

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 29, 2017

**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, Second 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

- Emerging growth company
- 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 1.01 Entry into a Material Definitive Agreement.**

The information set forth in Item 3.02 of this Current Report on Form 8-K is incorporated into this Item 1.01 by reference.

**Item 3.02 Unregistered Sales of Equity Securities.*****Closing of Private Placement***

On September 5, 2017, Caladrius Biosciencies, Inc. (the “ Company,” “we,” “us,” “our,” or “Caladrius”) announced that the 70<sup>th</sup> subject had recently been enrolled in The Sanford Project: T-Rex Study, a prospective, randomized, placebo-controlled, double-blind Phase 2 clinical trial to evaluate the safety and efficacy of the Company’s CLBS03 as a treatment for recent-onset type 1 diabetes, which triggered payments totaling \$2.4 million pursuant to the terms of the September 2016 Securities Purchase Agreements (the “Private Placements”) with certain accredited investors (the “Investors”) for the sale an additional 508,475 shares of common stock at a purchase price of \$4.72 per share with a closing date of August 29, 2017 (the “Closing Date”).

In the aggregate, the amount of shares issued in the foregoing transactions exceeds 5% of the Company’s total outstanding shares. As of the date of this filing, the Company has 9,427,001 shares of common stock outstanding.

**Item 8.01 Other Events**

On September 5, 2017, the Company issued a press release announcing the second closing of the Private Placements. A copy of this press release is hereto attached as Exhibit 99.1 and is incorporated by herein by reference.

**Item 9.01 Financial Statements and Exhibits****(d) Exhibits**

<b>Exhibit No.</b>	<b>Description</b>	
99.1	September 5, 2017, announcing the second closing of the Private Placement.	Press release issued on

**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: September 5, 2017

## **Caladrius Biosciences Announces Enrollment of the 70<sup>th</sup> Subject in the Phase 2 T-Rex Clinical Trial of CLBS03 for Type 1 Diabetes**

*Milestone Achievement Triggered \$2.4 Million Payments to Caladrius*

**BASKING RIDGE, N.J. (September 5, 2017)** - Caladrius Biosciences, Inc. (NASDAQ: CLBS) (“Caladrius” or the “Company”), a development-stage biopharmaceutical company with multiple technology platforms targeting autoimmune and select cardiology indications, announces that the 70<sup>th</sup> subject has recently been enrolled in The Sanford Project: T-Rex Study, a prospective, randomized, placebo-controlled, double-blind Phase 2 clinical trial to evaluate the safety and efficacy of the Company’s CLBS03 as a treatment for recent-onset type 1 diabetes (“T1D”). Pursuant to the terms of September 2016 private placements, the achievement of this enrollment milestone triggered payments totaling \$2.4 million which have been received by Caladrius, with the delivery of an additional 508,475 shares of Caladrius common stock to those investors at a purchase price of \$4.72 per share.

CLBS03 is a personalized autologous cell therapy consisting of each patient's own regulatory T cells (“Tregs”), which have been expanded in number and functionally enhanced by a proprietary method developed through collaboration with Jeffrey Bluestone, Ph.D., and renowned researchers at the University of California, San Francisco. Caladrius holds exclusive rights to an international portfolio of issued and pending patents related to this product.

“We are pleased that enrollment in the landmark T-Rex study continues according to plan and that we have surpassed the important milestone of treating the 70<sup>th</sup> patient, triggering a capital infusion. This capital, coupled with support from our research partner, Sanford Research, existing capital on our balance sheet, as well as various grants, provides funding for this study and our current operations well beyond the end of 2018,” stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius. “We look forward to early 2018 and the expected pre-specified interim analysis of safety and potential early therapeutic effect after the six-month post-treatment follow-up visit of the first 56 subjects.”

### **About The Sanford Project: T-Rex Study**

The landmark T-rex study, which is being conducted in collaboration with Sanford Research, a Sanford Health subsidiary, is a prospective, randomized, placebo-controlled, double-blind Phase 2 clinical trial to evaluate the safety and efficacy of CLBS03 as a treatment for T1D in approximately 111 subjects, age 8 to 17, with recent-onset T1D. Subjects are randomized into one of three groups to receive, through a single administration, either a high dose of CLBS03, a low dose of CLBS03 or placebo. Enrollment of the first cohort of 19 subjects, designated for a preliminary safety evaluation, was completed in August 2016. The evaluation of safety data from this group was satisfactory and the Company began enrollment of the second cohort of subjects in October 2016. The key endpoints for the trial are the standard medical and regulatory endpoints for a T1D trial and include preservation of C-peptide (an accepted measure for pancreatic beta cell function), insulin use, severe hypoglycemic episodes and glucose and hemoglobin A1c levels. For more information on The Sanford Project: T-Rex Study, please visit <https://clinicaltrials.gov/ct2/show/NCT02691247>.

### **About Caladrius Biosciences**

Caladrius Biosciences, Inc. is a development stage biopharmaceutical company with multiple technology platforms targeting autoimmune and select cardiology indications. The Company is investigating its lead product candidate, CLBS03, an *ex vivo* expanded polyclonal T regulatory cell therapy for the treatment of

recent-onset T1D in a currently enrolling Phase 2 trial. For more information on Caladrius, please visit [www.caladrius.com](http://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 17, 2017, 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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