

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): October 19, 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, October 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: October 19, 2016



CORPORATE PRESENTATION

David J. Mazzo, PhD
Chief Executive Officer

October 2016 | NASDAQ: CLBS

Forward-looking statements advisory

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.

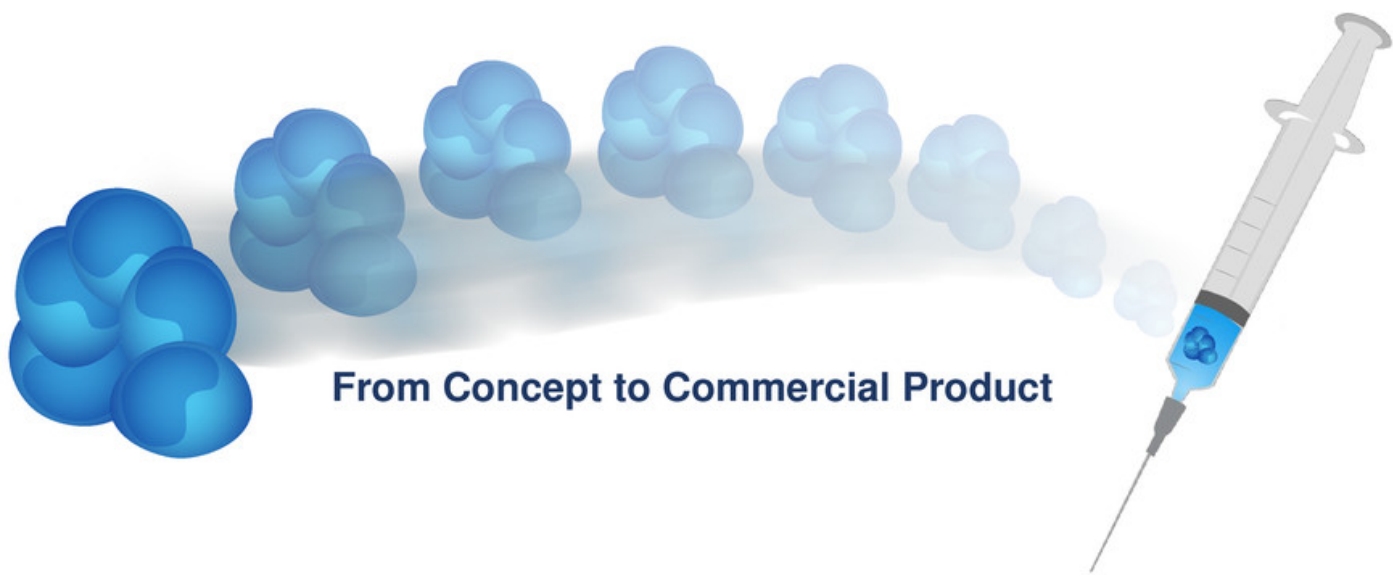
The Caladrius business model provides:

Complementary independent paths to value creation

- **Growing fundamental PCT business, a leading cell therapy development and manufacturing partner (CDMO)**
 - Strategic global collaboration with Hitachi
 - Growing revenues (avg. 24%/year growth since 2013)
 - Projected >30% revenue growth in 2016 to >\$30 million
 - Extensive list of noteworthy client companies
- **Promising T regulatory cell therapy (CLBS03) in Phase 2 for adolescents with recent-onset type 1 diabetes (T1D)**
 - First FDA Fast Track designation granted for T1D; FDA Orphan designation; EU ATMP classification
 - Targeting partnerships post-proof of concept capitalizes on value inflection and provides potential PCT client stream



For our own development candidates and those of our clients,
Caladrius transforms cells into therapies





CELL & CELL-BASED GENE THERAPY CDMO

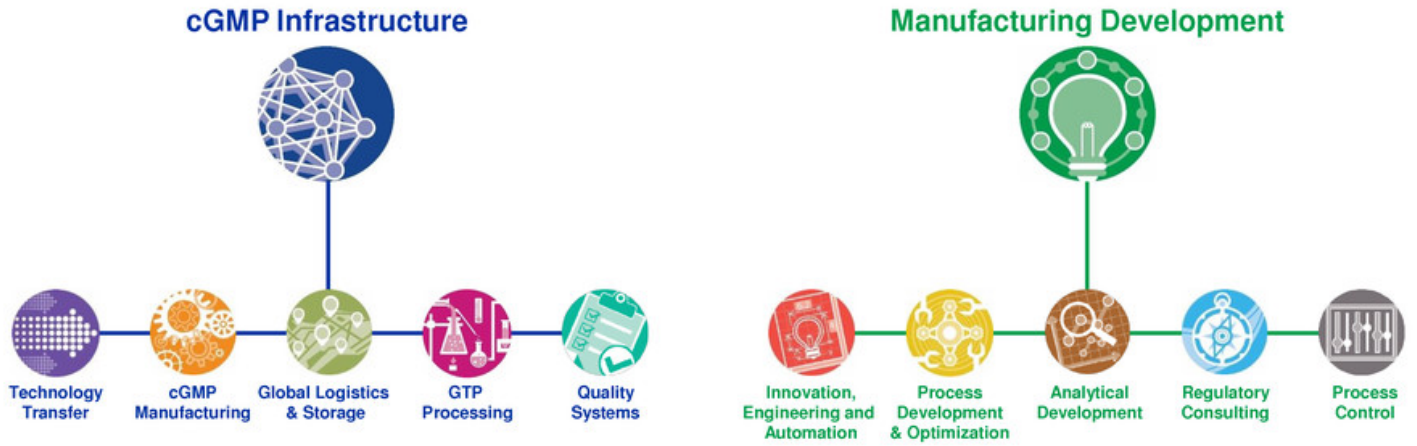
Excellence in Action



PCT has been:

A comprehensive development and manufacturing partner for over 17 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 for development and/or clinical manufacturing
- Several clients expected to be among next wave to reach commercialization

Selected Clients*

Dedicated capacity contracts with PCT

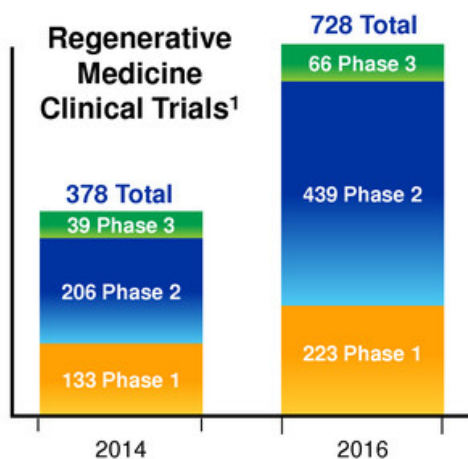


*Some clients request that PCT maintain their anonymity

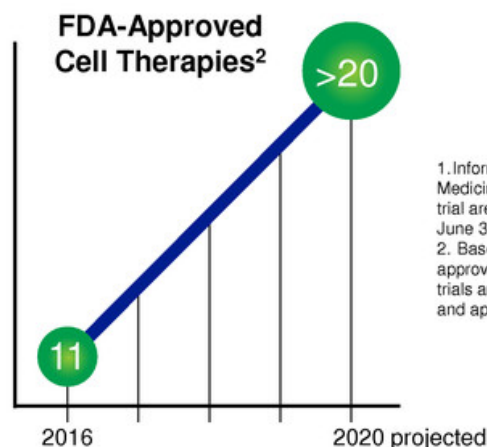


PCT growth driven by:

Growing and maturing cell and cell-based gene therapy market



- Expanding industry-wide pipeline with increasing number of players
- Attractive revenue growth for PCT based on clinical contracts alone (2016 projection >30%)



- Maturing development programs with commercial products on the near-term horizon
- Major revenue growth opportunity for PCT based on transitioning clients to commercial manufacturing contracts

1. Informa/Alliance for Regenerative Medicine. Regenerative medicine clinical trial are as of December 31, 2014 and June 30, 2016.
2. Based on company projections. FDA approvals based on pivotal cell therapy trials and historical rates of P3 success and approval.

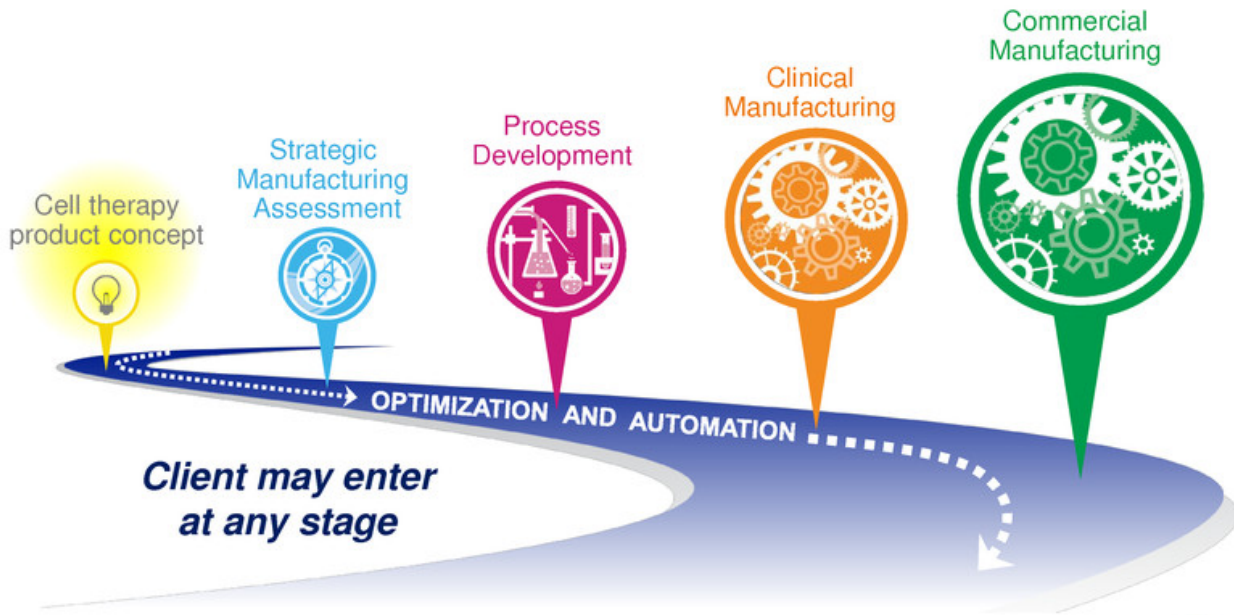
PCT's modern cGMP manufacturing facilities offer flexibility and mitigate risk

- **Allendale, NJ (30,000 ft²) - owned**
 - 3 US-compliant cleanrooms
 - 5 EU and US-compliant cleanrooms (expansion completion in 1H 2017)
 - Commercial product infrastructure
- **Mountain View, CA (25,000 ft²) - leased**
 - 7 US-compliant cleanrooms
 - Dedicated clinical manufacturing
- **Both locations feature:**
 - Process development, process and quality control, cryostorage capabilities
 - Convenient proximity to major transportation hubs (EWR, LGA, JFK / SFO, SJC, OAK)



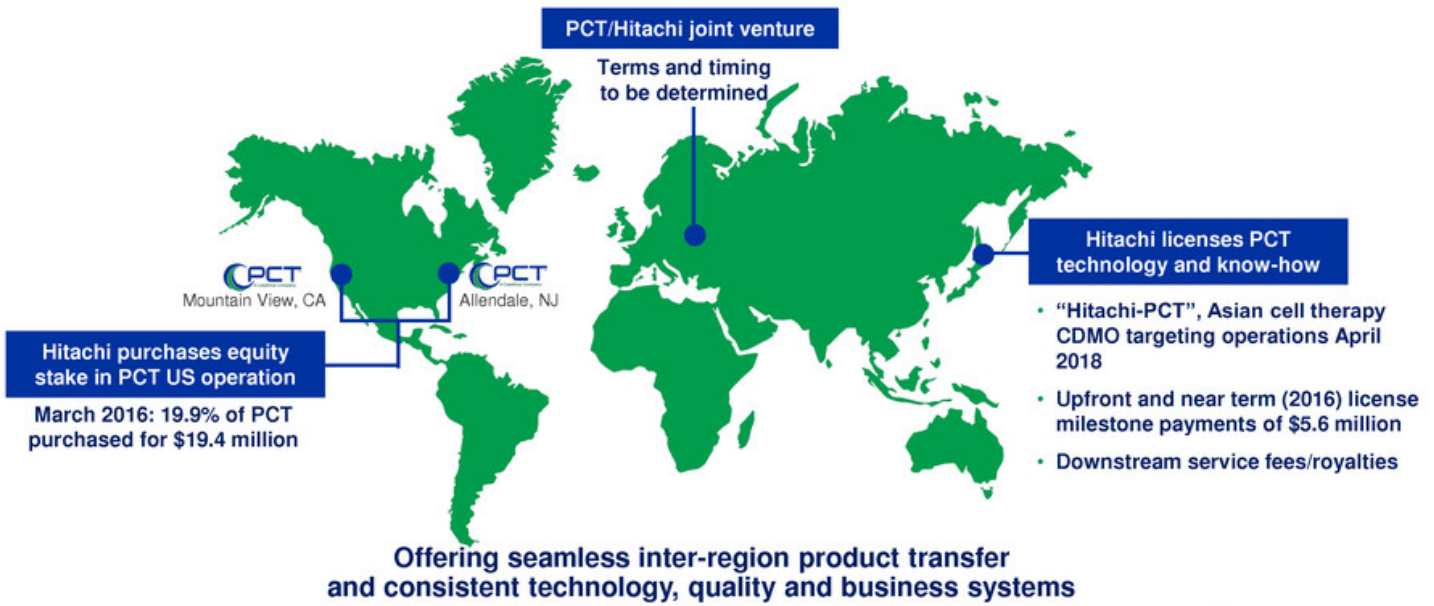
PCT delivers:

A strategic solution that moves well beyond fee-for-service



PCT & Hitachi Chemical comprise:

A global specialized enterprise with deep engineering expertise



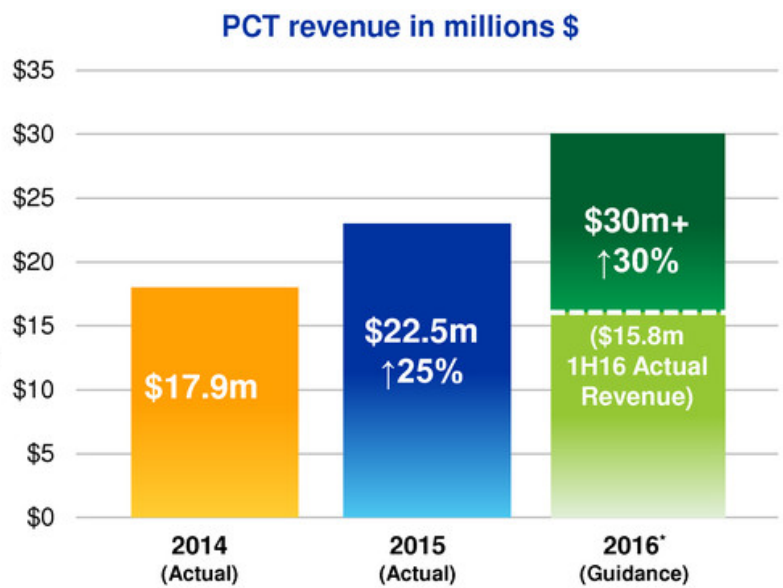
Select Caladrius financial information

- **As of June 30, 2016**

- Cash: \$17.7m
- Long-term debt: \$8.7m
- Common outstanding: 5.9m
- Options outstanding: 700k
- Warrants outstanding: 460k

- **September 2016 \$25m Equity Financing**

- Common stock "at-market" pricing/no warrants
- \$10.6m received (2.2 m shares issued) in September
- \$6m targeted to be received (1.3m shares to be issued) in October
- \$8.4m triggered (1.8m shares to be issued) upon 70th patient enrolled in CLBS03 trial
- \$3m long-term debt paid down using proceeds





IMMUNE MODULATION

CLBS03

*Autologous ex-vivo expanded polyclonal T regulatory cells
for type 1 diabetes*

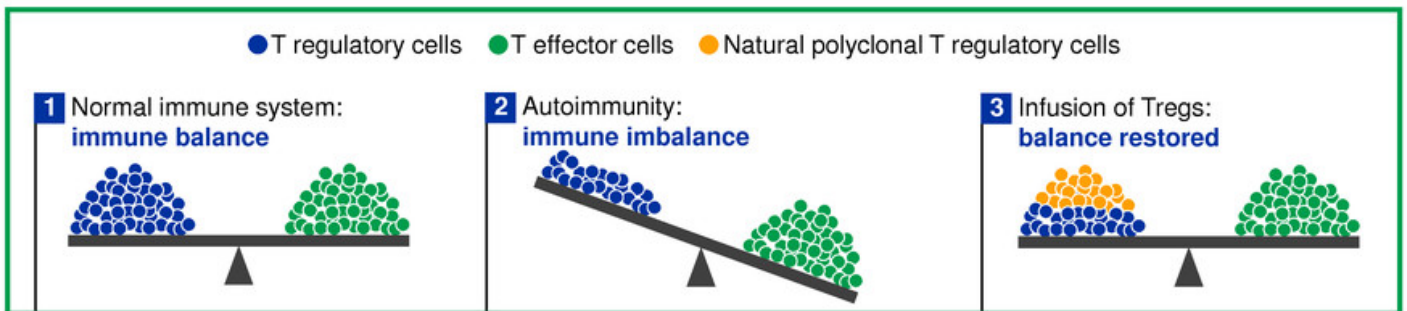
A unique and promising cell therapy platform for autoimmune diseases

- T cell technology from University of California at San Francisco (Jeffrey Bluestone, et al)
- Exclusive rights to approximately 10 corresponding international issued and pending patents
- Polyclonal T regulatory cell platform technology potentially applicable across multiple autoimmune, alloimmune and allergic diseases
- PCT-developed and optimized manufacturing process
- On-going Phase 2 clinical study in T1D
- Strategic collaboration with Sanford Research
- International regulatory recognition
 - FDA Fast Track designation – First time granted to a T1D program
 - FDA Orphan designation
 - EU ATMP (Advanced Therapeutic Medicinal Product) designation

T Regulatory Cell (Tregs) therapy offers:

An attractive medical and commercial opportunity for T1D

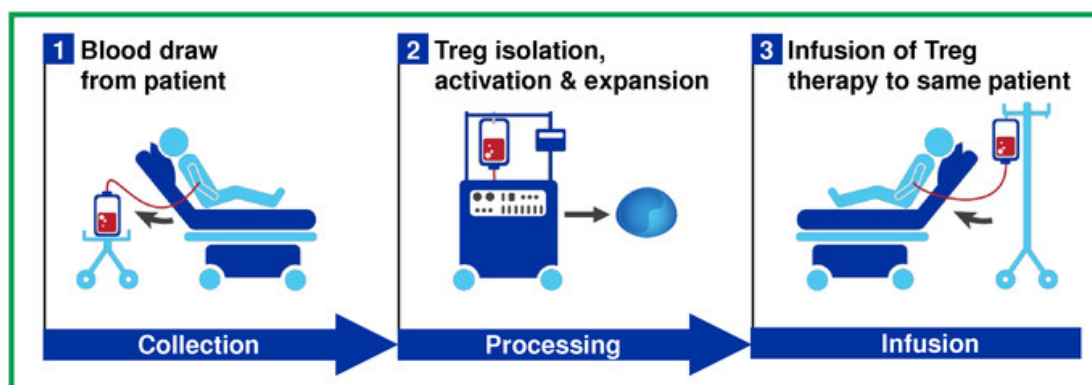
- Each year >18,000 newly diagnosed patients under 20 years of age in US¹; 3% CAGR worldwide²
- No curative treatments, only lifelong insulin therapy (often with serious co-morbidities)
- Deficiency in number or function of Tregs vs. T effector cells manifests as autoimmune disease
- Preserving remaining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



1. SEARCH for National Diabetes Statistic Report, 2014 2. Maahs DM, et al. *Endocrinol Metab Clin North Am.* 2010

Simple, cost-effective, proprietary

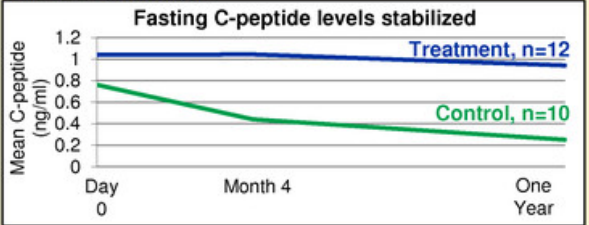
Manufacturing process is scalable and commercially viable



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

- Less intrusive cell collection process than other approaches (whole blood vs. apheresis or bone marrow aspiration)
- cGMP process developed by PCT based on academic Phase 1 process
- Extremely high Phase 2 manufacturing success rate to date

Published Phase I studies demonstrated Treg cell therapy to be well tolerated^{1,2}, durable¹ and to preserve beta cell function in children²

	US Open Label Study ¹	European Open Label Study ²												
Dose	4-dose escalation cohorts (0.05×10^8 to 26×10^8 cells)	1 dose (10 or 20 million cells/kg) or 2 doses (30 million cells/kg)												
Patients	14 adult patients with established T1D	22 patients aged 5-18 with T1D												
Results	<ul style="list-style-type: none"> • Demonstrated safety/tolerance • Established manufacturing feasibility <div style="background-color: #fff9c4; padding: 5px; margin-top: 10px;"> <ul style="list-style-type: none"> • Implied durability of effect <ul style="list-style-type: none"> - Infused Tregs were stable and detected in peripheral circulation for 1 year </div>	<p>At 12 months, 2 treated patients achieved insulin independence and an additional 6 treated patients achieved remission³</p>  <table border="1"> <caption>Fasting C-peptide levels stabilized</caption> <thead> <tr> <th>Time Point</th> <th>Treatment (n=12) Mean C-peptide (ng/ml)</th> <th>Control (n=10) Mean C-peptide (ng/ml)</th> </tr> </thead> <tbody> <tr> <td>Day 0</td> <td>~1.0</td> <td>~0.8</td> </tr> <tr> <td>Month 4</td> <td>~1.0</td> <td>~0.4</td> </tr> <tr> <td>One Year</td> <td>~1.0</td> <td>~0.2</td> </tr> </tbody> </table>	Time Point	Treatment (n=12) Mean C-peptide (ng/ml)	Control (n=10) Mean C-peptide (ng/ml)	Day 0	~1.0	~0.8	Month 4	~1.0	~0.4	One Year	~1.0	~0.2
Time Point	Treatment (n=12) Mean C-peptide (ng/ml)	Control (n=10) Mean C-peptide (ng/ml)												
Day 0	~1.0	~0.8												
Month 4	~1.0	~0.4												
One Year	~1.0	~0.2												

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

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 12 to <18 with recent-onset 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 and ~12 study sites in the USA
Powering	<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 dose of CLBS03 (dose cohorts of 2.5 or 20 million cells/kg) or placebo infusion (control)
Analyses	<ul style="list-style-type: none">• First 19 subjects DSMB safety evaluation 1 month post treatment• Interim analysis of early therapeutic effect after 6 month follow-up of ~50% of subjects – ~year-end 2017• Full study results after all patients complete 12-month follow-up – mid-2018

NCT02691247 at www.clinicaltrials.gov for more details



Polyclonal T regulatory cell therapy has:

Potential application across multiple autoimmune, alloimmune and allergic diseases



Steroid-resistant
asthma



Multiple sclerosis
(MS)



Inflammatory
bowel disease



Lupus



Chronic obstructive
pulmonary disease
(COPD)



Graft vs. Host
disease



Rheumatoid
arthritis

**Multibillion-dollar lifecycle opportunity
over these and other indications**



ADDITIONAL PARTNERING OPPORTUNITIES

Ischemic repair & Immuno-oncology

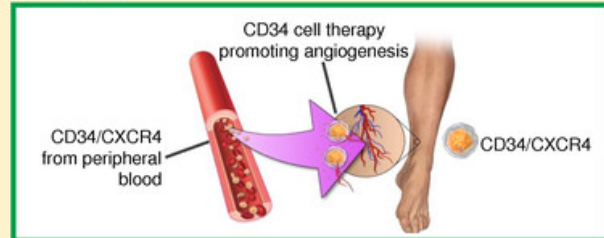


Opportunity for route to conditional approval in Japan

- CD34 cells shown to induce the development of new blood vessels, preventing tissue death by improving blood flow
- Encouraging Phase 2 data applicable to multiple indications
- Out-licensed for chronic heart failure/AMI in specific ex-US territories
- Multiple pending grant opportunities in cardiovascular clinical indications
- Significant unmet need for critical limb ischemia (CLI) and chronic heart failure

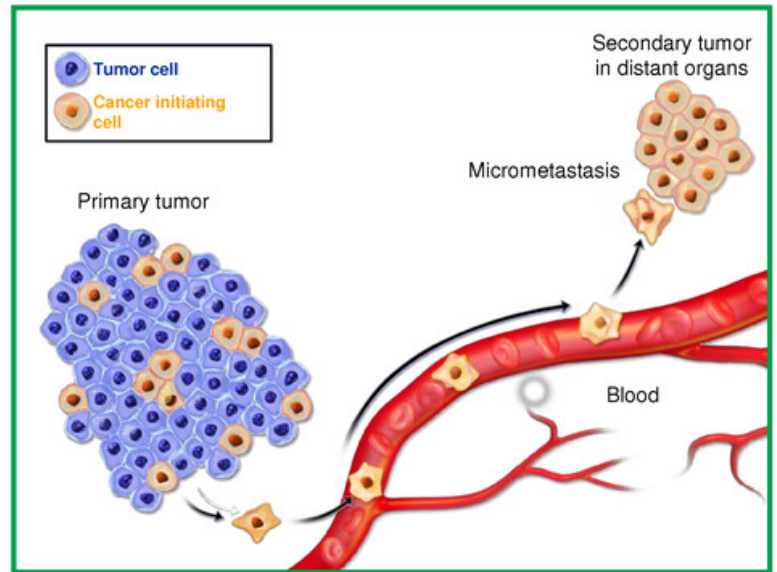
- **Japanese development for CLI**

- Program designed to leverage new Japanese regulatory path to early conditional approval
- Phase 2 protocol and CMC strategy completed in consultation with Japanese PMDA
 - 35-patient, open label, prospective, randomized, controlled multicenter study in patients with no-option CLI
 - Advantageous primary endpoint of time to continuous CLI free status



Tumor cell/dendritic cell technology for immuno-oncology

- Uniquely targets cancer-initiating cells
- Phase 2 data applicable to multiple indications
- Promising Phase 2 melanoma therapeutic effect results with no major safety issues
- CLBS technology may open entirely new paths to multiple-antigen recognition - Checkpoint inhibitors reduce impediments to an existing path
- Out-licensed for ovarian cancer indication
- Licensing opportunities available worldwide



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 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 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 Senior VP, General Counsel and Corporate Secretary	Seasoned attorney with 25+ years of legal, finance and biotechnology industry experience

Track record of achievement based on execution of the 2016 strategic plan

Goal	Progress in 2016
Grow and expand the PCT business on all fronts	<ul style="list-style-type: none"> • On track to 30% annual revenue growth and annual revenue >\$30 million (\$15.8m revenue in 1H 2016) • Initiated global collaboration and license agreement with Hitachi Chemical • Began 5-year agreement with Adaptimmune for late-stage clinical supply
Advance the Phase 2 T-Rex Study of CLBS03 for the treatment of recent-onset T1D	<ul style="list-style-type: none"> • Initiated Phase 2 trial in 1Q 2016 • Completed enrollment of first cohort of 18 patients in 3Q 2016
Maintain financial discipline and further reduce expenses	<ul style="list-style-type: none"> • Reduced R&D and SG&A (>35%) expenses significantly from 2015 levels
Continue to monetize non-core assets	<ul style="list-style-type: none"> • Out-licensed certain cardiovascular, oncology and dermatology product candidates

Caladrius offers multiple near-term value creating milestones and opportunities

PCT	• 2016 Operating Results vs. Guidance (projected >30% revenue growth to >\$30 million)	End of 2016
	• PCT Allendale, NJ expansion completion: 60% capacity increase with US and EU qualified clean rooms	Mid-2017
	• Conversion of at least one clinical client to commercial contract: Possible major additional inflection in PCT revenues	Mid-2017 to 2018
CLBS03	• DSMB safety assessment on 1 st patient cohort	4Q16
	• Initiation of enrollment of 2 nd patient cohort	4Q16
	• 50% of patients treated: starts clock to 6-mos. follow-up interim analysis	Mid-2017
	• 70 th patient enrolled: triggers \$8.4 million capital infusion	Mid-2017
Other Technologies	• Interim analysis assessing early therapeutic effect: 6 months post treatment of 50% patients	End of 2017
	• Multiple grant funding opportunities: CD34 program, multiple clinical indications	End of 2016 & 1 st half 2017
	• Licensing opportunities for CLI in Japan and immuno-oncology in China: CLI program eligible for early conditional approval	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



