

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 22, 2019

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 7.01 Regulation FD Disclosure.

On January 22, 2019, Caladrius Biosciences, Inc. (the "Company") posted a letter to its shareholders on its website in connection with the Company's recent accomplishments, goals and objectives for the calendar year 2019 and beyond. In addition, a copy of this letter is being mailed to shareholders. A copy of this letter 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 Statement and Exhibits.

| Exhibit No. | Description |
|-----------------------------|--|
| <u>99.1</u> | Shareholder Letter, dated January 22, 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: January 22, 2019



January 22, 2019

Dear Caladrius Shareholders,

Happy New Year! If you've been a longtime owner of CLBS stock, you know that we typically do not issue a shareholder letter outside of the cover note to the Annual Report. This year, however, promises to be such a pivotal one for Caladrius Biosciences that I wanted to make sure that you, our investors, fully appreciate the progress we have made, the expectations we have for the near future and, most of all, the latent value in our company that we hope can be finally realized.

To set the stage, let's look back to when together we started this journey and then let me summarize what we've accomplished. In January 2015, when I assumed the role of CEO at what was then called NeoStem, our company had these challenges:

- a pipeline lacking therapeutic focus with limited commercial potential;
- a financial profile encumbered by about \$16 million of debt;
- only about 6 months of available operating cash;
- a projected annual spend of more than \$58 million;
- a contract manufacturing subsidiary that was, at best, cash flow neutral and in dire need of capital simply to maintain its position in an increasingly competitive market; and
- a complicated and expensive corporate structure with as many as five operating subsidiaries, more than 200 employees and an 11-member board of directors.

Since then, Caladrius has completed a significant evolution. We installed a new, dynamic executive leadership team and a diverse board of directors less than half the size of the previous board, but with substantially more relevant pharmaceutical development and commercialization experience. We have transformed the company into a streamlined, pure-play therapeutics development company with fewer than 30 employees, a therapeutically focused pipeline of development candidates, no debt, a very manageable current operating spend of approximately \$20 million annually and more than 18 months' worth of cash (as of January 1, 2019).

Completing the divestiture in 2017 of PCT, our contract development and manufacturing subsidiary, for almost \$100 million in cash allowed us to amass sufficient capital to operate for several years without additional dilutive funding, even while retiring all of our debt. This capital provided the foundation for us to achieve a number of significant project advancements, most notable among them:

- the design and execution of the landmark Sanford Project: T-Rex study for CLBS03 in type 1 diabetes while securing a substantial equity investment and operational funding support from our research partner, Sanford Research, as well as major grant funding from the California Institute for Regenerative Medicine and the Juvenile Diabetes Research Foundation;

110 Allen Road, 2nd Floor
Basking Ridge, NJ 07920
caladrius.com

- the design and initiation of a registration eligible program for CLBS12 in critical limb ischemia in Japan after achieving SAKIGAKE “breakthrough” designation;
- the design and initiation of a proof-of-concept study for CLBS14-CMD in coronary microvascular dysfunction after being awarded a grant from the National Institutes of Health that essentially covers the cost of the trial; and
- the consummation of a data license with Shire for what is now called CLBS14-NORDA (formerly CLBS14-RfA) and the subsequent attainment of a Regenerative Medicine Advanced Therapy (RMAT) “breakthrough” designation.

Today, Caladrius is focused on the scientifically rigorous and efficient development of our autologous and disease-modifying cell therapies — therapies designed to use a patient’s own cells as a safe and effective treatment — in cardiovascular and autoimmune diseases for which there are clear, unmet medical needs. Our analyses show our programs to have an attractive commercial potential and a favorable competitive position with two of them having the equivalent of “breakthrough” designation in their respective development jurisdictions. Over the next 18 months, we expect to report important milestones for all four of our development programs. In brief:

CLBS03: This therapy, based on autologous polyclonal T regulatory cells, is currently being studied for its effectiveness in treating recent-onset type 1 diabetes mellitus in adolescents by restoring immune balance. Our Phase 2a Sanford Project: T-Rex clinical study is completely enrolled and all patients have completed their 12-month follow-up visit. Milestone: We expect to release topline results from this study in the first quarter of 2019.

CLBS12: This therapy uses autologous CD34+ cells to stimulate the growth of microvasculature in the affected limbs of patients with critical limb ischemia. CLBS12 is currently undergoing a clinical trial in patients with no-option critical limb ischemia in Japan, where the therapy has received SAKIGAKE designation for expedited development and review and has been deemed eligible for early conditional approval by the Japanese regulatory authorities upon study completion. Milestone: We anticipate having the last patient enrolled in this trial by the end of 2019, with topline results available in 2020.

CLBS14-CMD: This therapy, also based on our autologous CD34+ cell technology, is being developed as a treatment for the millions of patients suffering from coronary microvascular dysfunction and is currently being tested in a proof-of-concept study in the U.S. Milestone: We expect the last patient to be enrolled in the ongoing study this spring, with topline results expected late in 2019.

CLBS14-NORDA (No Option Refractory Disabling Angina), formerly known as CLBS14-RfA: This therapy, the most clinically advanced of our CD34+ programs, is aimed at addressing no-option refractory disabling angina, a condition affecting a precisely defined population of patients in dire need of treatment. It works by stimulating the growth of new microvasculature in an oxygen-deprived heart. We plan to initiate a Phase 3 clinical trial for CLBS14-NORDA in the U.S. upon finalization of a protocol design with FDA.

110 Allen Road, 2nd Floor
Basking Ridge, NJ 07920

caladrius.com

Milestone: We expect to communicate the details of our final Phase 3 protocol design during 1Q2019 and are targeting initiation of the trial in the second half of 2019.

As you can see, we have much to anticipate in 2019. We are extremely enthusiastic about the future of our company and hope that you share our enthusiasm. As I stated at the outset of this letter, this year promises to be a year of critical results for Caladrius as we complete certain studies and initiate important others. We thank you for your patience and support to date and ask for your continued support as we continue our quest to bring new treatments to patients and create value for our shareholders.

Sincerely,



David J. Mazzo, Ph.D.
President and CEO

Certain statements in this letter constitute "forward-looking statements" within the meaning of the federal securities laws. While the Company believes these forward-looking statements are reasonable based on information available to us on the date of this letter and upon current estimates and assumptions, they are subject to various risks and uncertainties. The Company expressly disclaims any obligation to update or alter statements whether as a result of new information, future events or otherwise, except as required by law.

110 Allen Road, 2nd Floor
Basking Ridge, NJ 07920

caladrius.com
