

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 5, 2016

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.)

106 Allen Road, 4th 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))

Item 7.01 Regulation FD Disclosure.

On May 5, 2016, Caladrius Biosciences, Inc. issued a press release in connection with its 2016 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 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.

Exhibit

No.

99.1

Description

Press release, dated May 5, 2016

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: May 5, 2016

Caladrius Biosciences Reports 2016 First Quarter Financial Results

Total Quarterly Revenues Increase 136% versus Prior Year

Conference Call Begins Today at 5:00 pm Eastern Time

BASKING RIDGE, N.J. (May 5, 2016) - Caladrius Biosciences, Inc. (NASDAQ: CLBS) (“Caladrius”), a cell therapy company combining an industry-leading development and manufacturing services provider (through its subsidiary, PCT, LLC a Caladrius Company™ (“PCT”)) with a select therapeutic development pipeline, announces financial results for the three months ended March 31, 2016.

Financial and Business Highlights

- Achieved total revenues of \$7.5 million for the first quarter of 2016, up 136% compared with \$3.2 million in the first quarter of 2015 driven by higher Clinical Services revenue at PCT.
- Entered into a global collaboration and license agreement with Hitachi Chemical Co. America, Ltd. and Hitachi Chemical Co., Ltd. (collectively, “Hitachi Chemical”), selling a 19.9% equity stake in PCT for \$19.4 million and licensing PCT’s cell therapy technology and know-how for certain Asian territories for \$5.6 million and future royalties.
- Enrolled the first patient in The Sanford Project: T-Rex Study, a Phase 2 trial of CLBS03 (autologous expanded regulatory T cells, or Tregs) for the treatment of recent-onset type 1 diabetes (T1D) in adolescents.
- Received classification from the European Medicines Agency (EMA) of CLBS03 as an Advanced Therapeutic Medicinal Product (ATMP).
- Reached agreement with Japanese regulators on a Phase 2 development plan that could qualify for early conditional approval for CD34 cell therapy as a treatment for critical limb ischemia.

Management Commentary

“The significant revenue growth at PCT along with Hitachi Chemical’s implied valuation of our subsidiary further support our strategy to focus on growth opportunities in the emerging cell therapy manufacturing market,” stated David J. Mazzo, PhD, Chief Executive Officer of Caladrius. “In addition to validating our expertise and know-how, the strategic partnership with Hitachi Chemical strengthens our financial position with \$25 million in non-dilutive capital.

“We will continue to leverage the significant momentum in the regenerative medicine and cell therapy industries to grow our PCT business. We believe that the quality of PCT’s services, the increasing number of clinical trials planned and underway and the number of clinical programs nearing commercialization will provide a healthy platform for growth at PCT throughout 2016 and beyond.

“We are delighted that patients are being enrolled in the Sanford Project: T-Rex Study. Sanford Research, a leader of innovation and research in T1D, will provide and cover the costs of two initial clinical trial sites, which are expected to enroll most of if not all of the first cohort of subjects. After this first cohort has completed the three-month post-treatment visit, an interim safety analysis and early analysis of immunological biomarkers will be conducted. With positive results, more sites will be added to facilitate the timely enrollment of the second cohort of this important proof-of-concept study designed to show that CLBS03 can preserve pancreatic beta cell function and lower insulin use in adolescents with recent-onset T1D,” concluded Dr. Mazzo.

First Quarter Financial Highlights

Total revenues for the first quarter of 2016 increased 136% to \$7.5 million compared with \$3.2 million for the first quarter of 2015. Gross margin on revenues was 17% in the first quarter of 2016, compared with gross margin of negative 6% in the first quarter of 2015.

Research and development (R&D) expenses for the first quarter of 2016 decreased 14% to \$5.9 million compared with \$6.8 million for the first quarter of 2015. The decrease was primarily related to lower costs subsequent to the discontinuation of Caladrius' Intus Phase 3 clinical trial as well as decreased costs associated with our ischemic repair platform, compared to the prior year periods. These decreases were partially offset by an increase in expenses related to the initiation of The Sanford Project: T-Rex Phase 2 Study in type 1 diabetes, as well as one-time restructuring costs for severance and asset impairments.

Selling, general and administrative (SG&A) expenses decreased 42% to \$6.5 million for the first quarter of 2016 compared with \$11.1 million for the same period in 2015, which included expenses associated with executive management changes including one-time new hire compensation-related costs as well as separation-related costs. Equity-based compensation expenses were also significantly lower in the first quarter of 2016 compared to the prior year period.

The operating loss for the first quarter of 2016 was \$11.1 million compared with an operating loss of \$18.1 million for the first quarter of 2015, reflecting higher gross margin on sales, and lower R&D and SG&A expenses.

Total net loss for the first quarter of 2016 was \$12.0 million, and \$0.21 per share for Caladrius stockholders, compared with a net loss for the first quarter of 2015 of \$19.2 million and \$0.51 per share.

Balance Sheet and Cash Flow Highlights

As of March 31, 2016, Caladrius had cash and cash equivalents of \$25.4 million. The cash and cash equivalents balance includes the receipt of \$22.5 million from the Hitachi Chemical transaction and the payment of \$7.0 million to Oxford Finance LLC for repayment of long-term debt, interest and fees. The net cash used in operating activities in the first quarter of 2016 was \$8.0 million, compared with \$14.2 million in the first quarter of 2015. During the current quarter, Caladrius also invested \$1.0 million in capital expenditures primarily related to improvements to PCT's Allendale, N.J. manufacturing facility.

2016 Financial Guidance

- **Consolidated Revenues:** exceed \$30 million (greater than 30% increase compared with 2015) (*guidance reaffirmed*)
- **Capital Improvements at PCT's Allendale, NJ facility:** ~\$6 million in 2016 (*guidance reaffirmed*)
- **CLBS03 Phase 2 Study Costs in 2016:** \$6 million to \$7 million (*guidance reaffirmed*)
- **Consolidated Annual Operating Cash Burn:** \$25 million to \$28 million (*new guidance*) (lower operating cash burn in the second half of 2016 than in the first half of the year)

Conference Call

As previously announced, Caladrius will host a conference call to discuss these results and provide a company update today at 5:00 pm Eastern time. To participate in the conference call, dial 877-562-4460 (U.S.) or 513-438-4106 (international) and provide conference ID 95709217.

To access the live webcast, visit the Investor Relations section of the Company's website at <http://www.caladrius.com/events>. The webcast will be archived on the website for 90 days.

About Caladrius Biosciences

Caladrius Biosciences, Inc., through its subsidiary, PCT, is a leading development and manufacturing partner to the cell therapy industry. PCT works with its clients to overcome the fundamental challenges of cell therapy manufacturing by providing a wide range of innovative services including product and process development, GMP manufacturing, engineering and automation, cell and tissue processing, logistics, storage and distribution, as well as

expert consulting and regulatory support. PCT and Hitachi Chemical Co. have entered into a strategic global collaboration to accelerate the creation of a global commercial cell therapy development and manufacturing enterprise with deep engineering expertise. Around the core expertise of PCT, Caladrius strategically develops select product candidates, which currently includes an innovative therapy for type 1 diabetes based on a proprietary platform technology for immunomodulation. For more information, visit www.caladrius.com.

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 15, 2016, and in the Company's other periodic filings with the SEC, including: risks related to: (i) our expected continued losses and negative cash flows; (ii) our anticipated need for substantial additional financing; (iii) the significant costs and management resources required to comply with the requirements of being a public company; (iv) the possibility that a significant market for cell therapy may not emerge; (v) the potential variability in PCT's revenues; (vi) PCT's limited manufacturing capacity; (vii) the need to improve manufacturing efficiency at PCT; (viii) the limited marketing staff and budget at PCT; (ix) the logistics associated with the distribution of materials produced by PCT; (x) government regulation; (xi) our intellectual property; (xii) cybersecurity; (xiii) the development, approval and commercialization of our products; (xiv) enrolling patients in and completing, clinical trials; (xv) the variability of autologous cell therapy; (xvi) our access to reagents we use in the clinical development of our cell therapy product candidates; (xvii) the validation and establishment of manufacturing controls; (xviii) the failure to obtain regulatory approvals outside the United States; (xix) our failure to realize benefits relating to "fast track" and "orphan drug" designations; (xx) the failure of our clinical trials to demonstrate the safety and efficacy of our product candidates; (xxi) our current lack of sufficient manufacturing capabilities to produce our product candidates at commercial scale; (xxii) our lack of revenue from product sales; (xxiii) the commercial potential and profitability of our products; (xxiv) our failure to realize benefits from collaborations, strategic alliances or licensing arrangements; (xxv) the novelty and expense of the technology used in our cell therapy business; (xxvi) the possibility that our competitors will develop and market more effective, safer or less expensive products than our product candidates; (xxvii) product liability claims and litigation, including exposure from the use of our products; (xxviii) our potential inability to retain or hire key employees; and (xxix) risks related to our capital stock. 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.

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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,	
	2016	2015
Statement of Operations Data:		
Revenues	\$ 7,489	\$ 3,172
Costs and expenses:		
Cost of revenues	6,228	3,369
Research and development	5,876	6,804
Selling, general, and administrative	6,458	11,088
Total operating costs and expenses	18,563	21,260
Operating loss	(11,074)	(18,088)
Other income (expense), net	6	(546)
Interest expense	(927)	(551)
Loss before income taxes and noncontrolling interests	(11,994)	(19,185)
Provision for income taxes	53	47
Net loss	(12,048)	(19,231)
Less - loss attributable to noncontrolling interests	(67)	(45)
Net loss attributable to Caladrius Biosciences, Inc. common stockholders	\$ (11,981)	\$ (19,187)
Basic and diluted loss per share attributable to Caladrius Biosciences, Inc. common shareholders	\$ (0.21)	\$ (0.51)
Weighted average common shares outstanding	57,380	37,595

	March 31, 2016	December 31, 2015
	Balance Sheet Data:	
Cash and cash equivalents	\$ 25,426	\$ 20,318
Total assets	63,185	57,205
Total liabilities	30,602	33,921
Total redeemable securities	19,400	0
Total equity	13,183	23,284

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