

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 11, 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.

The Exhibit Index immediately following the signature page to this Current Report on Form 8-K is incorporated herein by reference.

**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: January 11, 2016

**Exhibit Table**

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

# Caladrius Biosciences

## Corporate Presentation

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



# Forward-looking statements

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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 2, 2015, 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 (xxviii) 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.



# Investment summary

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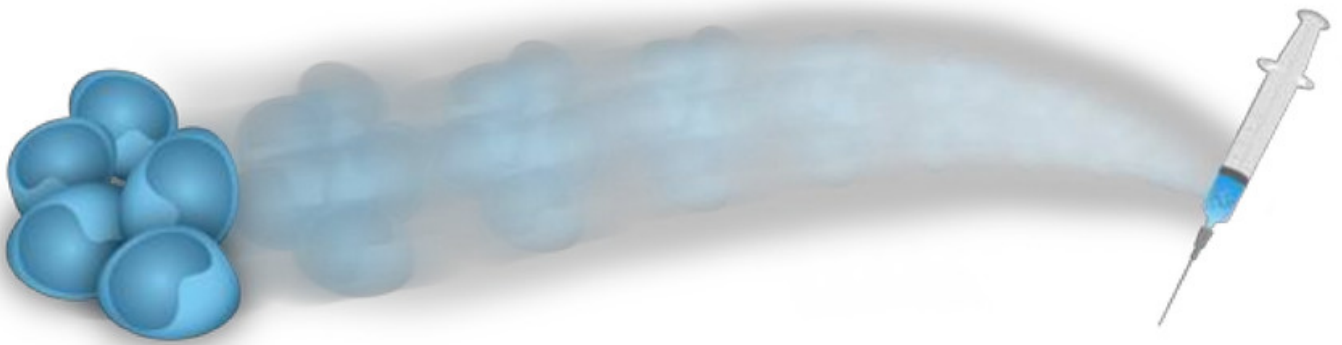
- **PCT: growing business providing development, manufacturing and delivery of cell-based therapies**
    - Averaging 25% year-over-year revenue growth over past two years
    - Unmatched cell and cell-based gene therapy-specific experience and expertise
    - Expansive list of noteworthy cell and cell-based gene therapy clients
- 

- **Focused pipeline of highly promising cell therapies**
    - Leverages internal specialized cell therapy clinical development expertise and PCT's CMC prowess
    - Partnering post-POC provides value inflection and an additional stream of new PCT clients
    - CLBS03 – Treg cell therapy targeting adolescents with recent-onset type 1 diabetes
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- **Highly experienced management and domain-specific scientific team**
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# Transforming cells into therapies

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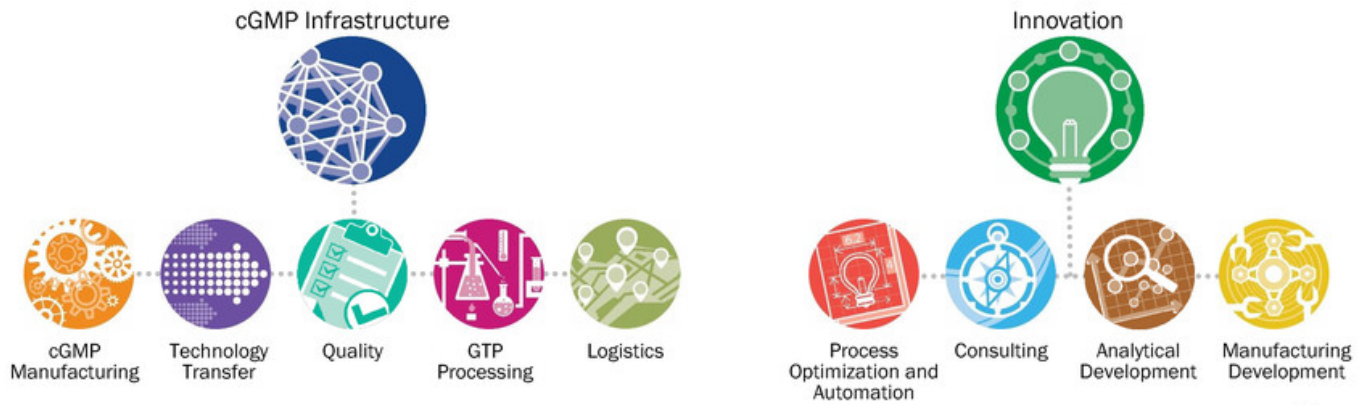


*From Concept to Commercial Product*



# PCT: Premier cell therapy development and manufacturing partner

Caladrius Biosciences' Center of Excellence for process development, engineering and manufacturing



# Unmatched experience: >120 clients, 20,000 products and 6,000 patients over 17 years validate the benefits of PCT



# PCT is a premier cell therapy service provider

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- **Specializes 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+ EU and US regulatory filings
- **Established process optimization and automation expertise**
- **US- and EU-compliant systems and facilities**

Multiple cGMP manufacturing facilities

**Allendale, NJ** (30,000 ft<sup>2</sup>)

ISO Class 7 / Class 10,000 suites

ISO Class 6 / Class 1,000 suite

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

**Mountain View, CA** (25,000 ft<sup>2</sup>)

ISO Class 7 / Class 10,000 suites



# Expertise in multiple therapeutic applications and cell types

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- **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

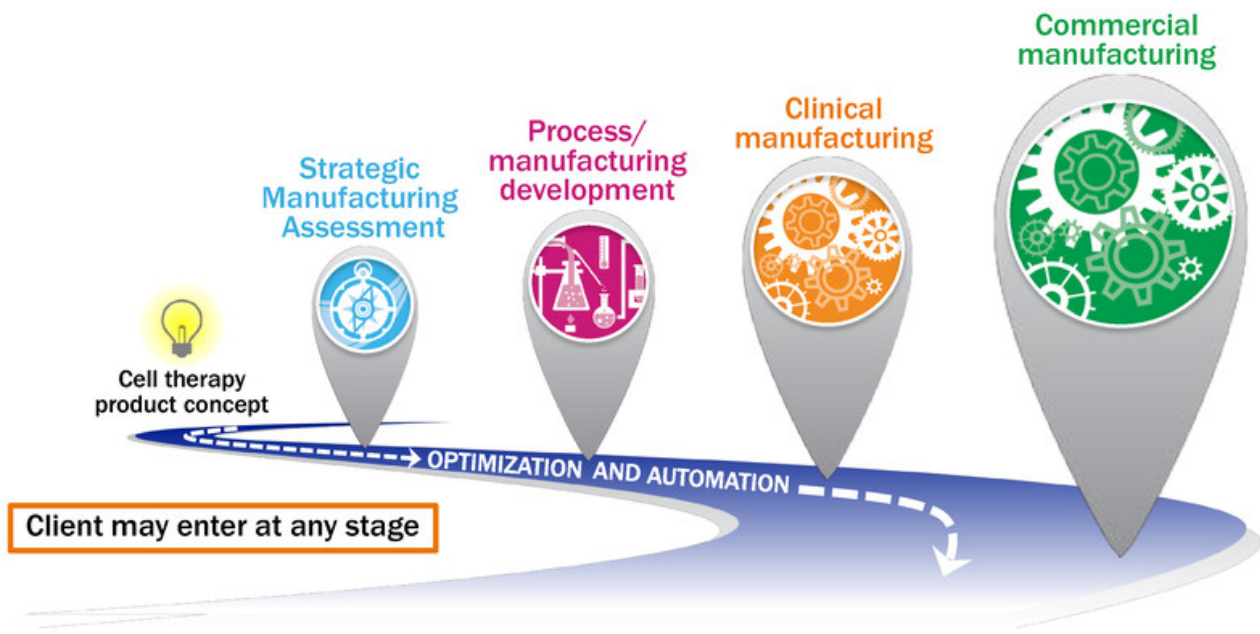


- **Tissue repair/regeneration**

- Fibroblasts
- Keratinocytes
- Multipotent mesenchymal stromal cells



# PCT offers a complete development pathway



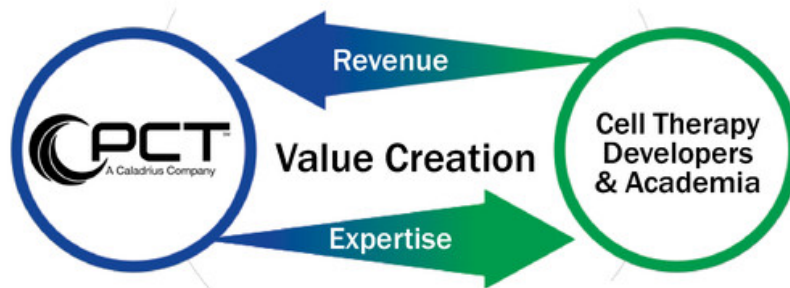
# Delivering a strategic solution through flexible capacity

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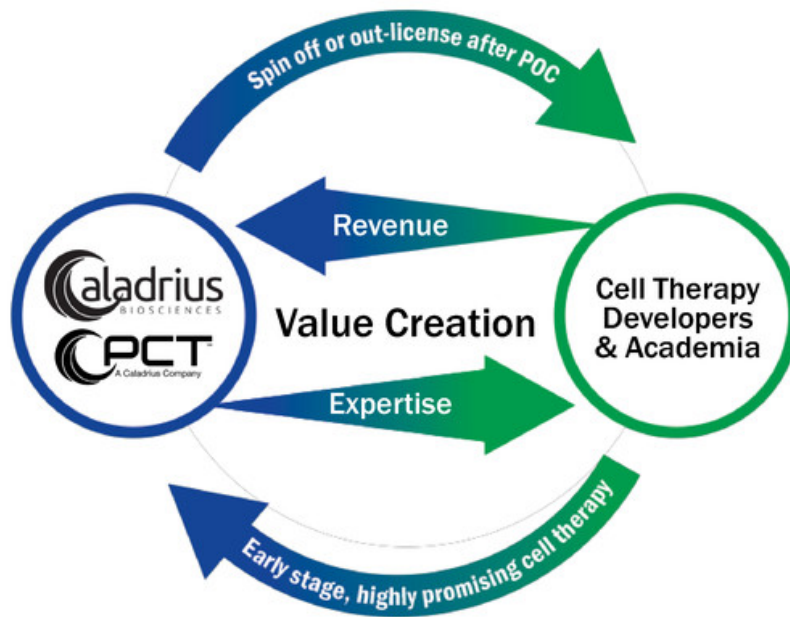
- **Supplants expensive, time-consuming facility build-outs and challenges in forecasting capacity use**
- **Provides client-specific dedicated or shared scalable manufacturing solutions**
- **“Partnership” model anticipates and provides prospective options for evolving client needs**
- **“Quality by Design” approach to high-quality, robust, scalable and sustainable products with optimal COGs**

# Caladrius base business model

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# Caladrius enhanced business model





# Immune Modulation

## CLBS03: Type 1 Diabetes Mellitus (T1D)

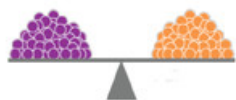
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- T Cell technology
- Strategic collaboration with Sanford Research
- Phase 2 proof-of-concept stage
- PCT-developed manufacturing process

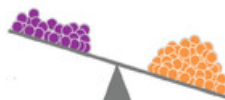


# T Regulatory Cells (Tregs): restoring immune balance and function

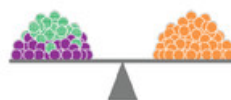
Normal immune system:  
immune balance



Autoimmunity:  
immune imbalance

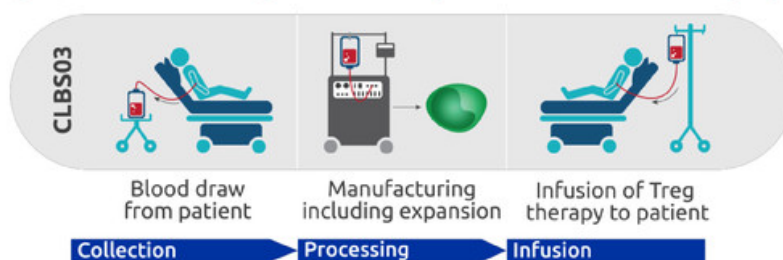


Infusion of Tregs:  
balance regained



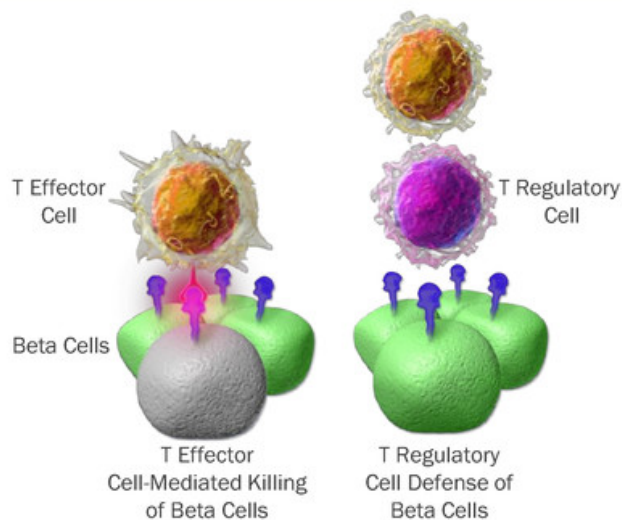
- T regulatory cells
- T effector cells
- Natural polyclonal T regulatory cells

Simple, cost-effective process with protected intellectual property



# T1D: unmet medical needs create attractive commercial opportunity

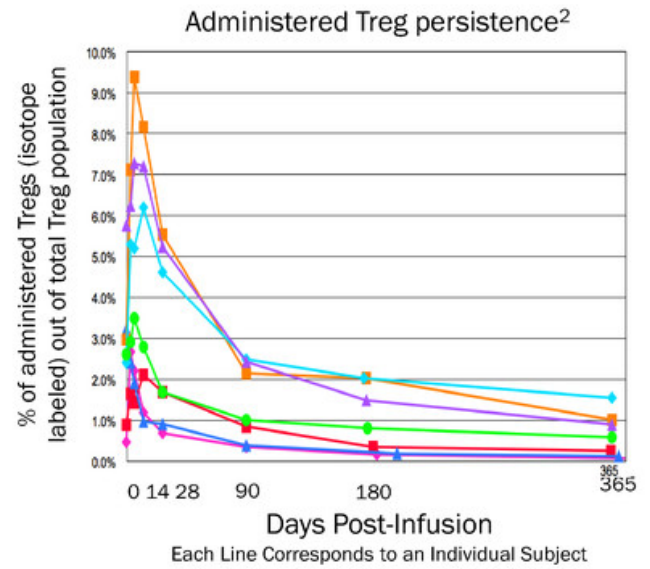
- 18,000 children under 20 in US with recent-onset T1D per year<sup>1</sup>
- 3% annual growth rate worldwide<sup>2</sup>
- No curative treatments for T1D, only lifelong insulin therapy
- Many serious co-morbidities:
  - Kidney failure
  - New cases of adult blindness
  - Non-traumatic lower-limb amputations



1. Hamman RF, et al. *Diabetes Care*. 2014; Sosenko JM, et al. *Diabetes Care*. 2008; Palmer JP. *Diabetes/metabolism research and reviews*. 2009  
2. The DIAMOND Project Group. *Diabetic Medicine*. 2006;23:857-866.

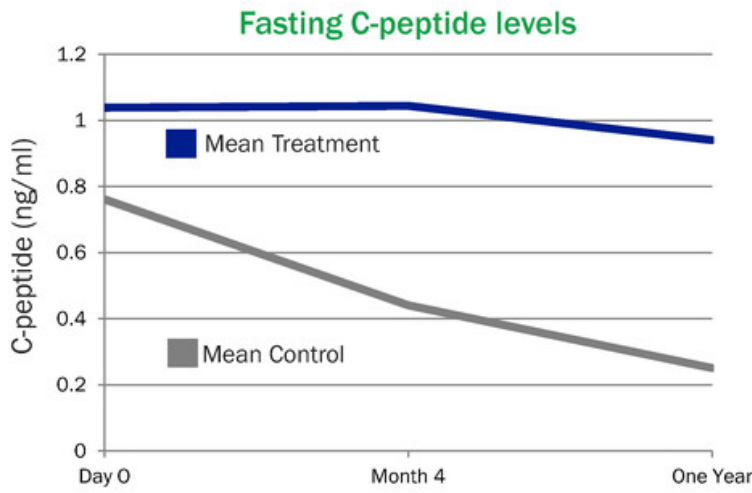
# Treg cell therapy appears durable in humans<sup>1</sup>

<b>Study Leadership</b>	Jeffrey Bluestone, PhD of UCSF, leader in field of Tregs
<b>Design</b>	US UCSF/Yale open-label Phase 1 study, 4-dose escalation cohorts
<b>Patients</b>	14 adult patients with established T1D
<b>Results</b>	<ul style="list-style-type: none"><li>• Preliminary data indicate safety and tolerability</li><li>• Established manufacturing feasibility</li><li>• Implied sustainability of effect</li><li>• Infused Tregs were stable and detected in peripheral circulation for 1 year<sup>2</sup></li></ul>



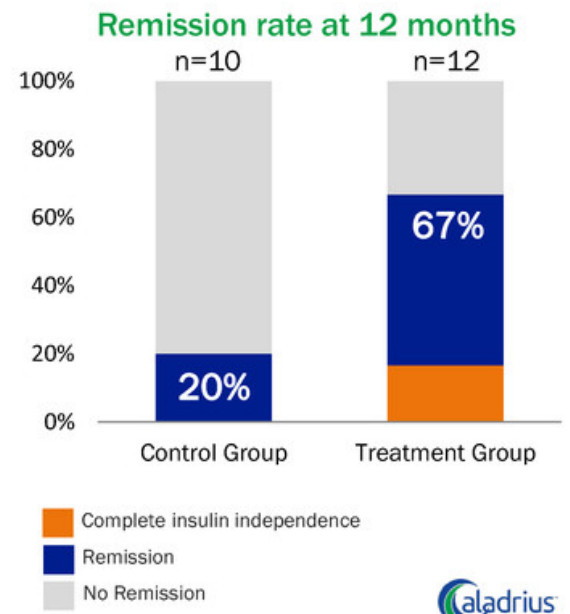
1. Gitelman et al, American Diabetes Association Abstract, 2014. 2. Dr. Jeffrey Bluestone Lab

# Treg cell therapy preserves beta cell function in children<sup>1</sup>



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



# TRex Study: Phase 2 proof-of-concept in adolescents with T1D<sup>1</sup>

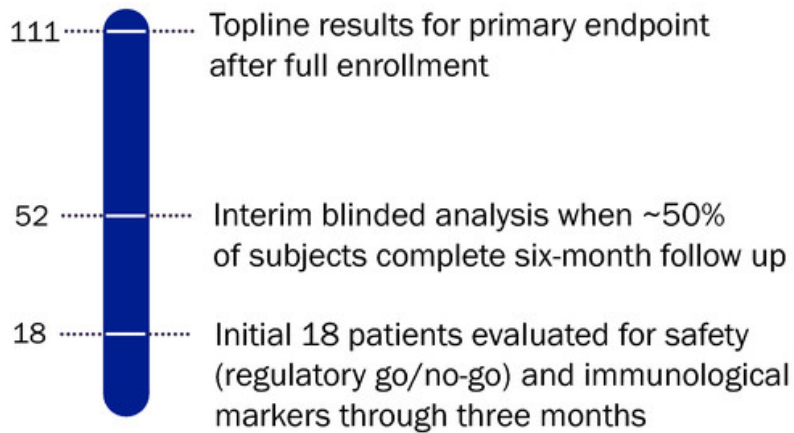
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<b>Design</b>	<ul style="list-style-type: none"><li>• Double-blind, placebo-controlled, randomized (1:1:1) trial</li><li>• Adolescent patients ages 12 to 18 with recent-onset T1D</li></ul>
<b>Key Endpoints</b>	<ul style="list-style-type: none"><li>• Preservation of C-peptide level, insulin use, hypoglycemic episodes, Hemoglobin A1 C level (all in comparison to placebo)</li></ul>
<b>Powering</b>	<ul style="list-style-type: none"><li>• 80% power to detect 50% attenuation in fasting C-peptide levels</li></ul>
<b>Study Size</b>	<ul style="list-style-type: none"><li>• 111 patients to be enrolled including 18-patient initial cohort</li><li>• 12 to 15 US sites</li><li>• <b>Supported by strategic collaboration with Sanford Research – The Sanford Project</b></li></ul>
<b>Treatment</b>	<ul style="list-style-type: none"><li>• CLBS03: Dose cohorts of 10 or 20 million cells/kg</li></ul>
<b>Control</b>	<ul style="list-style-type: none"><li>• Placebo infusion</li></ul>

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

# TRex Study: efficient asset de-risking study design

## Patient Enrollment

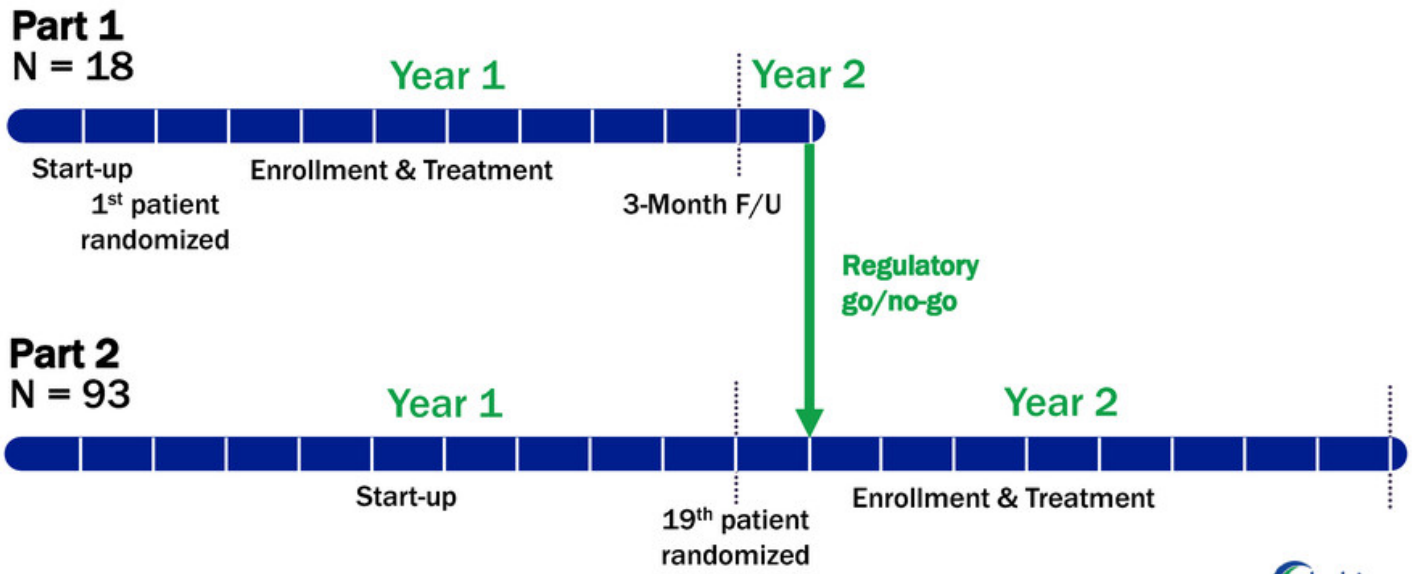


## Sanford Research will:

- Provide and cover costs of two initial clinical sites
- Enroll study subjects across nine-state footprint at their cost
- Provide funding/operational resources to execute subject recruitment, enrollment, treatment and monitoring



# Trex study timeline





# Potential application across multiple autoimmune and allergic diseases

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Steroid-resistant asthma



Multiple sclerosis (MS)



Chronic obstructive pulmonary disease (COPD)



Inflammatory bowel disease



Graft vs. Host disease



Lupus



Rheumatoid arthritis

***Multibillion-dollar lifecycle opportunity***



# Additional Technology Platforms for Partnering

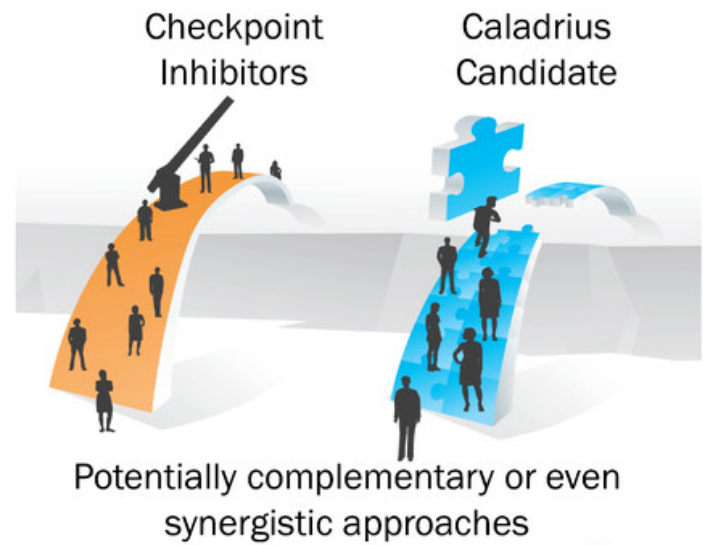
- Tumor cell/dendritic cell technology for immuno-oncology
  - CD34 cell technology for ischemic repair
- 

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



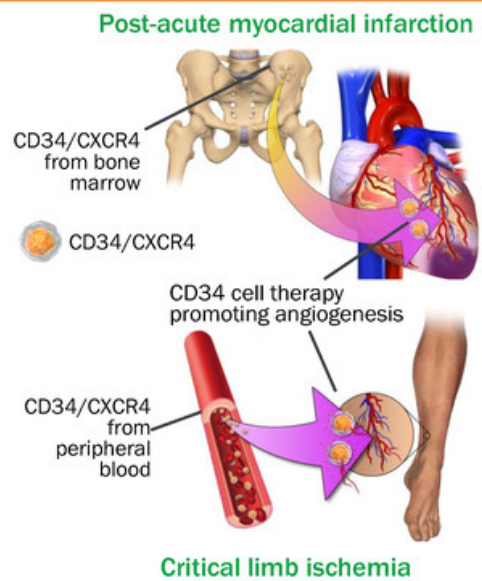
# Tumor cell/dendritic cell technology for immuno-oncology

- 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 (melanoma)



# 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)
- Seeking partnership for Japanese development for no-option 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



## Experienced executive team with broad domain-specific expertise

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**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, Dev. 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**

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**

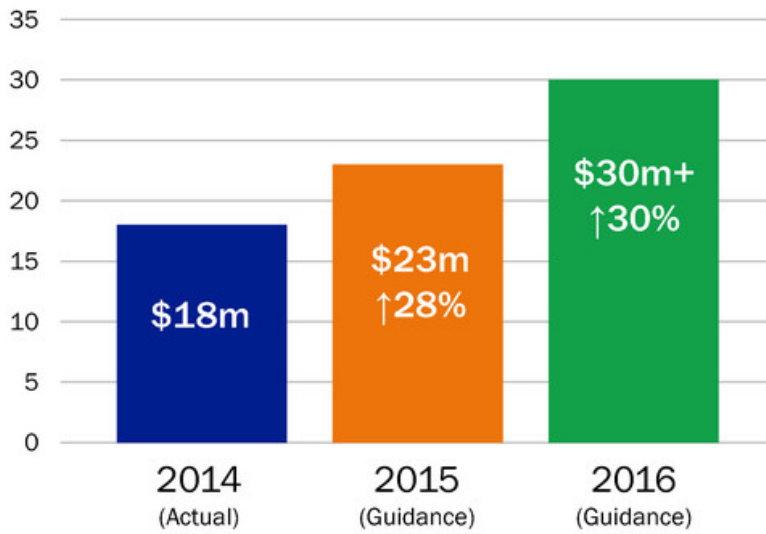
General Counsel and Corporate Secretary

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



## Select financial information

Revenue in millions \$



- Cash, cash equivalents and marketable securities\*: \$29.4 million
- Long-term debt\*: \$15 million

\* As of September 30, 2015



# Investment summary

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- **PCT: growing business providing development, manufacturing and delivery of cell-based therapies**
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- **Highly experienced management and domain-specific scientific team**
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# NASDAQ: CLBS

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**Investor Relations Contact:**

LHA Investor Relations

Anne Marie Fields, Senior Vice President

**Phone:** 212.838.3777

**Email:** [afields@lhai.com](mailto:afields@lhai.com)

**Web:** [www.caladrius.com](http://www.caladrius.com)





