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): November 7, 2016

CALADRIUS BIOSCIENCES, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware	001-33650	22-2343568
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 Results of Operations and Financial Condition

On November 7, 2016, Caladrius Biosciences, Inc. (the "Company") issued a press release in connection with its 2016 Third Quarter Financial Results. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K (the "Current Report") and is incorporated into this Item 2.02 by reference.

Item 7.01. Regulation FD Disclosure.

A copy of a slide presentation that the Company will use at investor and industry conferences and presentations is attached to this Current Report as Exhibit 99.2 and is incorporated herein solely for purposes of this Item 7.01 disclosure. The information in this Current Report, including Exhibits 99.1 and 99.2 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 Exhibits 99.1 and 99.2 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 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.

Exhibit No.	Description
99.1	Press Release, dated November 7, 2016
99.2	Caladrius Biosciences Corporate Presentation, November 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: November 7, 2016

EXHIBIT 99.1

Caladrius Biosciences Reports 2016 Third Quarter Financial Results

Revenues Increase 58% Versus Prior Year

Conference Call Begins Today at 5:00 pm Eastern Time

BASKING RIDGE, N.J. (November 7, 2016) - Caladrius Biosciences, Inc. (NASDAQ:CLBS) ("Caladrius" or the "Company"), a cell therapy company combining an industry-leading development and manufacturing services provider through its subsidiary PCT, LLC a Caladrius Company™ ("PCT") with a select therapeutic development pipeline, announces financial results for the three and nine months ended September 30, 2016.

Business and financial highlights for the third quarter of 2016 and recent weeks include:

- Achieved total quarterly revenues of $9.3 million, up 58% compared with $5.9 million for the third quarter of 2015;
- Received Fast Track designation from the U.S. Food and Drug Administration (FDA) for CLBS03 (autologous expanded regulatory T cells, or Tregs) for the treatment of type 1 diabetes (T1D), making it the first known therapeutic candidate for the treatment of T1D to receive the designation;
- Completed enrollment of the first patient cohort of The Sanford Project: T-Rex Study, the Company's Phase 2 clinical trial of CLBS03 for the treatment of recent-onset T1D in adolescents;
- Received a favorable recommendation from the independent Data Safety Monitoring Board (DSMB) to proceed with enrollment of the second cohort of the T-Rex Study following the safety evaluation of the first cohort of 19 patients;
- Entered into a new five-year strategic manufacturing services agreement under which PCT will produce SPEAR® T-cell therapies for Adaptimmune Therapeutics plc; and
- Entered into agreements with several accredited investors, including previous investors and strategic collaborator Sanford Health, to sell up to $25 million in common equity priced at market without warrants.

Management Commentary

"Throughout 2016, we consistently increased revenues at our PCT subsidiary and are poised to achieve our stated goal of 2016 annual revenue in excess of $30 million, which represents annual growth of more than 30%. In addition, year-to-date we secured over $50 million in strategic and/or committed financings, about half of which was non-dilutive with the remainder under favorable terms relative to the market rates for companies like ours. We also paid back to our lender over $9 million of long-term debt, significantly reduced our operating expenses and monetized non-core assets, all while advancing our key immune modulation program's Phase 2 clinical study of CLBS03 to treat T1D," stated David J. Mazzo, Ph.D., Chief Executive Officer of Caladrius.

"We are particularly pleased with the progress of The Sanford Project: T-Rex Study in T1D. We completed enrollment of the first cohort of 19 patients and were delighted that the DSMB recommended continuation of the study based on a favorable safety assessment. We have begun enrolling patients into the second cohort of this 111-patient study earlier than originally expected and plan to reach the 50% enrollment mark in mid-2017. Enrollment of the 70th patient, which triggers an $8.4 million capital infusion under the terms of the September private placements, is expected to occur shortly thereafter. We continue to benefit from the support of Sanford Research. In addition to their equity investment, Sanford has agreed to extend operational support at their clinical sites for the remainder of the study. We continue to be excited by the promise of CLBS03, a novel therapeutic being developed to address the significant unmet medical need in this chronic disease that affects children and young adults. We have made significant achievements across a number of key areas that we believe position Caladrius for continued growth and success throughout the balance of 2016 and beyond," concluded Dr. Mazzo.

Third Quarter Financial Highlights

Total revenues for the third quarter of 2016 increased 58% to $9.3 million compared with $5.9 million for the third quarter of 2015 and increased 12% compared with $8.3 million for the second quarter of 2016. Gross margin on revenues was 8% in the third quarter of 2016 compared with 18% in the third quarter of 2015, directly impacted by the non-payment of approximately $600,000 in billings for work the Company performed and billed to a single customer during the third quarter of 2016, which customer is currently experiencing financial difficulties. Accordingly, the Company has delayed revenue recognition until such time as payment is reasonably assured. The Company continues to work with this client to obtain payment and will recognize any such receipts as revenue in the periods received.

Research and development (R&D) expenses for the third quarter of 2016 decreased 58% to $2.6 million compared with $6.3 million for the third quarter of 2015. The majority of current quarter expenses were dedicated to the Company's immune modulation platform and, specifically, costs related to the T-Rex Study. The decline in R&D expenses over the prior year quarter was primarily related to the discontinuation of non-core R&D programs announced at the beginning of 2016 and related reductions in R&D staffing and departmental costs.

Selling, general and administrative (SG&A) expenses for the three months ended September 30, 2016 were $4.9 million, a small reduction from $5.1 million reported for the same period in 2015. This reflected significantly lower operational and compensation-related costs during the current year quarter compared with the prior year quarter, partially offset by higher equity-based compensation expenses compared with the prior year quarter.

The operating loss for the third quarter of 2016 was $6.9 million compared with an operating loss of $10.4 million for the third quarter of 2015, reflecting higher revenues and lower R&D expenses.

The Company reported a net loss attributable to Caladrius common stockholders for the third quarter of 2016 of $6.9 million, or $1.09 per share, compared with a net loss attributable to Caladrius common stockholders for the third quarter of 2015 of $11.4 million, or $2.06 per share.

Nine Month Financial Highlights

Total revenues for the nine months ended September 30, 2016 increased 68% to $25.1 million compared with $14.9 million for the first nine months of 2015. Gross margin for the first nine months of 2016 was 13% compared with 6% for the first nine months of 2015.

R&D expenses for the first nine months of 2016 decreased to $12.5 million compared with $20.7 million for the first nine months of 2015. The decline in R&D expenses over the first nine months of 2015 was primarily related to the discontinuation of non-core R&D programs announced at the beginning of 2016 and related reductions in R&D staffing and departmental costs.

SG&A expenses decreased to $16.1 million for the first nine months of 2016 compared with $25.0 million for the same period in 2015. This reflected operational and compensation-related cost reductions, as well as equity-based compensation expenses that were significantly below the prior year SG&A expense levels.

The operating loss for the first nine months of 2016 was $25.4 million compared with an operating loss of $54.1 million for the first nine months of 2015.

The net loss attributable to Caladrius common stockholders for the nine months ended September 30, 2016 was $26.7 million, or $4.45 per share, compared with a net loss attributable to Caladrius common stockholders for the nine months ended September 30, 2015 of $47.7 million, or $10.40 per share.

Balance Sheet and Cash Flow Highlights

As of September 30, 2016, Caladrius had cash and cash equivalents of $18.6 million, which included $10.6 million received from the previously announced equity financing in September 2016 and the payment of $3.0 million to Oxford Finance LLC for repayment of long-term debt. Net cash used in operating activities for the nine months ended September 30, 2016 was $20.3 million, compared with $30.5 million for the nine months ended September 30, 2015. Caladrius also invested $2.3 million in capital expenditures, primarily related to improvements to PCT's Allendale, N.J. manufacturing facility.

2016 Financial Guidance

The Company updates its previous 2016 guidance as follows:

- ***Consolidated 2016 Annual Revenues:*** affirms guidance to exceed $30 million or a greater than 30% increase compared with 2015.
- ***Capital Improvements at PCT's Allendale, N.J. Facility:*** affirms guidance that improvements will be completed in 2017, and updates guidance that approximately $2 million will be spent in calendar 2016. Overall cost to complete capital improvements in 2017, including the implementation of commercial grade quality systems, to be provided when 2017 guidance is announced.
- ***CLBS03 Phase 2 Study Costs in 2016:*** affirms guidance of $6 million to $7 million.
- ***Consolidated 2016 Operating Activities Cash Burn:*** affirms guidance of $25 million to $28 million, or between $5 million and $8 million in the fourth quarter of 2016, but with a trend toward the lower end of the range.

Conference Call

As previously announced, Caladrius management will host a conference call to discuss these results and provide a company update today at 5:00 pm Eastern Time. To participate in the conference call, dial 877-562-4460 (U.S.) or 513-438-4106 (international) and provide conference ID 95709220.

To access the live webcast, visit the Investor Relations section of the Company's website at www.caladrius.com/events. The webcast will be archived on the website for 90 days.

About Caladrius Biosciences

Caladrius Biosciences, Inc. is advancing a proprietary platform technology for immunomodulation by pioneering the use of regulatory T cells as an innovative therapy for recent onset type 1 diabetes. The product candidate, CLBS03, is the subject of an ongoing Phase 2 clinical trial (The Sanford Project: T-Rex study) in collaboration with Sanford Research, and has been granted Orphan Drug and Fast Track designation by the U.S. Food and Drug Administration and Advanced Therapeutic Medicinal Product classification by the European Medicines Agency. The Company's PCT subsidiary is a leading development and manufacturing partner to the cell therapy industry. PCT works with its clients to overcome the fundamental challenges of cell therapy manufacturing by providing a wide range of innovative services including product and process development, GMP manufacturing, engineering and automation, cell and tissue processing, logistics, storage and distribution, as well as expert consulting and regulatory support. PCT and Hitachi Chemical Co., Ltd. have entered into a strategic global collaboration to accelerate the creation of a global commercial cell therapy development and manufacturing enterprise with deep engineering expertise. For more information, visit www.caladrius.com.

Forward Looking Statements

This press release 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 press release, and involve certain risks and uncertainties. All statements other than statements of historical fact contained in this press release 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 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. 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.

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-Tables to Follow-

Caladrius Biosciences, Inc. Selected Financial Data (unaudited)

(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Statement of Operations Data:				
Revenues	$ 9,317	$ 5,888	$ 25,107	$ 14,928
Costs and expenses:				
Cost of revenues	8,611	4,809	21,891	13,976
Research and development	2,631	6,316	12,535	20,720
Impairment of intangible assets	—	—	—	9,400
Selling, general, and administrative	4,936	5,147	16,101	24,971
Total operating costs and expenses	16,178	16,271	50,526	69,068
Operating loss	(6,861)	(10,383)	(25,419)	(54,140)
Other income (expense), net	5	(410)	18	4,399
Interest expense	(385)	(553)	(1,671)	(1,651)
Loss before income taxes and noncontrolling interests	(7,241)	(11,346)	(27,073)	(51,392)
Provision for income taxes	47	47	147	(3,610)
Net loss	(7,288)	(11,393)	(27,220)	(47,782)
Less - loss attributable to noncontrolling interests	(405)	(17)	(522)	(93)
Net loss attributable to Caladrius Biosciences, Inc. common stockholders	$ (6,883)	$ (11,376)	$ (26,698)	$ (47,689)
Basic and diluted loss per share attributable to Caladrius Biosciences, Inc. common stockholders	(1.09)	(2.06)	(4.45)	(10.40)
Weighted average common shares outstanding	6,323	5,524	6,002	4,587

	September 30, 2016	December 31, 2015
Balance Sheet Data:		
Cash, cash equivalents, and marketable securities	$18,607	$20,318
Total assets	57,279	57,205
Total liabilities	27,889	33,921
Total redeemable securities	19,400	—
Total equity	9,989	23,284

# # #

CORPORATE PRESENTATION

David J. Mazzo, PhD
Chief Executive Officer

November 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.

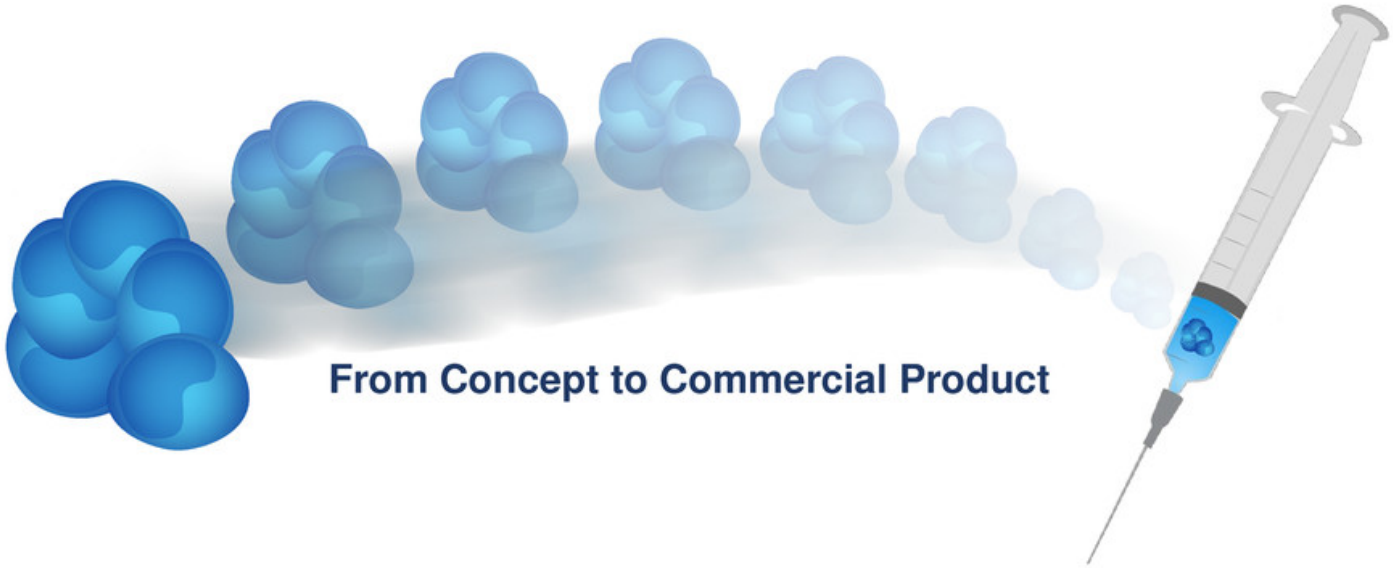
The Caladrius business model provides:

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

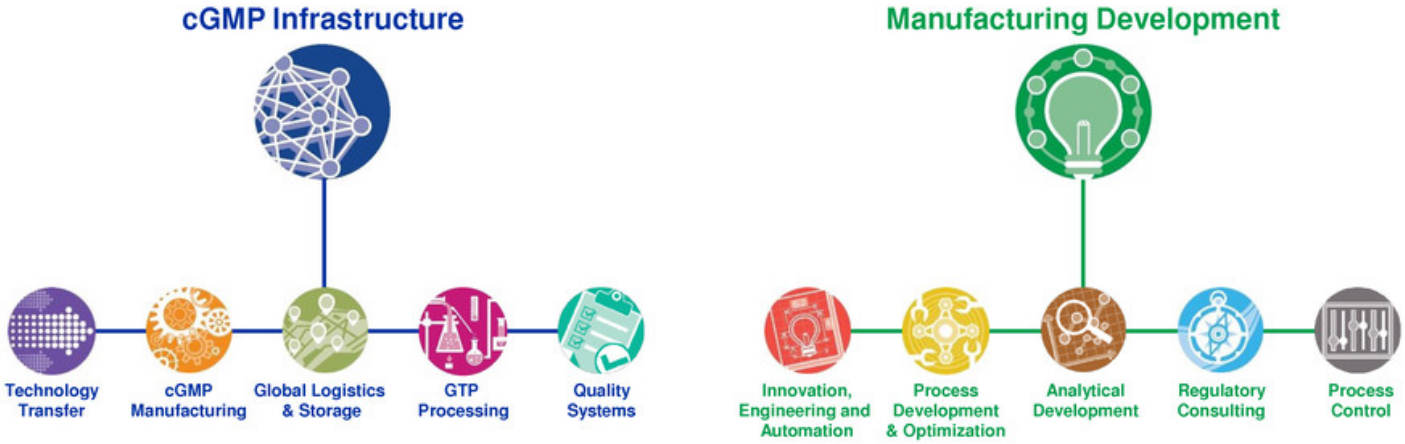



PCT
A Caladrius Company
CELL & CELL-BASED
GENE THERAPY CDMO
Excellence in Action
caladrius
5

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 to development and/or clinical manufacturing**
- **Several clients expected to be among next wave to reach commercialization**

Selected Clients*

Dedicated capacity contracts with PCT

ImmunoCellular Immunocellular Therapeutics Ltd. | Kite Pharma | ADAPTIMMUNE transforming T cell therapy | Kiadis pharma

TxCell | NOVARTIS | Sangamo BioSciences | IRX Therapeutics | ADAPTIMMUNE transforming T cell therapy | cellectis | Biogen

rocket pharma | Rubius Therapeutics | FORTRESS Biotech | Athersys | Universal Cells | rti surgical | PRIMA BIOMED

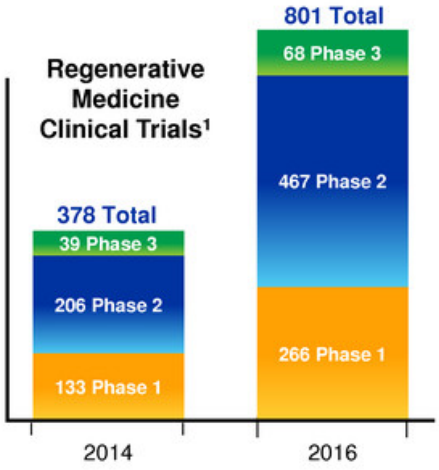
Dendreon | Erytech Pharma | Osiris | sentien | STEMCELLS | Therakos | HackensackUMC | Sutter Health

*Some clients request that PCT maintain their anonymity

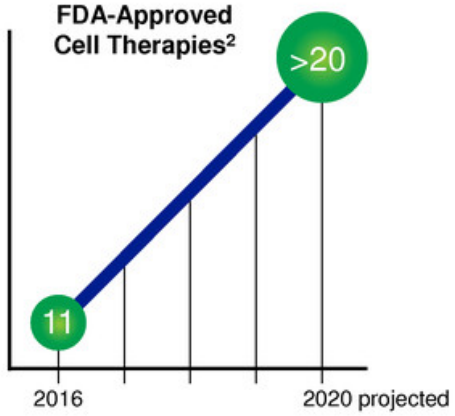
caladrius Biosciences

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**

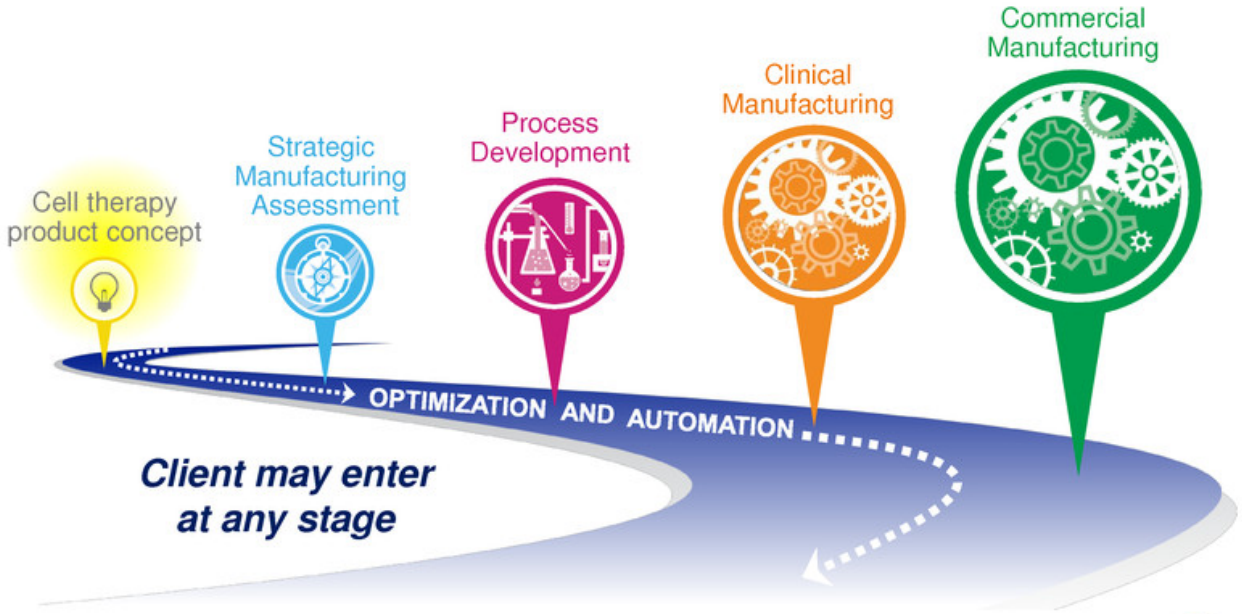
1. Informa/Alliance for Regenerative Medicine. Regenerative medicine clinical trials are as of December 31, 2014 and September 30, 2016.
2. Based on company projections. FDA approvals based on pivotal cell therapy trials and historical rates of P3 success and approval.

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)

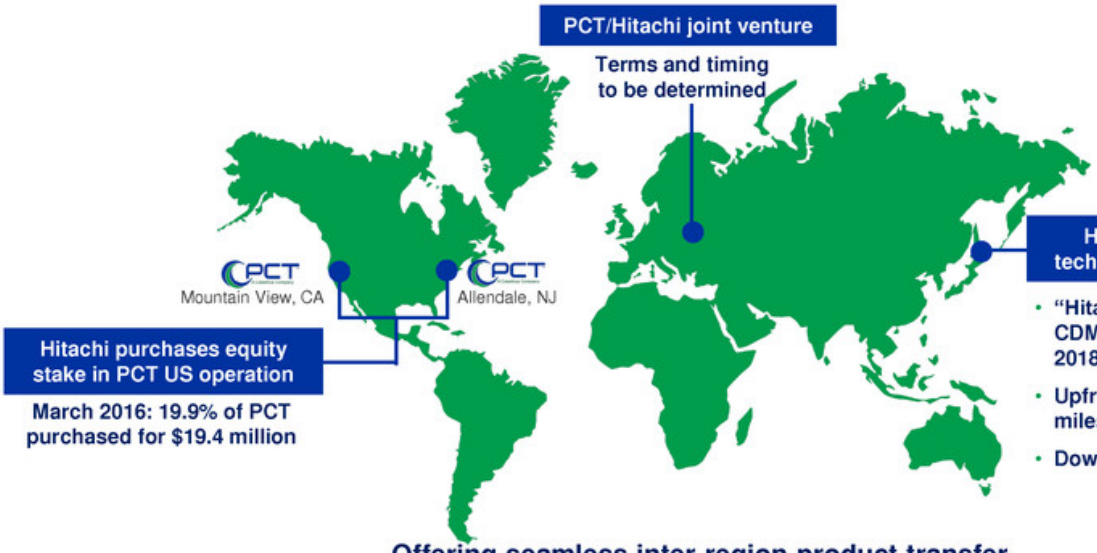
PCT delivers:

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



PCT & Hitachi Chemical comprise:

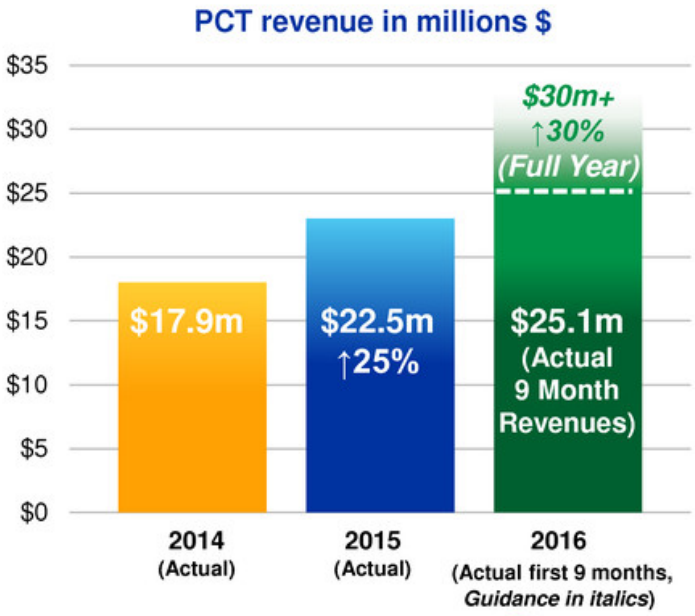
A global specialized enterprise with deep engineering expertise



Offering seamless inter-region product transfer and consistent technology, quality and business systems

Select Caladrius financial information

- **As of September 30, 2016**
  - Cash: $18.6m
  - Long-term debt: $5.7m
  - Common outstanding: 8.1m
  - Options outstanding: 942k
  - Warrants outstanding: 362k
- **September 2016 $25m Equity Financing**
  - Common stock "at-market" pricing/no warrants
  - $10.6m received (2.2m shares issued) in September
  - $6m targeted to be received (1.3m shares to be issued) in 4Q 2016
  - $8.4m triggered (1.8m shares to be issued) upon 70th patient enrolled in CLBS03 trial



IMMUNE MODULATION

CLBS03

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

CLBS03 is based on:

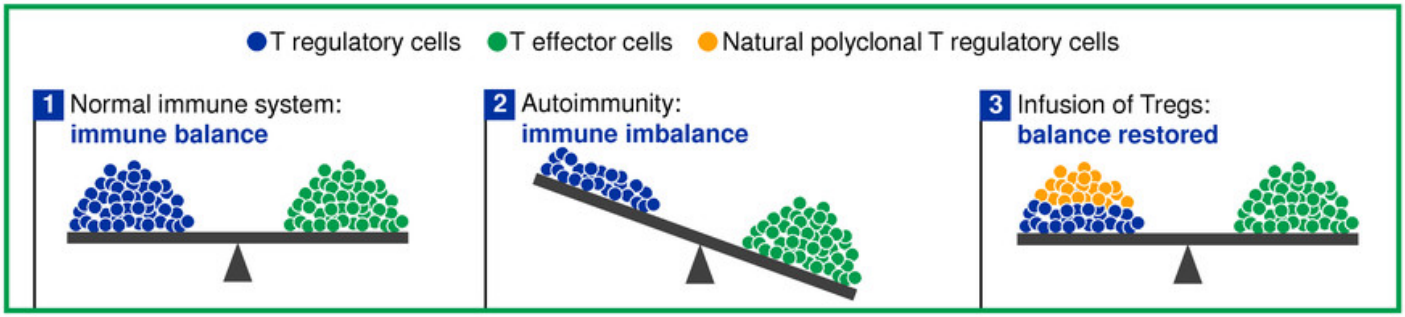
A unique and promising cell therapy platform for autoimmune diseases

- **T cell technology from University of California at San Francisco (Jeffrey Bluestone, et al)**
- **Exclusive rights to an international portfolio of 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) classification

T Regulatory Cell (Tregs) therapy offers:

An attractive medical and commercial opportunity for T1D

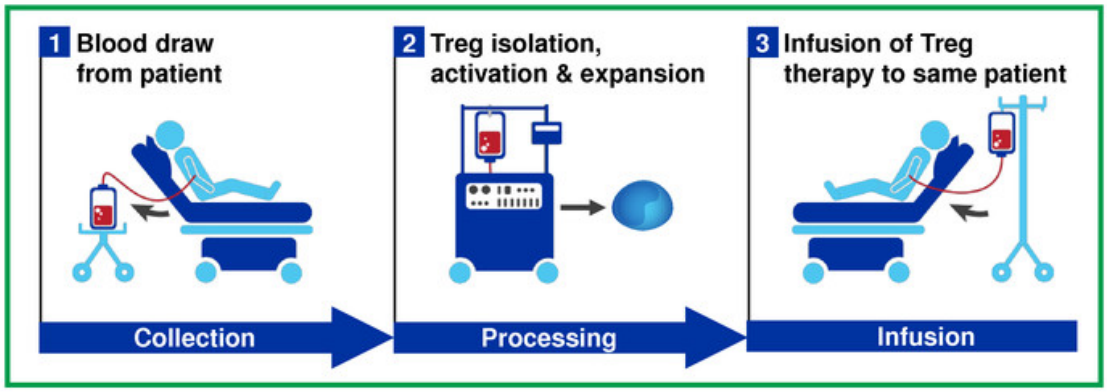
- **Each year >18,000 newly diagnosed patients under 20 years of age in US[1]; 3% CAGR worldwide[2]**
- **No curative treatments, only lifelong insulin therapy (often with serious co-morbidities)**
- **Deficiency in number or function of Tregs vs. T effector cells manifests as autoimmune disease**
- **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

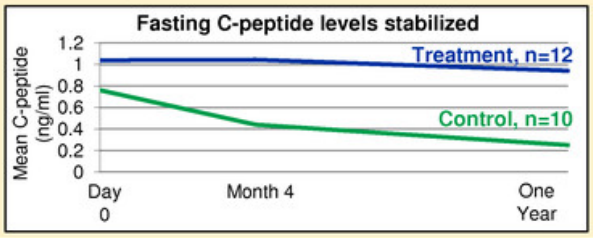
Manufacturing process is scalable and commercially viable



- **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 improving upon 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], durable[1] and preserving of beta cell function in children[2]

	US Study[1]	EU Study[2]
Dose	4-dose escalation cohorts (0.05 x 10^8 to 26 x 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	• Demonstrated safety/tolerance • Established manufacturing feasibility • Implied durability of effect - Infused Tregs were stable and detected in peripheral circulation for 1 year	At 12 months: • 6 treated patients achieved remission[3] • 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 UI/kg body weight & fasting c-peptide > 0.5 ng/ml at 12 months after recruitment

T-Rex Study:

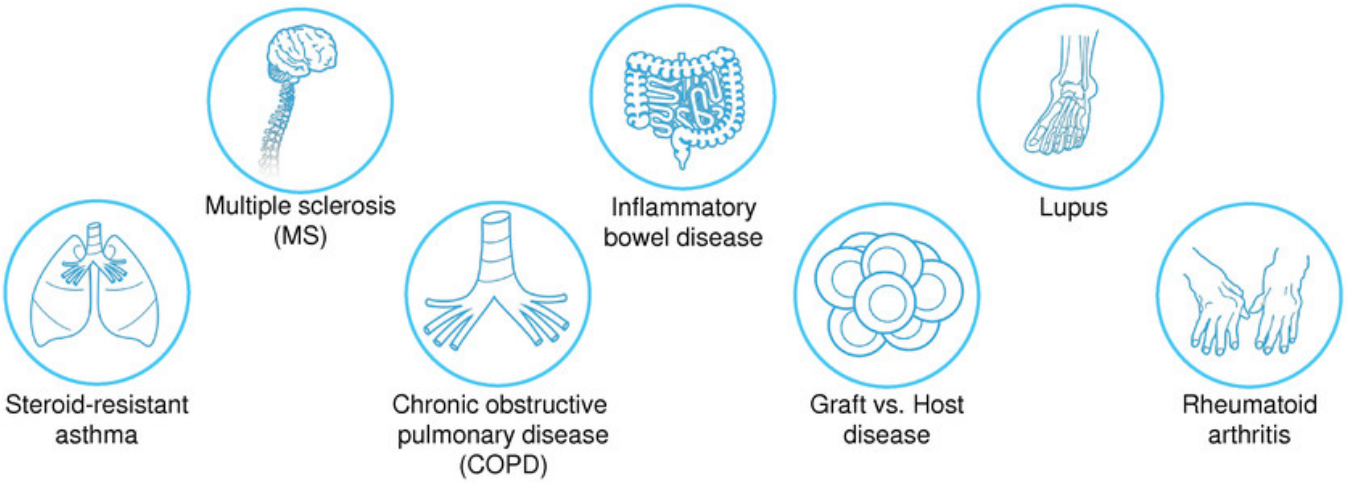
Phase 2 trial in adolescents with T1D initiated in March 2016

Rigorous Design	• Double-blind, placebo-controlled, randomized (1:1:1) trial • Adolescent patients ages 12 to <18 with recent-onset T1D
Standard Endpoints	• Preservation of C-peptide level, insulin use, severe hypoglycemic episodes, glucose and hemoglobin A1c levels
Study Size	• 111 patients enrolled across ~12 study sites in the USA
Power	• 80% power to detect a 0.2 pmol/mL difference in AUC mean C-peptide between active and placebo
Study Execution	• Strategic collaboration with Sanford Research providing operational resources and capital
Treatment	• Single dose of CLBS03 (dose cohorts of 2.5 or 20 million cells/kg) or placebo infusion (control)
Analyses	• First 19 subjects DSMB safety evaluation 1 month post treatment – ***Completed; study continued*** • Interim analysis of early therapeutic effect after 6 month follow-up of ~50% of subjects – ~year-end 2017 • Efficacy results after all patients complete 12-month follow-up – late 2018/early 2019

NCT02691247 at www.clinicaltrials.gov for more details

Polyclonal T regulatory cell therapy has:

Potential application across multiple autoimmune, alloimmune and allergic diseases



Multibillion-dollar lifecycle opportunity over these and other indications

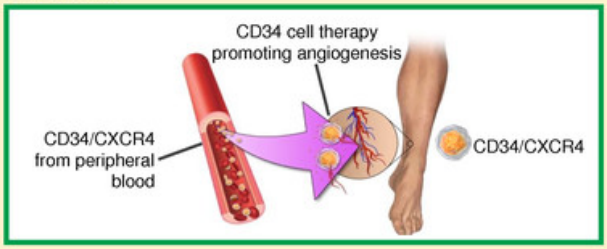

ADDITONAL
PARTNERING
OPPORTUNITIES
Ischemic repair & Immuno-oncology
caladrius
20

CD34 cell technology for ischemic repair with:

Opportunity for route to conditional approval in Japan

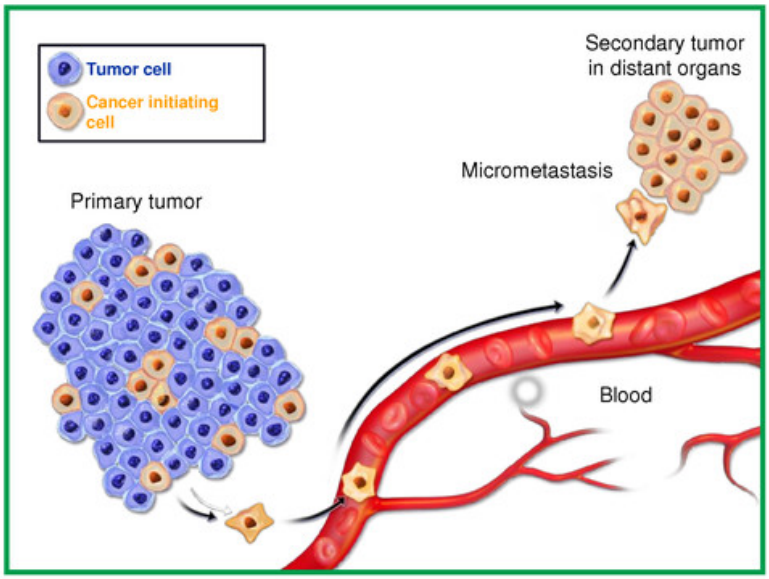
- **CD34 cells shown to induce the development of new blood vessels, preventing tissue death by improving blood flow**
- **Encouraging Phase 2 data applicable to multiple indications**
- **Out-licensed for chronic heart failure/AMI in specific ex-US territories**
- **Multiple pending grant opportunities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

Caladrius established a:

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	• 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 CLBS03	• Initiated Phase 2 T-Rex trial in T1D 1Q 2016 • Completed enrollment of first cohort of 18 patients in 3Q 2016
Execute with financial discipline	• Reduced R&D and SG&A (>35%) expenses significantly from 2015 levels
Monetize non-core assets	• 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 >$30m)	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 1st patient cohort	*Completed Oct. 2016*
	• Initiation of enrollment of 2nd patient cohort	*Completed Oct. 2016*
	• 50% of patients treated: starts clock to 6-mos. follow-up interim analysis	Mid-2017
	• 70th patient enrolled: triggers $8.4 million capital infusion	Mid-2017
	• Interim analysis assessing early therapeutic effect: 6 months post treatment of 50% patients	Late 2017/Early 2018
Other Technologies	• Multiple grant funding opportunities: CD34 program, multiple clinical indications	End of 2016 & 1st half 2017
	• Licensing opportunities for CLI in Japan and immuno-oncology in China: CLI program eligible for early conditional approval	2017

NASDAQ: CLBS

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