

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 17, 2016

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))

Item 7.01. Regulation FD Disclosure.

A copy of a slide presentation that Caladrius Biosciences, Inc. (the “Company”) uses at investor and industry conferences and presentations is attached to this Current Report on Form 8-K (“Current Report”) as Exhibit 99.1 and is incorporated herein solely for purposes of this Item 7.01 disclosure.

The information in this Current Report, 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 Current Report, including Exhibit 99.1 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 Current Report will not be deemed an admission as to the materiality of any information in this Current Report that is required to be disclosed solely by Regulation FD.

Item 9.01. Financial Statement and Exhibits.

(d) Exhibits.

		<u>Exhibit No.</u>	<u>Description</u>
99.1	Caladrius Biosciences Corporate Presentation, March 2016		

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: March 17, 2016

Caladrius Biosciences

Corporate Presentation

David J. Mazzo, PhD, *Chief Executive Officer*
March 2016
NASDAQ: CLBS



Forward-looking statements

This presentation 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 presentation, and involve certain risks and uncertainties. All statements other than statements of historical fact contained in this presentation are forward-looking statements, including statements regarding our expected financial results, as well as the potential of our product candidates. 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 materially differ 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 15, 2016, and in the Company's other periodic filings with the SEC, including, without limitation, risks related to: (i) our expected continued losses and negative cash flows; (ii) our anticipated need for substantial additional financing; (iii) the significant costs and management resources required to comply with the requirements of being a public company; (iv) the possibility that a significant market for cell therapy may not emerge; (v) the potential variability in PCT's revenues; (vi) PCT's limited manufacturing capacity; (vii) the need to improve manufacturing efficiency at PCT; (viii) the limited marketing staff and budget at PCT; (ix) the logistics associated with the distribution of materials produced by PCT; (x) government regulation; (xi) our intellectual property; (xii) cybersecurity; (xiii) the development, approval and commercialization of our products; (xiv) enrolling patients in and completing, clinical trials; (xv) the variability of autologous cell therapy; (xvi) our access to reagents we use in the clinical development of our cell therapy product candidates; (xvii) the validation and establishment of manufacturing controls; (xviii) the failure to obtain regulatory approvals outside the United States; (xix) our failure to realize benefits relating to "fast track" and "orphan drug" designations; (xx) the failure of our clinical trials to demonstrate the safety and efficacy of our product candidates; (xxi) our current lack of sufficient manufacturing capabilities to produce our product candidates at commercial scale; (xxii) our lack of revenue from product sales; (xxiii) the commercial potential and profitability of our products; (xxiv) our failure to realize benefits from collaborations, strategic alliances or licensing arrangements; (xxv) the novelty and expense of the technology used in our cell therapy business; (xxvi) the possibility that our competitors will develop and market more effective, safer or less expensive products than our product candidates; (xxvii) product liability claims and litigation, including exposure from the use of our products; (xxviii) our potential inability to retain or hire key employees; and (xxix) risks related to our capital stock. Although the Company believes the expectations contained in such forward-looking statements are based on reasonable assumptions, it can give no assurance that its expectations will be attained. The forward-looking statements are made as of the date of this presentation, and the Company undertakes no obligation to publicly update or revise any forward-looking statements, as a result of new information, future events or otherwise, except as required by law.



Company Overview

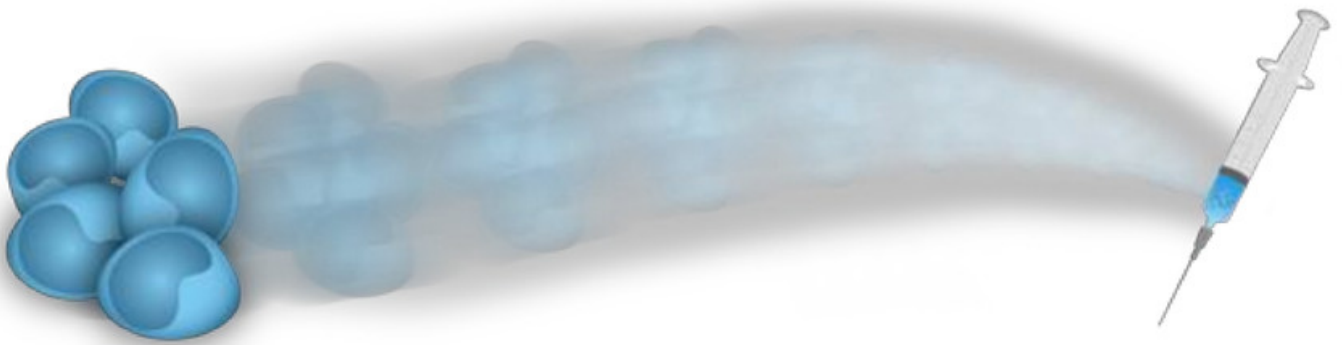
- Caladrius, through its subsidiary, PCT, is a leading development and manufacturing partner to the cell therapy industry
 - 2015 Revenues: \$22.5 Million (averaging 25% annual growth over past three years)
 - Headquarters in Basking Ridge, NJ with locations in Allendale, NJ, New York, NY, Mountain View, CA and Irvine, CA
 - Strategic collaboration with Hitachi Chemical to create a global commercial enterprise
- Caladrius develops select early stage candidates to proof-of-concept
 - T regulatory cell therapy (CLBS03) targeting adolescents with recent onset type 1 diabetes in Phase 2 trial

Investment Opportunity

- Projected >30%/year PCT revenue growth in 2016
- Growing cell therapy clinical manufacturing as well as several PCT clients reaching potential commercialization over next few years
- Value inflection upon proof-of-concept and eventual out-licensing of promising early stage candidates – currently CLBS03
- Partnering opportunity in Japan for CLBS12 for critical limb ischemia; Phase 2 protocol designed in consultation with PMDA eligible for conditional early approval upon study success
- Spin-out or licensing of additional cell therapy candidates



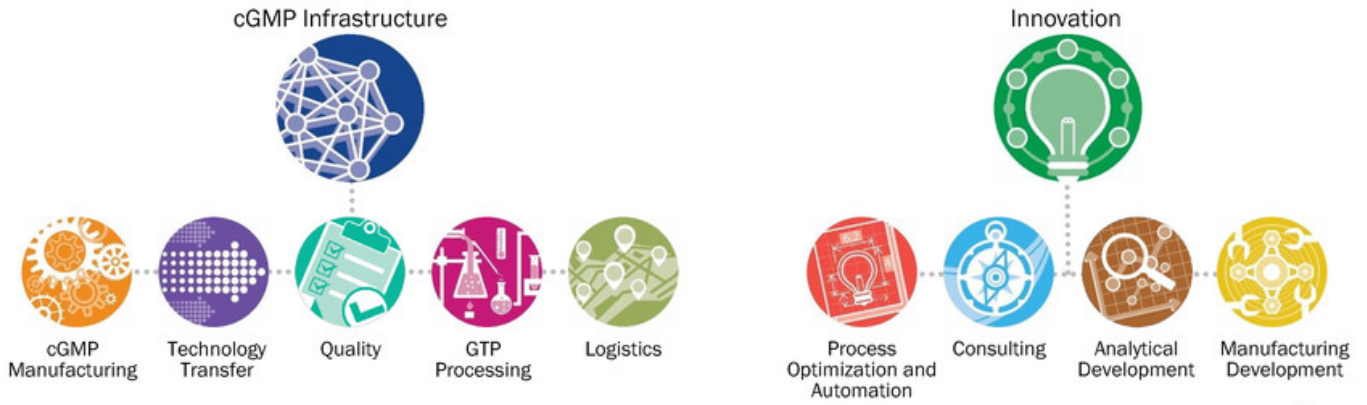
Transforming cells into therapies



From Concept to Commercial Product

PCT: Premier cell therapy development and manufacturing partner

PCT is a subsidiary of Caladrius Biosciences and is its Center of Excellence for process development, engineering and manufacturing



Unmatched experience: >100 clients, 20,000 products and 6,000 patients over 17 years validate the benefits of PCT

Selected Clients:



Clients with late phase clinical programs expected to be among the first to potential commercialization



PCT is a premier cell therapy service provider

- **Specializes only in cell and cell-based gene therapy development and manufacturing**
- **Proven efficiency enhancement and reduced capital investment for clients vs. internal commitment**
 - From preclinical to commercial
- **Demonstrated regulatory expertise**
 - 50+ US and EU regulatory filings
- **Established process optimization and automation expertise**
- **US and EU compliant systems and facilities**

Multiple cGMP manufacturing facilities

Allendale, NJ (30,000 ft²)

ISO Class 7 suites

ISO Class 6 suite

Expansion underway to increase capacity by 60% including additional EU-compliant suites

Mountain View, CA (25,000 ft²)

ISO Class 7 suites



Expertise in multiple cell types and therapeutic applications

- **Immunotherapy**

- T cells / CAR-T cell therapy
- Tumor cells
- Dendritic cells
- Natural killer cells
- B cells
- Macrophages
- Donor lymphocyte infusion



- **Neuro/endocrine**

- Neural stem cells
- Porcine islets



- **Hematopoietic replacement**

- CD34+ selected cells
- Ex vivo gene therapy
- HSC / ASC / HPC
- Genetic disease



- **Tissue repair/regeneration**

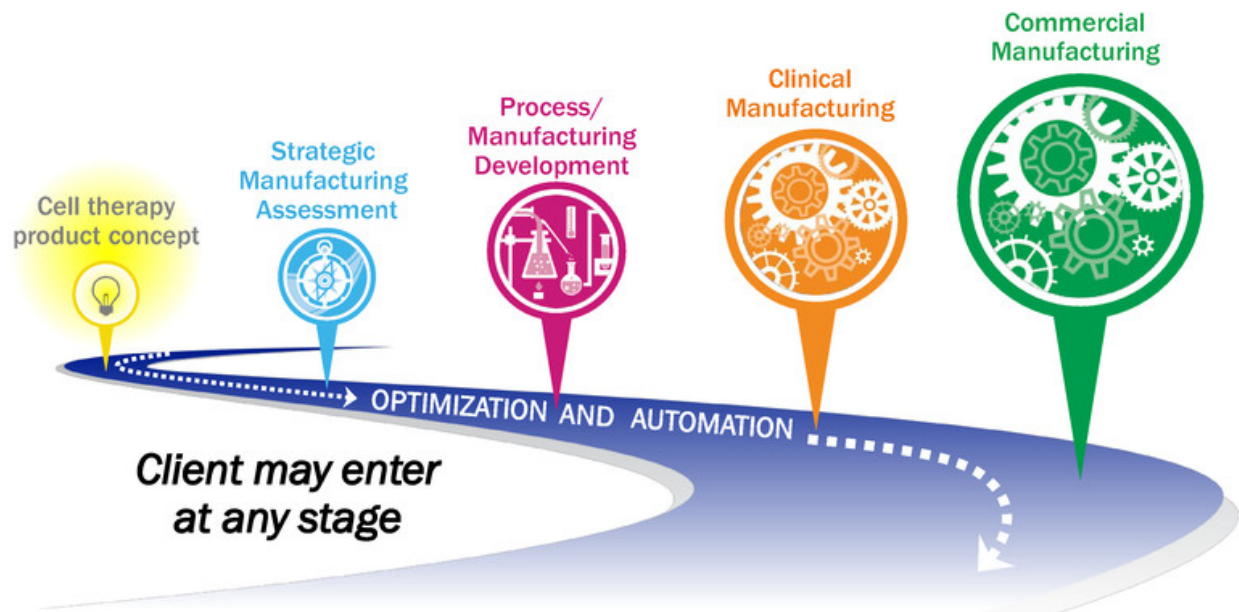
- Fibroblasts
- Keratinocytes
- Multipotent mesenchymal stromal cells



Delivering a strategic solution through flexible capacity

- Supplants expensive, time-consuming facility build-outs
- Mitigates challenges in forecasting capacity use
- Provides client-specific scalable manufacturing solutions
- Anticipates and provides solutions for evolving regulatory needs
- Introduces “Quality by Design” to optimize COGs

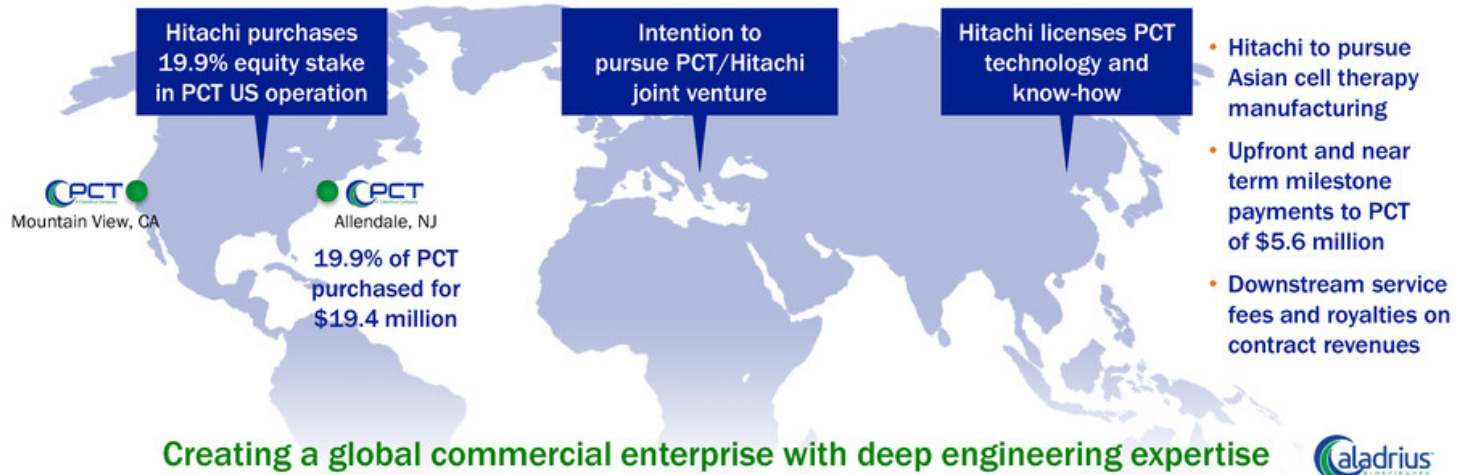
PCT offers a complete development pathway



Strategic global collaboration with Hitachi Chemical Co.

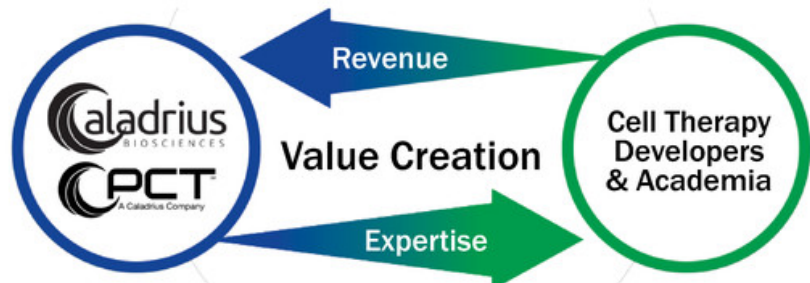


Hitachi Chemical



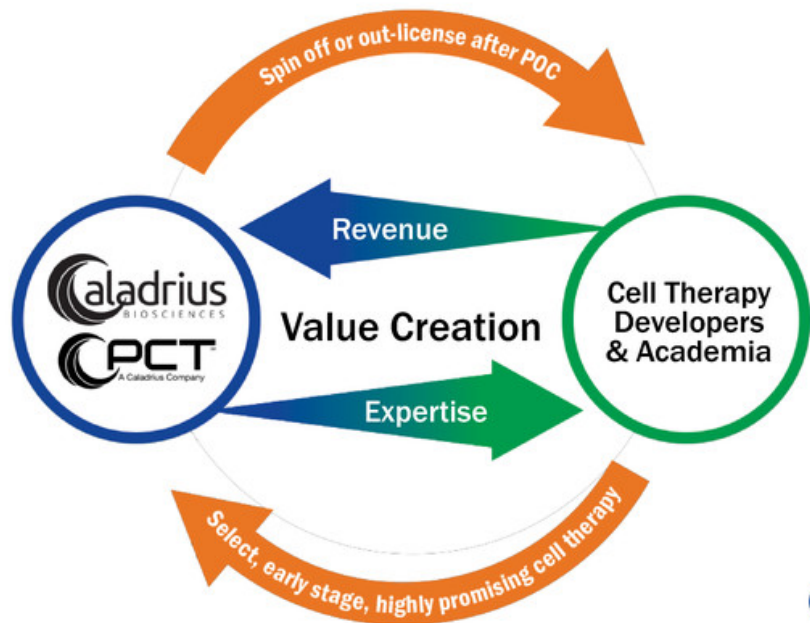
Caladrius base business model

PCT: a growing business providing development, manufacturing and delivery of cell-based therapies



Caladrius enhanced business model

Partnering post-POC provides value inflection and an additional stream of new PCT clients



Immune Modulation

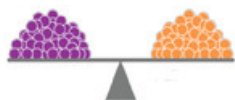
CLBS03: Type 1 Diabetes Mellitus (T1D)

- T Cell technology
- Phase 2 proof-of-concept stage
- PCT-developed manufacturing process
- Strategic collaboration with Sanford Research

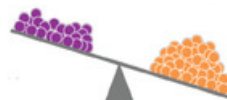


T Regulatory Cells (Tregs): restoring immune balance and function

Normal immune system:
immune balance



Autoimmunity:
immune imbalance

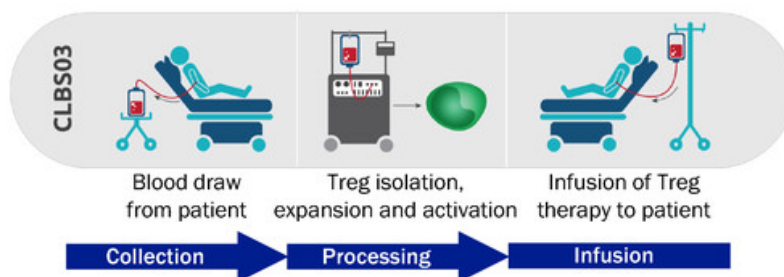


Infusion of Tregs:
balance regained



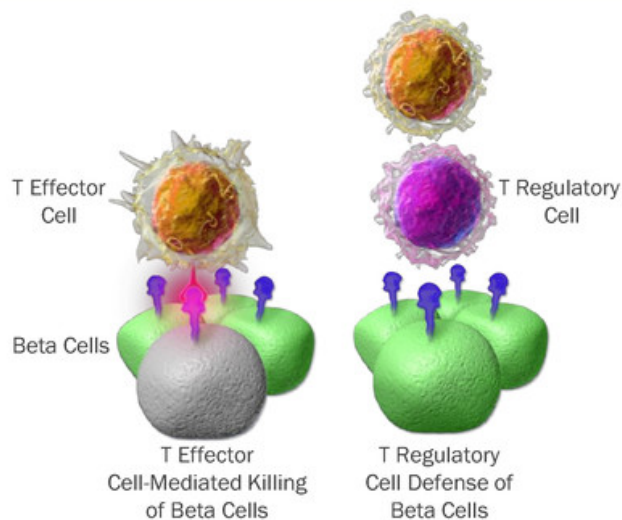
- T regulatory cells
- T effector cells
- Natural polyclonal T regulatory cells

Simple, cost-effective process with protected intellectual property



Type 1 Diabetes: Unmet needs create an attractive medical and commercial opportunity

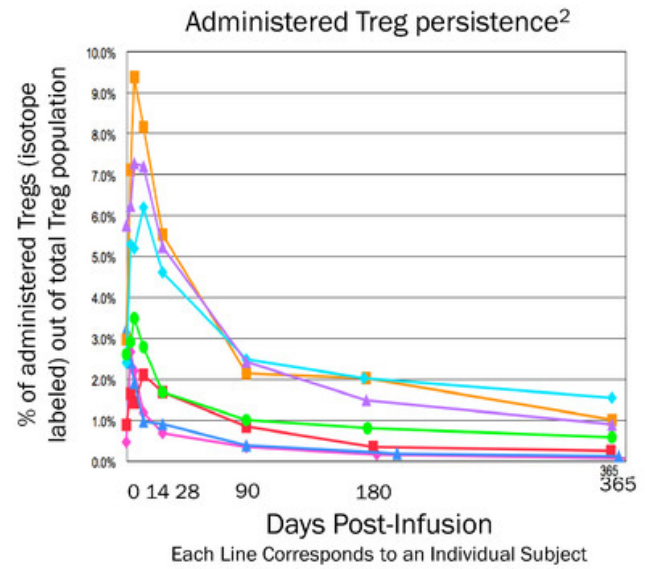
- Over 15,000 children and 15,000 adults in US with recent-onset T1D per year¹
- 3% annual growth rate worldwide²
- No curative treatments for T1D, only lifelong insulin therapy (without adequate glycemic control)
- Many serious co-morbidities:
 - Cardiovascular co-morbidities
 - Diabetic neuropathy/neuropathic pain
 - Kidney failure
 - New cases of adult blindness (diabetic retinopathy)
 - Non-traumatic lower-limb amputations



1. Information T1D. *National Diabetes Statistics*. 2011
2. Maahs DM, et al. *Endocrinol Metab Clin North Am*. 2010

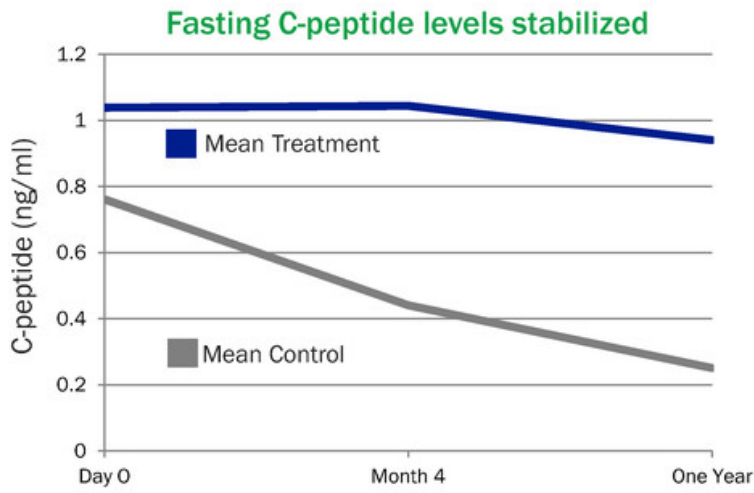
Treg cell therapy appears well tolerated and durable¹

Study Leadership	Jeffrey Bluestone, PhD of UCSF, leader in field of Tregs
Design	US UCSF/Yale open-label Phase 1 study, 4-dose escalation cohorts
Patients	14 adult patients with established T1D
Results	<ul style="list-style-type: none">• Results demonstrate safety/tolerance• Manufacturing feasibility established• Implied durability of effect<ul style="list-style-type: none">• Infused Tregs were stable and detected in peripheral circulation for 1 year²



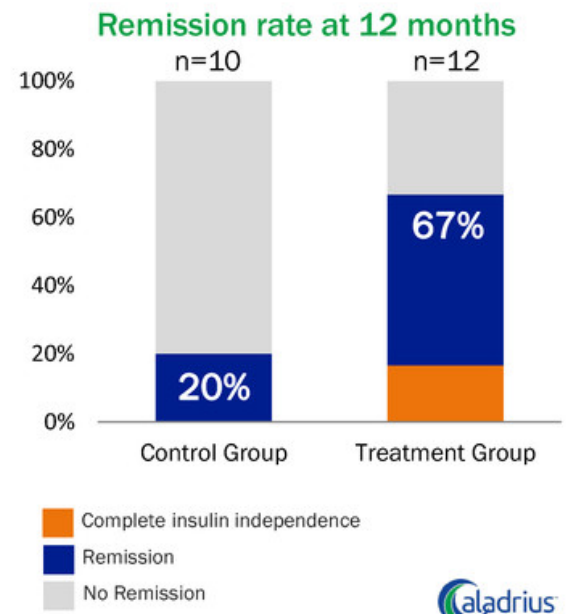
1. Gitelman et al, American Diabetes Association Abstract, 2014. 2. Dr. Jeffrey Bluestone Lab

Treg cell therapy preserves beta cell function in children¹



Marek-Trzonkowska, N t al. *Clinical Immunology* 2014

1. Children aged 5-18 administered 1 (10 or 20 mil cells/kg) or 2 doses (total 30 mil cells/kg) of Tregs



T-Rex Study: Phase 2 proof-of-concept in adolescents with T1D¹

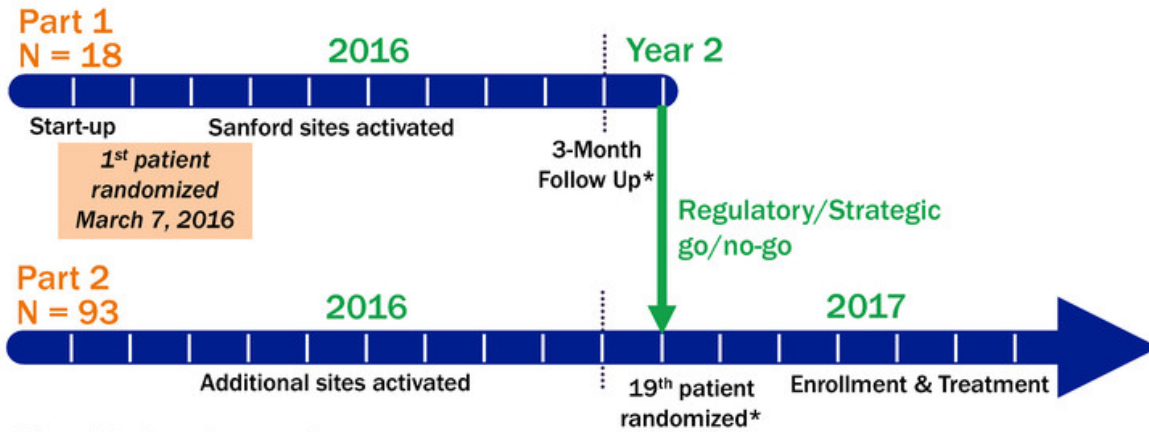
Design	<ul style="list-style-type: none">• Double-blind, placebo-controlled, randomized (1:1:1) trial• Adolescent patients ages 12 to 17 with recent-onset T1D
Key Endpoints	<ul style="list-style-type: none">• Preservation of C-peptide level, insulin use, hypoglycemic episodes, hemoglobin A1c level (all in comparison to placebo)
Powering	<ul style="list-style-type: none">• 80% power to detect a 0.2pmol/mL difference in AUC mean C-peptide between active and placebo
Study Size	<ul style="list-style-type: none">• 111 patients to be enrolled including 18-patient initial cohort• Approximately 20 sites expected, including US and, possibly, Canada• Supported by strategic collaboration with Sanford Research – The Sanford Project
Treatment	<ul style="list-style-type: none">• CLBS03: Dose cohorts of 2.5 or 20 million cells/kg (single dose)
Control	<ul style="list-style-type: none">• Placebo infusion (single dose)

1. Study cleared by FDA to proceed based on efficacy data in children establishing prospect of direct benefit



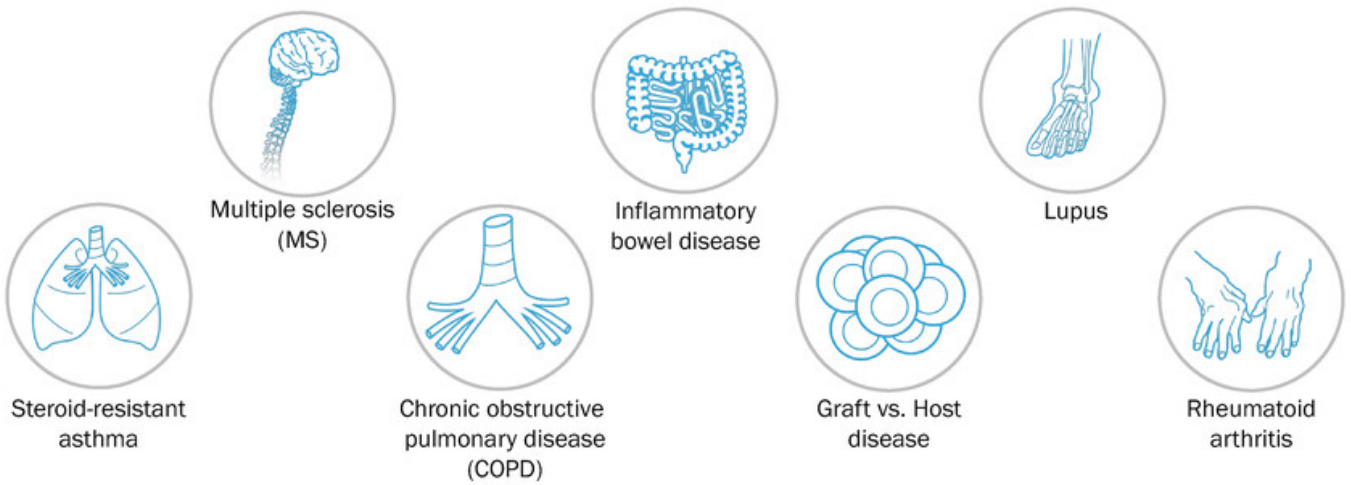
T-Rex Study: Efficient asset de-risking study design

- Initial 18 patients evaluated for safety and immunological markers 3 months post treatment
- Interim blinded efficacy analysis when ~50% of subjects complete 6-month follow up
- Top-line full study results after 111 patients complete 12-month follow up
- Partnering discussions underway



* Exact timing dependent on enrollment rate

Potential application across multiple autoimmune and allergic diseases



Multibillion-dollar lifecycle opportunity



Additional Technology Platforms for Partnering

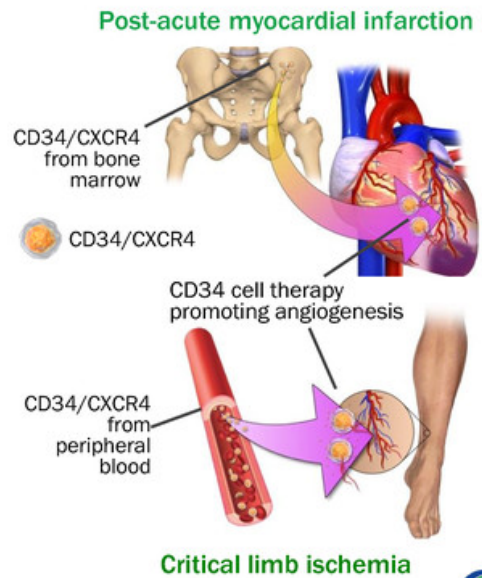
- CD34 cell technology for ischemic repair
 - Tumor cell/dendritic cell technology for immuno-oncology
-

- Phase 2 data for both platforms
- Applicability to multiple indications



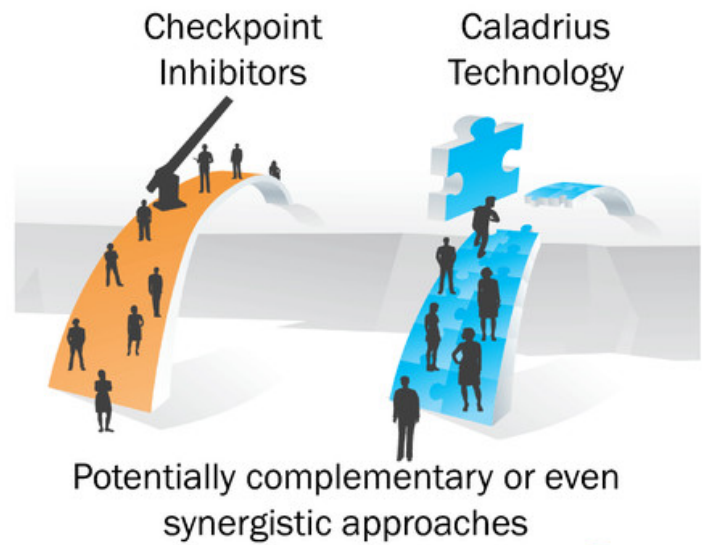
CD34 cell technology for ischemic repair

- CD34 cells shown to induce the development of new blood vessels, preventing tissue death by improving blood flow
- Significant unmet need for critical limb ischemia (CLI) and chronic heart failure (CHF)
- Partnering discussions advancing for Japanese development for CLI
 - Designed to leverage new Japanese regulatory path to early conditional approval
 - Phase 2 protocol and CMC strategy completed in consultation with Japanese PMDA
- Out-licensing completed for CHF/AMI opportunity in specific ex-US territories



Tumor cell/dendritic cell technology for immuno-oncology

- Uniquely targets cancer-initiating cells, applicability to multiple indications
- Checkpoint inhibitors reduce impediments to an existing path - CLBS technology may open entirely new paths to multiple-antigen recognition
- Promising Phase 2 melanoma efficacy results with no major safety issues
 - R.O. Dillman, et al. *Cancer Biother Radiopharm* 2009
 - R.O. Dillman, et al. *Journal Immunotherapy* 2012



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

Robert A. Preti, PhD

Senior VP, Manuf. and Tech. Operations and Chief Technology Officer; President of PCT

Leading authority on cell-based therapy engineering; unique development and commercialization experience; 30+ years of experience

Douglas W. Losordo, MD

Senior VP, Clinical, Medical and Regulatory Affairs and Chief Medical Officer

Leader in cell therapy research and development; renowned clinician with noteworthy academic and industry credentials; 25+ years of experience

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

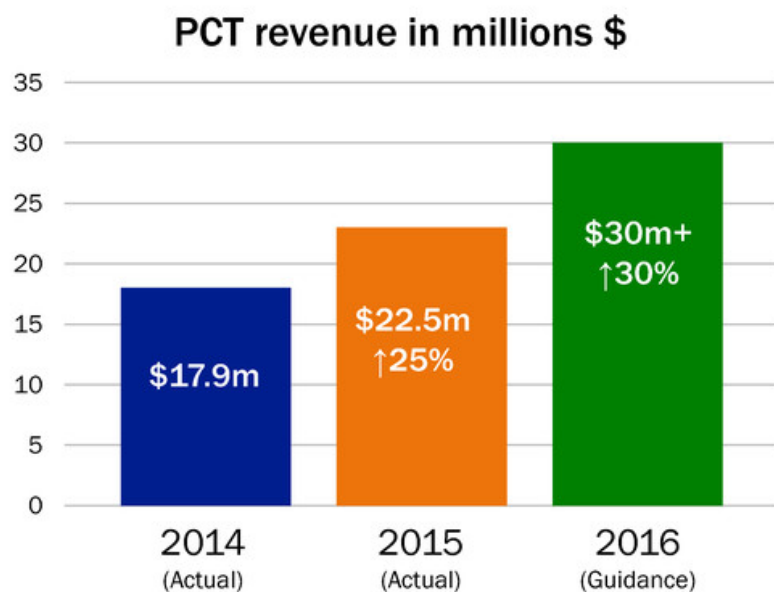
Todd Girolamo, JD, MBA

General Counsel and Corporate Secretary

Seasoned attorney with 25 years of legal, finance and biotechnology industry experience



Select financial information



As of December 31, 2015

- Cash: \$20.3m (1)
- Long-term debt: \$15m (1)
- Common outstanding: 57m
- Options outstanding: 7m (avg. \$5.56)
- Warrants outstanding: 3m (avg. \$13.71)

(1) On March 11, 2016, \$19.4 million in cash received in the Hitachi transaction, and \$7.0 million paid to reduce long-term debt



NASDAQ: CLBS

Investor Relations Contact:

LHA Investor Relations

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Web: www.caladrius.com



