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): January 6, 2016

CALADRIUS BIOSCIENCES, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware	001-33650	22-2343568
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 January 6, 2016, Caladrius Biosciences, Inc. (the "Company") issued a press release entitled, "Caladrius Tightens Strategic Focus and Provides 2016 Revenue Guidance," which is filed as Exhibit 99.1 to this Form 8-K (the "Press Release"). As disclosed in the Press Release, the Company expects total revenue to be approximately $23 million for 2015.

Item 2.05. Costs Associated with Exit or Disposal Activities.

On January 6, 2016, the Company's board of directors (the "Board") determined to discontinue the Company's Phase 3 clinical study with CLBS20 as a monotherapy for the treatment of recurrent Stage III or Stage IV metastatic melanoma (the "Phase III Study Termination"). The Board made this determination based on the accelerating adoption of alternative treatments as described in the Press Release, as described in Item 8.01 below. In connection with the Phase III Study Termination, the Company will reduce associated staff by approximately 40 employees at its Irvine, California facility. The Company expects to incur restructuring charges of approximately $1.0 million in the first quarter of 2016 in connection with one-time employee termination costs, including severance and other benefits. The Company expects to incur significant non-cash intangible asset and goodwill impairment charges in connection with the Phase III Study Termination. However, the Company cannot currently estimate the amount or range of amounts of such charges. The Company will file an amendment to this Form 8-K within four business days after it makes a determination of such estimates or ranges.

The information in Item 8.01 below is incorporated herein by reference.

Item 7.01. Regulation FD Disclosure.

The Press Release is incorporated herein by reference.

The information in Item 7.01 of this Form 8-K, including the Press Release filed as Exhibit 99.1 hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of such section. The information in Item 7.01 of this Form 8-K, including the Press Release filed as Exhibit 99.1 hereto, shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any incorporation by reference language in any such filing.

Item 8.01. Other Information.

The following information is disclosed in the Press Release and is filed pursuant to Item 8.01:

Following a comprehensive review of the Company's existing operations and development pipeline, as well as an updated assessment of current market dynamics, current and expected future competitive therapies, and the Company's financial resources, Caladrius has decided to shift greater focus and resources to its growing cell therapy process development, optimization and manufacturing services business at its PCT subsidiary. The rapidly developing cell therapy industry, with several cell-based therapies approaching market approvals which are expected to generate additional demand for commercial manufacturing infrastructure, along with PCT's continued trend of strong revenue growth, supports the Company's commitment to focus on growth opportunities for PCT. The Company has also reconfirmed its commitment to pursue further development of its immune modulation platform, with a Phase 2 proof-of-concept clinical trial for a T regulatory cell therapy as the primary focus, while choosing to discontinue the current Phase 3 study of CLBS20 as monotherapy for metastatic melanoma.

"Moving forward, we strongly believe PCT represents a compelling opportunity for near- and long-term shareholder value creation and we intend to continue to invest resources in expanding that business, where we are already experiencing noteworthy year-over-year revenue growth," stated David J. Mazzo, Ph.D., Chief Executive Officer of Caladrius.

"For nearly 17 years, PCT has been an integral partner to the regenerative medicine industry by leveraging its cell therapy-focused, bicoastal development and manufacturing infrastructure to support biotechnology and cell therapy companies," said Robert A. Preti, Ph.D., Chief Technology Officer of Caladrius and President of PCT. "We continue to focus on the design and implementation of sustainable, scalable, reliable and well-controlled manufacturing processes with optimized cost-of-goods as these are all critical success parameters in bringing new cell therapy and immunotherapy treatments to market. We are looking forward to further acceleration of these activities."

Dr. Mazzo continued, “The treatment paradigm in metastatic melanoma was transformed during the course of 2015 by the accelerating adoption of multiple immune checkpoint inhibitors used as monotherapy and in combination treatments. These new drugs have significantly improved outcomes in metastatic melanoma and therefore have altered the opportunity for a monotherapy such as CLBS20 in a landscape that is quickly converting to combination therapies. Therefore, we have concluded that, as designed, our current program in metastatic melanoma will not optimally leverage this asset and we will therefore discontinue the ongoing Phase 3 clinical study with CLBS20 as a monotherapy for the treatment of recurrent Stage III or Stage IV metastatic melanoma. As a result, we will reduce associated staff by approximately 40 employees at our Irvine, California facility. That said, we continue to believe in the potential of CLBS20 as a life-prolonging immunotherapeutic and will pursue licensing or partnership opportunities for its continued development as part of a combination therapy and in different oncology indications. The emphasis will be on collaborating with a company that will allow us to exploit the novel antigen presentation and T cell activation approach of CLBS20.”

On the development front, Caladrius will focus its efforts on its T regulatory (Treg) cell therapy product candidate, CLBS03. CLBS03 is based on the Company’s novel immune modulation approach that seeks to restore immune balance by enhancing Treg cell number and function. The Company is planning to commence enrollment in a Phase 2 study for adolescents with recent-onset type 1 diabetes in the first quarter of 2016, in collaboration with Sanford Research, a non-profit research organization that supports an emerging translational research center focused on finding a cure for type 1 diabetes.

“The opportunity provided by polyclonal T cells in the treatment of autoimmune diseases is compelling and we are excited to be at the forefront of this technology’s development and to be working with recognized leaders in the field, such as Drs. Jeffrey Bluestone and Stephen Gitelman of the University of California, San Francisco and Dr. Kevan Herold of Yale University. We believe CLBS03 has the potential to be paradigm-changing in the treatment of recent-onset diabetes and, potentially, other autoimmune diseases. We look forward to initiating our Phase 2 clinical program in conjunction with Sanford Research in the first quarter of 2016,” concluded Dr. Mazzo.

Forward-Looking Statements

This Form 8-K 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 Form 8-K, and involve certain risks and uncertainties. All statements other than statements of historical fact contained in this Form 8-K are forward-looking statements, including statements regarding our expected revenues, personnel reductions, as well as the potential of CLBS03 in the treatment of recent-onset type 1 diabetes. 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, 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; (xx) our current lack of sufficient manufacturing capabilities to produce our product candidates at commercial scale; (xxi) our lack of revenue from product sales; (xxii) the commercial potential and profitability of our products; (xxiii) our failure to realize benefits from collaborations, strategic alliances or licensing arrangements; (xxiv) the novelty and expense of the technology used in our cell therapy business; (xxv) the possibility that our competitors will develop and market more effective, safer or less expensive products than our product candidates; (xxvi) product liability claims and litigation, including exposure from the use of our products; (xxvii) our potential inability to retain or hire key employees; and (xxviii) 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.

Item 9.01. Financial Statement and Exhibits.

(d) Exhibits.

The Exhibit Index immediately following the signature page to this Current Report on 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/ David J. Mazzo
Name: David J. Mazzo, PhD
Title: Chief Executive Officer

Dated: January 6, 2016

Exhibit Table

Exhibit No.	Description
99.1	Press Release, dated January 6, 2016, entitled, "Caladrius Tightens Strategic Focus and Provides 2016 Revenue Guidance"

Exhibit 99.1

Caladrius Tightens Strategic Focus and Provides 2016 Revenue Guidance

- *Emphasizes PCT subsidiary's leadership position in the emerging cell therapy market with expectations for >30% revenue growth in 2016*
- *Focuses clinical development on innovative platform of immune modulation with T regulatory cell therapy program in type 1 diabetes*
- *Discontinues Phase 3 study of CLBS20 as monotherapy for metastatic melanoma and seeks strategic partner for combination therapy and/or other oncology indications*
- *Conference call begins at 8:30 am Eastern time tomorrow*

BASKING RIDGE, N.J. (January 6, 2016) - Caladrius Biosciences, Inc. ("Caladrius" or the "Company") (NASDAQ: CLBS), a cell therapy company combining an industry-leading development and manufacturing services provider with a therapeutic development pipeline, announces an increased focus of its strategic priorities and provides 2016 revenue guidance based on growth at its PCT subsidiary.

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Dr. Mazzo continued, "The treatment paradigm in metastatic melanoma was transformed during the course of 2015 by the accelerating adoption of multiple immune checkpoint inhibitors used as monotherapy and in combination treatments. These new drugs have significantly improved outcomes in metastatic melanoma and therefore have altered the opportunity for a monotherapy such as CLBS20 in a landscape that is quickly converting to combination therapies. Therefore, we have concluded that, as designed, our current program in metastatic melanoma will not optimally leverage this asset and we will therefore discontinue the ongoing Phase 3 clinical study with CLBS20 as a monotherapy for the treatment of recurrent Stage III or Stage IV metastatic melanoma. As a result, we will reduce associated staff by approximately 40 employees at our Irvine, California facility. That said, we continue to believe in the potential of CLBS20 as a life-prolonging immunotherapeutic and will pursue licensing or partnership opportunities for its continued development as part of a combination therapy and in different oncology indications. The emphasis will be on collaborating with a company that will allow us to exploit the novel antigen presentation and T cell activation approach of CLBS20."

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Financial Guidance

For 2015, Caladrius expects total revenue to be approximately $23 million, representing an increase of approximately 28% compared with 2014. For 2016, Caladrius expects total revenue to exceed $30 million, representing an increase of greater than 30% compared with the expected results for 2015. In order to accommodate this projected growth, Caladrius has budgeted to spend $6 million in capital improvements to increase PCT's Allendale, NJ clean room capacity by 60%, and expects to complete the build-out in 2016. Caladrius also estimates that it will incur restructuring charges of approximately $1.0 million in connection with one-time employee termination costs, including severance and other benefits, in the first quarter of 2016. The Company estimates that the staff reduction will result in over $4 million in annualized compensation-related savings, and anticipates significant cost savings associated with terminating the CLBS20 study, which had been estimated to cost $35 million through its completion. In addition, with a narrowed focus on research and development initiatives, as well as a re-sizing of the Company's general and administrative infrastructure, Caladrius expects to lower R&D, G&A and overall cash burn in 2016 compared to 2015. The Company also expects to incur significant non-cash intangible asset and goodwill impairment charges associated with the termination of the CLBS20 study and will assess the impact as of December 31, 2015 during its annual intangible asset impairment review process.

Conference Call

Company management will host a conference call to discuss this announcement on January 7, 2016, at 8:30 am Eastern time. To participate in the conference call, dial 877-562-4460 (U.S.) or 513-438-4106 (international) and provide conference ID 15555219. To access the live webcast, visit the Investor Relations section of the Company's website at www.caladrius.com/investors/overview/. The webcast will be archived on the website for 90 days.

About Caladrius Biosciences

Caladrius Biosciences, Inc., through its wholly-owned subsidiary, PCT, is a leading development and manufacturing partner to the cell therapy industry. Caladrius works with its clients to overcome the fundamental challenges presented by 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. Around this core expertise, Caladrius strategically develops product candidates, which currently include an innovative therapy for type 1 diabetes based on a proprietary platform technology for immunomodulation, and holds intellectual property around other cell therapy platform technologies. 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 our expected revenues and capital expenditures, personnel reductions, as well as the potential of CLBS03 in the treatment of recent-onset type 1 diabetes and the expected cost savings associated with the termination of the CLBS20 study. 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, 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; (xx) our current lack of sufficient manufacturing capabilities to produce our product candidates at commercial scale; (xxi) our lack of revenue from product sales; (xxii) the commercial potential and profitability of our products; (xxiii) our failure to realize benefits from collaborations, strategic alliances or licensing arrangements; (xxiv) the novelty and expense of the technology used in our cell therapy business; (xxv) the possibility that our competitors will develop and market more effective, safer or less expensive products than our product candidates; (xxvi) product liability claims and litigation, including exposure from the use of our products; (xxvii) our potential inability to retain or hire key employees; and (xxviii) 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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