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): August 6, 2015

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 August 6, 2015, Caladrius Biosciences, Inc. ("Caladrius Biosciences" or the "Company") issued a press release relating to, among other things, the results of the Company's second quarter ended June 30, 2015. A copy of this press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 2.02 by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 7.01 Regulation FD Disclosure.

Caladrius Biosciences, Inc. intends, from time to time, to present and/or distribute to the investment community and utilize at various industry and other conferences a slide presentation. The slide presentation is accessible on the Company's website at www.caladrius.com and is attached hereto as Exhibit 99.2. Caladrius Biosciences undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.2, shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by reference in such a filing.

Forward Looking Statements

This Current Report on Form 8-K, including Exhibits 99.1 and 99.2, contains "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are typically preceded by words such as "believes," "expects," "anticipates," "intends," "will," "may," "should," or similar expressions, although some forward-looking statements are expressed differently. Forward-looking statements represent the Company's management's judgment regarding future events. Although the Company believes that the expectations reflected in such forward-looking statements are reasonable, the Company can give no assurance that such expectations will prove to be correct. All statement other than statements of historical fact included in the Current Report on Form 8-K are forward-looking statements. The Company cannot guarantee the accuracy of the forward-looking statements, and you should be aware that the Company's actual results could differ materially from those contained in the forward-looking statements due to a number of factors, including the statements under "Risk Factors" contained in the Company's reports filed with the Securities and Exchange Commission.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated August 6, 2015*
99.2	Power Point Presentation dated August 2015*

*Exhibits 99.1 & 99.2 are furnished as part of this Current Report on Form 8-K.

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/ Robert S. Vaters
Name: Robert S. Vaters
Title: President and CFO

Dated: August 6, 2015

Exhibit 99.1

Caladrius Biosciences, Inc. Announces Second Quarter 2015 Financial Results and Provides Corporate Update

Revenues up 31% from 2Q 2014 and Company Sets Future Direction for its Ischemic Repair Program

NEW YORK, August 6, 2015 (GLOBE NEWSWIRE) - Caladrius Biosciences, Inc. (Nasdaq:CLBS) ("Caladrius" or the "Company"), a company combining a leading cell therapy service provider with a development pipeline including a Phase 3 clinical program in immuno-oncology and a portfolio of projects in immune modulation and ischemic repair, announced today 2015 second quarter results.

The Company reported a 31% increase in revenues from the second quarter of 2014 to the second quarter of 2015. In addition, the Company has decided to explore chronic heart failure and/or critical limb ischemia as targets for further development within its ischemic repair program.

“We are excited and encouraged by strong revenue growth at our wholly-owned subsidiary, PCT,” said Dr. David J. Mazzo, Chief Executive Officer of Caladrius. “Additionally, the Company followed through on its promise to set an optimized pathway forward for our ischemic repair program.”

Business Highlights

- First patient dosed in Phase 3 trial (the Intus Study) of CLBS20 for patients with stage III recurrent or stage IV metastatic melanoma;
- Receipt of $17.7 million grant award from California Institute for Regenerative Medicine (CIRM) to support the Intus Study, reflecting significant endorsement of the potential of CLBS20 and expected to fund a significant portion of the study;
- Research collaboration with the University of Southern California and California Institute of Technology to explore next-generation strategies for the Company’s core cancer technology;
- Establishment of a new cardiovascular scientific advisory board;
- National Institutes of Health (NIH) grant to fund retinal disease research;
- Expansion of relationship between PCT, a Caladrius company, and ImmunoCellular Therapeutics to provide manufacturing for ImmunoCellular’s Phase 3 trial; and
- Closing of $28.75 million public offering of common stock which introduced a strong contingent of new institutional investors.

After a thorough review, the Company has set the future direction for its ischemic repair program. Based on an analysis of the available Phase 2 data from the PreSERVE-AMI trial, an updated commercial assessment considering all major potential relevant cardiovascular indications and consultation with the Company’s new cardiovascular scientific advisory board and the Science and Technology Committee of the Board of Directors, Caladrius has decided that it will not pursue further development of the acute myocardial infarction indication upon completion of the ongoing PreSERVE-AMI Phase 2 clinical study. However, the positive suggestion of safety and therapeutic activity seen to date in the PreSERVE-AMI trial supports the underlying platform technology and enables the Company’s exploration of more commercially viable indications of chronic heart failure and/or critical limb ischemia as targets for further development. The Company will continue to seek partnerships for all the indications in this platform, which will be necessary for Caladrius to proceed to the next steps in clinical development.

2015 Second Quarter Financial Highlights

Total revenue for the quarter was approximately $5.9 million compared to $4.5 million for 2Q 2014, an increase of 31%, which was primarily due to higher reported Clinical Services revenues at PCT. Total non-GAAP Adjusted Revenue, which excludes the impact of deferred revenue adjustments, was approximately $5.0 million for 2Q 2015 compared to $5.3 million for 2Q 2014 (see below for reconciliation).

Research and development expenses were approximately $7.6 million for the quarter compared to $5.8 million for 2Q 2014. The increase was primarily related to an increase in expenses for the Company's immuno-oncology program, primarily associated with the Intus Phase 3 clinical trial, as well as a minor increase in expenses for the ischemic repair program for a potential critical limb ischemia development program in Japan. These expenses were partially offset by lower continued costs associated with the PreSERVE-AMI Phase 2 clinical trial for the Company's product candidate CLBS10 and lower expenses associated with the immune modulation program, including our efforts focused on initiating our Phase 2 study of CLBS03 in type 1 diabetes.

Selling, general and administrative expenses were approximately $8.7 million for the quarter compared to $7.4 million for 2Q 2014. The increase is primarily due to higher equity-based compensation in the current quarter compared to 2Q 2014.

Net loss for 2Q 2015 was approximately $17.2 million compared to net loss of $12.8 million for 2Q 2014. Net loss for 2Q 2015 excluding non-cash charges was $26.1 million, compared with $19.4 million for 2Q 2014 (see below for reconciliation).

Net loss for 2Q 2015 included the impact of changes in the Company's ischemic repair program. As a result, the Company determined that IPR&D valued at $9.4 million was fully impaired, and the associated deferred tax liability of $3.7 million was reversed. In addition, the fair value of contingent consideration associated with earn out payments on CLBS10 future revenues was reduced from $5.6 million to $0 as of June 30, 2015. The overall net impact for these changes was a $20,000 increase in net loss.

At June 30, 2015, Caladrius' cash, cash equivalents and marketable securities totaled $39.2 million.

As previously announced, Dr. David J. Mazzo, Chief Executive Officer, and Robert S. Vaters, President and Chief Financial Officer, will discuss results and provide a company update via a webcast and conference call today at 4:30 pm ET. To access the webcast, visit the Investor Relations section of the Company's website at http://www.caladrius.com/investors/overview/. Alternatively, callers may participate in the conference call by dialing 877-562-4460 or, for international callers, 513-438-4106, and providing conference ID 91597846.

Use of Non-GAAP Financial Measures

The Company uses "Adjusted Revenues" and "Net Loss Excluding Non-Cash Charges" as non-GAAP financial measures in evaluating its performance.

- Adjusted Revenues represents GAAP revenues less the impact of the change in unearned revenues. The Company believes that providing this measure to investors provides important supplemental information relating to its performance and permits investors and management to evaluate the impact of the Company's revenue-generating activities on its cash position. Additionally, the Company believes this information is frequently used by securities analysts, investors and other interested parties in the evaluation of performance. Management uses, and believes that investors benefit from, this non-GAAP financial measure in assessing the Company's revenue-generating activities, as well as in planning, forecasting and analyzing future periods.

- Net Loss Excluding Non-Cash Charges represents net loss, less equity-based compensation, depreciation and amortization, impairments of intangible assets, and other non-cash adjustments included in calculating net loss. The Company believes that providing this measure to investors provides important supplemental information relating to its performance and permits investors and management to evaluate the core operating performance and cash utilization of the Company by excluding the use of these non-cash adjustments. Additionally, the Company believes this information is frequently used by securities analysts, investors and other interested parties in the evaluation of performance. Management uses, and believes that investors benefit from, this non-GAAP financial measure in assessing the Company's operating results, as well as in planning, forecasting and analyzing future periods.

These non-GAAP measures have limitations as an analytical tool, and investors should not consider these measures in isolation, or as a substitute for analysis of the Company's results as reported under generally accepted accounting principles in the United States ("GAAP"). For example, Net Loss Excluding Non-Cash Charges does not reflect the Company's cash expenditures, future requirements for capital expenditures, contractual commitments or cash requirements for working capital needs. Although depreciation and amortization are non-cash charges, the assets being depreciated or amortized often will have to be replaced in the future, and Net Loss Excluding Non-Cash Charges does not reflect any cash requirements for such replacements. Given these limitations, the Company relies primarily on its GAAP results and uses the Net Loss Excluding Non-Cash Charges measure only as a supplemental measure of its financial performance and cash utilization.

GAAP to Non-GAAP Reconciliation

Adjusted Revenues Reconciliation (unaudited)

(in millions)	For the three months ended June 30, 2015	For the three months ended June 30, 2014
Revenues	$5.9	$4.5
Change in Unearned Revenue	(0.9)	0.8
Adjusted Revenues	$5.0	$5.3

Net Loss Excluding Non-Cash Charges Reconciliation (unaudited)

(in millions)	For the three months ended June 30, 2015	For the three months ended June 30, 2014
Net loss	$(36.4)	$(26.6)
Equity-based compensation	8.1	5.7
Depreciation and amortization	1.3	1.0
Changes in acquisition-related contingent consideration	(4.8)	0.4
Impairment of intangible assets	9.4	0
Deferred income taxes	(3.7)	0.1
Net Loss Excluding Non-Cash Charges	$(26.1)	$(19.4)

About Caladrius Biosciences

Caladrius Biosciences, Inc. is among the first of a new breed of immunotherapy companies with proven expertise and unique experience in cell process optimization, development, and manufacturing. Caladrius is a company combining a leading cell therapy service provider with a development pipeline including late-stage clinical programs based on proprietary platform technology for immuno-oncology, as well as additional platform technologies for ischemic repair and immunomodulation. This integrated approach supports the industry in bringing significant life-improving medical treatments to market. 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. Forward-looking statements include, among others, statements herein with respect to the commercial viability of the chronic heart failure and/or critical limb ischemia indications within the Company’s ischemic repair program and the Company’s seeking of partnerships for its ischemic repair programs. 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. The Company's further development is highly dependent on future medical and research developments and market acceptance, which is outside of its control.

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Delivering Personalized Medicine

Corporate Presentation

NASDAQ: CLBS

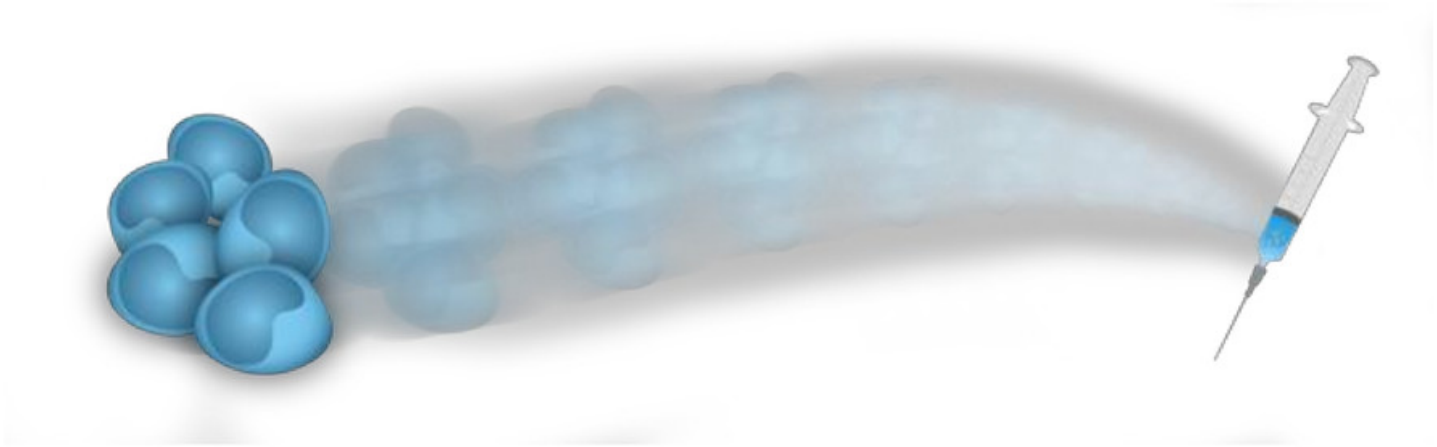
David J. Mazzo, PhD
Chief Executive Officer

August 2015

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. Forward-looking statements include statements herein with respect to the successful execution of the Company's business strategy, the Company's ability to develop and grow its business, the successful development of cellular therapies with respect to the Company's research and development and clinical evaluation efforts in connection with the Company's Immuno-oncology Program, Ischemic Repair Program, Immune Modulation Program and other cell therapies, the future of the regenerative medicine industry and the role of stem cells and cellular therapy in that industry, and the performance and planned expansion of the Company's wholly-owned subsidiary and its center of excellence for cell therapy process development, engineering and manufacturing, PCT. The Company's further development is highly dependent on future medical and research developments and market acceptance, which is outside of its control. The Company's actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the Company in general, see the factors described under the heading, “Item 1A. Risk Factors" in the Company's Annual Report on Form 10-K filed with the SEC on March 2, 2015 and those described in the Company's other periodic filings with the SEC. The Company undertakes no obligation to update or revise any forward-looking statements.

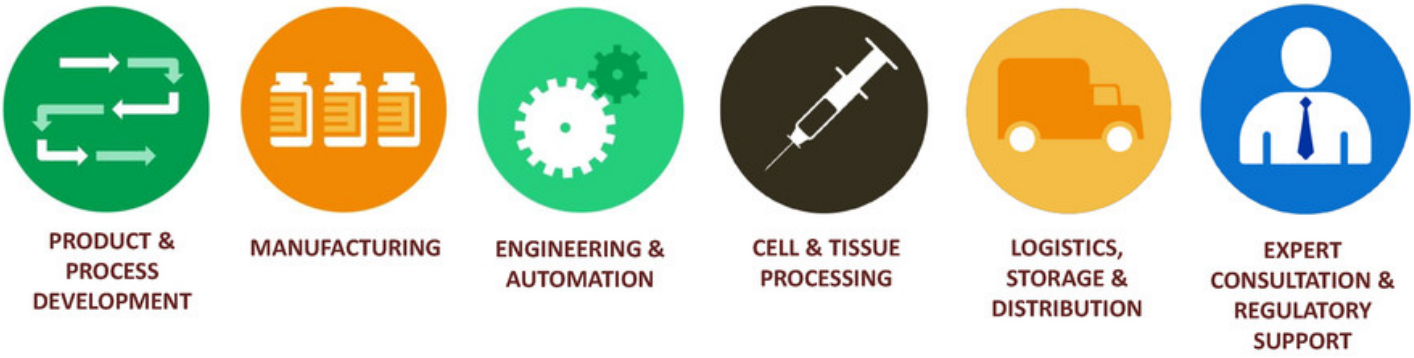
Transforming cells into therapies



PCT, a Caladrius company:

Industry-recognized single source premier cell therapy service provider

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



PRODUCT & PROCESS DEVELOPMENT

MANUFACTURING

ENGINEERING & AUTOMATION

CELL & TISSUE PROCESSING

LOGISTICS, STORAGE & DISTRIBUTION

EXPERT CONSULTATION & REGULATORY SUPPORT

Unmatched experience: >100 clients and 30,000 products over 15 years

At a glance

- Unifying platform approach yielding a robust, balanced pipeline targeting critical unmet medical needs

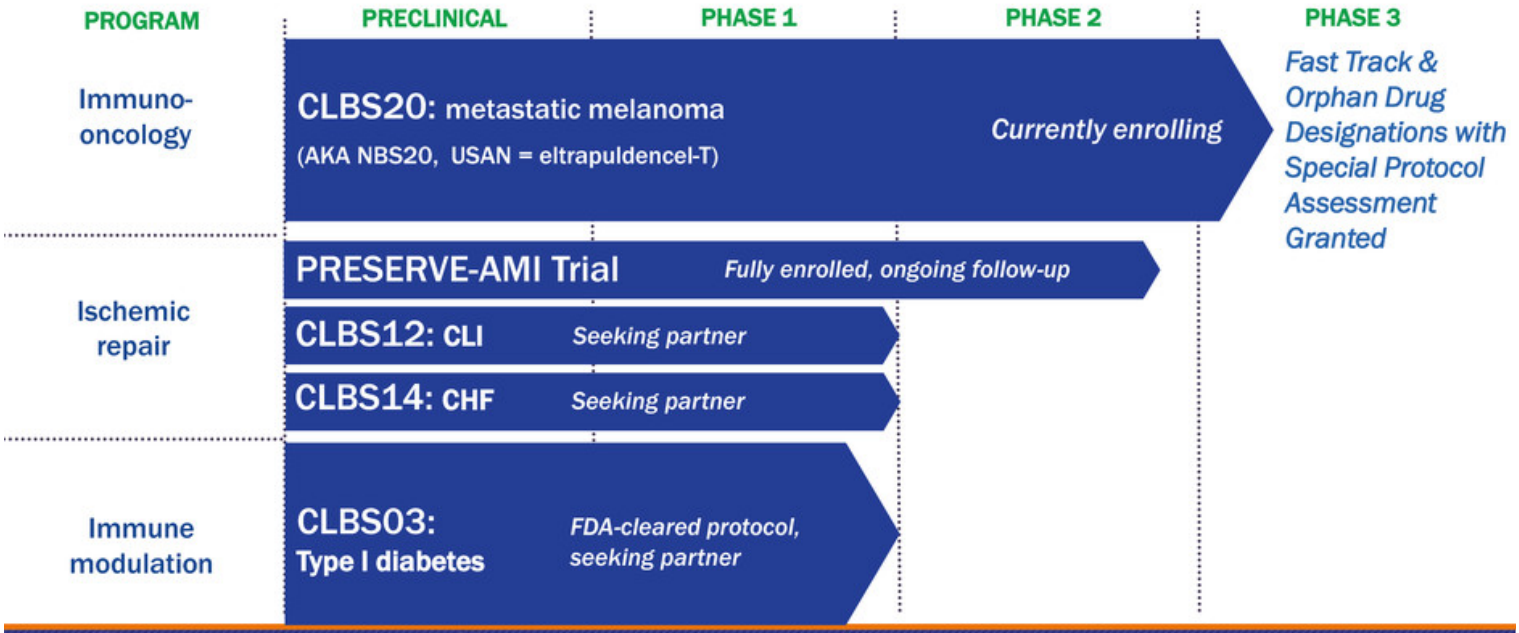
- Proven internal center of excellence (PCT) with bicoastal facilities innovating discovery, development, manufacturing and delivery of cell-based therapies

- Highly experienced management and scientific team

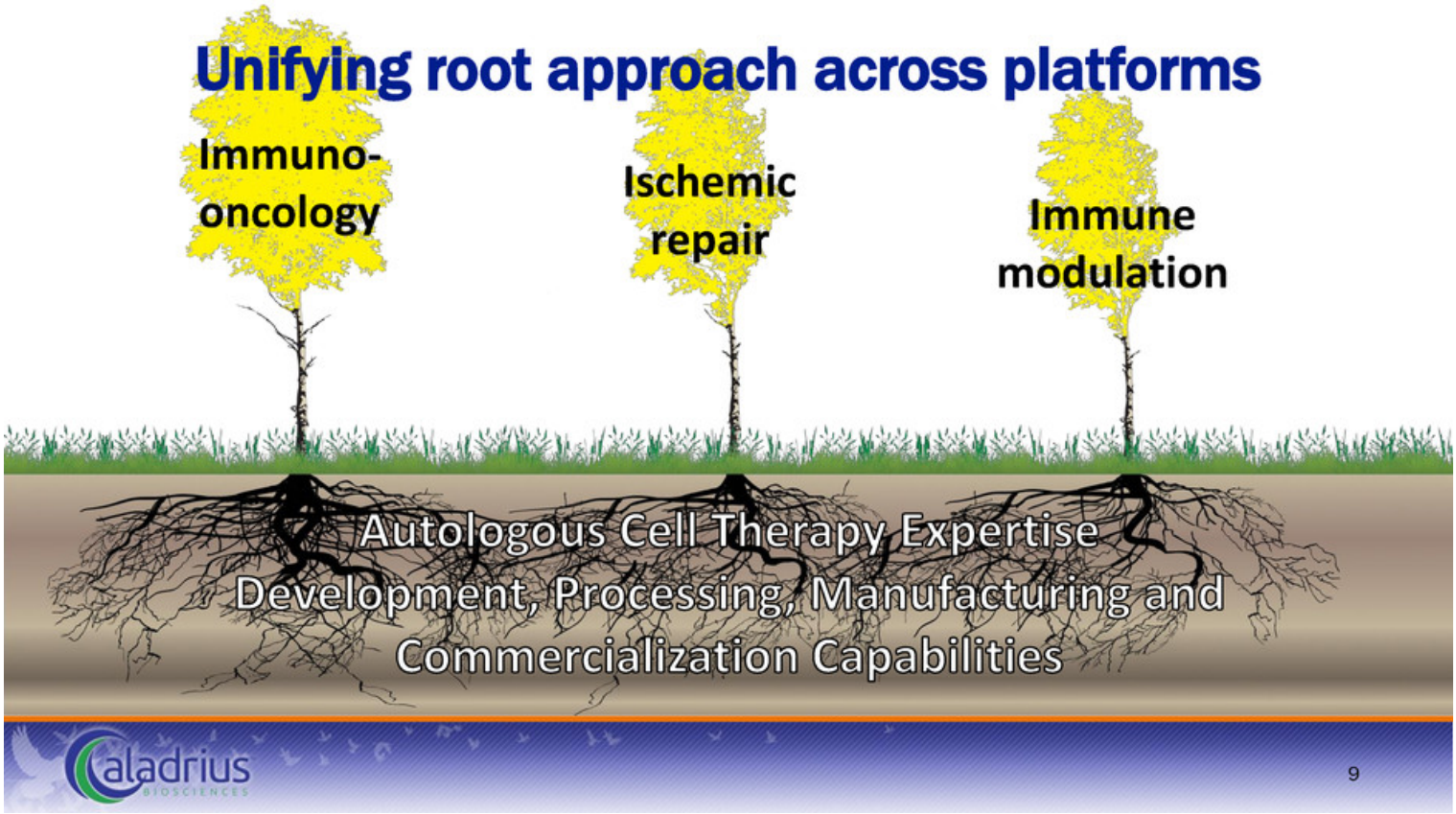
Experienced executive and scientific team

David J. Mazzo, PhD Chief Executive Officer	30+ years' experience - all aspects of large and emerging global biotech, biopharma company operations, successful international drug development
Robert S. Vaters, MBA President and Chief Financial Officer	25+ years' financial and management experience in a variety of healthcare, biotechnology, biologics, medical device and pharmaceutical companies
Douglas W. Losordo, MD Senior VP, Clinical, Medical and Regulatory Affairs and Chief Medical Officer	Leader in cell therapy research and development; renowned cardiologist with noteworthy academic and industry credentials
Hans Keirstead, PhD Senior VP, Research and Chief Science Officer	Internationally known stem cell expert; CEO of California Stem cell prior to acquisition by Caladrius; Founder of Stem Cell Research Center, University of California, Irvine
Robert A. Preti, PhD Senior VP, Development and Technical Operations and Chief Technology Officer; President of PCT, a Caladrius company	Leading authority on cell-based therapy engineering; unique development and commercialization experience

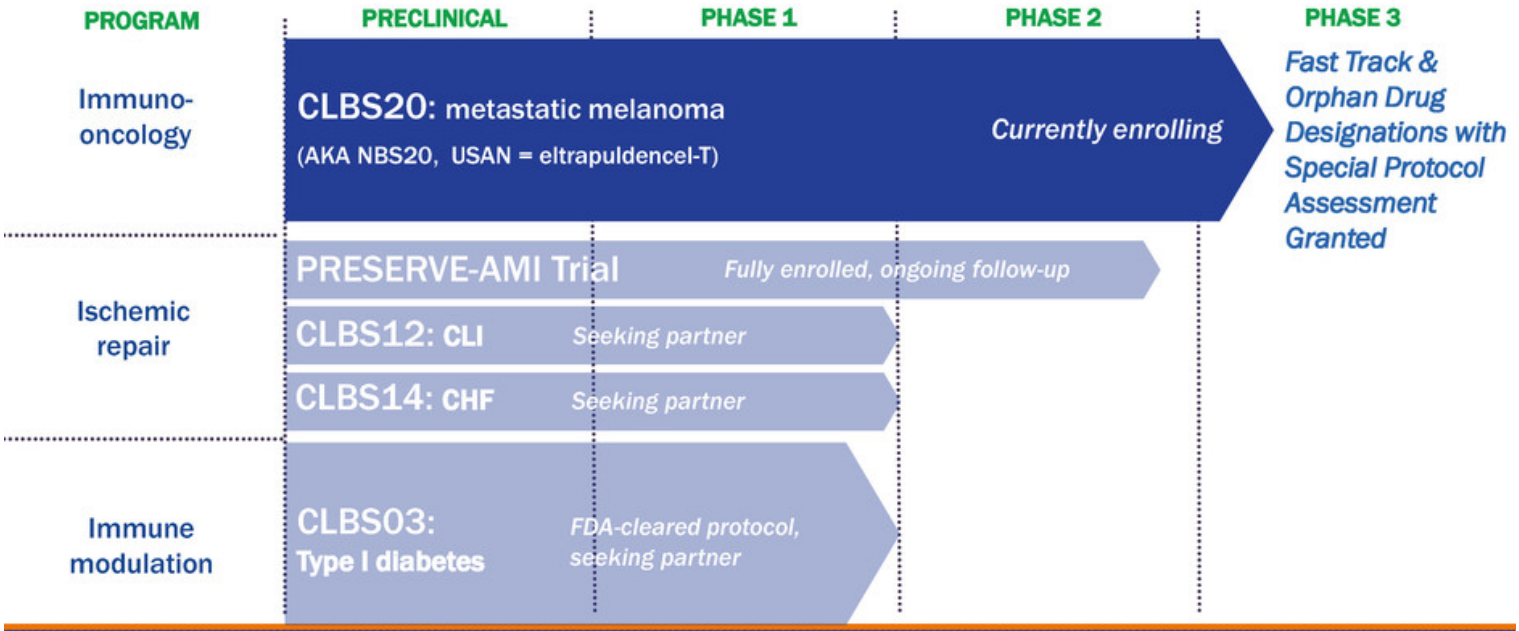
Robust and balanced pipeline



Unifying root approach across platforms



Robust and balanced pipeline



Immuno-oncology:
Turning cancer against itself

Metastatic melanoma:
CLBS20 (AKA NBS20, USAN = eltrapuldencel-T)

- Fast Track & Orphan Drug designations
- Special Protocol Assessment
- ATMP (EMA)
- $17.7 million CIRM grant award

Stage III recurrent/stage IV metastatic melanoma

PREVALENCE AND UNMET MEDICAL NEED

~20,000 estimated new cases per year in U.S.[1]

~10,000 deaths per year in U.S.[1]

~15% five-year survival rate[2]

~$1 billion U.S. market size[3]

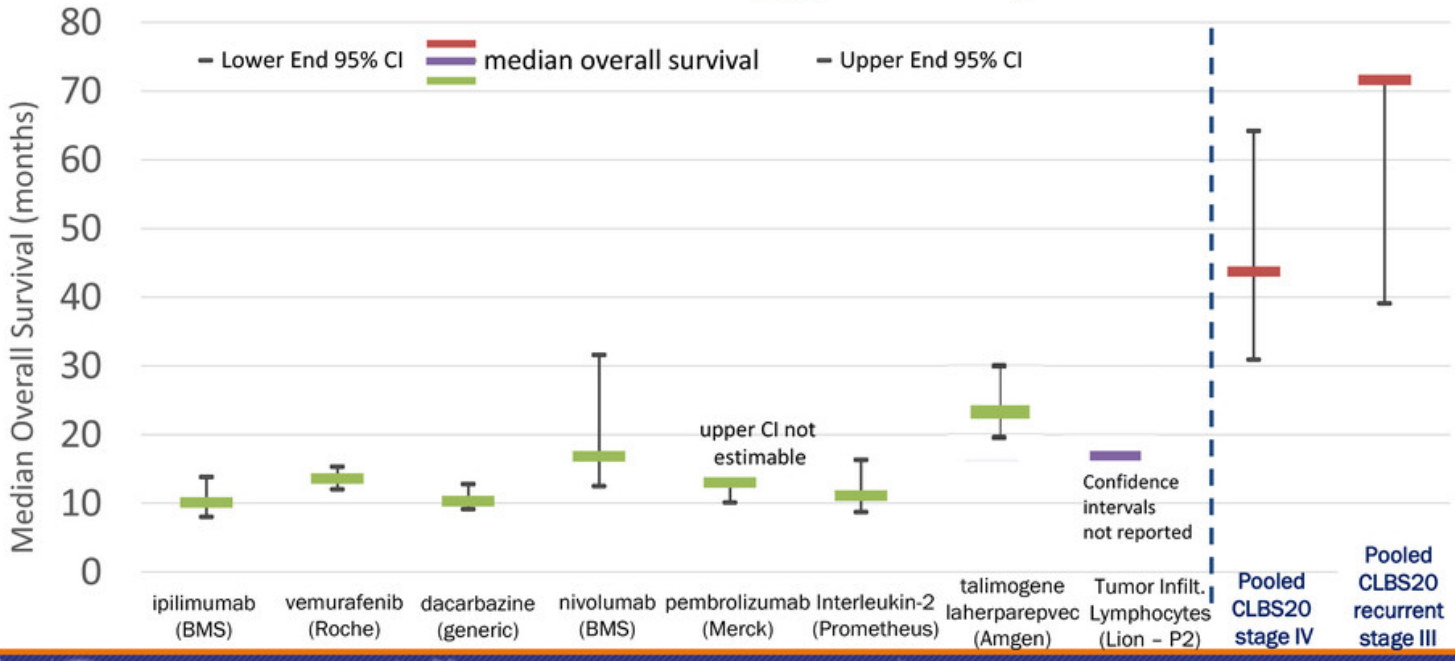
Distant metastases commonly in brain, lung, liver, small bowel, lymph nodes, bone, and cutaneous and soft tissue

NUMEROUS NON-SYNONYMOUS INTER-PATIENT MUTATIONS

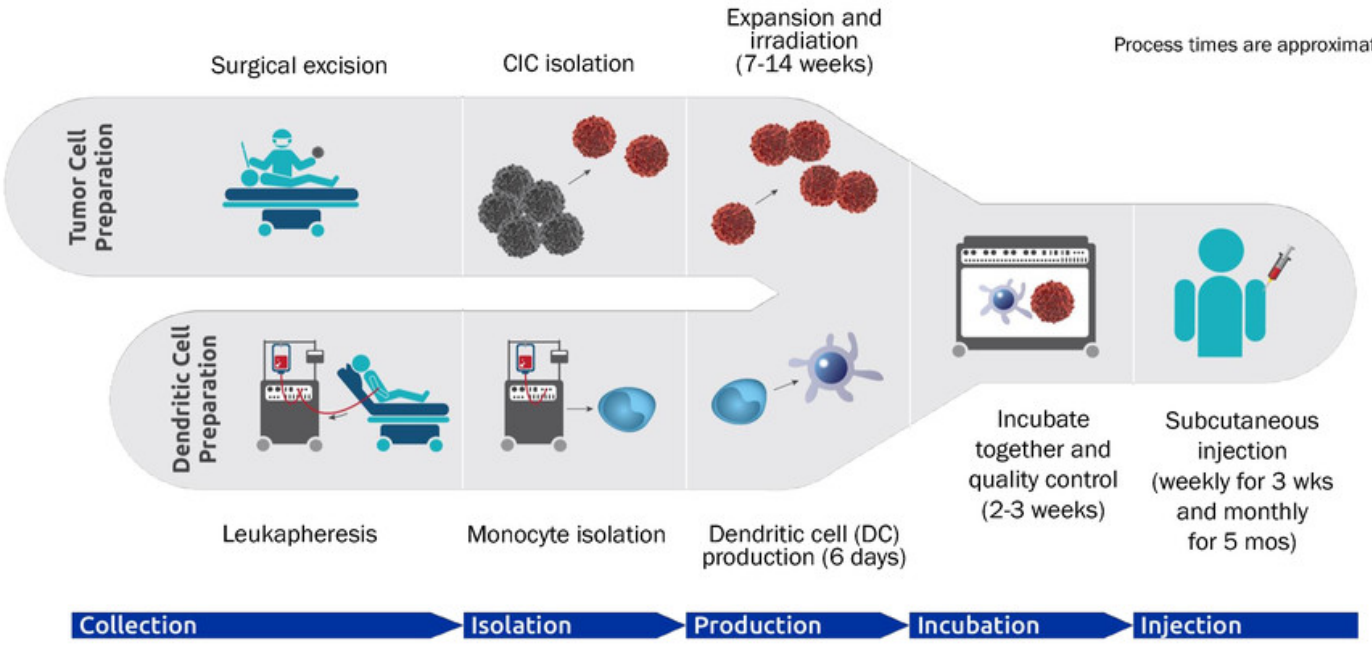
- Unique patient-specific antigenic fingerprints
- Ideal target for autologous immunotherapy

1. American Cancer Society, 2014 SEER
2. For Stage IV metastatic melanoma - *AJCC* Cancer Staging 2010 (based on 17 academic centers) (Five-year data for recently approved melanoma immunotherapies is not yet reflected)
3. GBI Research – 2013

CLBS20 Phase 2 data suggests superior survival



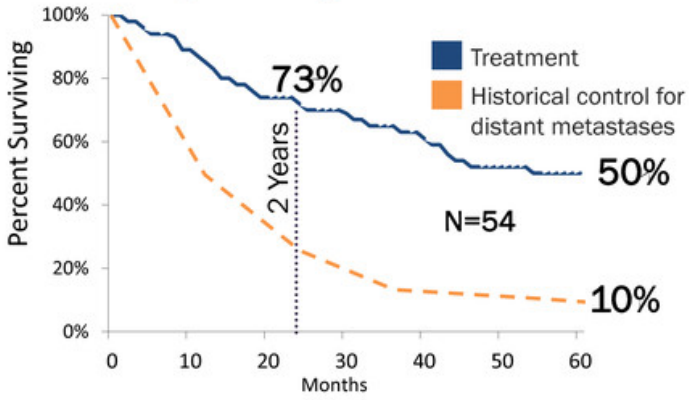
CLBS20: Uniquely targets cancer-initiating cells (CICs)



Phase 2: two trials; consistent, compelling data

5-YEAR OVERALL SURVIVAL

54 patient single arm P2 trial



50% observed 5-year survival rate

Treatment considered safe and generally well tolerated

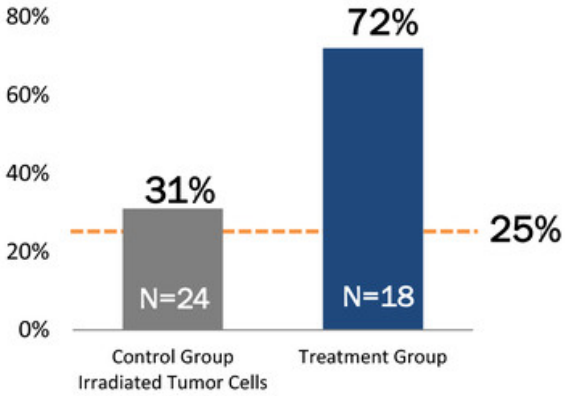
– Minor local injection site reactions

Dillman, et al. *Cancer Biother Radiopharm* 2009

Historical control: *Balch J Clin Oncol* 2009

2-YEAR OVERALL SURVIVAL

42 patient randomized P2 trial



p = 0.007; Hazard ratio = 0.27

Treatment considered safe and generally well tolerated

– Minor local injection site reactions

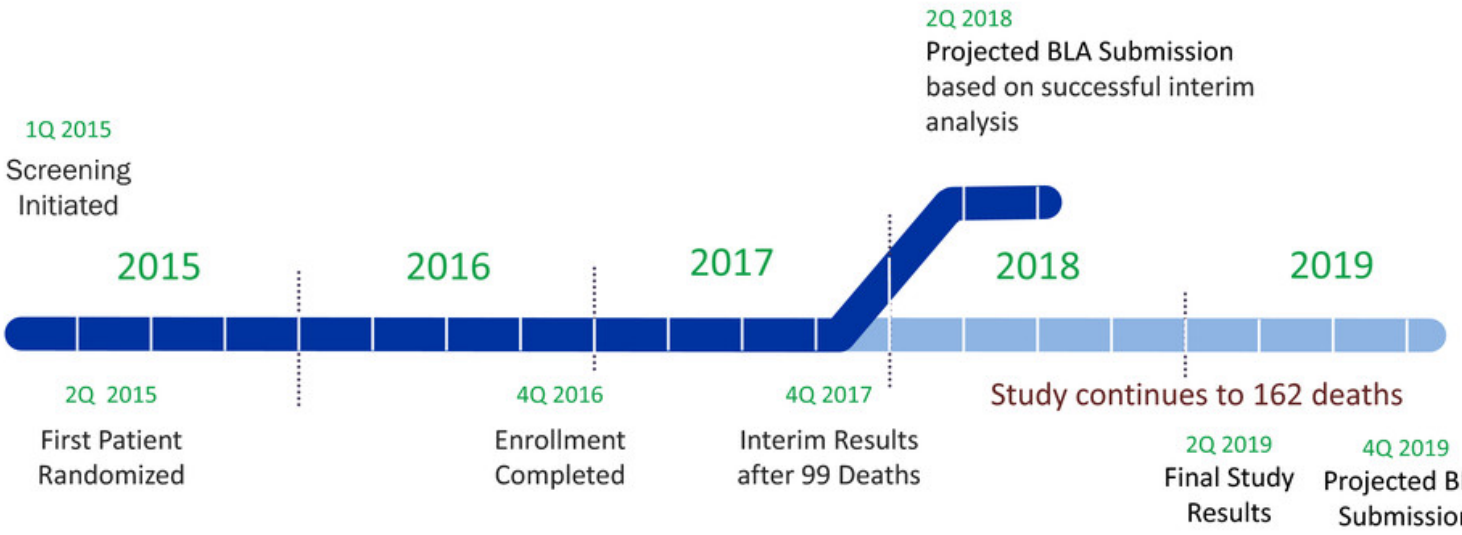
Dillman, et al. *Journal Immunotherapy* 2012

Historical control for distant metastases

The Intus study: Phase 3 with SPA and orphan drug and fast track designations

DESIGN	• Randomized (2:1), double blind, placebo controlled trial • Stage III recurrent or stage IV metastatic melanoma • Single trial for registration assuming positive outcome
ENDPOINT	• Overall survival
POWERING	• 80% power to detect 37.5% reduction in risk of death
RELATION TO STANDARD THERAPIES	• Adjunctive • Clinical practice based trial
STUDY SIZE	• Planned 250 eligible patients • Approximately 50 sites (U.S., Canada, Australia, New Zealand, considering E.U.)
TREATMENT	• CLBS20: Autologous DC loaded with antigens from autologous CICs, in GM-CSF
CONTROL	• Autologous monocytes in GM-CSF

Timeline to BLA



Total trial cost to earliest projected BLA: ~$45 million

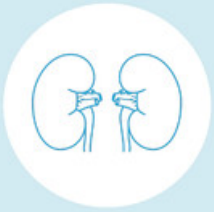
Potential application for multiple solid tumor types

OVARIAN CANCER

(US FDA-cleared phase 2 protocol, cell line feasibility established)

HEPATOCELLULAR CARCINOMA (LIVER)

(8 HCC patients with HBV treated, no toxicity)

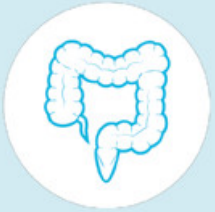


RENAL CELL CARCINOMA (KIDNEY)

(9 RCC patients treated)

LUNG CANCER

(Feasibility of cell lines from biopsies initiated)



COLON CANCER

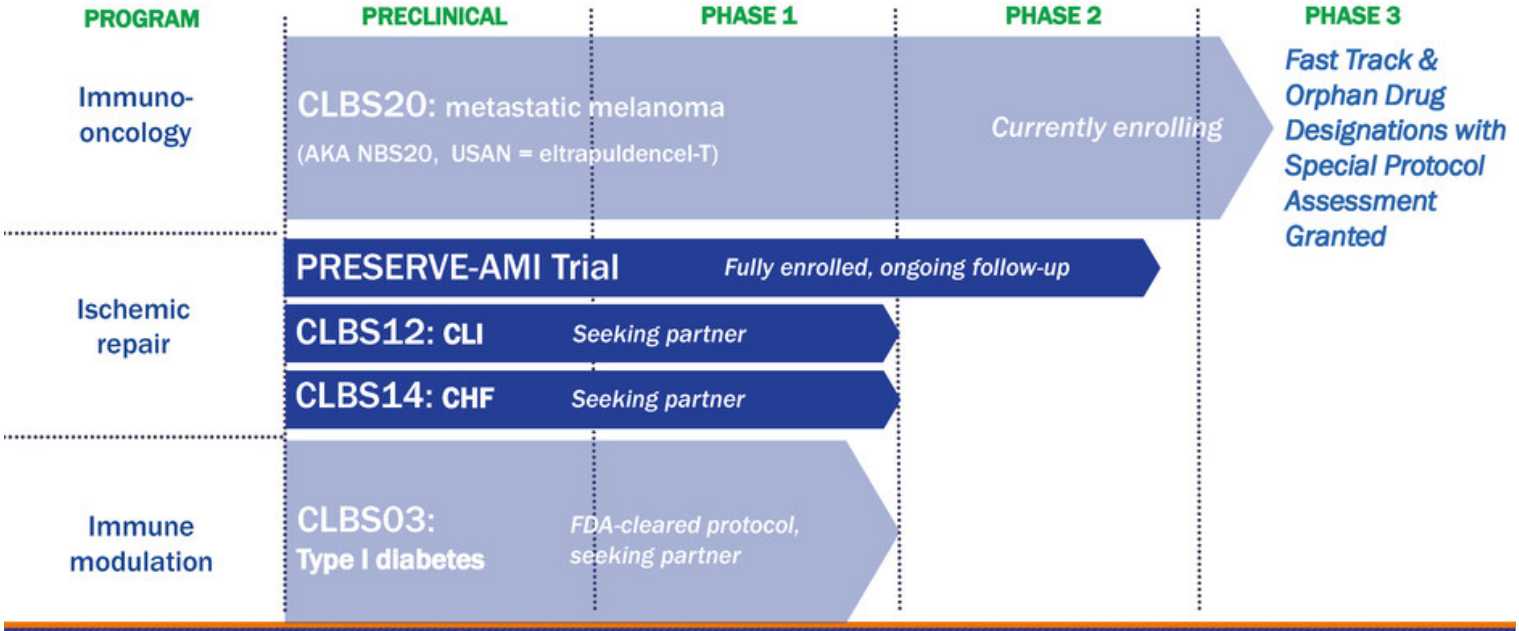
(Feasibility of cell lines planned)

GLIOBLASTOMA MULTIFORME (BRAIN)

(Feasibility under investigation)

Multi-billion dollar lifecycle opportunity

Robust and balanced pipeline



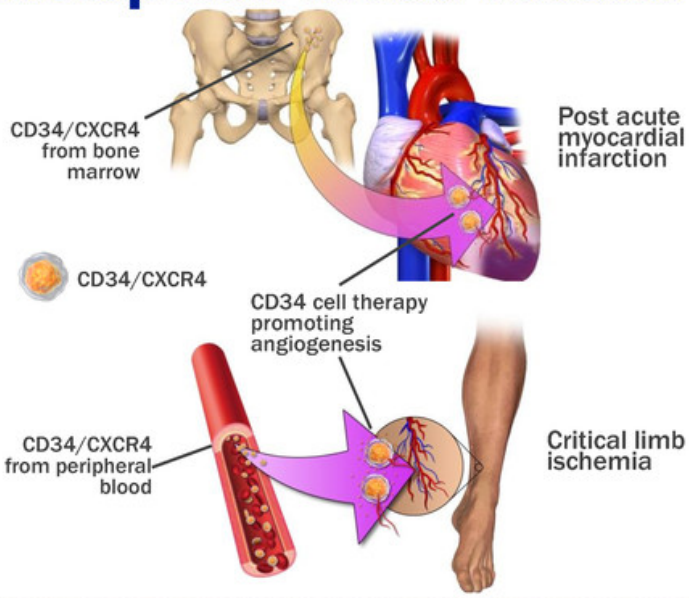
Ischemic repair

Critical Limb Ischemia: **CLBS12**

Chronic Heart Failure: **CLBS14**

Ischemic repair: Leveraging the body's natural repair mechanism to develop new blood vessels

- **Ischemic events** – caused by restriction of blood to tissue, e.g., stroke, acute myocardial infarction and claudication
- **Results of ischemia** include chronic heart failure, critical limb ischemia and more
- **CD34+ cells** have been shown to induce the development of new blood vessels, preventing tissue death by improving blood flow



PreSERVE study: enrolled Phase 2 study in follow-up

DESIGN	• Randomized (1:1), Phase 2, double blind, placebo controlled trial • Post-AMI (STEMI) patients
PRIMARY ENDPOINTS AND KEY SECONDARY ENDPOINT	• Change in cardiac perfusion from baseline to 6 months (exploratory endpoint) • Incidence rates of Serious Adverse Events (SAEs) and Major Adverse Cardiac Events (MACE) (FDA guidance-driven endpoint) • LVEF change from baseline to 6 months (FDA guidance-driven endpoint)
KEY INCLUSION CRITERIA	• Confirmation of ST Elevation MI • Ejection fraction $\leq$ 48% at day 4 by CMR • State-of-the-art care post stenting
STUDY SIZE	• 161 patients, 60 centers in United States
TREATMENT	• Single dose via infarct related artery with minimum dose ≥10M (million) ±20% CD34+ cells. • Actual dose determined by intrinsic number of cells in marrow and processing success rate
CONTROL	• Placebo infusion

PreSERVE interim conclusions emphasize cell dose-dependent trends*

- CD34 cell dose-dependent trend in reduction of MACE
  — Signal for a mortality benefit (12 month data)
- Signal for reduction in frequency of SAEs in higher dose groups (12 month data)
- CD34 cell dose-dependent trend in improvement of left ventricular ejection fraction and reduction in infarct size
- No correlation between exploratory endpoint of perfusion and treatment

- Favorable trends in clinical events encourage continued development for platform

*Based on data collected at 6 months except where noted

Significant Unmet Need for CLI and CHF

NO-OPTION CRITICAL LIMB ISCHEMIA

- If options for surgical or endovascular therapies are exhausted, patients only receive pain management, wound care or amputation
- Even with surgical options over 50% lead to amputation or death within one year[1]
- Prevalence (Japan): 21K CLI no-option patients[2]
- Incidence (Japan): ~2K – 8K per year[3]

CHRONIC HEART FAILURE

- Heart failure is the only major cardiovascular disorder still on the rise with incidence of CHF doubling with each decade of life
- Most Class III patients are hospitalized two to three times per year[4]
- Prevalence (U.S.): 5M heart failure patients[5]
- Incidence (U.S.): ~550K per year[5]

1. TASC II Guidelines, Huron Primary Research (Sept-Oct/2014); 2. ; 3. Source: Nihon GekaGakkaiZasshi. 2007 Jul;108(4):171-5, Am FamPhysician. 1999 Apr 1;59(7):1899-1908; TASC II Guidelines, Huron Primary Research (Sept-Oct/2014); 4. ; 5;

CLBS12 CLI Japan Program Update

Objective: file J-IND approval and consummate partnership to allow for clinical study execution

Could take advantage of new Japanese regulatory path to early conditional approval

Clinical background: Previous studies of autologous CD34+ cells in no-option CLI patients in Japan and U.S. (combined total, N=56)

- Conclusions from 2 previous studies in Japan:
  - Study 1: CD34 cell injection was safe and led to improvement in all clinical parameters
  - Study 2: CD34 cell injection was safe and led to improvement in CLI-free status as well as other clinical parameters

- Conclusion from previous study in U.S.:
  - CD34 cell injection was safe and led to improved amputation free survival

Study 1: Kawamoto A et al. Stem Cells 2009; Study 2: Fujita Y et al. Circ J 2014; Study 3: Losordo et al. Circ Cardiovasc Interv 2012.

Phase 2 study in Japan, targeting conditional approval
Study designed in consultation with PMDA

DESCRIPTION	• Prospective, open label controlled, randomized, multicenter study in patients with no-option CLI
DOSAGE	• Up to 10^6 autologous G-CSF-mobilized peripheral blood-derived CD34+ cells/kg per affected limb
STUDY SIZE	• 35 subjects
PRIMARY ENDPOINT	• Time to continuous CLI free status
DOSAGE FORM	• Solution/suspension; injectable
DOSAGE FREQUENCY	• Once
MODE OF ADMINISTRATION	• Intramuscular
CONTROL/COMPARATOR	• SOC pharmacotherapy with drugs approved in Japan (e.g., antiplatelets, anticoagulants, and vasodilators) • The choice of pharmacotherapy will be made by the investigators

Potential application across several indications


N-STEMI


STROKE


CLAUDICATION

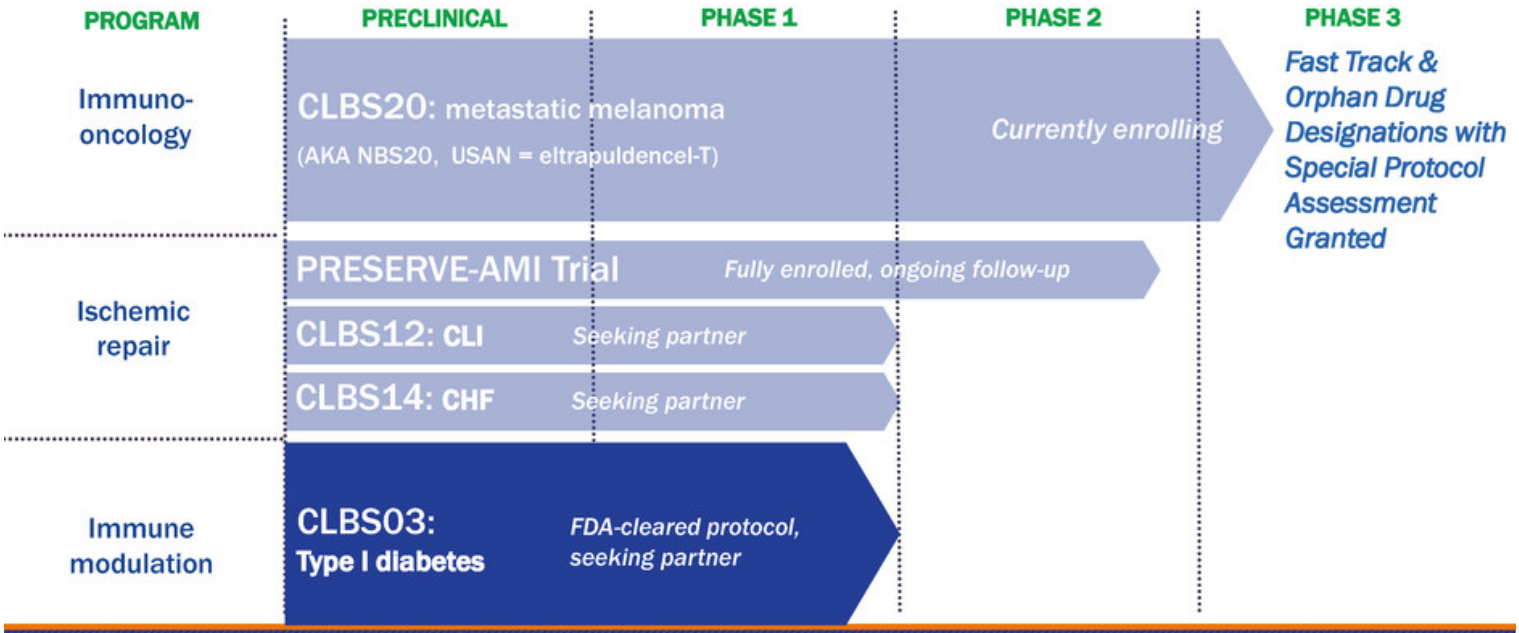

REFRACTORY ANGINA


SYNDROME X

Platform supported by independent preclinical and early clinical data, as well as positive suggestion of safety and therapeutic activity seen to date in the PreSERVE-AMI trial

Multi-billion dollar lifecycle opportunity

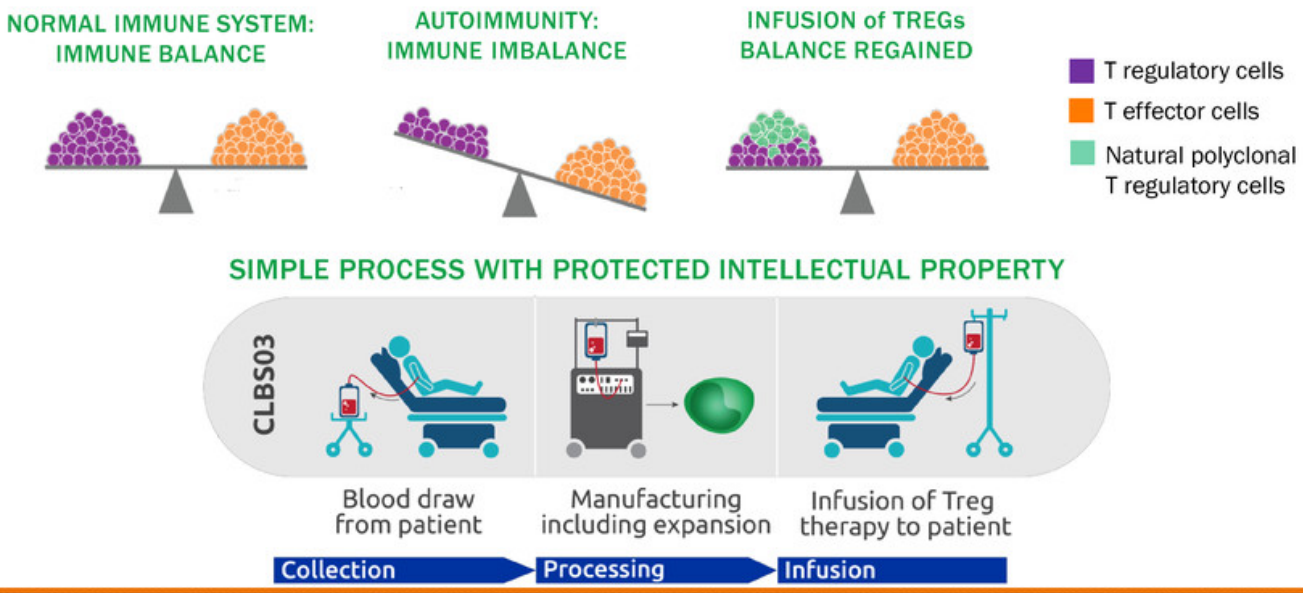
Robust and balanced pipeline



Immune Modulation

Diabetes Mellitus Type-1 (T1D): **CLBS03**

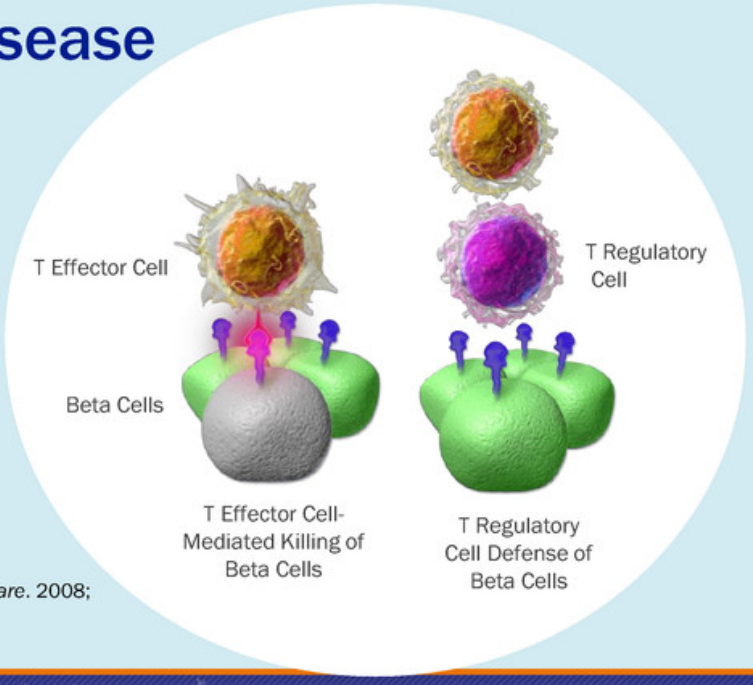
T Regulatory Cells (Tregs) : restoring immune balance and function



Diabetes Mellitus Type-1 (T1D): an autoimmune disease

PREVALENCE AND UNMET MEDICAL NEED

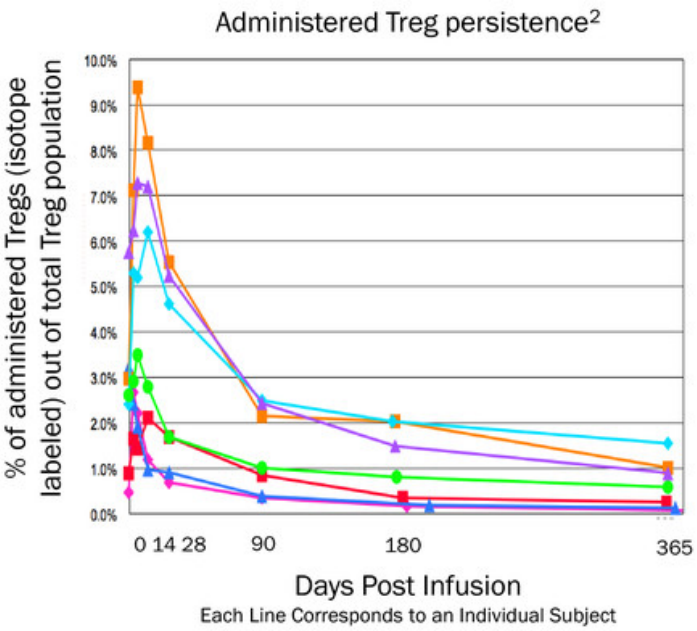
- 18,000 children under 20 in U.S. with new onset T1D per year[1]
- 3% annual growth rate worldwide[2]
- No curative treatments for T1D, only lifelong insulin therapy
- Diabetes is leading cause of:
  - kidney failure
  - new cases of adult blindness
  - non-traumatic lower-limb amputations



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[1]

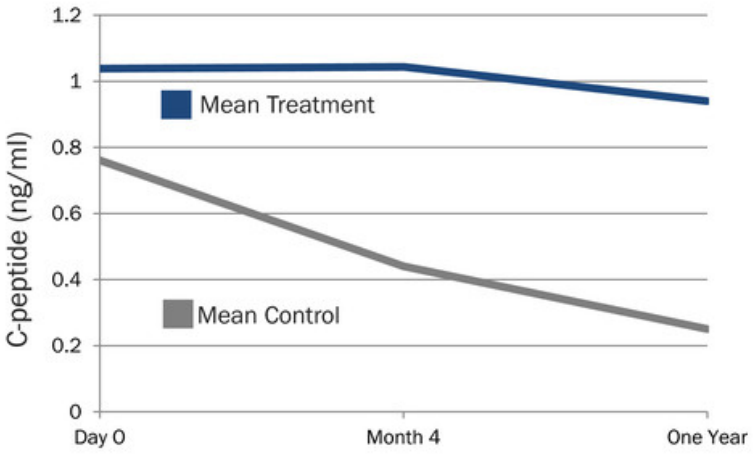
PI	Jeffrey Bluestone, PhD, of UCSF – leader in field of Tregs
DESIGN	U.S. UCSF/Yale open label Phase 1 study, 4-dose escalation cohorts
PATIENTS	14 adult patients with established T1D
RESULTS	• Preliminary data indicates safety and tolerability • Established manufacturing feasibility • Implied sustainability of effect • Infused Tregs were stable and detected in peripheral circulation for 1 year[2]



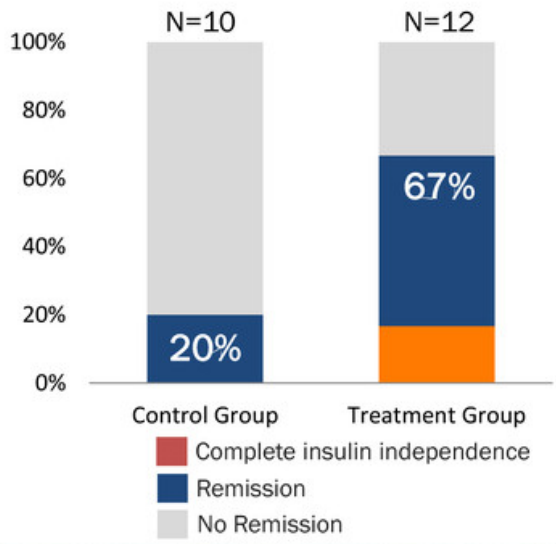
1. Gitelman et al, American Diabetes Association Abstract, 2014
2. Dr. Jeffrey Bluestone Lab

Treg cell therapy preserves beta cell function in children[1]

FASTING C-PEPTIDE LEVELS



REMISSION RATE AT 12 MONTHS



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

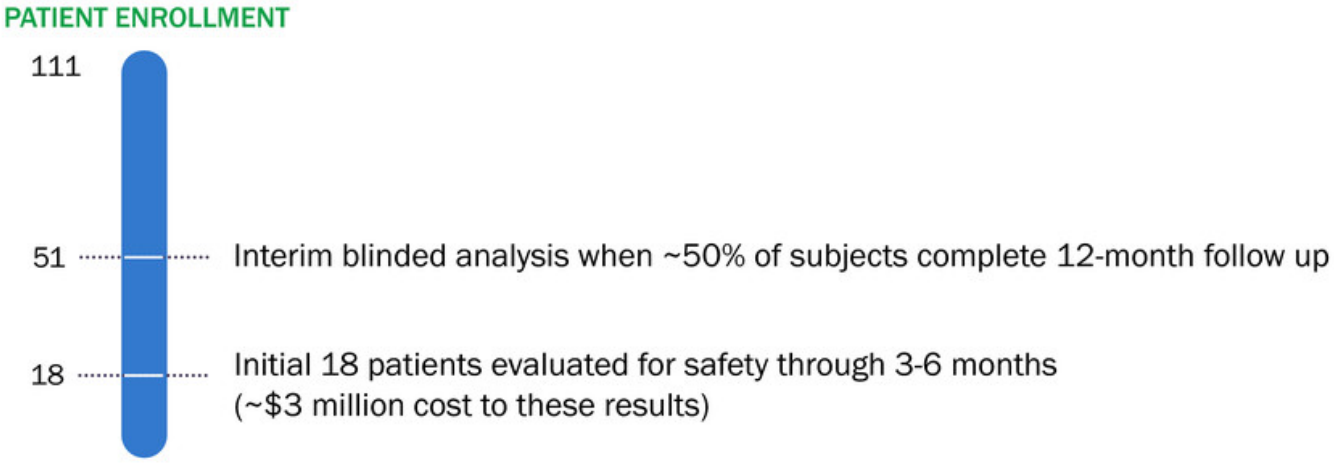
1. Children aged 5-18 administered 1 (10 or 20 mil cells/kg) or 2 doses (total 30 mil cells/kg) of Tregs

The Trutina study: Phase 2 in adolescents with T1D[1]

DESIGN	• Double blind, placebo controlled, randomized (1:1:1) • Adolescent patients with recent onset T1D ages 12 to 18
PRIMARY ENDPOINT	• Preservation of C-peptide at 52 weeks in comparison to placebo
POWERING	• 80% power to detect 50% attenuation in fasting c-peptide levels
STUDY SIZE	• 18 patient cohort with early interim safety analysis, total of 111 patients to be enrolled • ~11 U.S. sites
TREATMENT	• CLBS03: Dose cohorts of 10 or 20 million cells/kg
CONTROL	• Placebo infusion

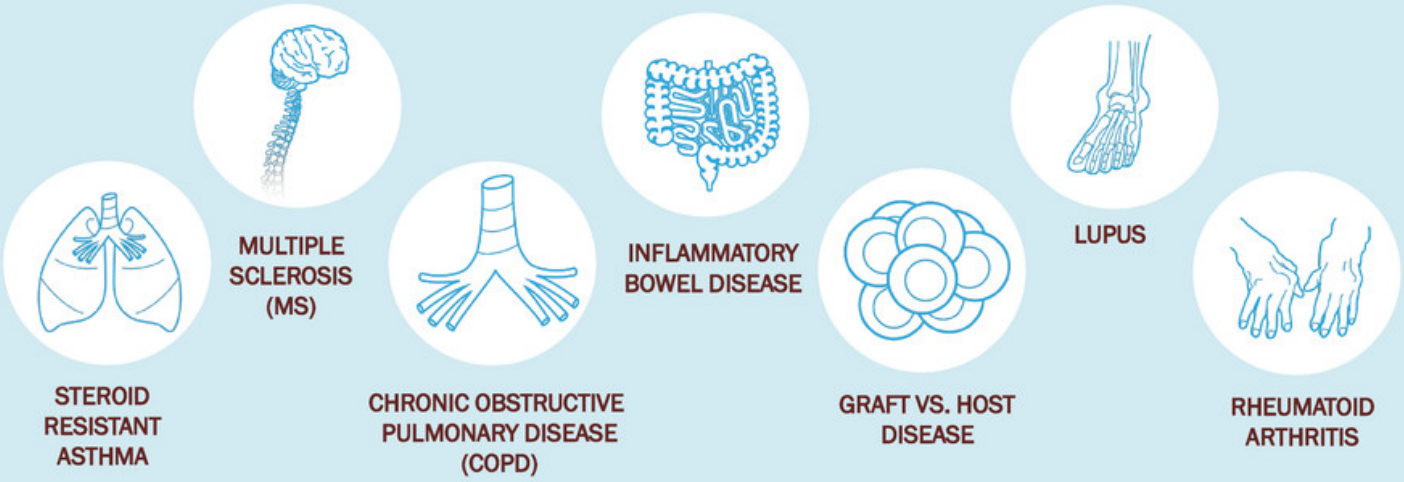
1. Study cleared by FDA to proceed based on efficacy data in children establishing prospect of direct benefit

Trutina study: Efficient asset de-risking study design



Expected cost of trial: ~$22.5 million

Potential application across multiple autoimmune and allergic diseases



Multi-billion dollar lifecycle opportunity

Investment summary

- ✓ Lead immuno-oncology program (Phase 3 study in metastatic melanoma) with Fast Track and Orphan Drug designations and a SPA
- ✓ Additional platforms for autoimmune disorders (FDA-cleared Phase 2 study in adolescents with type I diabetes) and multiple cardiovascular indications
- ✓ Internal center of excellence (PCT) with bicoastal facilities and proven capabilities innovating discovery, development, manufacturing and delivery of cell-based therapies
- ✓ Highly experienced management and scientific team

Delivering Personalized Medicine

NASDAQ: CLBS

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