

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 14, 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, 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.

A copy of a slide presentation that Caladrius Biosciences, Inc. (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.	Description
<u>99.1</u>	Caladrius Biosciences, Inc. Corporate Presentation, March 2018

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: March 14, 2018



Corporate Presentation

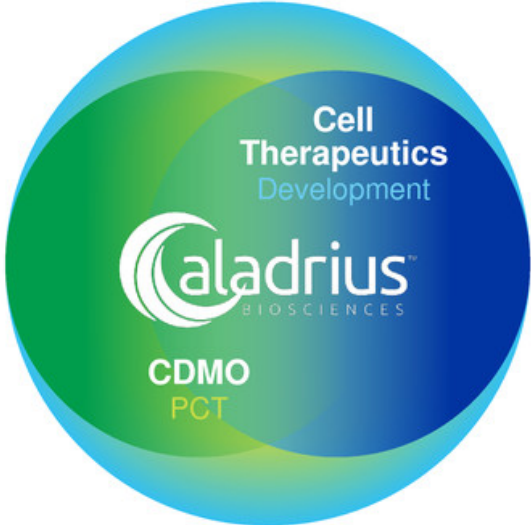
David J. Mazzo, PhD
President and Chief Executive Officer

March 2018 | NASDAQ: CLBS

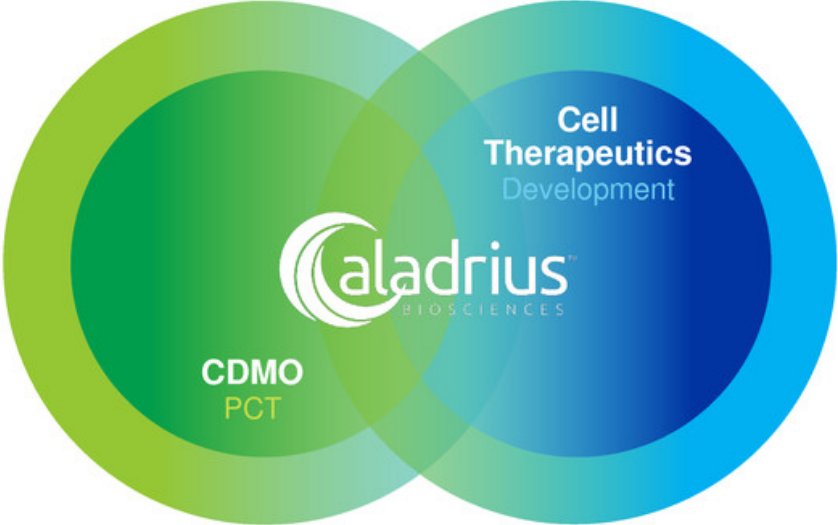
Safe Harbor for forward-looking statements advisory

This Investor Presentation contains forward-looking statements within the meaning of Private Securities Litigation Reform Act of 1995. Forward-looking statements reflect management's current expectations, as of the date of this presentation, and involve certain risks and uncertainties. All statements other than statements of historical fact contained in this Investor Presentation 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 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 Investor Presentation. Caladrius does not intend, and disclaims any obligation, to update or revise any forward-looking information contained in this Investor Presentation or with respect to the matters described herein.

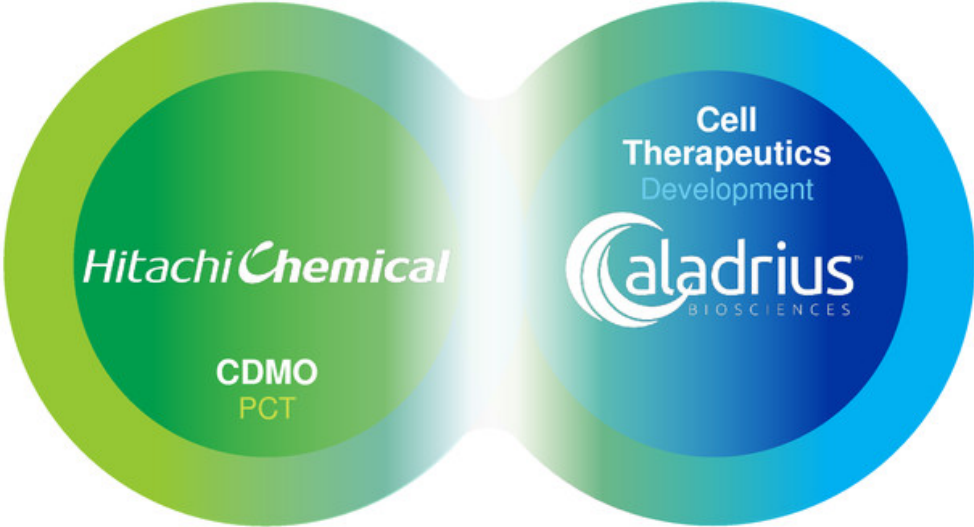
Caladrius historical hybrid business model



Caladrius recent business model evolution



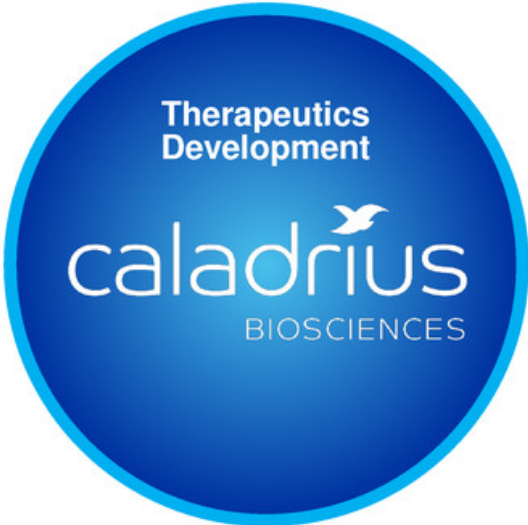
Caladrius recent business model evolution



Caladrius business model evolution – two healthy companies emerge



Hitachi Chemical
HCATS
CDMO



Therapeutics
Development
caladrius
BIOSCIENCES

Caladrius redefined as financially stable with a simplified corporate profile



Caladrius Biosciences: Focused, funded and poised for growth

- **Pure-play clinical stage therapeutics development company with two technology platforms**
 - T regulatory cells for immune modulation
 - CD34 cells for ischemic repair
- **Well-funded and debt-free**
- **On-going landmark phase 2 study of CLBS03 in recent onset Type 1 Diabetes**
 - Strategic relationship with Sanford Research (CLBS retains all product rights)
 - Up to ~\$12.2 million California Institute for Regenerative Medicine (CIRM) grant awarded
 - ~\$600,000 Juvenile Diabetes Research Foundation (JDRF) grant to Benaroya as direct CLBS03 study subsidy
- **Phase 2 study in Critical Limb Ischemia (CLI) for CLBS12 initiated in Japan**
 - Based on discussions with Japanese regulatory authorities, we believe that positive results will qualify the product for consideration of early conditional approval in Japan
- **Phase 2 study in Coronary Microvascular Dysfunction (CMD) for CLBS14 initiating in USA in early 2018**
 - ~\$1.9 million grant from the NIH awarded
- **Late Stage CD34 cell therapy program for the treatment of Refractory Angina exclusive license acquired**
 - Development plan to be determined following discussions with the FDA

Immune Modulation

Autologous, polyclonal T regulatory cells



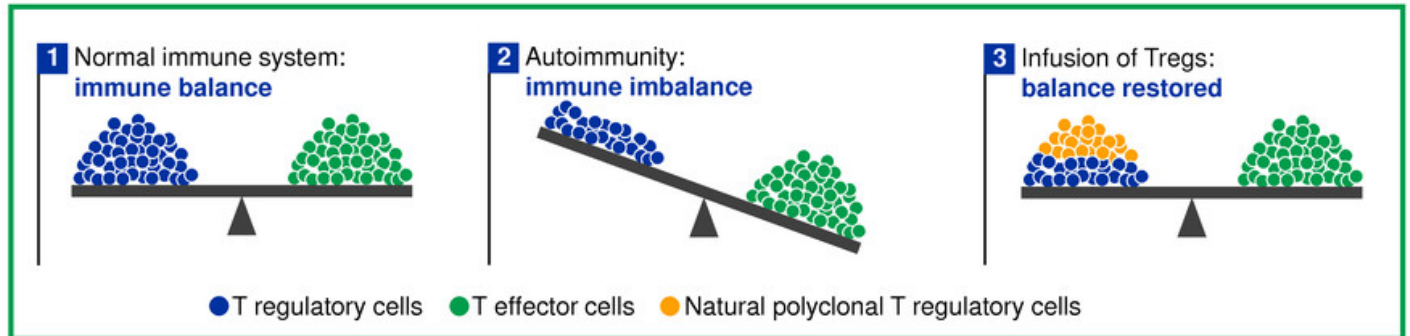
T regulatory cell technology platform built on a strong foundation

- **T cell technology licensed from University of California at San Francisco (Prof. Jeffrey Bluestone – pioneer in T cell biology, et al) and the Centenary Institute**
- **Autologous, ex-vivo expanded and activated, polyclonal T regulatory cells**
- **Exclusive rights to an international portfolio of issued and pending patents**
- **Well-characterized and optimized proprietary manufacturing process**
 - Discounted development and manufacturing services rates from HCATS through 2024

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, many qualifying as orphan

Combined markets represent a multi-billion dollar opportunity:



	Recent-Onset Type 1 Diabetes	Neuromyelitis Optica (NMO)	Uveitis	Cutaneous Lupus	Graft-versus-host Disease (GVHD)	Kidney Transplant	Scleroderma	SLE - Lupus
Global Patients¹	86,000 ²	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

Additional potential indications:

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

1. Global Patient numbers include total patients from US, EU and Japan only.

2. Annual incidence of type 1 diabetes for patients <15 years old. IDF Diabetes Atlas, 7th Edition.

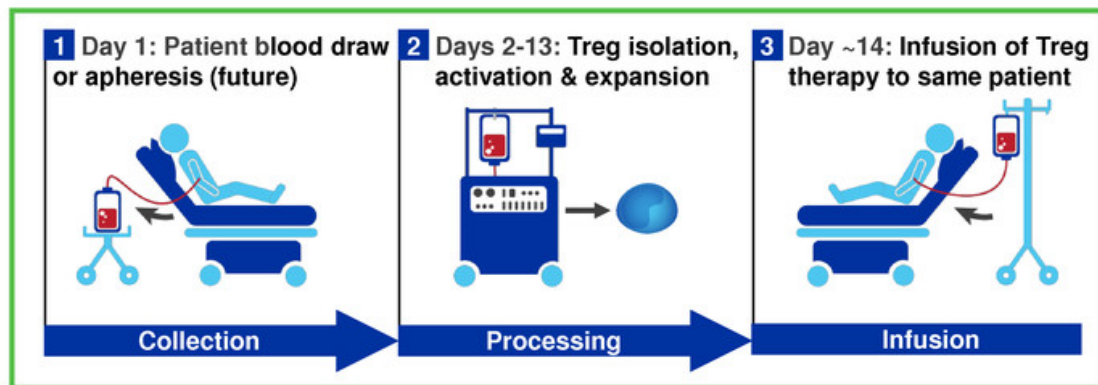
T Regulatory Cell (Treg) therapy offers:

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 hypothesized to slow/stop disease progression and lead to long-term medical and pharmaco-economic benefits³**

1. National Diabetes Statistic Report, 2014
2. Maahs DM, et al. Endocrinol Metab Clin North Am. 2010
3. Nathan DM, et al. Arch Intern Med. 2009

Manufacturing process is scalable and economically viable



- **Proprietary and efficient clinical manufacturing process:**

- Simple, minimally intrusive cell collection process (whole blood or, eventually, apheresis)
- Reliable and well-characterized cGMP process
- High Phase 2 manufacturing success rate
- Introduction of apheresis and cryopreservation step(s) are likely

CLBS03: Recent onset Type 1 Diabetes program overview

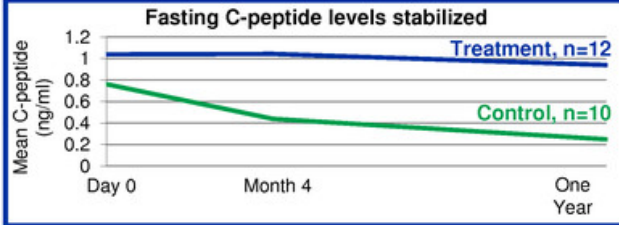
- **Ongoing landmark Phase 2 clinical study in T1D (T-Rex trial)**
 - CIRM grant for up to \$12.2 million based on specified milestone achievement
 - JDRF grant to Benaroya Research Institute to conduct extensive immune profile (study cost offset)
 - DSMB satisfactory assessment of safety of initial cohort achieved ahead of schedule
 - Enrollment and interim analysis completed finding that the drug continues to be well tolerated and non-futile for therapeutic effect; primary endpoint analysis expected in early 2019
- **Strategic collaboration with Sanford Research**
 - \$5 million equity investment in CLBS made in 2016 and 2017
 - 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

CLBS03 to be uniquely positioned in the type 1 diabetes treatment paradigm



	Chronic blood glucose management	Disease Modification (CLBS03)	Function regeneration
Approach	Symptom management	Reduce or eliminate disease progression; potentially "curative"	Replace depleted cells/organs producing insulin; potentially "curative"
Insulin Impact	Improve therapeutic effect and/or efficiency of delivery of insulin/analogs	Avoid or reduce need for insulin by preserving active beta cells	Avoid or reduce need for externally-sourced insulin by providing new beta cells
Availability	Currently available with more in development	Currently in Phase 2 trial	Many years of development remaining

Published Phase 1 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 (0.05×10^8 to 26×10^8 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	<ul style="list-style-type: none"> • Demonstrated safety/tolerance <ul style="list-style-type: none"> - No cytokine release, infectious complications or infusion reactions observed - >500 fold dose range tested • Established manufacturing feasibility <ul style="list-style-type: none"> - Can produce expanded Treg cell population with enhanced functionality • Implied durability of effect <ul style="list-style-type: none"> - Infused Tregs were stable and detectable in peripheral circulation for 1 year 	<p>At 12 months:</p> <ul style="list-style-type: none"> • 6 treated patients achieved remission³ • 2 treated patients achieved insulin independence 

1. Bluestone, et al. Science Translational Medicine 2015

2. Marek-Trzonkowska, N et al. Clinical Immunology 2014

3. Remission Definition: Daily dose of insulin ≤ 0.5 Ull/kg body weight & fasting c-peptide > 0.5 ng/ml at 12 months after recruitment

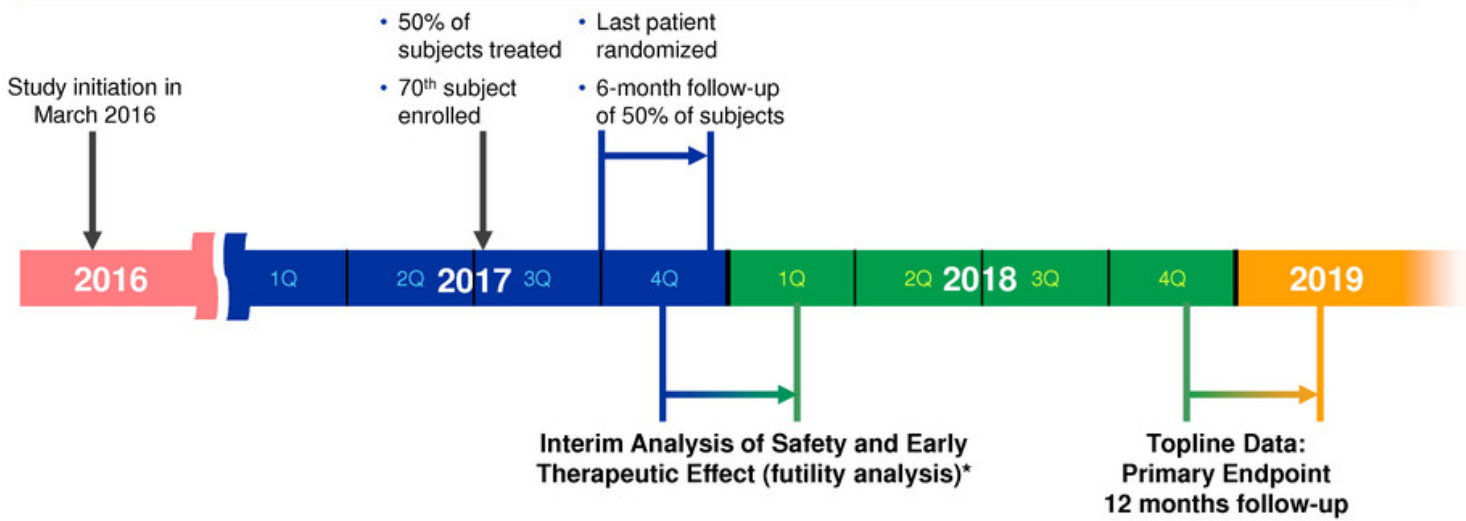
T-Rex Study:

Phase 2 trial in adolescents with T1D initiated in March 2016

Rigorous Design	<ul style="list-style-type: none">• Double-blind, placebo-controlled, randomized (1:1:1) trial• Adolescent patients ages 8 to <18 with recent-onset (diagnosed within last 100 days) T1D
Standard Endpoints	<ul style="list-style-type: none">• Preservation of C-peptide level, insulin use, severe hypoglycemic episodes, glucose and hemoglobin A1c levels
Study Size	<ul style="list-style-type: none">• 110 patients enrolled across ~15 study sites in the USA (enrollment completed in Dec. 2017)
Power	<ul style="list-style-type: none">• 80% power to detect a 0.2 pmol/mL difference in AUC mean C-peptide between active and placebo
Study Execution	<ul style="list-style-type: none">• Strategic collaboration with Sanford Research providing operational resources and capital
Treatment	<ul style="list-style-type: none">• Single infusion of CLBS03 (dose cohorts of 2.5 or 20 million cells/kg) or placebo infusion (control)

For more details: NCT02691247 at www.clinicaltrials.gov

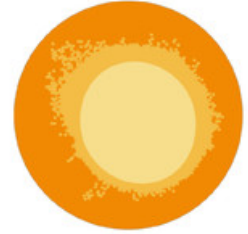
T-Rex study timeline to primary endpoint analysis after 12 months of follow-up



***March 8, 2018:** *Treatment continues to be well-tolerated and deemed non-futile for therapeutic effect*

Ischemic Repair

CD34 cells



CD34 cell therapy is supported by a substantial body of clinical evidence

- **CD34 cells have been investigated in clinical studies with >400 patients exposed**
 - Pre-clinical studies document improved microcirculation¹
 - Phase 2 clinical studies provide consistent evidence of benefit in safety and function
 - o Reduced amputation in critical limb ischemia²
 - o Improved function in claudication³
 - o Reduced angina and improved ETT in refractory angina⁴
 - o Improved mortality and LVEF in dilated cardiomyopathy⁵
- **Opportunities exist across multiple underserved cardiovascular indications**
 - Critical limb ischemia (“CLI”) (with specific emphasis in Japan at present)
 - Coronary microvascular dysfunction (“CMD”) aka Coronary Syndrome X
 - Refractory angina

1. Kalka et al. PNAS. 2000; Schatteman et al. J Clin Invest 2000.; Madeddu et al. FASEB. 2004.
2. Losordo et al. Circ Cardiovasc Interv 2012.
3. From US study (n=17); Not yet published
4. Losordo et al. Circ Res 2011.; Povsic et al. JACC Cardiovasc Interv. 2016.
5. Vrtovec et al. Circ Res 2013.

Japanese development program for critical limb ischemia (CLBS12):

Designed to leverage new regulatory path to early conditional approval

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

Design	<ul style="list-style-type: none">• Prospective, open label, controlled, randomized trial• Patients with no-option CLI
Advantageous Primary Endpoint	<ul style="list-style-type: none">• Time to continuous CLI-free status (2 consecutive monthly visits, adjudicated independently)
Study Size	<ul style="list-style-type: none">• 35 patients to be enrolled across multiple centers in Japan
Treatment	<ul style="list-style-type: none">• Up to 10^6 autologous G-CSF-mobilized peripheral blood-derived CD34 cells/kg per affected limb
Control/ comparator	<ul style="list-style-type: none">• SOC pharmacotherapy with drugs approved in Japan (e.g., antiplatelets, anticoagulants and vasodilators)• Choice of pharmacotherapy will be made by the investigators
Mode of administration	<ul style="list-style-type: none">• Intramuscular, 20 injections in affected lower limb in single administration
Timing	<ul style="list-style-type: none">• Study enrollment open with final results expected mid-late 2019

Phase 1/2 proof-of-concept study in Coronary Microvascular Dysfunction

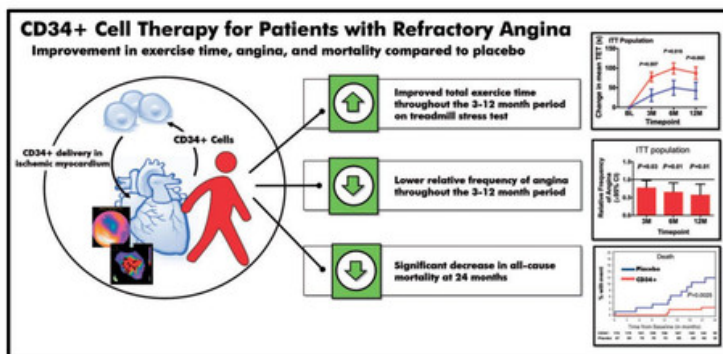
Design	<ul style="list-style-type: none">• Interventional, open label, exploratory (proof-of-concept) trial
Primary Endpoint	<ul style="list-style-type: none">• Safety and the evaluation of adverse events
Secondary Endpoints	<ul style="list-style-type: none">• Changes from baseline to 6 months for coronary flow reserve, endothelial-dependent microvascular function, time to angina; other cardiovascular performances
Study Size	<ul style="list-style-type: none">• 20 patients to be enrolled at 2 centers in the USA (Cedars Sinai, LA & Mayo Clinic)
Mode of administration	<ul style="list-style-type: none">• CLBS14 infused into a coronary artery
Timing	<ul style="list-style-type: none">• Initiation targeted for early Q2 2018 with results expected by end of 2019
Funding	<ul style="list-style-type: none">• SBIR (NIH) grant for \$1.9 million

Robust data included in exclusive license

- Phases 1, 2, & 3 clinical studies^{1,2,3} (combined n=304)
 - o Meta-analysis results using all three trials (published in the European Heart Journal, 1/18) statistically positive, with improvement in total exercise time, angina frequency and major cardiac events
 - o Phase 3 study sponsored by Baxter (prior to Shire and Baxalta merger) stopped early for strategic reasons

CLBS development next steps:

- Reactivate existing (Shire) IND with CLBS as Sponsor
- Meet with the FDA to determine remaining development requirements to BLA
- Seek grant funding to supplement costs, if available

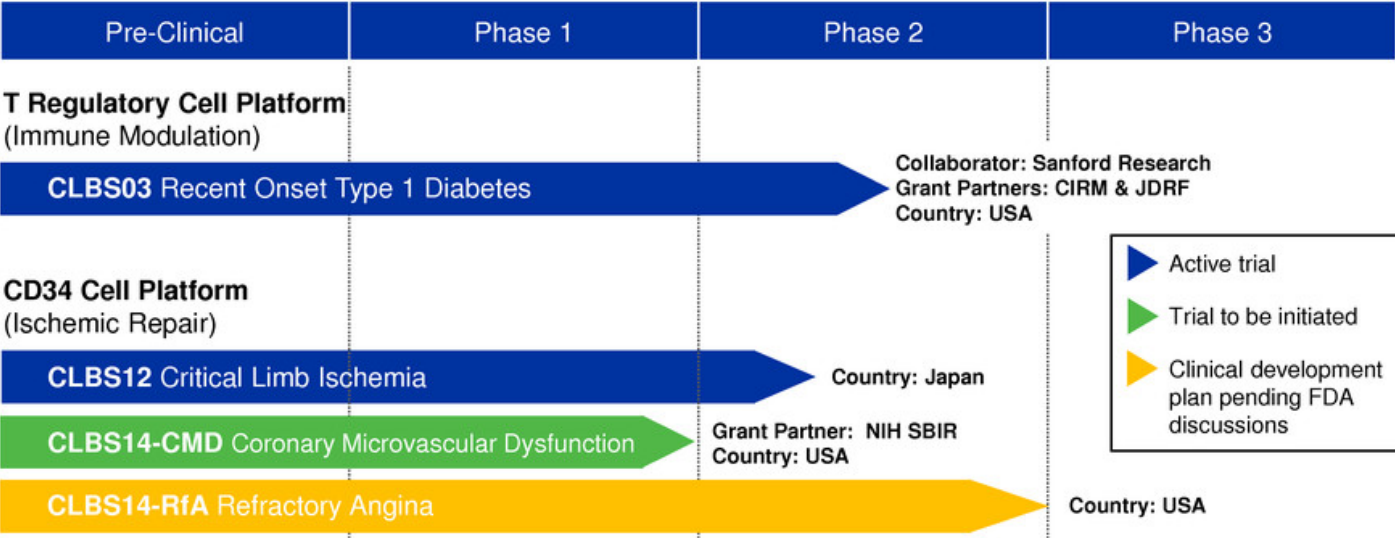


¹ Losordo, D.W., et al, Intramyocardial transplantation of autologous CD34+ stem cells for intractable angina: a phase I/IIa double-blind, randomized controlled trial. Circulation, 2007. 115(25): p. 3165-3172

² Losordo, D.W., et al., Intramyocardial, autologous CD34+ cell therapy for refractory angina. Circ Res, 2011. 109(4): p. 428-36.

³ Povsic, T.J., et al., The RENEW Trial: Efficacy and Safety of Intramyocardial Autologous CD34(+) Cell Administration in Patients With Refractory Angina. JACC Cardiovasc Interv, 2016. 9(15): p. 1576-85.

Multi-Product Pipeline Based on Proprietary Technology Platforms



Experienced executive team with broad domain-specific expertise

David J. Mazzo, PhD President and Chief Executive Officer	30+ years of experience in all aspects of large pharma (Merck, Baxter, RPR, HMR, Schering-Plough) and emerging biopharma (Chugai USA, Regado) company operations, successful international drug development across all therapeutic areas and international capital raising and business transactions
Joseph Talamo, CPA, MBA Senior VP and Chief Financial Officer	Versatile finance executive with leadership experience in publicly traded development and commercial-stage companies (OSI Pharmaceuticals, Bristol-Myers Squibb); 25+ years of experience (KPMG)
Douglas W. Losordo, MD Senior VP and Chief Medical Officer	Leader in cell therapy research and development; renowned clinician with noteworthy academic (Tufts, Northwestern, NYU) and industry (Baxter) credentials; 25+ years of experience
Todd Girolamo, JD, MBA Senior VP, General Counsel and Corporate Secretary	Seasoned attorney with 25+ years of legal (Cahill, Gordon & Reindel; Reid & Priest), finance and biotechnology industry experience (Oppenheimer, CIBC, Leerink Swann)

Key Financials Figures¹

Current Cash ² :	\$64.5m
2017 Average Quarterly Operating Cash Burn ³ :	\$5.4m
Long-term Debt:	\$0
Common Shares Outstanding:	9.4m shares
Options Outstanding:	1.1 m shares (average exercise price \$33.30)
Warrants Outstanding:	0.3m shares (average exercise price \$54.80)

¹ As of September 30, 2017

² Cash, Cash Equivalents, Restricted Cash and Marketable Securities

³ Nine-months ended September 30, 2017

Caladrius offers multiple potential near-term value creating milestones

		Timeframe
Treg Platform	• T-rex interim analysis 6 months post treatment of 50% patients	1Q2018 (completed)
	• Analysis of 12 month data (primary efficacy endpoint)	Early 2019
	• 2-year follow-up complete	Late 2019
CD34 Platform	• Initiate 35 patient Phase 2 trial of CLBS12 in Japan for critical limb ischemia (CLI)	1Q2018 (completed)
	• Begin patient enrollment in 20 patient Phase 2 trial CLBS14-CMD for coronary microvascular dysfunction (CMD)	1Q2018
	• Acquire an exclusive license to a late stage program for the treatment of refractory angina	1Q2018 (completed)
	• Reactive IND from Shire for CLBS14-RfA (refractory angina)	2Q2018
	• Meet with FDA to finalize CLBS14-RfA development plan	2H2018
	• Seek additional grant funding: multiple clinical indications	2018
	• Explore additional licensing opportunities	2018



NASDAQ: CLBS

Investor Relations Contact

John D. Menditto

Phone: 908.842.0084

Email: jmenditto@caladrius.com

Web: www.caladrius.com

