

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 9, 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 2.02 Results of Operations and Financial Condition

On August 9, 2016, Caladrius Biosciences, Inc. (the "Company") issued a press release in connection with its 2016 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 2.02 by reference.

The information in this Item 2.02, 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 2.02, 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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On August 9, 2016, Dr. Douglas W. Losordo entered into an employment agreement (the "Employment Agreement") by and between Dr. Losordo and the Company, confirming the terms and conditions of his current employment. Dr. Losordo currently serves as Senior Vice President, Clinical, Medical and Regulatory Affairs and Chief Medical Officer of the Company.

Under the terms of the Employment Agreement, Dr. Losordo will continue to be employed as the Company's Senior Vice President, Clinical, Medical and Regulatory Affairs and Chief Medical Officer. Pursuant to the Employment Agreement, among other things:

- The Company will pay Dr. Losordo an annual base salary of \$417,960.
- Dr. Losordo will be eligible to receive an annual cash bonus for each full calendar year during the term of the Employment Agreement. His target annual bonus will be 30% of his base salary based on defined goals and objectives to be determined and at the discretion of management.
- Dr. Losordo will be entitled to reimbursement up to a total of \$10,000 annually for Supplemental Term Life Insurance and/or Supplemental Long Term Disability coverage
- Dr. Losordo will be entitled to severance in the amount of six months current base salary and benefits continuation should the Company terminate employment without cause.
- In the event of a "double-trigger" change in control (as such term is defined in the Employment Agreement) where Dr. Losordo is terminated or his position is reduced within two years after such change of control, Dr. Losordo will be entitled to 12 months of his base salary, 100% of his target annual bonus and 12 months of health benefits.

The above summary of the Employment Agreement is qualified in its entirety by reference to the text of the Employment Agreement, a copy of which is attached hereto as Exhibit 10.1 and incorporated herein by reference.

EXHIBIT INDEX

Exhibit No.	Description
10.1	Employment Agreement, dated as of August 9, 2016, by and between Caladrius Biosciences, Inc. and Douglas W. Losordo, MD
99.1	Press release, dated August 9, 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: August 9, 2016



August 9, 2016

Douglas W. Losordo
13 Fox Meadow Road
Scarsdale, NY 10583

Dear Dr. Losordo,

This letter serves to confirm the terms and conditions of your employment with Caladrius Biosciences, Inc. (the "Company") with immediate effect.

Title: Chief Medical Officer & Senior Vice President Clinical, Medical and Regulatory Affairs
Reporting To: Chief Executive Officer
Primary Office: Basking Ridge, NJ

In consideration for your services, you shall be entitled to annual compensation of \$417,960 ("Base Salary") which shall be paid in accordance with the Company's standard payroll practices. Additionally, you shall be eligible for a cash bonus of up to 30% of your base salary based on defined goals and objectives to be determined and at the discretion of management.

Should the Company terminate your employment without cause you shall be entitled to severance in the amount of six (6) months' current base salary and benefits continuation.

Should the Company terminate your employment without cause or should you terminate your employment with the Company for good reason during the period commencing on the effective date of a change in control and ending on the second anniversary of the effective date of a change in control and subject to Employee complying with his obligations to execute and deliver a Release, the Company will (a) continue to pay your current base salary for a period beginning on the date the termination becomes effective (the "Termination Date") and ending on the twelve (12) month anniversary of the Termination Date, commencing on the next payroll period following the Termination Date; (b) pay you a lump sum amount equal to 100% of your then annual target bonus on the next payroll period following the Termination Date; and (c) provided you then participant in the Company's medical and/or dental plans and you timely elect to continue and maintain group health plan coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended, ("COBRA"), pay monthly, on your behalf, the amount of the monthly premium for such coverage for twelve (12) months following your Termination Date. For purposes of this paragraph, a Change in Control means a transaction or a series of related transactions in which: (w) all or substantially all of the assets of the Company are transferred to any "person" or "group" (as such terms are defined in Section 13(d)(3) and 14(d)(2) of the Exchange Act); (x) any person or group becomes the "beneficial owner" (as defined in Rules 13d-3 and 13d-5 under the Exchange Act), directly or indirectly, of the Company's outstanding equity representing more than 30% of the total voting power of the Company's then-outstanding equity; (y) the Company undergoes a merger, reorganization or other consolidation in which the holders of the outstanding equity of the Company immediately prior to such merger, reorganization or consolidation own less than 50% of the surviving entity's voting power immediately after the transaction; or (z) the date a majority of the members of the Company's incumbent Board of Directors is replaced during any twelve month period by members whose appointment or election is not endorsed by a majority to the Company's incumbent Board of Directors before the date of the appointment or election, provided further that the Change in Control meets all of the requirements of a "change in the ownership of a corporation" within the meaning of Treasury Regulation §1.409A-3(i)(5)(v), a "change in the effective ownership of a corporation" within the meaning of Treasury Regulation §1.409A-3(i)(5)(vi), or "a change in the ownership of a substantial portion of the corporation's assets" within in the meaning of Treasury Regulation §1.409A-3(i)(5)(vii). For purposes of (z), the incumbent Directors of the Board of Directors includes the members of the Board of Directors as of the date of this agreement and any additional or replacement Director appointed or elected who is endorsed by a majority of the Company's incumbent Board of Directors."

Upon presentation of invoices, the Company will reimburse you up to a total of \$10,000 annually for Supplemental Term Life Insurance and/or Supplemental Long Term Disability coverage.

In signing this letter agreement and accepting our offer of continued employment, you certify your understanding that your employment will otherwise be on an at-will basis.

CALADRIUS BIOSCIENCES, INC.

By: /s/ David Schloss

Name: David Schloss

Title: Vice President Human Resources

/s/ Douglas W. Losordo

Douglas W. Losordo, MD

Caladrius Biosciences Reports 2016 Second Quarter Financial Results

Total Quarterly Revenues Increase 41% and Expenses Decrease 50% versus Prior Year

Conference Call Begins Today at 5:00 pm Eastern Time

BASKING RIDGE, N.J. (August 9, 2016) - Caladrius Biosciences, Inc. (NASDAQ: CLBS) ("Caladrius" or the "Company"), 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 and six months ended June 30, 2016.

Business highlights for the second quarter and recent weeks include:

- Achieved total revenues of \$8.3 million for the second quarter of 2016, up 41% compared with \$5.9 million in the second quarter of 2015;
- Achieved total operating costs and expenses reduction of 50% in the second quarter of 2016 when compared with the second quarter of 2015;
- Granted Fast Track designation from the U.S. Food and Drug Administration ("FDA") for CLBS03 for the treatment of recent onset type 1 diabetes mellitus ("T1D"), making it the first known therapeutic candidate to receive Fast Track designation for treatment of T1D;
- Granted Orphan Drug designation from the FDA for CLBS03 for the treatment of T1D with residual beta cell function;
- Expanded PCT's relationship with Kiadis Pharma with an agreement for the manufacturing of their lead product, ATIR101™, for the U.S. and Canadian Phase 3 trial in blood cancers;
- Announced the appointment of Robert A. Preti, Ph.D., the Company's Chief Technology Officer, Senior Vice President, Manufacturing and Technical Operations, and President of PCT, as Chairman of the Alliance for Regenerative Medicine ("ARM"), the international advocacy organization representing the gene and cell therapies and broader regenerative medicine sector; and
- Licensed exclusive global rights to the Company's tumor cell/dendritic cell technology for the treatment of ovarian cancer to AiVita Biomedical, Inc. In return, Caladrius will receive certain development milestone payments as well as royalties on sales.

Management Commentary

"We remain very pleased with our year-to-date performance as we continue to deliver on our strategic goals to grow and expand the PCT business, to reduce expenses, to advance our Phase 2 T-Rex clinical trial as a treatment for T1D and to monetize non-core assets," stated David J. Mazzo, Ph.D., Chief Executive Officer of Caladrius. "We are delighted to add Fast Track and Orphan Drug designations to CLBS03 for the treatment of T1D as they underscore the significant unmet medical need in this degenerative disease, and provide regulatory provisions that can accelerate the review process and expand our market exclusivity. We look forward to completing enrollment and treatment of the first cohort of approximately 18 patients toward the end of summer. Following the three-month post-treatment visit, an interim safety analysis will be conducted, and we expect to have these results by year-end 2016."

"We entered the second half of 2016 in a solid position to continue advancing our strategic goals and achieving our financial guidance for the year. We are delighted that a growing number of cell therapy developers are partnering with PCT to take advantage of our expertise and our quality, scalable, innovative, reliable and cost-efficient manufacturing platforms and services to advance their cellular therapies."

"Our leadership in regenerative and cell therapy was further solidified with the appointment of Dr. Robert Preti as Chairman of ARM. As a pioneer in cell therapy manufacturing and development, Dr. Preti remains at the forefront of the industry, influencing regulatory trends and policy making. ARM's dedication to advancing regenerative medicine and cell therapies and to bringing its stakeholders together is unprecedented, and aligns with PCT's vision of contributing to a world in which transformative cell-based therapeutics are accessible to all patients in need," concluded Dr. Mazzo.

Second Quarter Financial Highlights

Total revenues for the second quarter of 2016 increased 41% to \$8.3 million compared with \$5.9 million for the second quarter of 2015. Gross margin on revenues was 15% in the second quarter of 2016 compared with 1% in the second quarter of 2015.

Research and development (R&D) expenses for the second quarter of 2016 decreased 47% to \$4.0 million compared with \$7.6 million for the second quarter of 2015. The decrease was primarily related to lower costs subsequent to the discontinuation of the Intus Phase 3 clinical trial for metastatic melanoma as well as lower program expenses associated with the Company's ischemic repair platform, compared with the prior-year period. These decreases were partially offset by an increase in expenses related to The Sanford Project: T-Rex Phase 2 Study in T1D.

Selling, general and administrative (SG&A) expenses decreased 46% to \$4.7 million for the second quarter of 2016 compared with \$8.7 million for the same period in 2015. The decrease is due to both lower equity-based compensation costs and operational and compensation-related cost reductions compared to the prior year period.

The operating loss for the second quarter of 2016 was \$7.5 million compared with an operating loss of \$25.7 million for the second quarter of 2015, reflecting higher revenues and gross margin, and lower R&D and SG&A expenses, as well as an impairment of intangible assets in the second quarter of 2015.

The Company reported a net loss for the second quarter of 2016 of \$7.9 million, or \$1.33 per share, compared with a net loss for the second quarter of 2015 of \$17.2 million, or \$3.84 per share.

First Half Financial Highlights

Total revenues for the six months ended June 30, 2016 increased 75% to \$15.8 million compared with \$9.0 million for the first six months of 2015. Gross margin for the first half of 2016 was 16% compared with a negative 1% for the first half of 2015.

R&D expenses for the first half of 2016 decreased to \$9.9 million compared with \$14.4 million for the first half of 2015. SG&A expenses decreased to \$11.2 million for the first half of 2016 compared with \$19.8 million for the same period in 2015. The first half of 2015 included expenses associated with executive management changes including one-time new hire compensation-related costs. The first half of 2016 included separation-related costs incurred during the first quarter of 2016, while equity-based compensation expenses were significantly lower in the first half of 2016 compared to the prior year period.

The operating loss for the first half of 2016 was \$18.6 million compared with an operating loss of \$43.8 million for the first half of 2015.

The net loss for the six months ended June 30, 2016 was \$19.9 million, or \$3.39 per share, compared with a net loss for the six months ended June 30, 2015 of \$36.4 million, or \$8.83 per share.

Balance Sheet and Cash Flow Highlights

As of June 30, 2016, Caladrius had cash and cash equivalents of \$17.7 million. Net cash used in operating activities for the six months ended June 30, 2016 was \$14.6 million, compared with \$21.8 million for the six months ended June 30, 2015.

2016 Financial Guidance

The Company reaffirms its previous guidance as follows:

- **Consolidated Revenues:** to exceed \$30 million or a greater than 30% increase compared with 2015
- **Capital Improvements at PCT's Allendale, NJ facility:** ~\$6 million, to be completed by end of first half of 2017
- **CLBS03 Phase 2 Study Costs in 2016:** \$6 million to \$7 million
- **Consolidated Annual Operating Cash Burn:** \$25 million to \$28 million in 2016, with lower operating cash burn in the second half of 2016 than in the first half of the year

Conference Call

As previously announced, Caladrius management 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 95709219.

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

About Caladrius Biosciences

Caladrius Biosciences, Inc., through its PCT subsidiary, 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., Ltd. 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, including statements regarding the realization of the benefits of fast track designation for CLB03, the achievement of clinical milestones for CLB03 and the establishment of a partnership for CLBS03. 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.

Caladrius Biosciences, Inc. Selected Financial Data (unaudited)

(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Statement of Operations Data:				
Revenues	\$ 8,300	\$ 5,867	\$ 15,790	\$ 9,039
Costs and expenses:				
Cost of revenues	7,052	5,799	13,280	9,167
Research and development	4,028	7,601	9,904	14,404
Impairment of intangible assets	—	9,400	—	9,400
Selling, general, and administrative	4,706	8,736	11,164	19,824
Total operating costs and expenses	15,785	31,536	34,348	52,796
Operating loss	(7,485)	(25,669)	(18,558)	(43,757)
Other income (expense), net	7	5,355	13	4,809
Interest expense	(360)	(547)	(1,287)	(1,098)
Loss before income taxes and noncontrolling interests	(7,838)	(20,861)	(19,832)	(40,046)
Provision for income taxes	47	(3,703)	100	(3,657)
Net loss	(7,885)	(17,158)	(19,933)	(36,390)
Less - loss attributable to noncontrolling interests	(50)	(32)	(117)	(76)
Net loss attributable to Caladrius Biosciences, Inc. common stockholders	\$ (7,835)	\$ (17,126)	\$ (19,816)	\$ (36,313)
Basic and diluted loss per share attributable to Caladrius Biosciences, Inc. common stockholders				
	\$ (1.33)	\$ (3.84)	\$ (3.39)	\$ (8.83)
Weighted average common shares outstanding	5,907	4,457	5,840	4,110

	June 30, 2016	December 31, 2015
Balance Sheet Data:		
Cash, cash equivalents, and marketable securities	\$ 17,700	\$ 20,318
Total assets	56,713	57,205
Total liabilities	31,676	33,921
Total redeemable securities	19,400	0
Total equity	5,637	23,284

Investors:

LHA

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