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): March 22, 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.)

<u>106 Allen Road, 4th Floor, Basking Ridge, NJ 07920</u> (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)
- x 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 1.02 Termination of a Material Definitive Agreement

As previously reported on the Current Report on Form 8-K of Caladrius Biosciences, Inc. (the "Company"), dated September 15, 2016, on September 14, 2016, the Company entered into Securities Purchase Agreements (the "Purchase Agreements") with certain accredited investors, including Newhall Construction, Ltd. ("Newhall"), pursuant to which the investors agreed to purchase an aggregate of 4,449,153 shares of the Company's common stock, par value \$0.001 per share (the "Common Stock"), at a purchase price of \$4.72 per share in a private placement. The investments were placed in two tranches: (i) up to \$12.6 million upon the initial closing (the "Initial Closing"), and (ii) up to \$8.4 million, subject to certain conditions, including the enrollment of 70 subjects in the Company's Phase 2 CLBS03 clinical trial, in a second closing (the "Second Closing"). The Initial Closing occurred on September 19, 2016 and the Second Closing, if any, will occur within ten days after the satisfaction or waiver of the certain conditions set forth in the Purchase Agreements. The aggregate gross proceeds for the sale of the shares of Common Stock at the Initial Closing was \$6.6 million, which, as further discussed below does not include \$6.0 million expected to have been received by Newhall.

The Purchase Agreement relating to Newhall's investment (the "Newhall Purchase Agreement") contains certain conditions related to the purchase and sale of Common Stock. As a consequence of Newhall's failure to satisfy the conditions for the Initial Closing, including Newhall's failure to pay the purchase price for the shares of Common Stock at the Initial Closing, the Company terminated the Newhall Purchase Agreement on March 22, 2017, and no shares of Common Stock were issued to Newhall. As a result, a total of 1,416,305 shares were issued to the investors at the Initial Closing. Up to 932,204 shares remain subject to issuance at the Second Closing, if any, in connection with the receipt of up to \$4.4 million.

Item 7.01. Regulation FD Disclosure.

A copy of a slide presentation that the Company will use at investor and industry conferences and presentations is attached to this Current Report as Exhibit 99.1 and is incorporated herein solely for purposes of this Item 7.01 disclosure. 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 (the "Exchange Act"), or otherwise subject to the liabilities of such section. The information in this Item 7.01, including Exhibit 99.1 attached 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. This Item 7.01 will not be deemed an admission as to the materiality of any information in this Item 7.01 that is required to be disclosed solely by Regulation FD.

Item 9.01. Financial Statement and Exhibits.

(d) Exhibits.

Exhibit No.Description99.1Caladrius Biosciences, Inc. Corporate Presentation, March 2017

SIGNATURES

By:

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.

/s/ David J. Mazzo

Name:David J. Mazzo, PhDTitle:Chief Executive Officer

Dated: March 22, 2017

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Corporate Presentation

David J. Mazzo, PhD Chief Executive Officer

March 2017 | NASDAQ: CLBS

Forward-looking statements advisory

Additional Information About the Transaction and Where to Find it: Caladrius intends to file with the Securities and Exchange Commission ("SEC") and mail to its stockholders a proxy statement in connection with, among other things, the proposed sale to Hitachi Chemical Co. America, Ltd. ("Purchaser") of the 80.1% membership interest in PCT that Purchaser does not already own (the "Sale"). Investors and stockholders of Caladrius are urged to read the proxy statement and the other relevant materials when they become available because they will contain important information about Caladrius and the Sale. The proxy statement and other relevant materials (when they become available), and any other documents filed by Caladrius with the SEC, may be obtained free of charge at the SEC's website at www.sec.gov. In addition, investors and stockholders may obtain free copies of the documents filed with the SEC by Caladrius by directing such requests to Caladrius Biosciences, Inc., 420 Lexington Avenue, Suite 350, New York, NY 10170, Attn: Jacquelyn Briggs or jbriggs@caladrius.com, Telephone: (646) 606-2221.

Participants in the Solicitation: Caladrius and its directors and executive officers may, under SEC rules, be deemed to be participants in the solicitation of proxies from Caladrius' stockholders in connection with the Sale. Information regarding Caladrius' directors and executive officers is contained in Caladrius' proxy statement on Schedule 14A filed with the SEC on May 10, 2016. Additional information regarding the participants in the solicitation of proxies in respect of the Sale and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in the proxy statement when it becomes available.

Safe Harbor for Forward Looking Statements: This Corporate Presentation contains forward-looking statements within the meaning of Private Securities Litigation Reform Act of 1995, including forward-looking statements regarding the Sale, the possibility of obtaining the milestone payment, the possibility of obtaining stockholder or other approvals or consents for the Sale and Caladrius' future prospects. These statements are neither promises nor guarantees, but involve risks and uncertainties that could cause actual events or results to differ materially from those set forth in the forward-looking statements, including, without limitation: risks and uncertainties relating to potential adverse reactions or changes to business relationships resulting from the announcement or completion of the Sale; unexpected costs, charges or expenses relating to or resulting from the Sale; litigation or adverse judgments relating to the Sale; risks relating to the completion of the proposed Sale, including the risk that the required stockholder vote might not be obtained in a timely manner or at all, or other conditions to the completion of the Sale; any changes in general economic and/or industry-specific conditions; and other risks detailed in Caladrius' filings with the SEC, including those disclosed under "Item 1A. Risk Factors" in Caladrius' Annual Report on Form 10-K filed with the SEC on March 17, 2017 and in subsequent reports on Forms 10-Q and 8-K and other filings made with the SEC. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this Corporate Presentation. Caladrius does not intend, and disclaims any obligation, to update or revise any forward-looking information contained in this Corporate Presentation or with respect to the matters described herein.



Caladrius transforms cells into therapies



Caladrius historical hybrid business model





Caladrius business model evolution plan



Caladrius business model evolution plan



Caladrius business model evolution – two healthy companies emerge



Caladrius unlocks PCT value and preserves intimate working relationship





Focused, funded and poised for growth¹

- Pure-play Cell Therapy therapeutics development company
- Two technology platforms on which to build
 - T regulatory cells for immune modulation
 - CD34 for ischemic repair
- On-going landmark phase 2 study of CLBS03 in recent onset type 1 diabetes
 - Strategic relationship with Sanford Research (CLBS retains all product rights)
 - ~\$12.2 million CIRM grant awarded

- Phase 2 protocol in Critical Limb Ischemia for CLBS12 ready to initiate in Japan
 - Positive results should qualify product for early conditional approval in Japan
- Well-funded with cash on hand >~\$70 million
- Debt-free
 - 1. After the expected PCT sale in May 2017





Immune Modulation





T regulatory cell technology platform built on a strong foundation

- T cell technology licensed from University of California at San Francisco (Jeffrey Bluestone – pioneer in T cell biology, et al) and the Centenary Institute
- Autologous ex-vivo expanded polyclonal T regulatory cells
- Exclusive rights to an international portfolio of issued and pending patents
- PCT-developed and optimized proprietary manufacturing process
 - Discounted development and manufacturing services rates from PCT for seven years



T Regulatory Cells (Tregs): **Restoring immune balance and function**

- Deficiency in number or function of Tregs vs. T effector cells manifests as autoimmune disease
- Augmentation of number/potency of Tregs is intended to restore the immune system to its "native" state and reduce/eliminate autoimmune disease symptoms



Polyclonal T regulatory cell therapy is potentially applicable across multiple autoimmune, alloimmune and allergic diseases

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	Recent-Onset Type 1 Diabetes	Neuromyelitis Optica (NMO) ¹	Uveitis	Cutaneous Lupus	Graft-versus- host Disease (GVHD)	Kidney Transplant	Scleroderma	SLE - Lupus
Global Patients ²	86,000 ³	13,930	254,869	1,993,080	12,529	3,123	165,537	553,968
Clinical Study Endpoints	C-peptide, insulin use	EDSS, visual acuity	Response rates	CLASI, Skindex-29	GHVD-free survival	Failure rates	mRSS, CRISS, sHAQ	BILAG, SELENA- SLEDAI
Biomarkers	C-peptide, others	NMO-IgG antibody	N/A	Cell type analysis	N/A	Renal function	Cytokines, B cells	B cell counts

Combined markets represent a multi-billion dollar opportunity:

Additional potential indications:

• Lupus Nephritis • Steroid resistant asthma • Rheumatoid arthritis • Multiple sclerosis • Bullous pemphigoid • Crohn's Disease

Pending grant application to fund a Phase 1 study in NMO with decision expected in 1H 2017
 Global Patient numbers include total patients from US, EU and Japan only.
 Annual incidence of type 1 diabetes for patients <15 years old. IDF Diabetes Atlas, 7th Edition.



Simple, cost-effective, proprietary Manufacturing process is scalable and commercially viable



· Simple and efficient clinical manufacturing process:

- Simple, less intrusive cell collection process (whole blood or, eventually, apheresis)
- Reliable and well-characterized cGMP process
- Extremely high Phase 2 manufacturing success rate to date
- Introduction of cryopreservation step(s) is technically likely



CLBS03: Recent onset type 1 diabetes program overview

Ongoing Phase 2 clinical study in T1D (T-Rex trial)

- California Institute for Regenerative Medicine up to \$12 million grant awarded upon achievement of certain milestones
- DSMB satisfactory assessment of safety of initial cohort achieved ahead of schedule
- Final cohort enrollment underway

Strategic collaboration with Sanford Research

- \$5 million equity investment
- Providing operating support for trial and clinical sites

International regulatory recognition

- FDA Fast Track designation First time granted to a T1D program
- FDA Orphan designation
- EU ATMP (Advanced Therapeutic Medicinal Product) classification



T Regulatory Cell (Tregs) therapy offers: An attractive medical and commercial opportunity for T1D

- Each year >18,000 newly diagnosed patients under 20 years of age in US¹; 3% CAGR worldwide²
- No curative treatments, only lifelong insulin therapy (often with serious co-morbidities)
- Preserving remaining beta cell function in recent onset patients is expected to slow/stop disease progression and lead to long-term medical and pharmaco-economic benefits



CLBS03 occupies a unique position in the type 1 diabetes treatment paradigm

	Chronic symptom treatment	Disease Modification (CLBS03)	Function regeneration
Approach	Treatment of symptoms	Reduce or eliminate disease progression; potentially curative	Replace ability to produce insulin with new cells/organs; potentially curative
Insulin Impact	Improve therapeutic effect and/or efficiency of delivery of insulin and/or insulin analogs	Avoid or reduce need for insulin by preserving active beta cells	Avoid or reduce need for insulin by providing new beta cells
Availability	Currently available and more in development	Currently in Phase 2 trial	Many years of development remaining



Published Phase I studies demonstrated Treg cell therapy to be: Well tolerated^{1,2}, durable¹ and preserving of beta cell function in children²

	US Study ¹	EU Study ²
Dose	4-dose escalation cohorts (0.05 x 10 ⁸ to 26 x 10 ⁸ cells)	1 infusion (10 or 20 million cells/kg) or 2 infusions (30 million cells/kg total)
Patients	14 adult patients with established T1D	22 patients aged 5-18 with T1D
Results	 Demonstrated safety/tolerance No cytokine release, infectious complications or infusion reactions observed >500 fold dose range tested Established manufacturing feasibility Can produce expanded Treg cell population with enhanced functionality Implied durability of effect Infused Tregs were stable and detected in peripheral circulation for 1 year 	At 12 months: • 6 treated patients achieved remission ³ • 2 treated patients achieved insulin independence Fasting C-peptide levels stabilized Treatment, n=12 0.2 0.2 0.2 0.2 0.2 0.2 0.2 0.

Bluestone, et al. Science Translational Medicine 2015
 Marek-Trzonkowska, N et al. Clinical Immunology 2014
 Remission Definition: Daily dose of insulin ≤ 0.5 UI/kg body weight & fasting c-peptide > 0.5 ng/ml at 12 months after recruitment

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T-Rex Study: **Phase 2 trial in adolescents with T1D initiated in March 2016**

Rigorous Design	 Double-blind, placebo-controlled, randomized (1:1:1) trial Adolescent patients ages 12 to <18 with recent-onset (diagnosed within last 100 days) T1D
Standard Endpoints	 Preservation of C-peptide level, insulin use, severe hypoglycemic episodes, glucose and hemoglobin A1c levels
Study Size	 111 patients enrolled across ~12 study sites in the USA
Power	• 80% power to detect a 0.2 pmol/mL difference in AUC mean C-peptide between active and placebo
Study Execution	Strategic collaboration with Sanford Research providing operational resources and capital
Treatment	Single infusion of CLBS03 (dose cohorts of 2.5 or 20 million cells/kg) or placebo infusion (control)
VCT02691247 at v	www.clinicaltrials.gov for more details

T-Rex Study: Timeline including near-term milestones





Ischemic Repair



CD34 cell therapy is supported by a strong rationale

CD34 cells have been investigated in clinical studies encompassing >700 patients

- Pre-clinical studies document improved microcirculation¹
- Phase 2 clinical studies consistently show benefits in safety and function
 - Reduced amputation in critical limb ischemia²
 - Improved function in claudication³
 - Reduced angina and improved ETT in refractory angina⁴
 - o Improved mortality and LVEF in dilated cardiomyopathy5

Opportunities exist across multiple underserved cardiovascular indications

- Coronary microvascular dysfunction (CMD)
- Refractory angina
- Critical limb ischemia (CLI) in Japan



Japanese development program for critical limb ischemia: Designed to leverage new regulatory path to early conditional approval

Phase 2 protocol and CMC strategy completed in consultation with Japanese PMDA

Design	 Prospective, open label, controlled, randomized trial Patients with no-option CLI
Advantageous Primary Endpoint	Time to continuous CLI free status
Study Size	35 patients enrolled across multiple centers in Japan
Treatment	Up to 10 ⁶ autologous G-CSF-mobilized peripheral blood-derived CD34+ cells/kg per affected limb
Control/ comparator	 SOC pharmacotherapy with drugs approved in Japan (e.g. antiplatelets, anticoagulants and vasodilators) The choice of pharmacotherapy will be made by the investigators
Mode of administration	Intramuscular, 20 injections in lower limb in single administration
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Multiple grant opportunities in cardiovascular indications

Indication	Coronary Microvascular Dysfunction	Coronary Microvascular Dysfunction
Grantor	NIH Small Business Innovation Research	Department of Defense
Decision Expected	2Q17	2H17
Total Award Sought	\$1.9 million	\$6.9 million
Trial Phase	Early Phase 2	Phase 2
Number of Subjects	20	60
Study Initiation	Within 5 months of award date	1Q 2018
Timing of Results	2018	2019/2020

Experienced executive team with broad domain-specific expertise

David J. Mazzo, PhD Chief Executive Officer	30+ years of experience in all aspects of large and emerging global biotech, biopharma company operations, successful international drug development
Joseph Talamo, CPA, MBA Senior VP and Chief Financial Officer	Versatile finance executive with leadership experience in publicly traded development and commercial-stage companies; 20+ years of experience
Douglas W. Losordo, MD Senior VP and Chief Medical Officer	Leader in cell therapy research and development; renowned clinician with noteworthy academic and industry credentials; 25+ years of experience
Todd Girolamo, JD, MBA Senior VP, General Counsel and Corporate Secretary	Seasoned attorney with 25+ years of legal, finance and biotechnology industry experience
Raj Prabhakar, MBA Senior VP, Business Development	20+ years experience, 16+ in biopharma sector. Previously at Celsion, PATH Global Vaccines, Osiris. Extensive transaction experience in oncology and Asia-Pacific.
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Caladrius established a: Track record of achievement based on execution of the 2016 strategic plan

2016 Goals	Results in 2016	
Grow and expand the PCT business on all fronts	 57% annual revenue growth to annual revenue of \$35.3 million Initiated global collaboration and license agreement with Hitachi Chemical Began 5-year agreement with Adaptimmune for late-stage clinical supply 	
Advance CLBS03	 Initiated Phase 2 T-Rex trial in T1D 1Q 2016 Completed enrollment of first cohort of 19 patients in 3Q 2016 Procured financial and clinical support from Sanford Research 	
Execute with financial discipline	 Reduced R&D (37%) and SG&A (32%) expenses significantly from 2015 levels 	
Monetize non-core assets	Out-licensed certain oncology and dermatology product candidates	
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Select Caladrius financial information

	2017 Capital Catalysts and Impact			
YE2016 Financial Information	Hitachi Acquisition of 80.1% of PCT from CLBS	CIRM CLBS03 Grant Award (March 2017)	Sept. 2016 PIPE – Second Tranche	
Cash: \$14.7m	 \$5m on signing agreement (received March 17, 2017) \$2m from Sanford (accelerated payment from second tranche of Sept. 2016 PIPE) \$65m from Hitachi on closing, plus up to \$5m after indemnification escrow released (expected May 2017)* 	Up to \$12.2m with initial payment of ~\$5.5m expected in April 2017	\$2.4m triggered by 70 th patient enrolled in T-Rex Study (expected 2Q17)	
Long-term debt: \$5.7m	 Settle any remaining debt on closing of PCT sale 			

*pending, among other closing conditions, CLBS stockholder approval



Caladrius offers multiple potential near-term value creating milestones

		Expected Timeframe
	 DSMB safety assessment on 1st patient cohort 	Completed 2016
	 Initiation of enrollment of 2nd patient cohort 	Completed 2016
	 50% of patients treated: starts clock to 6-mos. follow-up interim analysis 	Mid-2017
CLBS03	 70th patient enrolled: triggers capital infusion 	Mid-2017
	 Interim analysis assessing early therapeutic effect: 6 months post treatment of 50% patients 	Late 2017/Early 2018
	 Analysis of 12 month data (primary efficacy endpoint); Go/No Go to Phase 3 	Late 2018/Early 2019
	2-year follow-up complete	Late 2019
	 Initiate 35 patient Phase 2 trial in Japan for critical limb ischemia 	2H 2017
046 T6 Ii	 Begin patient enrollment in 20 patient Phase 2 trial for coronary microvascular dysfunction based on NIH SBIR grant 	2H 2017
other rechnologies	 Additional grant funding opportunities: CD34 program, multiple clinical indications 	2017
	 Licensing opportunities for CLI in Japan and immuno-oncology in China: CLI program eligible for early conditional approval 	2017
Financing	 Closing of Hitachi Chemical purchase of PCT from Caladrius for \$75 million plus milestone (subject to shareholder approval and customary closing conditions) 	Early May 2017
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NASDAQ: CLBS

Investor Relations Contact

LHA Investor Relations Anne Marie Fields, Senior Vice President Phone: 212.838.3777 Email: afields@lhai.com Web: www.caladrius.com





Caladrius Company

PCT has been: A comprehensive development and manufacturing partner for 18 years

· Expertise in multiple cell therapy types and therapeutic applications, including:

- CAR-T, TCR, T-cell, NK cell, dendritic cells and CD34+ products, among others



PCT's deep experience is evidenced by: An extensive client list of renown cell therapy companies

- Historically: >100 clients, 20,000 products and 6,000 patients
- Critical contribution from PCT to development and/or clinical manufacturing





PCT growth driven by: Growing and maturing cell and cell-based gene therapy market



PCT's modern cGMP manufacturing facilities offer flexibility and mitigate risk

Allendale, NJ (30,000 ft²) - owned

- 3 US-compliant cleanrooms
- 5 EU and US-compliant cleanrooms (expansion completion in 2017)
- Commercial product infrastructure

Mountain View, CA (25,000 ft²) - leased

- 7 US-compliant cleanrooms
- Dedicated clinical manufacturing

Manufacturing Present

Both locations feature:

- Process development, process and quality control, cryostorage capabilities
- Convenient proximity to major transportation hubs (EWR, LGA, JFK / SFO, SJC, OAK)

Manufacturing Future



PCT delivers: A strategic solution that moves well beyond fee-for-service

