

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): March 22, 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 8.01 is incorporated by reference.

Item 2.02 Results of Operations and Financial Condition

On March 22, 2018, Caladrius Biosciences, Inc., a Delaware corporation (the "Company") issued a press release in connection with its fiscal year ended December 31, 2017. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 8.01 by reference.

Item 9.01. Financial Statement and Exhibits.

(d) Exhibits.

Exhibit No.[99.1](#)**Description**

Press Release, dated March 22, 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: March 22, 2018

Caladrius Biosciences Reports 2017 Fourth Quarter and Year End Financial Results

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

BASKING RIDGE, N.J. (March 22, 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 twelve months ended December 31, 2017 and provides a business update.

Highlights of the 2017 fourth quarter and recent weeks include:

- Completed enrollment in The Sanford Project: T-Rex Study;
- Dosed first patient in Phase 2 clinical trial in Japan with Caladrius’ proprietary CD34 cell therapy (CLBS12) for the treatment of non-option critical limb ischemia (“CLI”);
- Acquired from Shire plc (LSE: SHP, Nasdaq: SHPG) an exclusive worldwide license to data and regulatory filings from a late stage CD34 cell therapy program for the treatment of chronic myocardial ischemia targeting refractory angina (“RfA”); and
- Reported results from the predetermined interim analysis in The Sanford Project: T-Rex Study, which concluded the treatment to be well-tolerated and non-futile for therapeutic effect.

Management Commentary

“The past months have been especially productive as we made much progress advancing and expanding our clinical development pipeline,” stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius.

“We were particularly pleased to acquire the late-stage asset from Shire’s CD34 cell therapy program for the treatment of refractory angina. In addition to adding a potentially late-stage product candidate that is complementary to our current pipeline in ischemic repair, this program represents a large potential commercial opportunity as refractory angina afflicts approximately one million people in the U.S. alone, with an incidence rate of 50,000 to 100,000 annually.¹

“Our active clinical programs continue to progress well and we were delighted to complete enrollment in our landmark Phase 2 T-Rex study in children and adolescents with recent onset type 1 diabetes. We subsequently reported the conclusions of the independent statisticians for the predetermined interim analysis that the therapy continues to be well tolerated and was deemed non-futile as determined by pre-defined futility criteria for therapeutic effect. This analysis was triggered by 50% of the targeted total number of patients completing six months of follow-up. We look forward to completing and reporting the 12-month follow-up on all 110 patients in early 2019 as the complete data set will inform the next steps in our development plan.

¹ Global Cardiology Science & Practice: April 30, 2015

“We believe that we have an exciting year ahead as we plan to advance a number of key clinical programs in cardiovascular indications such as CLI, coronary microvascular dysfunction and RfA and as we near the completion of the T-Rex study in type 1 diabetes. We continue to build on our recent accomplishments and hope to attain a number of value-creating inflection points throughout the balance of the year and beyond,” Dr. Mazzo continued.

Fourth Quarter Financial Highlights

Note: Effective with the sale of PCT to Hitachi in the second quarter of 2017, all PCT-related activities and gain on sale results will be reported as discontinued operations. All remaining operations will be reported as continuing operations. In addition, all prior year comparative financial results will restate PCT operations as discontinued operations.

Research and development (R&D) expenses for the fourth quarter of 2017 of \$4.7 million increased 45% compared with \$3.2 million in the fourth quarter of 2016, as the Company focused its R&D efforts on the ongoing Phase 2 T-Rex Study and preparations for other pipeline programs, including the initiation of our CLI clinical program in Japan. Caladrius' clinical development programs are supported, in part, by grants and collaborations.

General and administrative (G&A) expenses for the fourth quarter of 2017 increased 17% to \$2.7 million, compared with \$2.3 million in the fourth quarter of 2016.

The net loss from continuing operations for the fourth quarter of 2017 was \$4.0 million, and included a non-cash tax benefit of \$3.2 million, compared with \$5.7 million for the comparable 2016 period. The non-cash tax benefit in 2017 is principally offset by non-cash tax expense reported in discontinued operations.

Income from discontinued operations for the fourth quarter of 2017 was \$1.1 million, which represented a non-cash income tax adjustment on gain on the sale of PCT to Hitachi in the second quarter of 2017.

Net loss per share from continuing operations attributable to Caladrius common stockholders for the fourth quarter of 2017 was \$0.40 per share compared to net loss per share of \$0.69 for the same period in 2016.

2017 Financial Highlights

R&D expenses for 2017 decreased 5% to \$15.8 million compared with \$16.7 million for the 2016 year. G&A expenses decreased 8% to \$11.8 million for 2017 compared with \$12.8 million for the 2016 year. 2017 included \$1.9 million of equity compensation expense related to the acceleration of employee equity stock and option award vesting triggered by the sale of the Company's PCT subsidiary to Hitachi.

The net loss from continuing operations for the twelve months ended December 31, 2017 was \$16.2 million, compared with the net loss from continuing operations of \$31.3 million for the same period of

2016. The continuing operations net loss includes a non-cash tax benefit of \$11.5 million, which is substantially offset by a non-cash tax expense reported in discontinued operations.

Income from discontinued operations during 2017 was \$38.4 million, which includes a \$41.2 million gain on the sale of PCT (net of \$10.5 million taxes), compared with a loss from discontinued operations of \$2.1 million in the same period in 2016.

Net loss per share from continuing operations attributable to Caladrius common stockholders for the twelve months ended December 31, 2017 was \$1.78 per share compared to a net loss per share of \$4.74 for the same period in 2016.

Balance Sheet Highlights

As of December 31, 2017, Caladrius had cash, cash equivalents, restricted cash and marketable securities of \$60.1 million compared with \$7.1 million as of December 31, 2016. During 2017, the Company received gross proceeds of \$79.4 million from the sale of PCT and \$5.7 million in proceeds from stock issuance.

Based on existing programs and projections, the Company is confident 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 beginning today at 4:30 p.m. Eastern Time to review financial results, provide a Company update and answer questions.

Shareholders and other interested parties may participate in the conference call by dialing 866-595- 8403 (U.S.) or 706-758-9979 (international) and providing conference ID 8668599. The call will also be broadcast live on the Company's website at www.caladrius.com/events.

For those unable to participate in the live conference call or webcast, a replay will be available beginning March 22, 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: 8668599.

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 autoimmune and select cardiovascular indications. The Company is investigating its lead product candidate, CLBS03, an *ex vivo* expanded polyclonal T regulatory cell therapy for the treatment of recent-onset type 1 diabetes, in an ongoing Phase 2 trial. CLBS14, CD34 cell therapy intended as a treatment for coronary microvascular dysfunction and refractory angina, 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. Its 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 enrolling in Japan, a successful outcome of which will qualify the program for consideration of early conditional approval based on discussions with the Japanese regulatory authorities as provided for under Japan's progressive regenerative medicine regulations. 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, 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:

Caladrius Biosciences, Inc.

John Menditto

Executive Director, Investor Relations and Corporate Communications Phone:

+1-908-842-0084

Email: jmenditto@caladrius.com

LHA Investor Relations Anne Marie Fields Senior Vice President Phone: +1-212-838-3777

Email: afields@lhai.com

--Tables to Follow --

	<u>Three Months Ended December 31,</u>	<u>Year Ended December 31,</u>
	(in thousands, except per share data) <u>2017</u> <u>2016</u>	
Statement of Operations Data:		20,172,016
Research and development	4,652,203	15,843
General and administrative	<u>2,668</u> <u>2,289</u> <u>11,750</u>	12,803
Total operating expenses	<u>7,320</u> <u>5,492</u> <u>27,593</u>	29,502
Operating loss	<u>(7,320)</u> <u>(5,492)</u> <u>(27,593)</u>	(29,502)
Other income (expense), net	136,427	24
Interest expense	<u>(6)</u> <u>(178)</u> <u>(378)</u>	(1,780)
Loss before income taxes and noncontrolling interests	<u>(7,190)</u> <u>(5,666)</u> <u>(27,698)</u>	(31,258)
Benefit from income taxes	<u>(3,225)</u> <u>-(11,527)</u>	0
Net loss from continuing operations	<u>(3,965)</u> <u>(5,666)</u> <u>(16,171)</u>	(31,258)
Discontinued operations	<u>1,069</u> <u>(423)</u> <u>38,399</u>	(2,052)
Net income (loss)	<u>(2,896)</u> <u>(6,089)</u> <u>22,228</u>	(33,310)
Less - net loss from continuing operations attributable to noncontrolling interests	(150)(55)(182)	(242)
Less - net income (loss) from discontinued operations attributable to noncontrolling interests	<u>-(77)</u> <u>(568)</u>	(411)
Net income (loss) attributable to Caladrius Biosciences, Inc. common stockholders	<u>\$(2,746)</u> <u>\$(5,957)</u> <u>\$22,978</u>	\$(32,657)
Basic and diluted loss per share attributable to Caladrius Biosciences, Inc. common stockholders		
Continuing operations	\$(0.40) \$(0.69) \$(1.78)	\$(4.74)
Discontinued operations	\$0.11 \$(0.04) \$4.34	\$(0.25)
Caladrius Biosciences, Inc. common shareholders	\$(0.29) \$(0.73) \$2.56	\$(4.99)
Weighted average common shares outstanding	9,459,817	6,548,969

	December 31, December 31,	
	2017 2016	
Balance Sheet Data:		
Cash, cash equivalents, restricted cash and marketable securities	\$60,085	\$7,077
Total assets		63,376
Total liabilities		13,186
Total equity		50,190

###