

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): June 5, 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.)

106 Allen Road, 4th 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
99.1	Caladrius Biosciences, Inc. Corporate Presentation, June 2017

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: June 5, 2017



Corporate Presentation

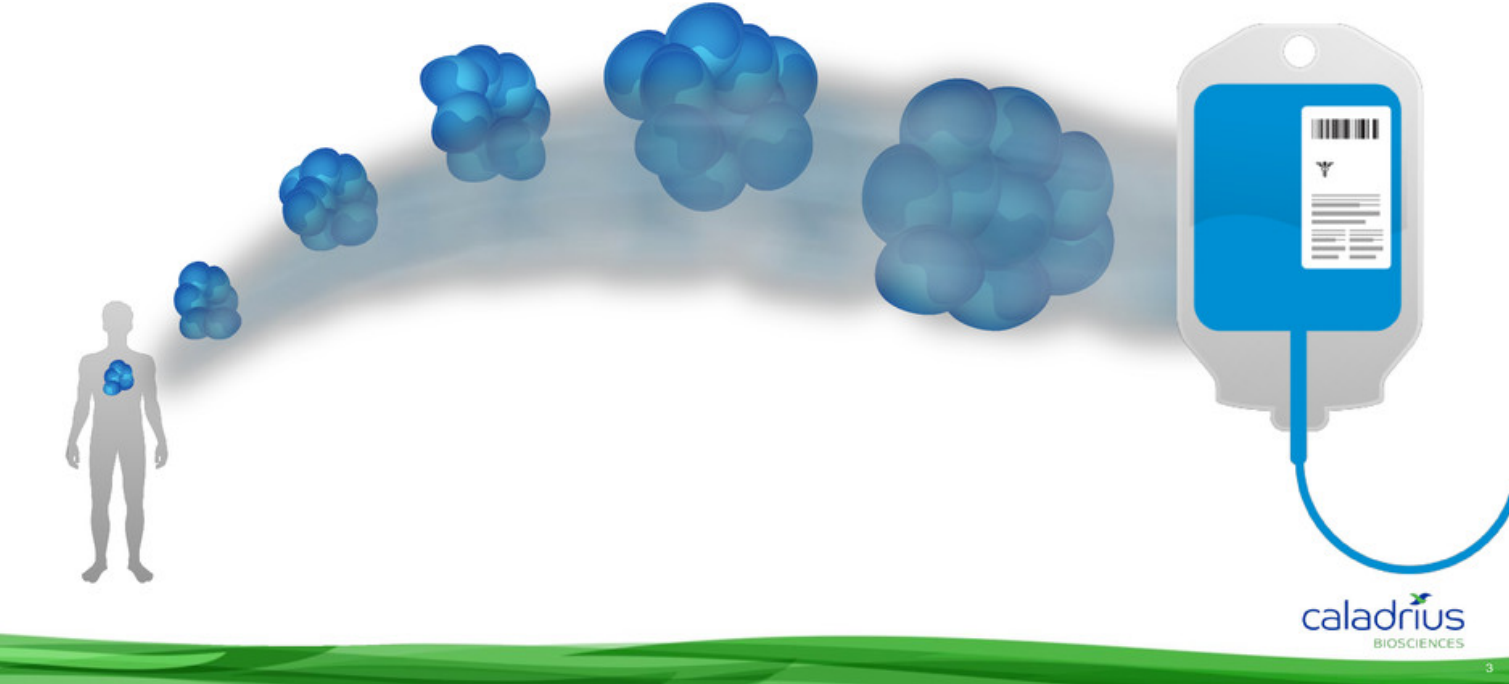
David J. Mazzo, PhD
Chief Executive Officer

June 2017 | NASDAQ: CLBS

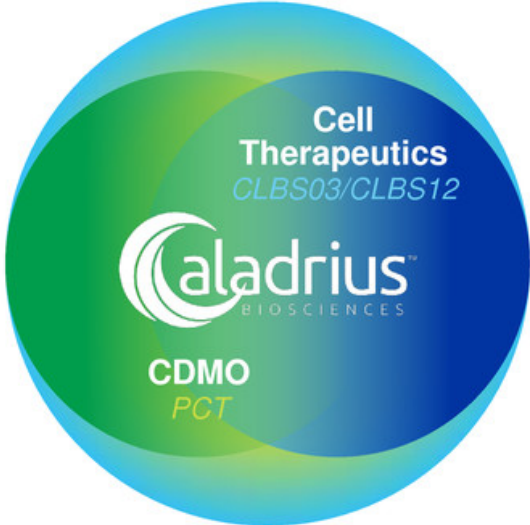
Safe Harbor for forward-looking statements advisory

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.

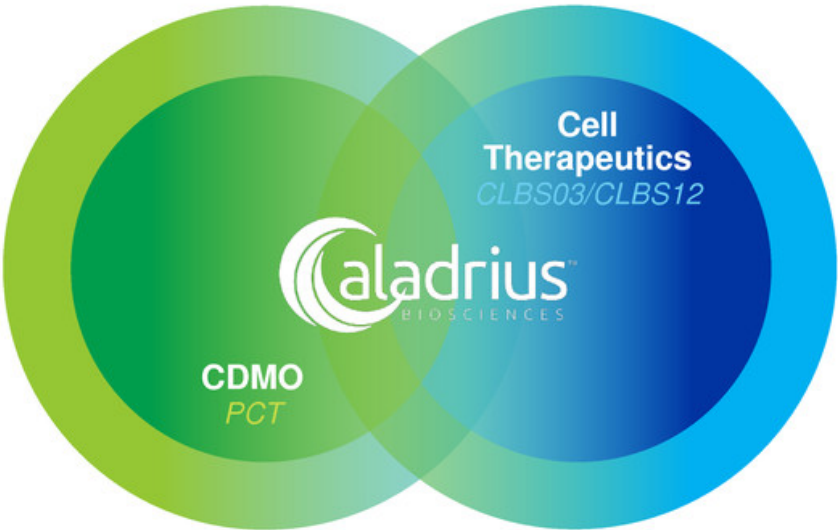
Caladrius transforms cells into therapies



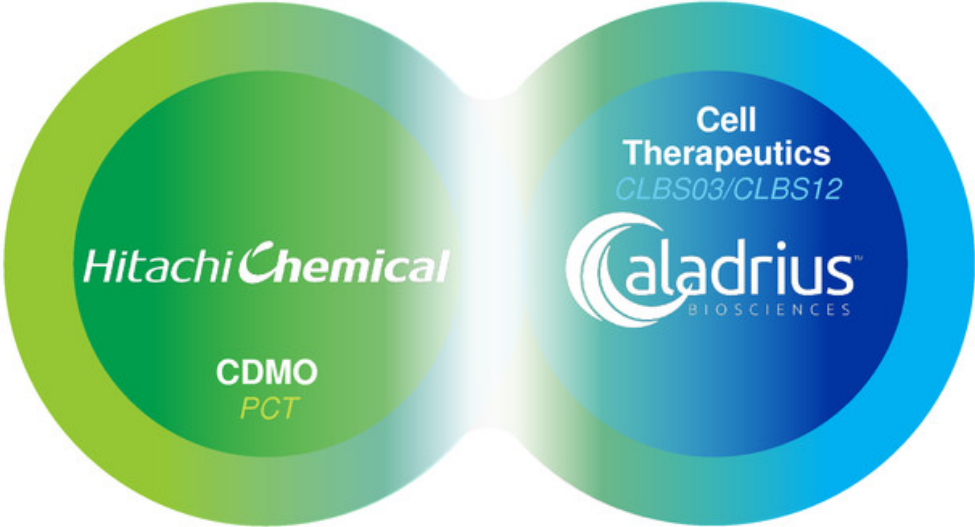
Caladrius historical hybrid business model



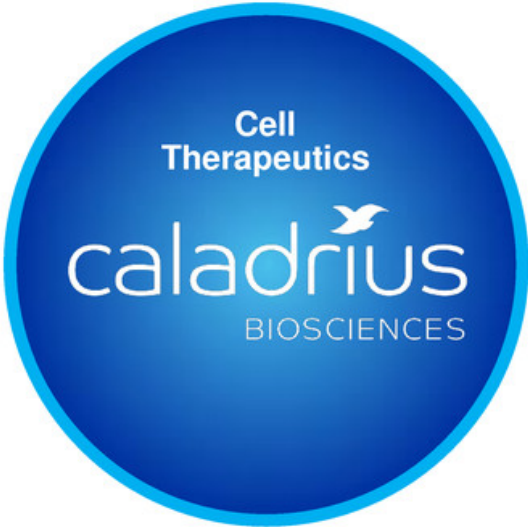
Caladrius recent business model evolution



Caladrius recent business model evolution



Caladrius business model evolution – two healthy companies emerge



Caladrius unlocks PCT value and preserves intimate working relationship



Caladrius Biosciences: Focused, funded and poised for growth

- **Pure-play clinical stage therapeutics development company**
- **Two technology platforms on which to build**
 - T regulatory cells for immune modulation
 - CD34+ cells for ischemic repair
- **Well-funded with cash of ~\$70 million**
- **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)
 - ~\$12.2 million California Institute for Regenerative Medicine (C.I.R.M.) grant awarded
 - ~\$600,000 Juvenile Diabetes Research Foundation (JDRF) grant to Benaroya as direct CLBS03 study subsidy
- **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

Immune Modulation

Autologous, polyclonal T regulatory cells



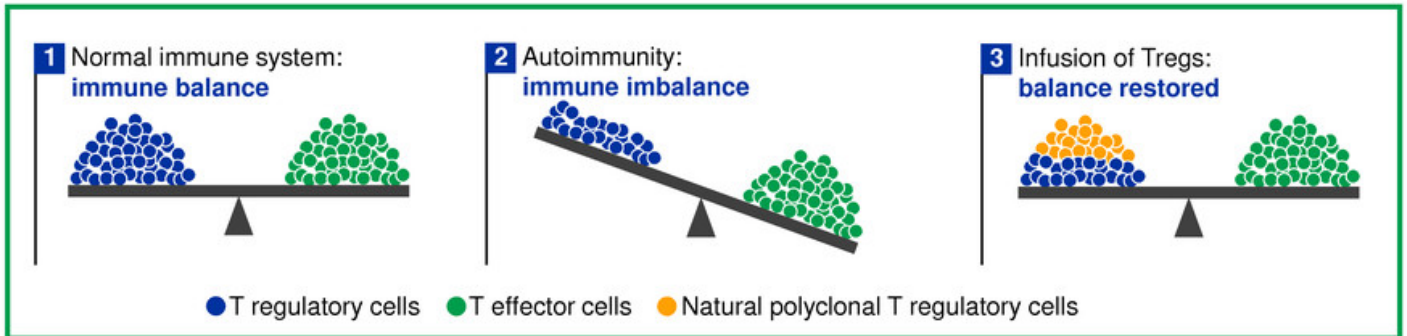
T regulatory cell technology platform built on a strong foundation

- **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 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, 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

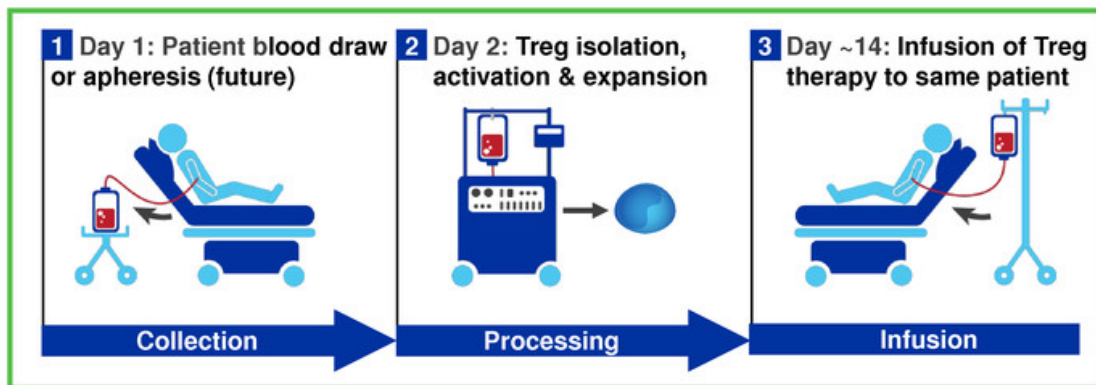
Additional potential indications:

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.

Simple, cost-effective, proprietary

Manufacturing process is scalable and economically viable



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

- Simple, minimally 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 apheresis and cryopreservation step(s) are expected to be likely

CLBS03: Recent onset type 1 diabetes program overview

- **Ongoing landmark Phase 2 clinical study in T1D (T-Rex trial)**
 - C.I.R.M. 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
 - 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 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

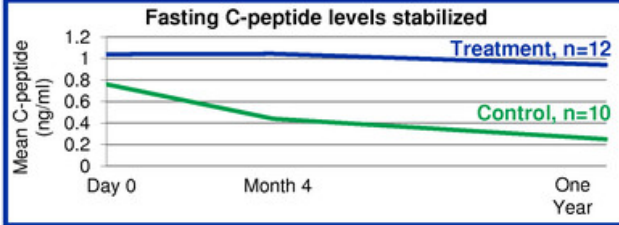
CLBS03 occupies a unique position in the type 1 diabetes treatment paradigm



	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

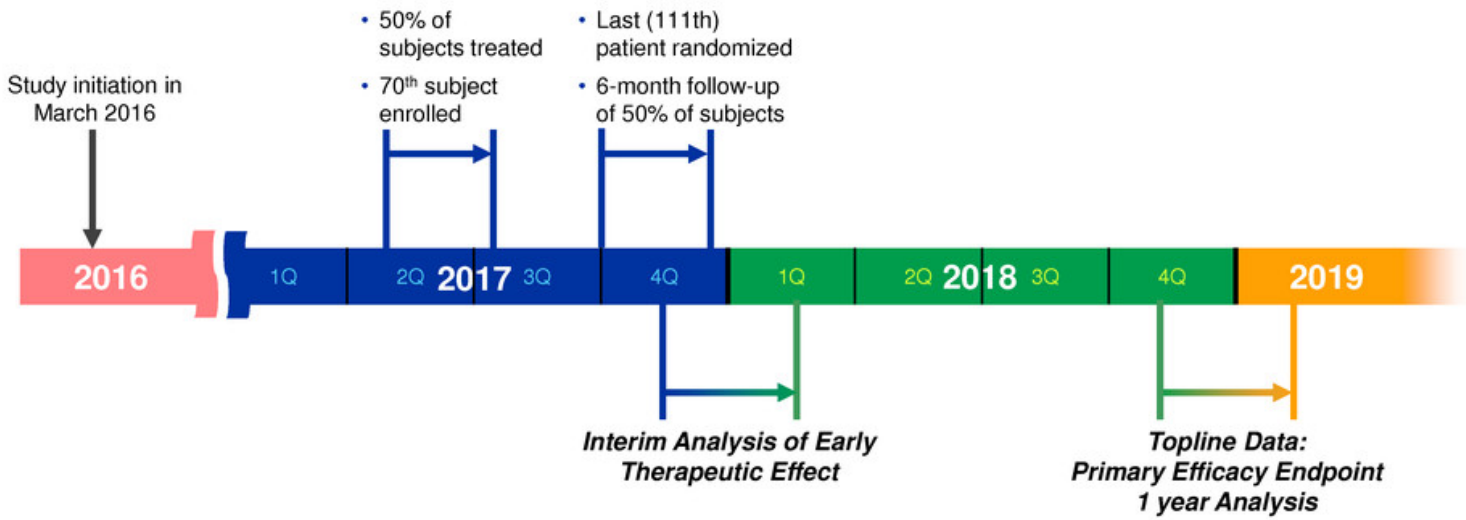
T-Rex Study:

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">• 111 patients enrolled across ~12 study sites in the USA
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 including near-term milestones



Ischemic Repair

CD34+ cells



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

- **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
 - 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) in Japan
 - Coronary microvascular dysfunction (CMD)
 - 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.

Designed to leverage new regulatory path to early conditional approval

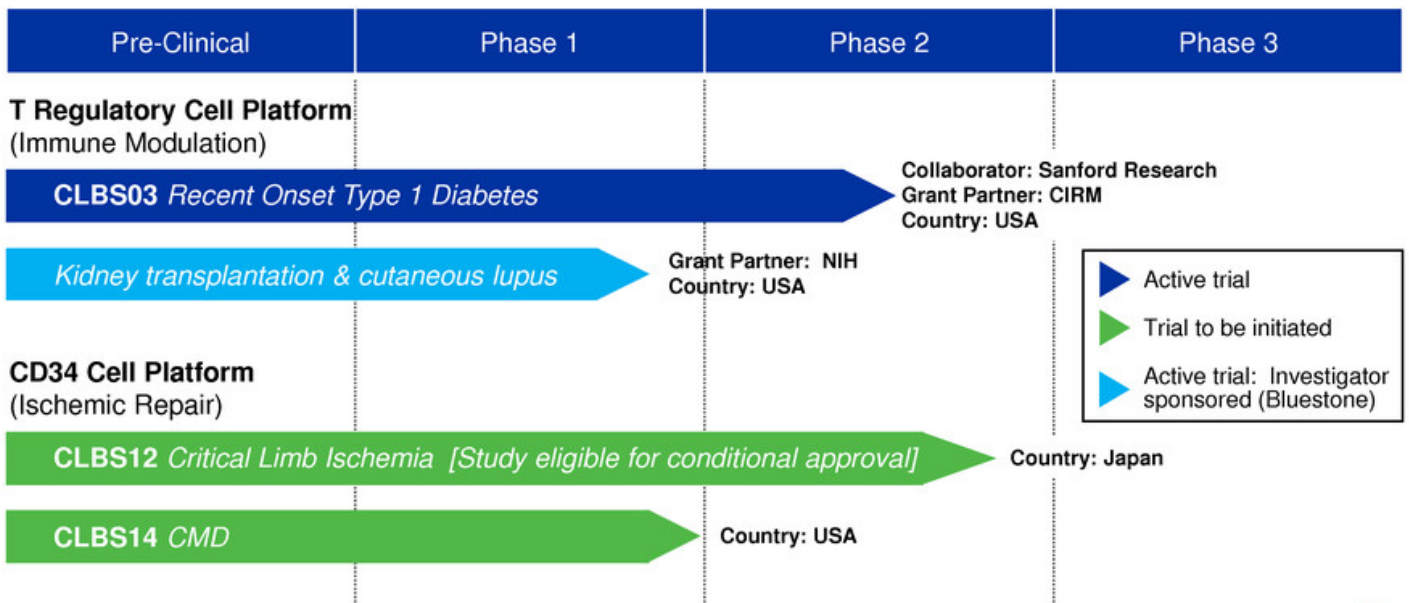
Phase 2 protocol and CMC strategy completed in consultation with Japanese PMDA

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 (defined as 2 consecutive monthly visits)
Study Size	<ul style="list-style-type: none">• 35 patients 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)• The 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">• First-patient-in targeted for 4Q17/1Q18 with preliminary data expected within 6 months of initiation

Grant opportunity in additional cardiovascular indication

Indication	Coronary Microvascular Dysfunction
Grantor	NIH Small Business Innovation Research
Decision Expected	Mid-2017
Total Award Sought	\$1.9 million
Trial Phase	Early Phase 2
Number of Subjects	20
Study Initiation	Within 5 months of award date
Timing of Results	2018

Multi-Product Pipeline Based on Proprietary Technology Platforms



Experienced executive team with broad domain-specific expertise

David J. Mazzo, PhD Chief Executive Officer	30+ years of experience in all aspects of large pharma (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)
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.

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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Reduced R&D (37%) and SG&A (32%) expenses significantly from 2015 levels
Monetize non-core assets	<ul style="list-style-type: none">• Out-licensed certain oncology and dermatology product candidates

Select Caladrius financial information

2017 Capital Catalysts and Impact			
March 31, 2017 Financial Information	Hitachi Acquisition of 80.1% of PCT from CLBS for \$75m Cash (closed on May 18, 2017)	CIRM CLBS03 Grant Award	Sept. 2016 PIPE – Second Tranche
Cash: \$12.0m	\$75m Transaction <ul style="list-style-type: none"> • \$5m received as advance payment in 1Q17 • \$65m received on closing • \$5m deposited in escrow (release expected May 2018, subject to indemnification claims, if any) 	Total of up to \$12.2m with initial payment of ~\$5.7m received in May 2017	\$2.4m triggered by 70 th patient enrolled in T-Rex Study (expected mid-2017)
Long-term debt: \$4.9m	<ul style="list-style-type: none"> • Eliminated on May 18, 2017 commensurate with closing of Hitachi Transaction 		

Cash available (~\$70 million) as of June 2017 expected to fund the company's current business plan well beyond 2018

Caladrius offers multiple potential near-term value creating milestones

		Expected Timeframe
CLBS03	• DSMB safety assessment on 1 st patient cohort	Completed 2016
	• Initiation of enrollment of 2 nd patient cohort	Completed 2016
	• 50% of patients treated: starts clock to 6-mos. follow-up interim analysis	Mid-2017
	• 70 th 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
Other Technologies	• Initiate 35 patient Phase 2 trial in Japan for critical limb ischemia	4Q17/1Q18
	• Begin patient enrollment in 20 patient Phase 2 trial for coronary microvascular dysfunction based on NIH SBIR grant	2H2017
	• Additional grant funding opportunities: CD34 program, multiple clinical indications	2017
	• Licensing opportunity possibilities (e.g., CLI in Japan)	2017
Financing	• Closing of Hitachi Chemical purchase of PCT from Caladrius for \$75 million plus milestone	Completed May 2017



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

