caladrius
BIOSCIENCES

Committed to the Development of Novel Therapies Addressing Unmet Medical Needs

COMPANY OVERVIEW

Caladrius is a late-stage therapeutics development biopharmaceutical company committed to the development of innovative products that have the potential to restore the health of people with chronic illnesses. Our leadership team collectively has decades of biopharmaceutical development experience and world-recognized scientific achievement in the fields of cardiovascular and autoimmune disease, among other areas. The Company has a rich portfolio of novel and versatile products that address important unmet medical needs. Our current product candidates include three treatments for cardiovascular diseases based on our CD34+ cell therapy platform: CLBS12, in Phase 2 testing in Japan under a SAKIGAKE ("breakthrough") designation and eligible for early conditional approval for the treatment of critical limb ischemia; CLBS14-CMD, in Phase 2 testing for the treatment of coronary microvascular dysfunction; and CLBS14-NORDA, in Phase 3 development for no option refractory disabling angina for which it has received RMAT designation.

C-SUITE LEADERSHIP TEAM

David Mazzo, PhD
President
Chief Executive Officer

Douglas Losordo, MD
Executive Vice President
Global Head of R&D
Chief Medical Officer

Joseph Talamo, CPA, MBA
Senior Vice President
Chief Financial Officer

INVESTMENT HIGHLIGHTS

- ***Late-stage therapeutics development company***
  - Three principal development programs; 2 designated "breakthrough"*
    - CD34+ cells for ischemic repair (CLBS12*, CLBS14-CMD, CLBS14-NORDA*)
- ***CD34+ cell therapy technology platform includes nearer-term commercial opportunities***
  - CLBS12 is an ongoing critical limb ischemia study in Japan with SAKIGAKE designation for expedited review and eligible for early conditional approval
  - CLBS14-CMD is an ongoing proof-of-concept Phase 2 study in the USA for coronary microvascular dysfunction and is supported by a grant from the NIH
  - CLBS14-NORDA is in Phase 3 development in the USA for no option refractory disabling angina
- ***Financially stable and debt-free***
  - Strong balance sheet (~$43 million cash as of Dec. 31, 2018)
  - Low operating cash burn (~$20 million for year ended Dec. 31, 2018; Cash runway through May 2020)
- ***Dedicated and highly motivated leadership team with extensive experience in biopharmaceutical development***

MARKET SNAPSHOT

Ticker Symbol	CLBS
Exchange	NASDAQ
52-Week Price Range	$3.05 - $11.65
Shares Outstanding *(12/31/18)*	9.9 mil
Cash & Investments *(12/31/18)*	~$43 mil
Fiscal Year-End	December 31

POTENTIAL VALUE CREATING MILESTONES

❑ **2Q 2019**	Finalize CLBS14-NORDA clinical plan with FDA
❑ **1H 2019**	Complete enrollment in ESCaPE-CMD Phase 2 study
❑ **1H 2019**	CLBS12 RMAT application response (U.S.)
❑ **2H 2019**	Announce ESCaPE-CMD Phase 2 study topline data
❑ **2H 2019**	Complete enrollment in CLBS12 Phase 2 study
❑ **2H 2019**	Initiate CLBS14-NORDA pivotal Phase 3 study
❑ **1H 2020**	Announce CLBS12 Phase 2 study topline data

ROBUST PRODUCT PIPELINE

Pre-clinical	Phase 1	Phase 2	Phase 3

CD34+ Cell Therapy Platform
(Ischemic Repair)

- **CLBS12** *Critical Limb Ischemia* — **Country: Japan**
- **CLBS14-CMD** *Coronary Microvascular Dysfunction* — **Country: USA**
- **CLBS14-NORDA** *No Option Refractory Disabling Angina* — **Country: USA**

T Regulatory Cell Therapy Platform
(Immune Modulation)

- **CLBS03** *Recent Onset Type 1 Diabetes* — **Country: USA**

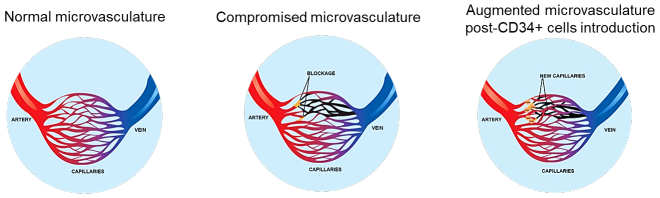
Active trial

Registration eligible trial

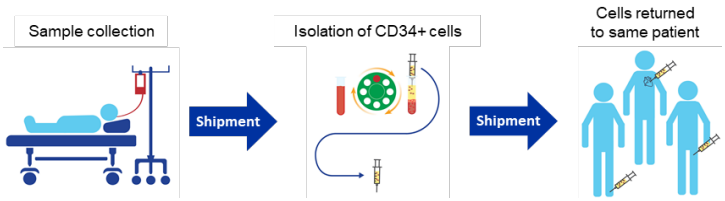
Next step in development a function of ongoing comprehensive database analysis and 2-year follow-up at end of 2019

CD34+ CELL THERAPY PLATFORM

- CD34 is a cell surface protein that identifies a subset of mononuclear cells in the bone marrow and circulation
- CD34+ cells are pre-programmed vascular repair cells that promote angiogenesis of the microvasculature. Caladrius' proprietary platform technology selects and delivers a potent, concentrated population of the patient's own CD34+ cells for optimal therapeutic benefit



Simple, scalable and economical autologous cell therapy process



Maximum of 4 days from donation to injection

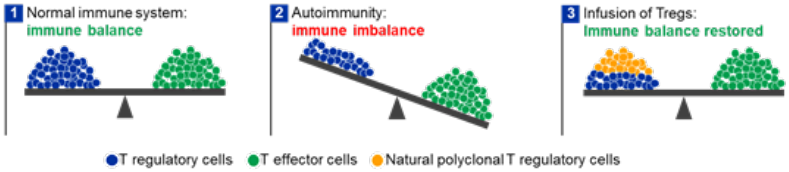
Day -3: Patient dosed with GCSF to mobilize CD34+ cells from bone marrow to peripheral blood; avoids bone marrow aspiration
Day 1: Sample collection via apheresis; shipment to processing center
Day 2: CD34+ cells isolated and prepared for patient injection; shipment to clinic
Day 3-4: Cells returned to patient through intramuscular, intracoronary or intramyocardial injection, depending on indication

- More than 700 subjects studied in randomized double-blind placebo-controlled trials provide consistent evidence of therapeutic benefit and tolerance
  - Improved mortality, reduced chest pain and increased exercise tolerance in refractory angina[1]
  - Reduced amputation in critical limb ischemia[2]
  - Improved function in claudication[3]

[1]Losordo et al. *Circ Res* 2011.; Povsic et al. *JACC Cardiovasc Interv*. 2016.
[2]Losordo et al. *Circ Cardiovasc Interv* 2012.
[3]From US study (n=17); Not yet published

T REGULATORY CELL THERAPY PLATFORM

- Caladrius' T regulatory cell technology is based on autologous *ex vivo* expanded polyclonal T regulatory cells, which are functionally enhanced prior to re-introduction to the patient
- Therapeutic T regulatory cells (Tregs) are thought to be active in the treatment of autoimmune diseases in which deficient Treg activity results in the patient's immune system attacking the body's own beneficial tissues
- Caladrius' technology to enhance autologous Treg number and function leverages the native immune regulatory mechanisms, offering a path to true disease modification



- The potential of Tregs as a therapeutic platform differentiates itself from available therapeutics and almost all other investigational agents in development through:
  - Disease modification via restoration of immune tolerance as the most proximal/root cause of the autoimmune disease pathways, in contrast to targeting less pivotal and redundant downstream effects
  - Freedom from indiscriminate immune suppression of vital effector functions of the immune system
  - Specific homing to disease affected organs, thus targeting tolerance to where it is needed most

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