

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): August 10, 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, 2nd 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 2.01 Results of Operations and Financial Condition.

The information in Item 7.01 is incorporated by reference.

Item 7.01 Regulation FD Disclosure.

On August 10, 2017, Caladrius Biosciences, Inc. issued a press release in connection with its 2017 Second 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 August 10, 2017, at 4:00 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 August 10, 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: Chief Executive Officer

Dated: August 10, 2017

Caladrius Biosciences Reports 2017 Second Quarter Results

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

BASKING RIDGE, N.J., (August 10, 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 six months ended June 30, 2017.

Highlights of the 2017 second quarter and recent weeks include:

- Completed the sale of Caladrius’ remaining 80.1% ownership interest in PCT to Hitachi America (Hitachi) for \$75 million in cash during the second quarter plus an additional \$4.4 million received in July 2017 as a final net cash settlement for a total of \$79.4 million;
- Retired all outstanding debt (approximately \$5 million) owed to Oxford Financial Services in conjunction with the closing of the sale of PCT to Hitachi;
- Reached 50% of subjects treated in The Sanford Project: 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) triggering a prescribed interim analysis of therapeutic effect and safety culminating when the 56th patient reaches their 6-month follow-up visit;
- Joined the Russell Microcap[®] Index as part of the Russell indexes annual reconstitution, effective as of June 26, 2017;
- Quarterly cash burn from ongoing operations being actively managed through various strategic cost management initiatives with notable reductions in real estate costs.

Management Commentary

“The sale of our remaining interest in PCT to Hitachi during the second quarter provides us with the capital and flexibility to advance our development pipeline,” stated David J. Mazzo, PhD, President and Chief Executive Officer of Caladrius.

“In addition to the sale of PCT, our Phase 2 T-Rex study of CLBS03 for the treatment of type 1 diabetes continues to advance on schedule. We reached the halfway point in treating subjects in the 111-patient study in July, triggering a pre-specified interim analysis of safety and potential early therapeutic effect to occur after the six-month post-treatment follow-up visit, and we expect to announce those topline results during the first quarter of 2018. We remain on track and optimistic to fully-enroll the T-Rex study by the end of 2017.

“We are excited about what lies ahead for Caladrius as we steadily manage our transition into a pure development-focused biopharmaceutical company,” concluded Dr. Mazzo.

Second Quarter Financial Highlights

Note: Effective with the sale of PCT to Hitachi in the second quarter, 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 second quarter of 2017 of \$4.3 million were down 5% compared to prior-year’s second quarter. Our current R&D is now primarily focused on the ongoing Phase 2 T-Rex Study and preparations for other pipeline programs.

General and administrative (G&A) expenses for the second quarter of 2017 were \$3.4 million, and included \$1.3 million of equity compensation expense (compared with equity compensation expense of \$253,000 in the prior year's second quarter). The unusually high equity compensation expense in the current year second quarter 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. Excluding equity compensation, G&A expenses were down 19% compared to the prior-year's second quarter.

The net loss from continuing operations for the second quarter of 2017 was \$2.0 million, compared with the net loss from continuing operations of \$7.7 million for the comparable 2016 period. The continuing operations net loss includes a tax benefit of \$5.9 million, which partially offsets the tax expense reported in discontinued operations.

Income from discontinued operations during the second quarter of 2017 was \$40.4 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 \$152,000 in the prior year's second quarter.

Net loss per share from continuing operations attributable to Caladrius common stockholders for the second quarter of 2017 was \$0.22 per share compared to net loss per share of \$1.30 for the same period in 2016.

Six Month Financial Highlights

R&D expenses for the first half of 2017 decreased 24% to \$8.0 million compared with \$10.5 million for the first half of 2016. G&A expenses were \$6.1 million for the first half of 2017 compared with \$7.7 million for the same period in 2016.

The net loss from continuing operations for the first half of 2017 was \$14.5 million, compared with the net loss from continuing operations of \$19.5 million for the first half of 2016.

The net loss from continuing operations for the first half of 2017 was \$8.6 million, compared with the net loss from continuing operations of \$19.5 million for the comparable 2016 period. The continuing operations net loss includes a tax benefit of \$5.9 million, which partially offsets the tax expense reported in discontinued operations.

Income from discontinued operations during the first half 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 \$432,000 in the prior year's second quarter.

Net loss per share from continuing operations attributable to Caladrius common stockholders for the first half of 2017 was \$0.99 per share compared to net loss per share of \$3.32 for the same period in 2016.

Balance Sheet Highlights

As of June 30, 2017, Caladrius had cash, cash equivalents and marketable securities of \$59.3 million compared with \$7.1 million (excluding cash held at PCT) as of December 31, 2016. During the first half of 2017, the Company received \$75 million in connection with the closing of the Hitachi transaction, of which \$5.0 million was placed in an escrow account to cover potential indemnification claims over the next 12 months. The latter is recorded as restricted cash on the balance sheet. In addition, upon closing the transaction, \$4.9 million was paid to Oxford Financial to retire all Caladrius' outstanding debt including any remaining principal, interest and fee obligations. Following the close of the second quarter, the Company received an additional \$4.4 million as a final net cash settlement of the PCT transaction for a total of \$79.4 million received to date related to the transaction.

During the second quarter of 2017, the Company received \$5.7 million in an upfront payment in connection with the up to \$12.2 million CIRM grant announced earlier this year, which is based on reaching certain milestones. In addition, the Company received \$2.0 million from Sanford Research in connection with a closing sale of the second tranche of securities pursuant to Sanford's equity investment in Caladrius in September 2016.

Based on existing programs and projections, the Company expects to have greater than \$50 million in cash and marketable securities at year end 2017. Caladrius also expects less than \$5 million of projected 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 with runway 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 65397809. The call will also be broadcast live on the Internet via 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 development stage biopharmaceutical company with multiple technology platforms targeting autoimmune and select cardiology indications. The Company is investigating its lead product candidate, CLBS03, autologous polyclonal T regulatory cells, for the treatment of recent-onset type 1 diabetes in a currently enrolling Phase 2 trial. For more information on 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.

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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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Research and development	4,278	4,489	8,004	10,537
Total operating expenses	7,710	7,406	14,143	18,282
Other income (expense), net	5	9	(40)	14
Loss before income taxes and noncontrolling interests	(7,910)	(7,733)	(14,546)	(19,501)
Net loss from continuing operations	(2,022)	(7,733)	(8,658)	(19,501)
Net income (loss)	38,465	(7,885)	28,672	(19,933)
Less - net income (loss) from discontinued operations attributable to noncontrolling interests	(199)	14	(568)	11
Continuing operations	\$ (0.22)	\$ (1.30)	\$ (0.99)	\$ (3.32)
Caladrius Biosciences, Inc. common shareholders	\$ 4.34	\$ (1.33)	\$ 3.39	\$ (3.39)

	June 30, 2017	December 31, 2016
Cash, cash equivalents and marketable securities	\$ 59,370	\$ 7,077
Total liabilities	18,211	30,048