administration (“FDA”) under the provisions of the RMAT designation for CLBS14-RfA for the treatment of refractory angina to define remaining steps to registration.

“We are pleased with the advancement of our clinical programs during the third quarter. We maintain our previous guidance regarding development milestones and continue to demonstrate efficient management of cash spend,” stated Dr. David J. Mazzo, President and CEO.

“The fully-enrolled T-Rex Study of CLBS03 in type 1 diabetes remains on track for top-line data in early 2019. Our programs studying our CD34 cell therapy platform for CMD here in the United States and CLI in Japan continue to enroll with a target for top-line data in the second half of 2019 and early 2020, respectively.

“We are also pleased to announce that we recently completed our Type B meeting with the FDA pertaining to CLBS14-RfA for the treatment of refractory angina. This meeting was conducted to obtain FDA guidance and to define the remaining requirements for registration of this product under the terms of its RMAT designation. We believe that the meeting was both collaborative and positive and our assessment of the conversation is that FDA is demonstrating maximum flexibility afforded under the RMAT designation as we work together to establish the development steps necessary to bring this product to registration. We will be working with FDA to finalize the next development steps and to formalize the minutes of the meeting. We look forward to providing further information once these actions are completed.”

Third Quarter Financial Highlights

Research and development expenses for the third quarter of 2018 were \$1.7 million, a 47% decrease compared with \$3.2 million for the third quarter of 2017. The current quarter expenses were principally comprised of costs in our ischemic repair programs for CLBS12 and CLBS14-CMD, as well as initial planning for our CLBS14-RfA

program. Conversely, the prior year quarter expenses were primarily focused on our T-Rex study for CLBS03, which completed enrollment in December 2017 and is now in the follow-up phase of the study.

General and administrative expenses for the third quarter of 2018 were \$2.1 million, a 30% decrease compared with \$2.9 million for the third quarter of 2017, due to lower general and administrative headcount and corporate-related activities compared with the prior year period.

The net loss from continuing operations for the third quarter of 2018 was \$3.5 million, or \$0.36 per share, compared with \$3.5 million, or \$0.38 per share, for the third quarter of 2017.

Nine Month Financial Highlights

Research and development expenses for the nine months ended September 30, 2018 were \$6.1 million, a 46% decrease compared with \$11.2 million for the nine months of 2017. The current year expenses were principally comprised of costs in our ischemic repair programs for CLBS12 and CLBS14-CMD as well as initial planning for our CLBS14-RfA program. Conversely, the prior year expenses were primarily focused on our T-Rex study for CLBS03, which completed enrollment in December 2017 and is now in the follow-up phase of the study.

General and administrative expenses for the nine months ended September 30, 2018 were \$7.1 million, a 22% decrease compared with \$9.1 million for the nine months of 2017. The decrease was due to lower general and administrative headcount and 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.

The net loss from continuing operations for the nine months ended September 30, 2018 was \$12.6 million, or \$1.31 per share, compared with \$25.8 million, or \$1.37 per share, for the nine months of 2017.

Balance Sheet Highlights

As of September 30, 2018, Caladrius had cash, cash equivalents and marketable securities of \$46.1 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: 9490459. 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 November 15, 2018, and can be accessed by dialing (855) 859-2056 or (404) 537-3406. All listeners should provide the following replay access code: 9490459.

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

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-RfA in late-stage 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.

Contacts:

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- Tables to Follow -

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

(in thousands, except per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Statement of Operations Data:				
Research and development	\$ 1,701	\$ 3,187	\$ 6,086	\$ 11,191
General and administrative	2,062	2,943	7,105	9,082
Total operating expenses	3,763	6,130	13,191	20,273
Operating loss	(3,763)	(6,130)	(13,191)	(20,273)
Other income (expense), net	214	177	585	137
Interest expense	—	(9)	(5)	(372)
Loss before income taxes and noncontrolling interests	(3,549)	(5,962)	(12,611)	(20,508)
Benefit from income taxes	—	(2,414)	—	(8,301)
Net loss from continuing operations	(3,549)	(3,548)	(12,611)	(12,206)
Discontinued operations	—	—	—	37,330
Net (loss) income	(3,549)	(3,548)	(12,611)	25,124
Less - net income (loss) from continuing operations attributable to noncontrolling interests	1	(119)	(2)	(150)
Less - net loss from discontinued operations attributable to noncontrolling interests	—	—	—	(568)
Net (loss) income attributable to Caladrius Biosciences, Inc. common stockholders	\$ (3,550)	\$ (3,429)	\$ (12,609)	\$ 25,842
Basic and diluted loss per share attributable to Caladrius Biosciences, Inc. common stockholders				
Continuing operations	\$ (0.36)	\$ (0.38)	\$ (1.31)	\$ (1.37)
Discontinued operations	\$ —	\$ —	\$ —	\$ 4.30
Caladrius Biosciences, Inc. common stockholders	\$ (0.36)	\$ (0.38)	\$ (1.31)	\$ 2.94
Weighted average common shares outstanding	9,745	9,094	9,634	8,804

	September 30, 2018	December 31, 2017
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	\$ 46,150	\$ 60,085
Total assets	47,854	63,376
Total liabilities	7,044	13,186
Total equity	40,809	50,190

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Caladrius Biosciences Appoints Cynthia Schwalm to Board of Directors

BASKING RIDGE, N.J. (November 8, 2018) - Caladrius Biosciences, Inc. (Nasdaq: CLBS) (“Caladrius” or the “Company”), a late-stage therapeutics development biopharmaceutical company with multiple technology platforms targeting select cardiovascular indications and autoimmune disease, announces today the appointment of Ms. Cynthia Schwalm to its Board of Directors.

“Cynthia brings extensive experience in leading and managing biopharmaceutical companies during transformative years of growth,” said David J. Mazzo, PhD, Chief Executive Officer of Caladrius. “We are delighted with her addition to our board and believe she will provide a fresh perspective while making important contributions to our progress, particularly when it comes to commercialization. We look forward to her guidance as we continue to advance our clinical programs through late-stage development and toward registration and eventual launch.”

In her most recent role, Ms. Schwalm was President and Chief Executive Officer of Ipsen North America, where she led the transformation of the company as it became the highest-growth subsidiary worldwide. Prior to joining Ipsen, she served as President of Eisai Pharmaceuticals, where she oversaw commercial operations, medical affairs and services, manufacturing, alliance management and other functions. She has also held general management roles, both domestically and internationally at Amgen Inc. and Johnson & Johnson. Ms. Schwalm began her career as an oncology/critical care nurse.

Ms. Schwalm currently serves on the board of G1 Therapeutics Inc., a clinical-stage oncology company. She has held positions on numerous corporate and non-profit boards, including the Women’s Leadership Advisory Board for the John F. Kennedy School of Government at Harvard University and the board of directors for the Sarah Cannon Oncology Research Institute. She currently serves as a Wharton Business School Leadership Advisor. Ms. Schwalm holds an MBA from the Wharton School of the University of Pennsylvania and a B.S.N. from the University of Delaware.

Ms. Schwalm will also serve as a member of the Audit Committee and the Science and Technology Committee of the Company. With this appointment, Caladrius’ Board of Directors expands to six members.

“Under the current management team’s guidance, Caladrius has evolved into an exciting, focused biopharmaceutical company with four clinical-stage products, two of which are at the latter stages of development and anticipating commercialization,” said Ms. Schwalm. “I look forward to working with the rest of the board and management team as they continue in their efforts to advance their clinical programs and eventually evolve into a commercial entity.”

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.

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