

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 9, 2017



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 November 9, 2017, Caladrius Biosciences, Inc. (the "Company") issued a press release in connection with its 2017 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 9, 2017 at 4:30 p.m. Eastern Standard 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 Statements and Exhibits.

**Exhibit
No.**

Description

[99.1](#)

Press release, dated November 9, 2017

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 9, 2017

Caladrius Biosciences Reports 2017 Third Quarter Results

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

BASKING RIDGE, N.J., (November 9, 2017) - Caladrius Biosciences, Inc. (NASDAQ: CLBS) (“Caladrius” or the “Company”), a development-stage biopharmaceutical company with multiple technology platforms targeting autoimmune and select cardiology indications, announces results for the three and nine months ended September 30, 2017.

Highlights of the 2017 third quarter and recent weeks include:

- Enrolled the 70th subject in The Sanford Project: T-Rex Study (the “T-Rex Study”), a prospective, randomized, placebo-controlled, double-blind Phase 2 clinical trial to evaluate the safety and efficacy of CLBS03 as a treatment for recent-onset type 1 diabetes (“T1D”), which triggered a \$2.4 million milestone payment and the delivery of 508,475 shares of Caladrius common stock as per the terms of the September 2016 private placements;
- Reached 50% of subjects, or 56 patients, treated in the T-Rex Study, which establishes a timeframe for a prescribed interim analysis when the first 56 patients reach their 6-month follow-up visit; and
- Awarded approximately \$2 million as a Small Business Innovative Research (“SBIR”) grant from the National Heart, Lung and Blood Institute of the National Institutes of Health (“NIH”) to support a Phase 2 clinical study with CLBS14 in patients with coronary microvascular dysfunction (“CMD”).

Management Commentary

“Throughout the third quarter and following the sale of our contract manufacturing business to Hitachi Chemical, we made significant progress advancing Caladrius as a purely development-focused biopharmaceutical company and achieved key milestones in a number of our clinical development programs,” stated David J. Mazzo, PhD, President and Chief Executive Officer of Caladrius. “Our lead program, the T-Rex study, remains on track to complete enrollment by the end of this year. Additionally, we expect to have the results of a planned pre-specified interim analysis of the data from the six-month follow-up of the first 56 patients around the end of the first quarter of 2018.”

“Furthermore, we continue to execute according to our strategy to advance our pipeline programs with collaborative support, such as grants, partnerships or licensing. During the third quarter 2017, we were pleased to receive an NIH grant to help fund our Phase 2 study of CLBS14 in CMD. We also continue to receive funding from the California Institute for Regenerative Medicine (“CIRM”) grant in support of the T-Rex study,” Dr. Mazzo continued. “The successful sale of our PCT manufacturing subsidiary earlier this year has resulted in Caladrius being well-funded and focused on advancing our clinical development programs, while also allowing us to opportunistically explore compelling therapeutic prospects through a comprehensive, disciplined and data-driven process. We look forward to achieving a number of value-creating milestones during the remainder of the year and into 2018.”

Third 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 third quarter of 2017 of \$3.2 million increased 8% compared with \$3.0 million in the third quarter of 2016, as the Company focuses its R&D efforts on the ongoing Phase 2 T-Rex Study and preparations for other pipeline programs. Caladrius’ clinical development programs are supported, in part, by grants and collaborations.

General and administrative (G&A) expenses for the third quarter of 2017 remained flat at \$2.9 million, compared with \$2.8 million in the third quarter of 2016.

The net loss from continuing operations for the third quarter of 2017 was \$3.5 million, compared with the net loss from continuing operations of \$6.1 million for the comparable 2016 period. The continuing operations net loss includes a tax benefit of \$2.4 million, which partially offsets the tax expense reported in discontinued operations.

Loss from discontinued operations during the third quarter of 2016 was \$1.2 million. Discontinued operations relate to our 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 third quarter of 2017 was \$0.38 per share compared to net loss per share of \$0.95 for the same period in 2016.

Nine-Month Financial Highlights

R&D expenses for the first nine months of 2017 decreased 17% to \$11.2 million compared with \$13.5 million for the same period in 2016. G&A expenses were \$9.1 million for the first nine months of 2017 compared with \$10.5 million for first nine months of 2016. The first nine months of 2017 included \$1.7 million of equity compensation expense. This unusually high expense was due 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 nine months ended September 30, 2017 was \$12.2 million, compared with the net loss from continuing operations of \$25.6 million for the same period of 2016. The continuing operations net loss includes a tax benefit of \$8.3 million, which partially offsets the tax expense reported in discontinued operations.

Income from discontinued operations during the first nine months of 2017 was \$37.3 million, which includes a \$40.2 million gain on the sale of PCT (net of \$11.6 million taxes), compared with a loss from discontinued operations of \$1.6 million in the same period in 2016.

Net loss per share from continuing operations attributable to Caladrius common stockholders for the nine months ended September 30, 2017 was \$1.37 per share compared to net loss per share of \$4.23 for the same period in 2016.

Balance Sheet Highlights

As of September 30, 2017, Caladrius had cash, cash equivalents and marketable securities of \$59.4 million compared with \$7.1 million as of December 31, 2016. During the third quarter of 2017, the Company received an additional \$4.4 million as a final net cash settlement of the PCT transaction, bringing the total received to \$79.4 million. Also during the third quarter of 2017, upon the enrollment of the 70th patient in the T-Rex study, the Company received \$2.4 million and delivered 508,475 shares of Caladrius common stock as per the terms of the September 2016 private placements.

Based on existing programs and projections, the Company expects to have more than \$50 million in cash and marketable securities at year-end 2017. Caladrius also expects less than \$5 million of CLBS03 external spending obligations after 2017 to reach the completion of the T-Rex study, excluding any further CIRM funding. 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 2018.

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 877-562-4460 (U.S.) or 513-438-4106 (international) and providing conference ID 6198497. The call will also be broadcast live on the Company's website at www.caladrius.com/events.

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 cardiology 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 a currently enrolling Phase 2 trial. CLBS14, CD34+ cell therapy intended as a treatment for coronary microvascular dysfunction, 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 specifically formulated for intramuscular administration for the treatment of lower extremity ischemia. A phase 2 study of CLBS12 as a treatment for critical limb

ischemia is about to initiate 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 17, 2017, 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:

Investors:

Caladrius Biosciences, Inc.

John Menditto

Executive Director, Investor Relations and Corporate Communications

Phone: 908-842-0084

Email: jmenditto@caladrius.com

LHA Investor Relations

Anne Marie Fields

Senior Vice President

Phone: 212-838-3777

Email: afields@lhai.com

Media:

Caladrius Biosciences, Inc.

Terrance Beckett

Communications and Marketing

Phone: 646-434-2681

Email: tbeckett@caladrius.com

-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 Sept 30,		Nine Months Ended Sept 30,	
	2017	2016	2017	2016
Statement of Operations Data:				
Research and development	3,187	2,959	11,191	13,496
General and administrative	2,943	2,769	9,082	10,514
Total operating expenses	6,130	5,728	20,273	24,010
Operating loss	(6,130)	(5,728)	(20,273)	(24,010)
Other income (expense), net	177	5	137	20
Interest expense	(9)	(368)	(372)	(1,601)
Loss before income taxes and noncontrolling interests	(5,962)	(6,091)	(20,508)	(25,591)
Benefit from income taxes	(2,414)	0	(8,301)	0
Net loss from continuing operations	(3,548)	(6,091)	(12,206)	(25,591)
Discontinued operations	0	(1,197)	37,330	(1,629)
Net income (loss)	(3,548)	(7,288)	25,124	(27,220)
Less - net loss from continuing operations attributable to noncontrolling interests	(119)	(59)	(150)	(187)
Less - net income (loss) from discontinued operations attributable to noncontrolling interests	0	(346)	(568)	(335)
Net income (loss) attributable to Caladrius Biosciences, Inc. common stockholders	\$ (3,429)	\$ (6,883)	\$ 25,842	\$ (26,698)
Basic and diluted loss per share attributable to Caladrius Biosciences, Inc. common stockholders				
Continuing operations	\$ (0.38)	\$ (0.95)	\$ (1.37)	\$ (4.23)
Discontinued operations	0	\$ (0.13)	\$ 4.30	\$ (0.22)
Caladrius Biosciences, Inc. common shareholders	(0.38)	(1.09)	2.94	(4.45)
Weighted average common shares outstanding	9,094	6,323	8,804	6,002

	September 30, 2017	December 31, 2016
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	\$ 59,449	\$ 7,077
Total assets	67,555	53,514
Total liabilities	14,575	30,048
Total equity	52,980	4,066