

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): June 20, 2018

**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))
- Emerging growth company

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (Section 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (Section 230.12b-2 of this chapter).

- 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 5.07. Submission of Matters to a Vote of Security Holders.**

On June 20, 2018, at the 2018 Annual Meeting of Stockholders (the "Annual Meeting") of Caladrius Biosciences, Inc. (the "Company"), the stockholders voted on and approved the six proposals listed below. The following is a brief description of each matter voted upon at the Annual Meeting (for a full description of each such matter see the Company's definitive proxy statement on Schedule 14A, filed with the Securities and Exchange Commission on April 24, 2018 (the "Proxy Statement")), as well as the final voting results with respect to each such matter:

*Proposal 1.* The stockholders re-elected Gregory B. Brown, MD and David J. Mazzo, PhD as Class II directors until the annual meeting to be held in 2021. The final voting results with respect to Gregory B. Brown, MD were as follows: 4,513,711 votes for; 558,931 votes against; 39,497 votes abstaining and 2,853,785 broker non-votes. The final voting results with respect to David J. Mazzo, PhD were as follows: 4,707,084 votes for; 358,656 votes against; 46,399 votes abstaining and 2,853,785 broker non-votes.

*Proposal 2.* The stockholders approved the adoption of the Caladrius Biosciences, Inc. 2018 Equity Incentive Compensation Plan. The final voting results with respect to this Proposal were as follows: 4,132,731 votes for; 971,575 votes against; 7,833 votes abstaining and 2,853,785 broker non-votes.

*Proposal 3.* The stockholders approved an amendment to the 2017 Employee Stock Purchase Plan to increase the number of shares available to 500,000. The final voting results with respect to this Proposal were as follows: 4,702,014 votes for; 398,354 votes against; 11,771 votes abstaining and 2,853,785 broker non-votes.

*Proposal 4.* The stockholders ratified the appointment of Grant Thornton LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2018. The final voting results with respect to this Proposal were as follows: 7,583,698 votes for; 351,101 votes against; 31,125 votes abstaining and 0 broker non-votes.

*Proposal 5.* The stockholders approved, on a non-binding advisory basis, the executive compensation of the Company's named executive officers as described in the Proxy Statement. The final voting results with respect to this Proposal were as follows: 4,078,120 votes for; 1,016,600 votes against; 17,419 votes abstaining and 2,853,785 broker non-votes.

*Proposal 6.* The stockholders approved an adjournment or postponement of the Annual Meeting, if necessary, if there were not sufficient votes to provide a quorum. The final voting results with respect to this Proposal were as follows: 6,778,859 votes for; 1,144,330 votes against; 42,735 votes abstaining and 0 broker non-votes.

#### **Item 7.01. Regulation FD Disclosure.**

On June 19, 2018, the Company issued a press release announcing that the U.S. Food and Drug Administration has granted regenerative medicine advanced therapy designation to the Company's late-stage CD34+ cell therapy program for the treatment of refractory angina. 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.

#### **Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

<b>Number</b>	<b>Description</b>
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- [10.1](#) 2018 Equity Incentive Compensation Plan (incorporated by reference to Appendix A of the Company's definitive proxy statement on Schedule 14A, filed with the Securities and Exchange Commission on April 24, 2018).
  - [10.2](#) Amendment to 2017 Employee Stock Purchase Plan (incorporated by reference to Appendix B of the Company's definitive proxy statement on Schedule 14A, filed with the Securities and Exchange Commission on April 24, 2018).
  - [99.1](#) Press release, dated June 19, 2018.
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**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: President and Chief Executive Officer

Dated: June 20, 2018

## **Caladrius Receives FDA Regenerative Medicine Advanced Therapy Designation for CD34+ Cell Therapy for Treating Refractory Angina**

**BASKING RIDGE, N.J. (June 19, 2018)** - Caladrius Biosciences, Inc. (Nasdaq: CLBS) (“Caladrius” or the “Company”), a clinical-stage biopharmaceutical company with multiple technology platforms targeting select cardiovascular indications and autoimmune diseases, announces today that the U.S. Food and Drug Administration (“FDA”) has granted regenerative medicine advanced therapy (“RMAT”) designation to the Company’s late-stage CD34+ cell therapy program for the treatment of refractory angina.

The FDA grants the RMAT designation to regenerative medicine therapies intended to treat a serious condition for which preliminary clinical evidence indicates a potential to address unmet medical needs for that condition. The RMAT designation affords regenerative therapies the advantages of expedited development and review of marketing applications as are available to drugs that receive breakthrough therapy designation, including increased meeting opportunities, early interactions to discuss potential surrogate or intermediate endpoints, shortened biologics license application (“BLA”) review times and the potential of accelerated approval.

“We are delighted and encouraged that the FDA has recognized our CD34+ cell therapy program with an RMAT designation. Refractory angina is a serious condition with high morbidity and no known effective treatments. We look forward to working with the FDA to define a path to registration for our therapy with the aim of providing expeditious treatment to patients suffering from this condition,” said David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius.

Caladrius acquired an exclusive worldwide license to the late-stage CD34+ program from Shire plc in March of this year. The acquisition included the data set and regulatory filings for the CD34+ cell therapy program for the treatment of refractory angina. This includes manufacturing procedures, preclinical (*in vivo* and *in vitro*) and Phase 1, Phase 2 and Phase 3 clinical study data of CD34 cell therapy as a treatment for no-option refractory angina, along with the corresponding regulatory filings.

### **About Refractory Angina**

It is estimated that as many as one million people in the United States have chronic symptomatic coronary artery disease (often referred to as refractory angina) that is recalcitrant to medical therapy and not amenable to conventional revascularization procedures. Patients have reproducible lifestyle-limiting symptoms such as chest pain and shortness of breath, and are easily fatigued. These symptoms are often due to totally occluded coronary arteries or to diffuse coronary atherosclerosis that makes revascularization problematic. As the population ages and the incidence of diabetes mellitus increases, this clinical condition is expected to become more prevalent. Patients with this condition have significant morbidity and experience a lower quality of life. Grise MA and Verma A. Ochsner J. 2009 Winter; 9(4): 220-226.

### **About Caladrius Biosciences**

Caladrius Biosciences, Inc. is a clinical-stage biopharmaceutical company with multiple technology platforms targeting select cardiovascular indications and autoimmune diseases. The Company is developing CLBS14, a CD34 cell therapy intended as a treatment for coronary microvascular dysfunction (CLBS14-CMD) and refractory angina (CLBS14-RfA). CLBS14 is Caladrius’ proprietary and patent protected formulation of CD34 cells designed specifically to enhance the potency of the CD34 cells for repair and regeneration of cardiovascular tissue. CLBS14-CMD is the subject of an ongoing Phase 2 proof-of-principal study being conducted in the USA at Cedars-Sinai (Los Angeles) and the Mayo Clinic (Minneapolis). A companion product, CLBS12, is formulated specifically for intramuscular administration for the treatment of lower extremity ischemia. A Phase 2 study of CLBS12 as a treatment for critical limb ischemia is being conducted in Japan, a successful outcome of which will, based on discussions with the Japanese regulatory authorities, qualify the program for consideration of early conditional

approval as provided for under Japan's progressive regenerative medicine regulations. CLBS12 has been granted SAKIGAKE designation in Japan for the CLI indication, a designation similar to "Breakthrough Therapy Designation" granted by the FDA in the USA. Additionally, the Company is investigating its CLBS03 product candidate, an ex vivo expanded polyclonal T regulatory cell therapy for the treatment of recent-onset type 1 diabetes, in an ongoing Phase 2 trial for which top-line data is expected in early 2019. CLBS03 has been granted Fast Track and orphan drug designations from the FDA as well as Advanced Therapeutic Medicinal Product ("ATMP") classification from the European Medicines Agency ("EMA"). For more information about Caladrius, please visit [www.caladrius.com](http://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 differ materially 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 22, 2018, as subsequently amended on April 2, 2018, 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.

### **Contacts:**

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