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): February 13, 2019

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.)

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:

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))

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).

o Emerging growth company

o 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 8.01 Other Events.

On February 13, 2019, Caladrius Biosciences, Inc. (the "Company") issued a press release in connection with results announced from The Sanford Project: T-Rex Study, a prospective, randomized, placebo-controlled, double-blind Phase 2a clinical trial of 110 subjects to evaluate the safety and efficacy of the Company's CLBS03 as a treatment for recent-onset type 1 diabetes ("T1D") in adolescents. The initial analysis of the one-year follow-up data for all subjects shows that CLBS03 was well-tolerated at the doses tested in the study (targeting 2.5 million cells/kg or 20 million cells/kg); however, no improvement in the primary endpoint of preservation of C-peptide levels vs. placebo at 1 year was observed at the group level (using the standard mixed meal tolerance test). A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statement and Exhibits.

Exhibit No.	Description
99.1	Press release, dated February 13, 2019

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: February 13, 2019

Exhibit 99.1

Caladrius Biosciences Reports Top-Line Data for the Phase 2a Sanford Project: T-Rex Trial of CLBS03 for Recent Onset Type 1 Diabetes

BASKING RIDGE, N.J. (February 13, 2019) - Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company"), a late-stage therapeutics development biopharmaceutical company with multiple development programs targeting select cardiovascular indications and autoimmune disease, today announced top-line results from The Sanford Project: T-Rex Study, a prospective, randomized, placebo-controlled, double-blind Phase 2a clinical trial of 110 subjects to evaluate the safety and efficacy of the Company's CLBS03 as a treatment for recent-onset type 1 diabetes ("T1D") in adolescents. The initial analysis of the 1-year follow-up data for all subjects shows that CLBS03 was well tolerated at the doses tested in the study (targeting 2.5 million cells/kg or 20 million cells/kg); however, no improvement in the primary endpoint of preservation of C-peptide levels vs. placebo at 1 year was observed at the group level (using the standard mixed meal tolerance test). As with many Phase 2a trials, the database from this study is very large and the analysis and interpretation of all the information will require several months of intensive evaluation and will be critical to the decision regarding the next steps in development of CLBS03. In addition, the data from the 2-year follow-up, once complete, will afford supplemental information and are necessary to complete the evaluation of this therapy.

"Given the heterogeneity of the patient population and disease progression rates of type 1 diabetes, it is not surprising that the cohort analysis in the study did not yield a positive result. Thorough examination and review of the complete database undoubtedly will uncover additional findings and will inform us on the next steps in development of CLBS03 in this indication," stated David Pearce, Ph.D., President of Innovation and Research at Sanford Health.

"We look forward to working with our research partner, Sanford Research, as well as with the distinguished panel of investigators and key opinion leaders in the field of type 1 diabetes to explore and understand the data from this study to its full extent," remarked David J. Mazzo, Ph.D., President and CEO of Caladrius Biosciences. Dr. Mazzo added, "As we've previously stated, we believe that the results from the T-rex study will yield a treasure-trove of information that will add materially to the understanding of T regulatory cells and their role in autoimmune disease and we look forward to seeing that information shared in the future. Finally, we express sincere gratitude to the patients, their parents and the investigators who were part of this study and we recognize that our development efforts could not have advanced without their participation."

About the Sanford Project: T Rex Study
The landmark T-rex study, which was conducted in collaboration with Sanford Research, a Sanford Health subsidiary, was a prospective, randomized, placebo-controlled, double-blind Phase 2a clinical trial to evaluate the safety and efficacy of CLBS03 as a treatment for T1D in approximately 110 subjects age 8 to 17 with recent-onset T1D. Subjects were 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. The key endpoints for the trial were 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 is a late-stage therapeutics development biopharmaceutical company committed to the development of innovative products that have the potential to restore the health of people with chronic illnesses. Our leadership team collectively has decades of biopharmaceutical development experience and world-recognized scientific achievement in the fields of cardiovascular and autoimmune disease, among other areas. The Company's goal is to build a broad portfolio of novel and versatile products that address important unmet medical needs. In addition to CLBS03, our current product candidates include three developmental treatments for cardiovascular diseases based on our CD34 cell therapy platform: CLBS12, recipient of SAKIGAKE designation, in Phase 2 testing in Japan and eligible for early conditional approval for the treatment of critical limb ischemia; CLBS14-CMD, in Phase 2 testing for the treatment of coronary microvascular dysfunction and CLBS14-NORDA (formerly CLBS14-RfA) in late-stage development for no option refractory disabling angina for which it has received RMAT designation. For more information on the company, please visit 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.

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