

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 5, 2015

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 2.02. Results of Operations and Financial Condition.

On November 5, 2015, Caladrius Biosciences, Inc. ("Caladrius Biosciences" or the "Company") issued a press release relating to, among other things, the results of the Company's third quarter ended September 30, 2015. A copy of this press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 2.02 by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

The information appearing under the heading "Exhibit Index" immediately following the signature page to this Form 8-K is incorporated herein by reference.

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/ Joseph Talamo

Name: Joseph Talamo

Title: Senior Vice President & Chief Financial Officer

Dated: November 9, 2015

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated November 5, 2015*

*Exhibit 99.1 is furnished as part of this Current Report on Form 8-K.

Caladrius Biosciences Announces Third Quarter 2015 Financial Results and Provides Corporate Update**Revenues Increase 43% Driven by Growth in Clinical Services at PCT Subsidiary**

BASKING RIDGE, N.J., Nov. 05, 2015 (GLOBE NEWSWIRE) -- Caladrius Biosciences, Inc. (NASDAQ:CLBS) ("Caladrius"), a company combining a leading cell therapy service provider with a development pipeline including a Phase 3 clinical program in immuno-oncology and a portfolio of projects in immune modulation and ischemic repair, announces financial results for the three months ended September 30, 2015.

Business Highlights

- Total revenues for the third quarter of 2015 increased 43% to \$5.9 million when compared with \$4.1 million in the year-ago third quarter, driven by increases in Clinical Service revenue at the Company's PCT subsidiary, an external development and manufacturing partner for the growing cell therapy industry
- PCT entered into a long-term dedicated capacity agreement with IRX Therapeutics, Inc. to support their anticipated clinical trial manufacturing needs including the manufacture of EU-compliant cell therapy product, adding to a growing list of immuno-oncology clients with similar arrangements including Kite Pharma and ImmunoCellular Therapeutics
- Continued patient enrollment in a Phase 3 clinical study of lead product candidate CLBS20 for the treatment of recurrent Stage III or Stage IV metastatic melanoma
- Presented data elucidating the mechanism of action of CLBS20, suggesting correlations between a distinct immune response triggered by CLBS20 and overall survival of melanoma patients
- Received an initial award of \$300,000 out of a potential award of up to \$2.3 million from the National Cancer Institute to fund the first phase of a project for process optimization of CLBS20
- Entered into a collaboration agreement with Sanford Research to develop CLBS03, the Company's T regulatory cell therapy product candidate, for the treatment of adolescents with recent-onset type 1 diabetes, which the Company expects to advance to a Phase 2 clinical study in early 2016
- Promoted Joseph Talamo to Chief Financial Officer and Todd Girolamo to General Counsel.

Management Commentary

"PCT continues to post strong revenue growth, which we expect to continue as the immuno-oncology sector is experiencing industry-wide advances and there are increasing numbers of such products on the market and in development. We expect PCT to continue to capitalize on its unmatched cell development and manufacturing expertise as industry demand for cell therapy services continues to grow," said David J. Mazzo, Ph.D., Chief Executive Officer of Caladrius. "In addition, we continued to advance our own clinical development programs in immuno-oncology (CLBS20) and immune modulation (CLBS03), while maintaining financial discipline that allowed us to lower our cash burn."

2015 Third Quarter Financial Highlights

Total revenue for the third quarter of 2015 increased 43% to \$5.9 million compared with \$4.1 million for third quarter of 2014, primarily due to higher reported Clinical Services revenues at PCT.

Research and development expenses in the third quarter of 2015 decreased 24% to \$6.3 million compared with \$8.5 million for the third quarter of 2014. The decrease was primarily related to lower costs associated with the Company's ischemic repair and immune modulation programs. The lower costs were partially offset by increased expenses associated with the Intus Phase 3 clinical trial that initiated in 2015.

Selling, general and administrative expenses were approximately \$5.1 million for the third quarter of 2015 compared with \$7.9 million for same period in 2014. The decrease was primarily due to lower equity-based compensation expenses in the current quarter compared with a year ago and, to a lesser extent, lower expenses associated with other general and administrative activities.

The net loss for the third quarter of 2015 was approximately \$11.4 million or \$0.21 per share, compared with a net loss of \$17.2 million or \$0.48 per share for same period in 2014.

As of September 30, 2015, Caladrius had cash, cash equivalents and marketable securities of \$29.4 million.

Conference Call

As previously announced, Dr. Mazzo and Mr. Talamo will host a conference call to discuss 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 95709215. To access the live webcast, visit the Investor Relations section of the Company's website at <http://www.caladrius.com/events>.

Caladrius Biosciences, Inc. Selected Financial Data (unaudited)

(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Statement of Operations Data:				
Revenues	\$ 5,888	\$ 4,118	\$ 14,928	\$ 12,662
Costs and expenses:				
Cost of revenues	4,809	4,012	13,976	11,515
Research and development	6,316	8,470	20,720	19,025
Impairment of intangible assets	—	—	9,400	—
Selling, general, and administrative	5,147	7,894	24,971	24,310
Total operating costs and expenses	16,271	20,376	69,068	54,850
Operating loss	(10,383)	(16,258)	(54,140)	(42,188)
Other income (expense), net	(410)	(687)	4,399	(1,063)
Interest expense	(553)	(183)	(1,651)	(384)
Loss before income taxes and noncontrolling interests	(11,346)	(17,129)	(51,392)	(43,634)
Provision (benefit) for income taxes	47	47	(3,610)	142
Net loss	(11,393)	(17,177)	(47,782)	(43,776)
Less - net income from continuing operations attributable to noncontrolling interests	(17)	(202)	(93)	(515)
Net loss attributable to Caladrius Biosciences, Inc. common stockholders	\$ (11,376)	\$ (16,974)	\$ (47,689)	\$ (43,261)
Basic and diluted loss per share attributable to Caladrius Biosciences, Inc. common shareholders				
	\$ (0.21)	\$ (0.48)	\$ (1.04)	\$ (1.37)
Weighted average common shares outstanding	55,239	35,053	45,868	31,663

	September 30, 2015	December 31, 2014
Balance Sheet Data:		
Cash, cash equivalents, and marketable securities	\$ 29,392	\$ 26,254
Total assets	119,703	126,275
Total liabilities	64,706	68,202
Total equity	54,996	58,074

About Caladrius Biosciences

Caladrius Biosciences, Inc. is among the first of a new breed of immunotherapy companies with proven expertise and unique experience in cell process optimization, development and manufacturing. Caladrius combines a leading cell therapy service provider with a development pipeline including late-stage clinical programs based on proprietary platform technology for immuno-oncology, as well as additional platform technologies for immune modulation and ischemic repair. This integrated approach supports the industry in bringing significant life-improving medical treatments to market. 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. Forward-looking statements include statements herein with respect to the successful execution

of the Company's business strategy, the Company's ability to develop and grow its business, the successful development of cellular therapies with respect to the Company's research and development and clinical evaluation efforts in connection with the Company's Immuno-oncology Program, Immune Modulation Program, Ischemic Repair Program and other cell therapies, the future of the regenerative medicine industry and the role of stem cells and cellular therapy in that industry, and the performance and planned expansion of the Company's wholly-owned subsidiary and its center of excellence for cell therapy process development, engineering and manufacturing, PCT, as well as its efforts to expand its capabilities into the cell therapy tools market. 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 2, 2015, and in the Company's other periodic filings with the SEC. The Company's further development is highly dependent on future medical and research developments and market acceptance, which is outside of its control.

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