caladrius

BIOSCIENCES

Pioneering Advancements in Therapies for Cardiovascular and Autoimmune Diseases

COMPANY OVERVIEW

Caladrius is a late-stage therapeutics development biopharmaceutical company pioneering advancements of cell therapies for select cardiovascular and autoimmune diseases. 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. Our current product candidates include three developmental treatments for cardiovascular diseases based on our CD34+ cell therapy platform: CLBS12, recipient of a SAKIGAKE designation, in Phase 2 testing in Japan and eligible for early conditional approval for the treatment of critical limb ischemia; CLBS16 (formerly known as CLBS14-CMD), subject of the proof-of-concept ESCaPE-CMD clinical trial in the U.S.A. for the treatment of coronary microvascular dysfunction; and CLBS14 (formerly known as CLBS14-NORDA), recipient of a RMAT designation in the U.S.A. and for which we are in preparations to commence a Phase 3 clinical trial in no option refractory disabling angina.

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***
  - Pioneering advancements of cell therapies in cardiovascular disease
  - Three principal development programs; 2 designated "breakthrough"*
    - CD34+ cells for ischemic repair (CLBS12*,CLBS14*, CLBS16)
- ***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 is in Phase 3 development in the USA for no option refractory disabling angina
  - CLBS16 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
- ***Financially stable and debt-free***
  - Strong balance sheet (~$38 million cash as of March 31, 2019)
  - Low operating cash burn (cash projected through 2Q 2020)
- ***Dedicated and highly motivated leadership team with extensive experience in biopharmaceutical development***

MARKET SNAPSHOT

Ticker Symbol	CLBS
Exchange	NASDAQ
52-Week Price Range	$2.77 - $11.65
Shares Outstanding *(3/31/19)*	~10.4 mil
Cash & Investments *(3/31/19)*	~$38 mil
Fiscal Year-End	December 31

POTENTIAL VALUE CREATING MILESTONES

- ❑ **2Q 2019** Finalize CLBS14 clinical plan with FDA
- ❑ **2H 2019** Announce ESCaPE-CMD Phase 2 study topline data
- ❑ **2H 2019** Complete enrollment in CLBS12 Phase 2 study
- ❑ **2H 2019** Initiate CLBS14 pivotal Phase 3 study
- ❑ **1H 2020** Announce CLBS12 Phase 2 study topline data

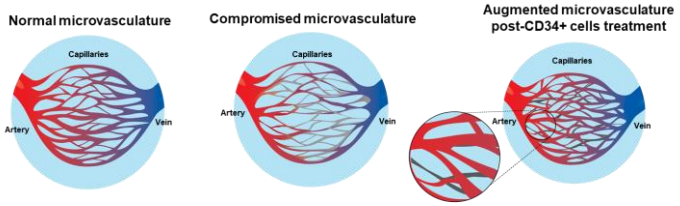
ROBUST PRODUCT PIPELINE

Pre-clinical	Phase 1	Phase 2	Phase 3
CD34+ Cell Therapy Platform (Ischemic Repair)			Registration eligible trial
CLBS12 *Critical Limb Ischemia*		**Country: Japan** *(ongoing)*	
CLBS16 *Coronary Microvascular Dysfunction*		**Country: USA** *(ongoing)*	
CLBS14 *No Option Refractory Disabling Angina*			**Country: USA** *(initiation targeted fall 2019)*
T Regulatory Cell Therapy Platform (Immune Modulation)			
CLBS03 *Recent Onset Type 1 Diabetes*		**Country: USA** *(ongoing)*	

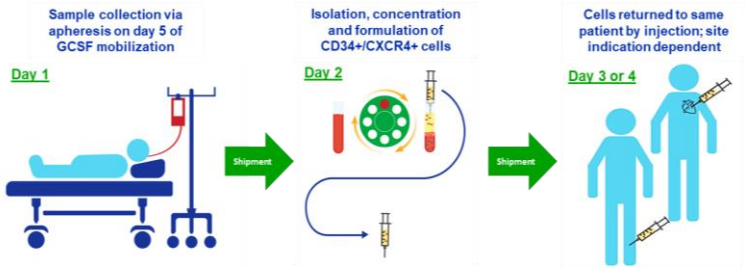
Results of comprehensive analysis of 1-year patient level data in conjunction with 2-year follow-up data (end 2019) will determine next development steps

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, rapid, scalable and economical autologous cell therapy process



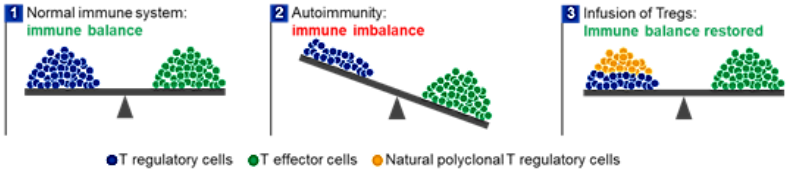
- GCSF mobilization eliminates need for surgical bone marrow aspiration
- Four days or less from donation to treatment
- Well characterized, reliable GMP process - easily scaled to meet increasing demand

- 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

CALADRIUS BIOSCIENCES, INC.
www.caladrius.com

CORPORATE HEADQUATERS
110 Allen Road, 2nd Floor
Basking Ridge, NJ 07920
Tel: 908.842.0100

INVESTOR RELATIONS CONTACT
John D. Menditto
Tel: 908.842.0084
E-mail: jmenditto@caladrius.com