**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

**FORM 8-K/A**

**(Amendment No.1)**

**CURRENT REPORT**
**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): April 11, 2019

**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.) |

110 Allen Road, 2nd 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))
- o Emerging growth company

  Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (Section 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (Section 230.12b-2 of this chapter).

- o If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**EXPLANATORY NOTE**

Caladrius Biosciences, Inc. (the "Company") filed a Current Report on Form 8-K on April 11, 2019 (the "Initial Form 8-K") that disclosed a slide presentation that the Company intended to use at investor and industry conferences and presentations. The Company is filing this Amendment No. 1 to the Initial Form 8-K to provide an updated slide presentation.

**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 99.1 and is incorporated herein solely for purposes of this Item 7.01 disclosure. The information in this Item 7.01, 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 Item 7.01, including Exhibit 99.1 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 Item 7.01 will not be deemed an admission as to the materiality of any information in this Item 7.01 that is required to be disclosed solely by Regulation FD.

**Item 9.01. Financial Statement and Exhibits.**

(d) Exhibits.

| Exhibit No. | Description |
|---|---|
| 99.1 | Caladrius Biosciences, Inc. Corporate Presentation, April 2019 |

**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.**

Dated: April 11, 2019

By: /s/ David J. Mazzo
Name: David J. Mazzo, PhD
Title: President and Chief Executive Officer

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BIOSCIENCES

# Corporate Presentation

David J. Mazzo, PhD
President and Chief Executive Officer

April 2019 | NASDAQ: CLBS

# Forward-looking statements advisory

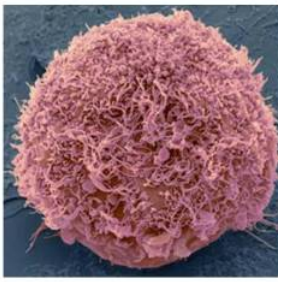
This Investor Presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements reflect management's current expectations, as of the date of this presentation, and involve certain risks and uncertainties. All statements other than statements of historical fact contained in this Investor Presentation 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 differ materially 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 14, 2019, as subsequently amended on March 19, 2019, 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. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this Investor Presentation. Caladrius does not intend, and disclaims any obligation, to update or revise any forward-looking information contained in this Investor Presentation or with respect to the matters described herein.

## Caladrius Biosciences: Uniquely positioned for near-term success

- Late-stage therapeutics development company
  - Three principal development programs; 2 designated “breakthroug
    - CLBS12*, CLBS14-CMD, CLBS14-NORDA*
- Financially stable and debt-free
  - Strong balance sheet (~$43 million cash as of Dec. 31, 2018)
  - Low operating cash burn (cash projected through May 2020)
- Multiple value creating events within the next 18 month
  - Key regulatory and data milestones across the pipeline

# Experienced executive team with broad domain-specific expertise

| | |
|---|---|
| David J. Mazzo, PhD<br>President and Chief Executive Officer | 35+ years of experience in all aspects of large pharma (Merck, Baxter, RPR, HMR, Schering-Plough) and emerging biopharma (Chugai USA, Regado); successful international drug development across all therapeutic areas, international capital raising and business transactions; Director and former Chairman of EyePoint Pharr |
| Douglas W. Losordo, MD<br>Executive VP, Global Head of R&D and Chief Medical Officer | 25+ years of experience as a leader in cell therapy research and development; renowned clinician with noteworthy academic (Tufts, Northwestern, NYU) and indus (Baxter) credentials; pioneer of CD34+ cell therapy |
| Joseph Talamo, CPA, MBA<br>Senior VP and Chief Financial Officer | 25+ years of experience as a versatile finance executive with strong accounting/aud background (KPMG) and leadership roles in publicly traded pharmaceutical development and commercial-stage companies (OSI Pharmaceuticals, BMS) |
| Todd Girolamo, JD, MBA<br>Senior VP, General Counsel and Corporate Secretary | 25+ years of legal experience as a practicing attorney (Cahill, Gordon & Reindel; R & Priest) as well as finance and biotechnology industry experience (Oppenheimer, CIBC, Leerink Swann) |
| John D. Menditto<br>Vice President,<br>Investor Relations and Corporate Communications | 20+ years of experience as an investor relations and corporate communications professional with a major focus on healthcare and life science (Novartis, Medco He Solutions, Argos Therapeutics) |



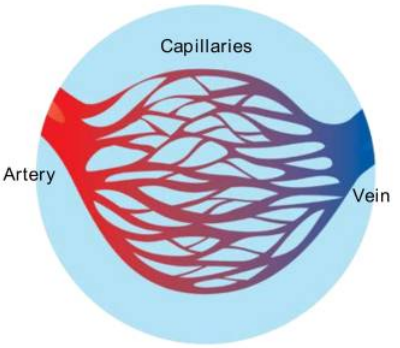
# Ischemic Repair

## Autologous CD34+ cells

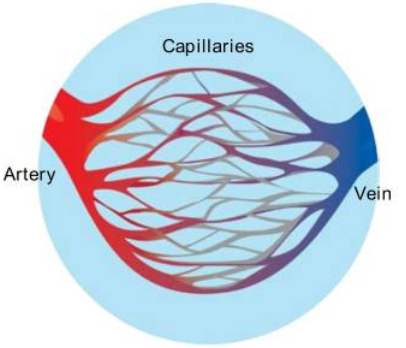
calad

# CD34+ cells promote angiogenesis of the microvasculature

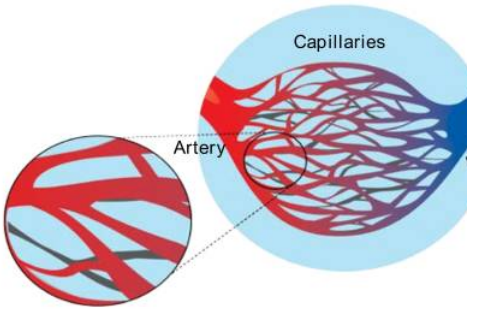
Normal microvasculature




Compromised microvasculature




Augmented microvascula
post-CD34+ cells introduc




- >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 angi
  - Reduced amputation in critical limb ischemia[2]
  - Improved function in claudication[3]

[1]Losordo et al. Circ Res 2011.; Povsic et al. JACC Cardiovasc Inte
[2]Losordo et al. Circ Cardiovasc Interv 2012.
[3]Losordo et al. US study (n=17); Pending publication

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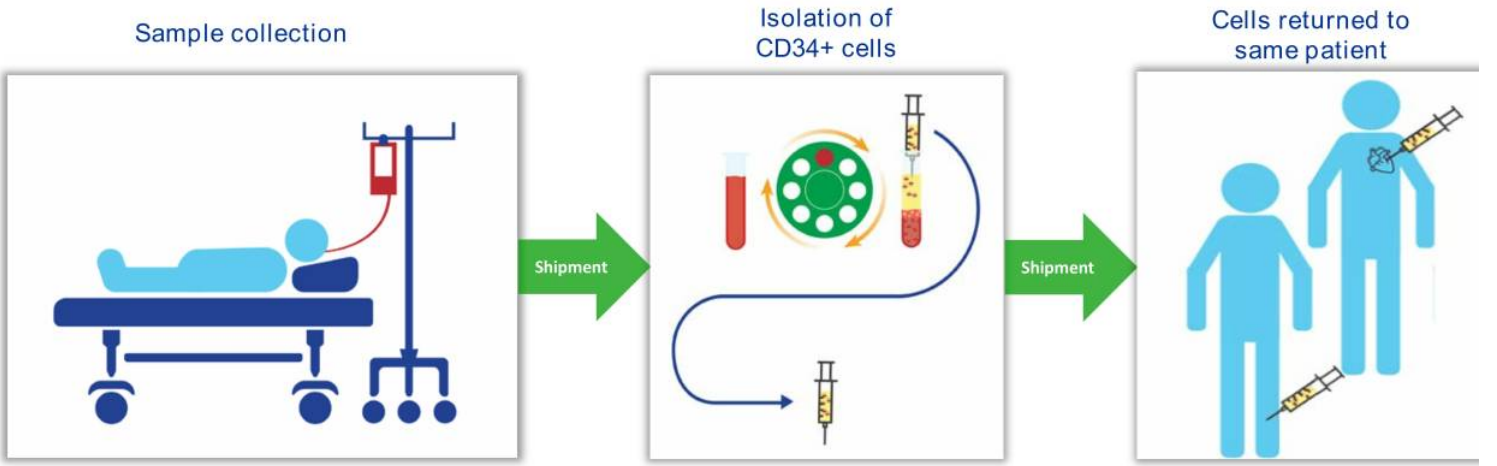
# Simple, scalable and economical autologous cell therapy process




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

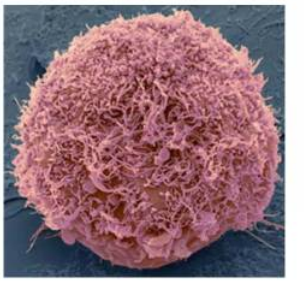
Day 2: CD34+ cells isolated and prepared for patient injection; shipment to clinic

Day 3-4: Cells returned to patient through intramuscular, intracoronary or intramyocardial injection, depending on indication

# CD34+ cell therapy patent estate provides for long-term exclusivity

## Composition of matter protection to 2031+

- 7 U.S. and 23 foreign composition of matter and methods patents granted
  - Japan, Russia, Canada, and the EU5 countries-France, Germany, Great Britain, Italy, and Spai
- 2 U.S. and 3 foreign patents pending
- Key claims cover a pharmaceutical composition of a therapeutic concentration of non-expanded CD34+/CXCR4+ stem cells ……. together with stabilizing serum ……. to repair an injury caused by vascular insufficiency
- Issued and pending claims can be applied to broad range of conditions caused by underlying ischemia
  - For example: CLI, CMD, NORDA, AMI, CHF and ischemic brain injury
- Expiries of granted patents ranging from 2031 – 2039 including patent term extension



# CLBS12

## Critical Limb Ischemia (CLI)

(Japan)

# CLI represents an expedited commercial opportunity in Japan

- Initiation in Japan prompted by early definition of accelerated path to regulatory approval
- Estimated >$100M initial commercial opportunity based on significant pharmaco-eco benefit
- CLBS12 could be a marketed product in Japan as early as 2021
- Positive results from ongoing trial in Japan should support expedited development in USA/E

## CLI Represents a Multi-billion Dollar Global Market Opportunity

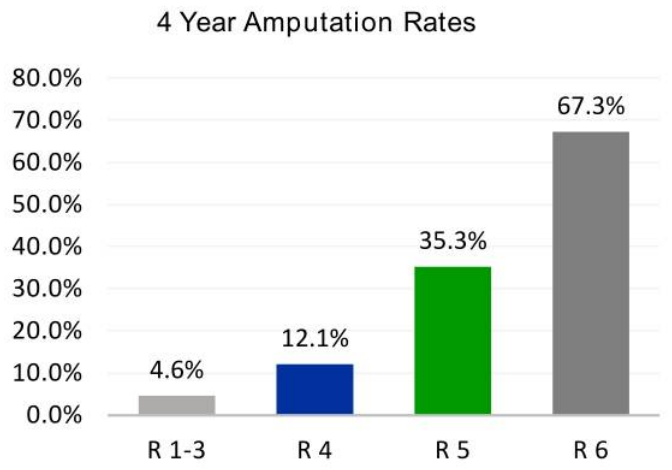
| | Japan | USA | Europe* |
|---|---|---|---|
| No-option CLI patients eligible for CLBS12<br>(not eligible for revascularization) | ~51,000 | ~300,000 | ~560,000 |

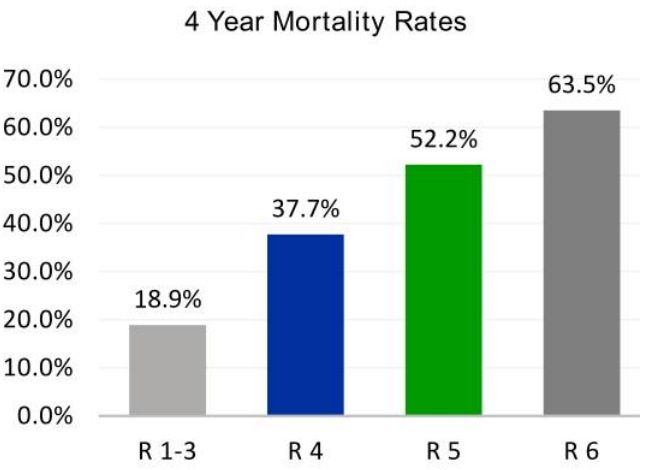
*Europe: 

Source: Independent Third-party analysis; Full report available upon request

# CLI amputation and mortality rates increase with disease severity

Retrospective outcomes analysis based upon
Rutherford (“R”) classification (n=41,882)



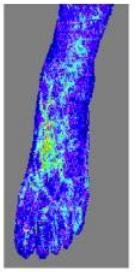

R 1-3: CLI-free
R 4: Debilitating rest pain
R 5: Minor tissue loss non-healing ulcer; focal gangrene with diffuse pedal ischemia
R 6: Functional foot no longer salvageable

Source: Reinecke H., European Heart Journal, 2015 Apr 14;36(15):932-8

# Single CD34+ cell therapy administration appears to reverse CLI

Actual CLI Patient
Laser Doppler Imager

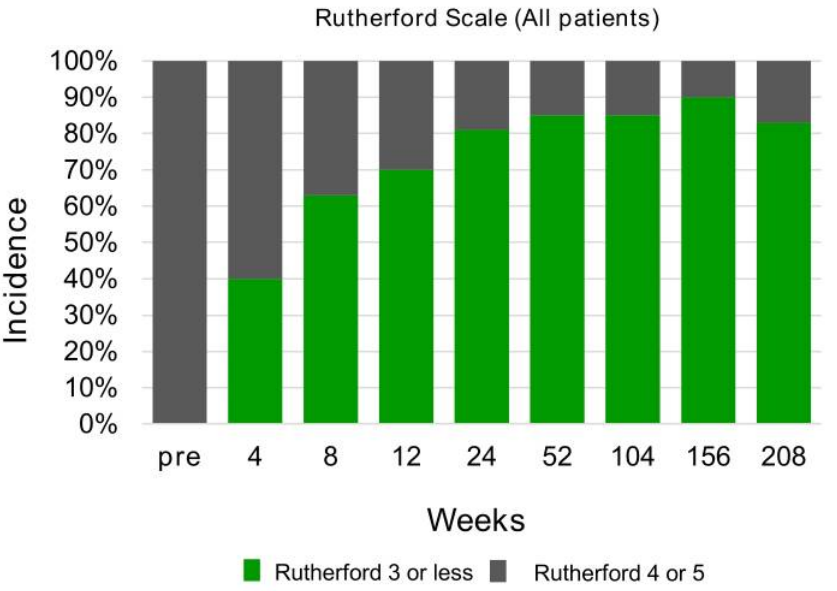
Before Treatment



Week 12 Post-treatment

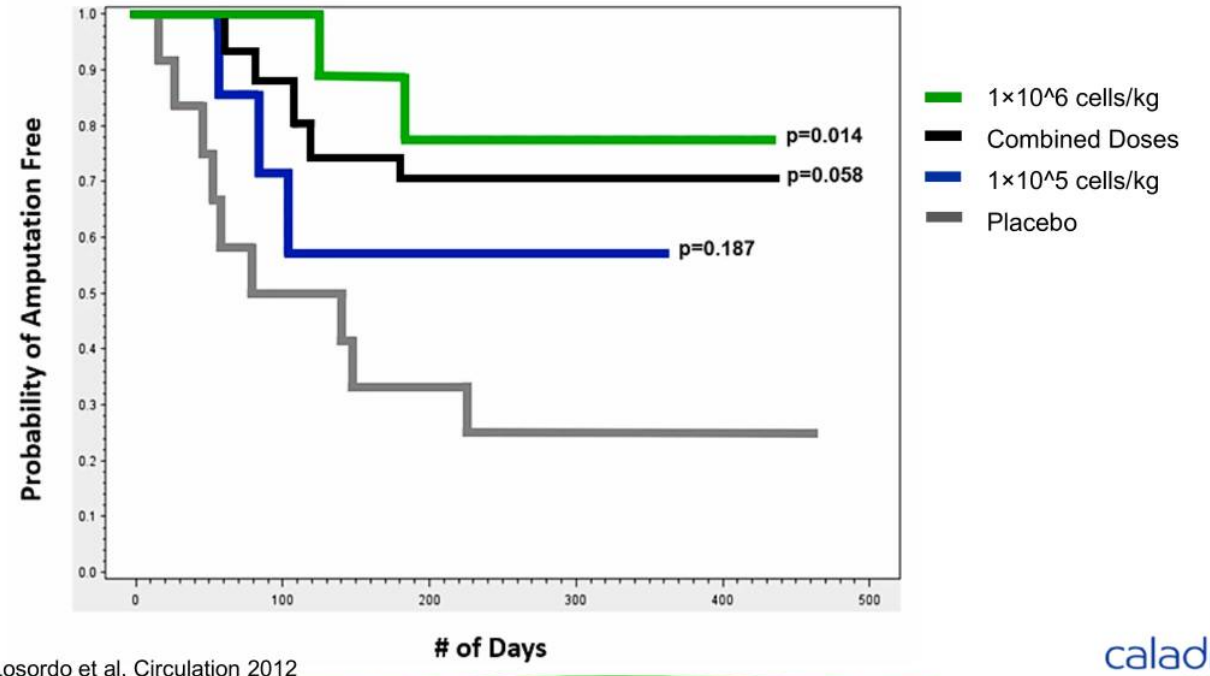
Source: Kinoshita et al, Atherosclerosis 2012

Single Center, Open-Label, Dose-Escalation Clinical Trial (n=17) - Jap



# Single CD34+ cell therapy administration increases amputation free surviva

Double-blind, Randomized, Placebo-controlled Clinical Trial (n=28)



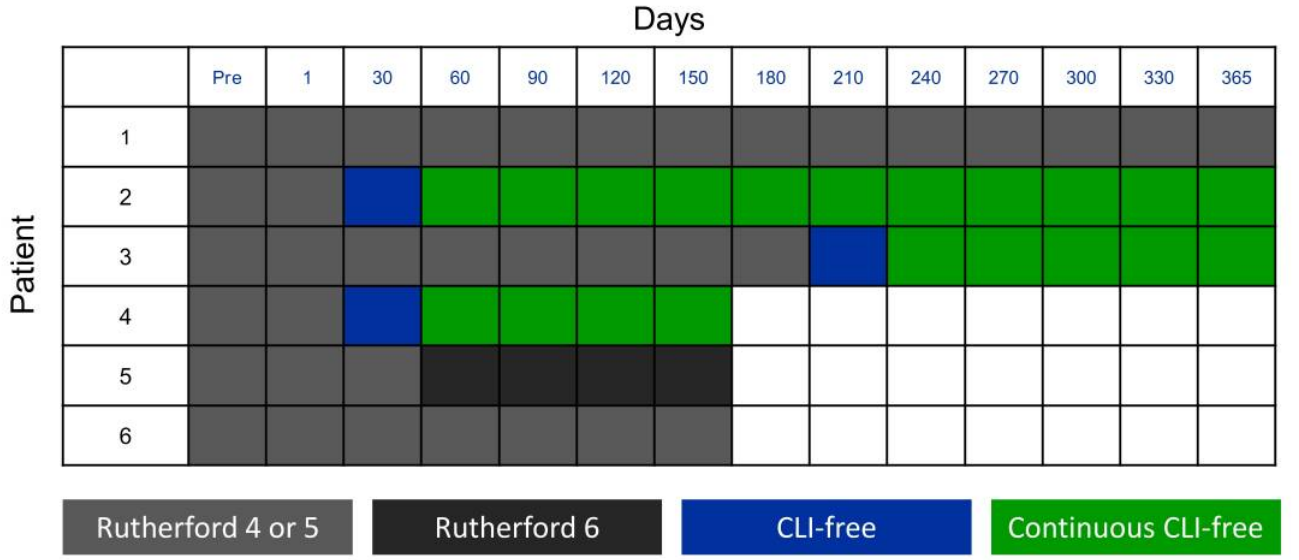

Source: Losordo et al, Circulation 2012

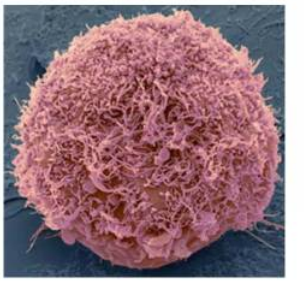
## CLBS12 eligible for early conditional approval in Japan based on ongoing s
## Awarded SAKIGAKE ("breakthrough") designation with priority review

| | |
|---|---|
| Design | ▪ Prospective, open label, controlled, randomized trial (1:1 w/SOC) CLI patients |
| Primary Endpoint | ▪ Time to continuous CLI-free status (2 consecutive monthly visits, adjudicated independe |
| Study Size | ▪ 30 patients with no-option CLI plus 5 patients with Buerger's Disease; ~10 centers in Ja |
| Dose | ▪ Up to $10^6$ autologous CD34+ cells/kg (CLBS12) per affected limb |
| Control/Comparator | ▪ Standard of Care drugs approved in Japan<br>  ▪ Including antiplatelets, anticoagulants and vasodilators<br>▪ Choice of pharmacotherapy will be made by the investigators according to protocol |
| Mode of administration | ▪ Intramuscular, 20 injections in affected lower limb in single administration |
| Timing/Cost | ▪ Top-line results expected 1H2020<br>▪ Study funded to completion in current budget projections |

# Preliminary Buerger's Disease cohort results in Japan are compelling

- Natural progression of Buerger's Disease is continual progression
- CLBS12 treatment has resulted in 50% of patients achieving a positive outcome to date





# CLBS14-CMD

## Coronary Microvascular Dysfunction (CMD)

(USA)

# CMD is an unmet medical need with significant market potential

- Nearly 50% of patients with Coronary Artery Disease have a CMD component
- Multi-billion dollar global opportunity based on significant pharmaco-eco benefit

## Patients Potentially Eligible for CLBS14-CMD

| USA[1] | Europe[2] | Japan[3,4] |
|---|---|---|
| ~8,300,000 | ~6,000,000 | ~1,000,000 |

Europe: 

[1]Cleveland Clinic/AHA (American Heart Association)
[2]Townsend, N, et al.; Cardiovascular disease in Europe: epidemiological update 2016, EHJ, Volume 37, Issue 42, 7 November 2016, Pages 3232-
[3]Kita, T; Coronary heart disease risk in Japan – an East/West divide?, EHJ Supplements, Volume 6, Issue suppl_A, 1 March 2004, Pages A8–A1
[4]Ueshima, H, et al.; Cardiovascular Disease and Risk Factors in Asia, AHA Journal, December 16/23, 2008, Volume 118, Issue 25

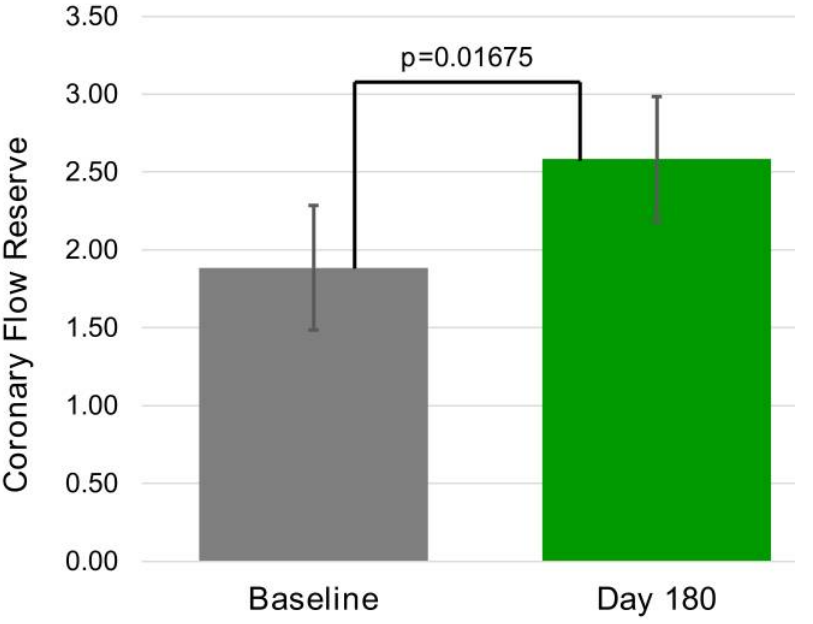
# CLBS14-CMD proof-of-concept study (ESCaPE-CMD)

## Enrollment completion expected in May 2019

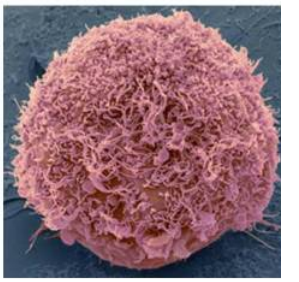
| | |
|---|---|
| Design | ▪ Interventional, open label, proof-of-concept trial |
| Primary Endpoint | ▪ Safety and the evaluation of adverse events |
| Secondary Endpoints | ▪ Changes from baseline to 6 months for coronary flow reserve, endothelial-dependent microvascular function, time to angina; other cardiovascular metrics |
| Study Size | ▪ 20 patients at 2 centers in the USA (Cedars Sinai, LA & Mayo Clinic) |
| Dose | ▪ Up to 300 x $10^6$ CD34+ cells |
| Control | ▪ No control arm |
| Mode of administration | ▪ Single intracoronary infusion |
| Timing/Cost | ▪ Top-line results expected by end of 2019<br>▪ Study funded to completion in current budget projections (NIH grant) |

# Preliminary ESCaPE-CMD results are encouraging

- N=6 (of target 20)
- Coronary flow reserve is defined as the ratio of maximal coronary blood flow to resting coronary blood flow[1]
- Increase in coronary flow reserve correlates with improvement in symptoms
- Complete results expected end of 2019




[1] Collins P. (1993). Coronary flow reserve. British heart journal, 69(4), 279–281.



# CLBS14-NORDA

## No Option Refractory Disabling Angina (NORDA)

(USA)

# NORDA presents a multi-billion dollar global market opportunity

- Currently, there are no effective treatments options for NORDA
- Patients with NORDA often have multiple costly comorbidities

Patients Eligible for CLBS14-NORDA

| USA | Europe | Japan |
|---|---|---|
| <100K | ~50K | ~30K |

Europe: 

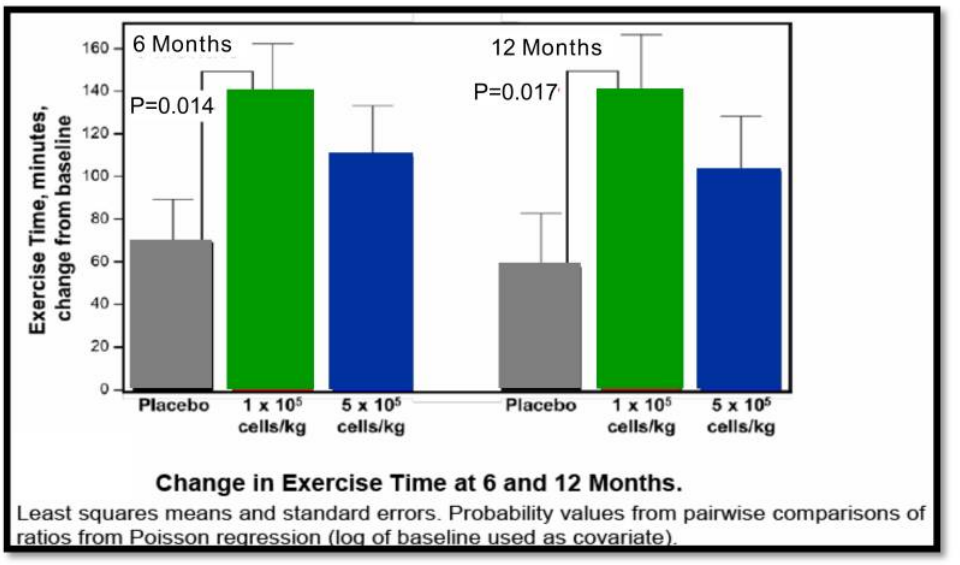
Source: Independent Third-party analysis; Full third-party report available upon request

## CLBS14-NORDA Phase 3 development status

- Data license obtained from Shire for previous clinical studies
  - Avoids need to repeat previous work and positions program in Phase 3
  - CLBS owns IP for product
- CLBS holds an open and active IND
- RMAT (Regen. Medicine Advanced Therapy) designation awarded 2Q18
  - Granted by the FDA for therapies intended to treat serious conditions
  - Therapy must show preliminary evidence of addressing unmet medical need
  - Similar to breakthrough therapy designation; includes potential for accelerated app
- Phase 3 protocol design discussions reaching conclusion with FDA
  - Finalization expected 2Q19 with first patient targeted for fall 2019

# Single administration of CLBS14-NORDA improves exercise time

Compelling results from the randomized, placebo-controlled, double blind Phase 2 Study (n=16



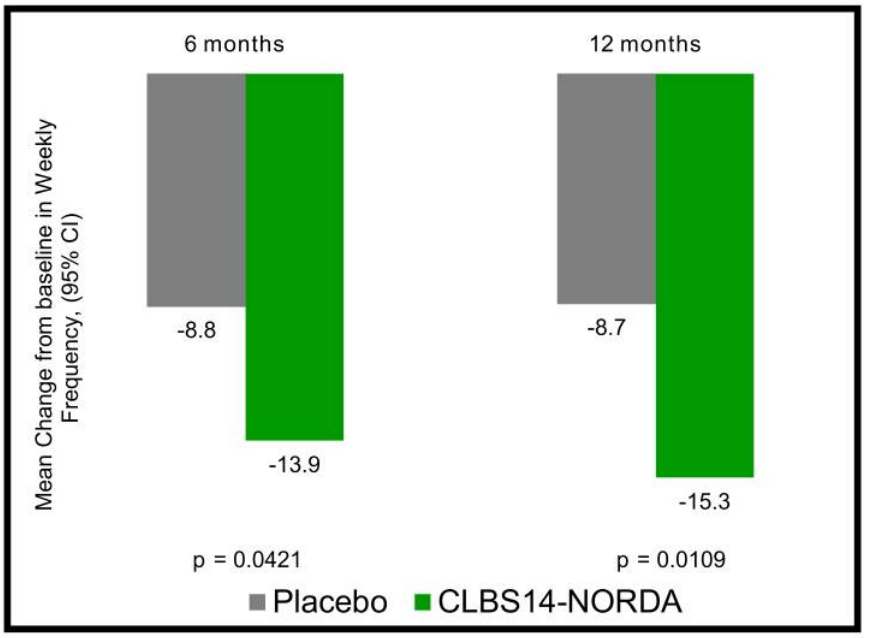

**Change in Exercise Time at 6 and 12 Months.**

Least squares means and standard errors. Probability values from pairwise comparisons of ratios from Poisson regression (log of baseline used as covariate).

Source: Losordo, D.W., et al., Circ Res, 2011

# Single administration of CLBS14-NORDA reduces angina frequency

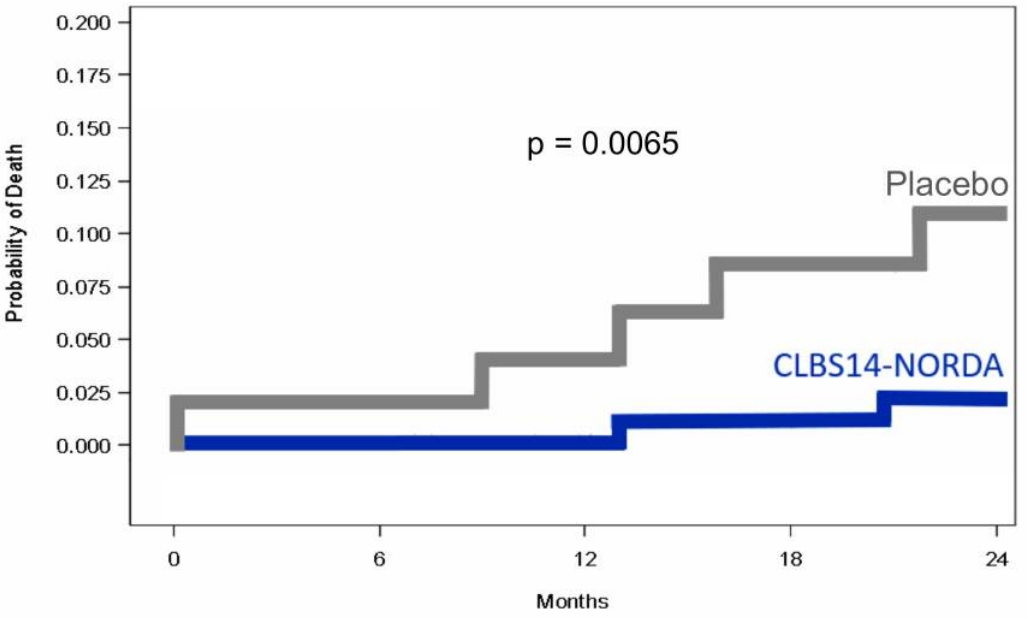
Compelling results from the randomized, double blind, placebo-controlled, Phase 2 Study (n=1




Source: Losordo et al, Circ Res 2011

# Single administration of CLBS14-NORDA reduces mortality

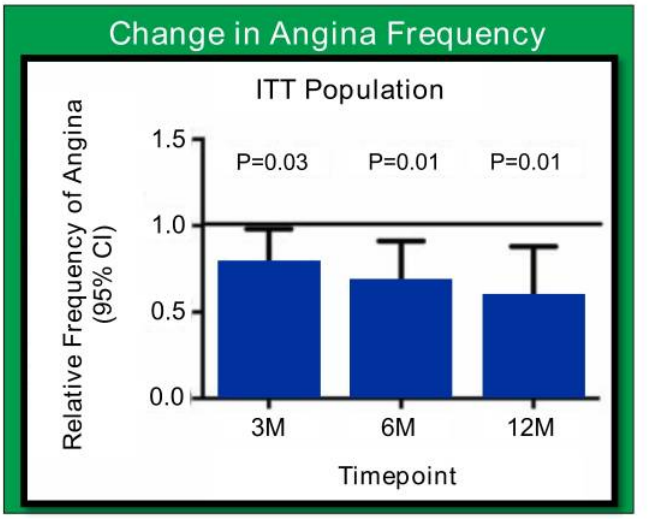
Compelling results of the randomized, double blind, placebo-controlled, Phase 2 Study (n=16




Source: Losordo, Circ Res 2011

# Combined CLBS14-NORDA clinical database corroborates success potenti

- Phases 1, 2, & partial 3 studies[1,2,3] completed (combined n=304)
- Two independent compelling patient-level pooled-analyses:
  - European Heart Journal, January 2018 (Henry, et al)
  - Cardiovascular Revascularization Medicine, June 2018 (Velagapudi, et al)
- Same NORDA definition in all studies





[1] Losordo, D.W., et al, Circulation, 2007, 115(25) pp. 3165-3172
[2] Losordo, D.W., et al, Circ Res, 2011, 109(4) pp. 428-36.
[3] Povsic, T.J., et al, JACC Cardiovasc Interv, 2016 9(15) pp. 1576-85.

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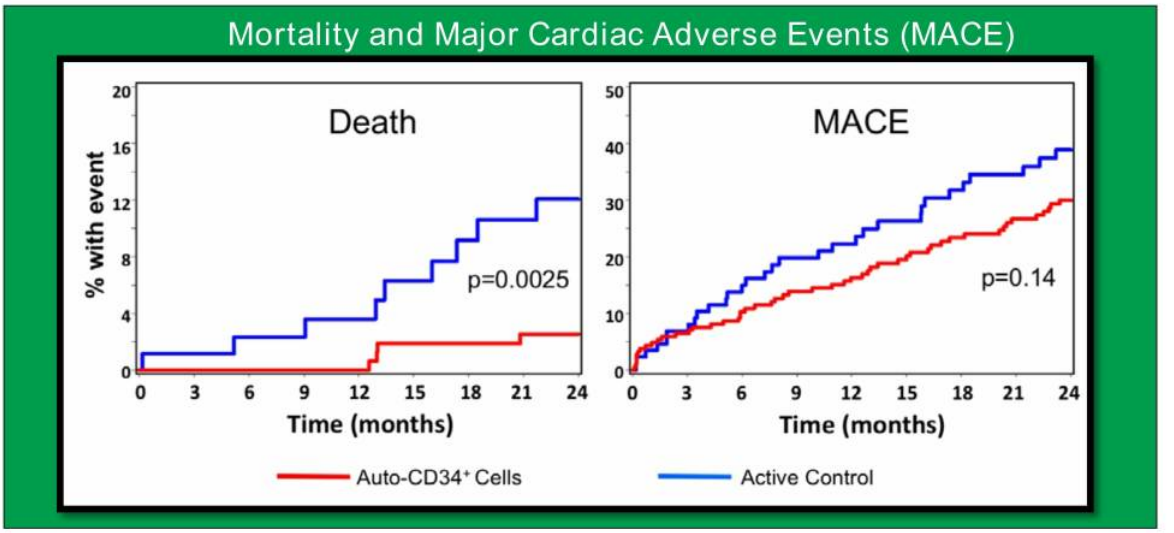


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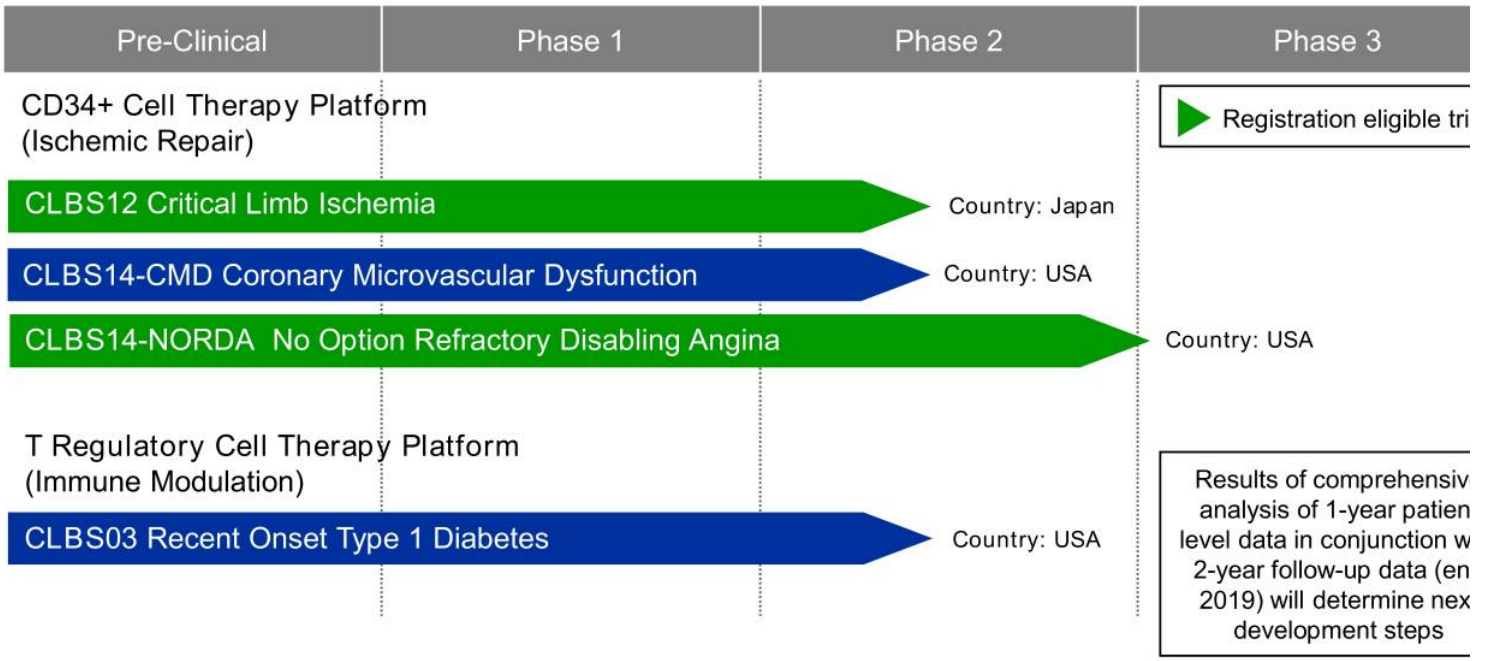
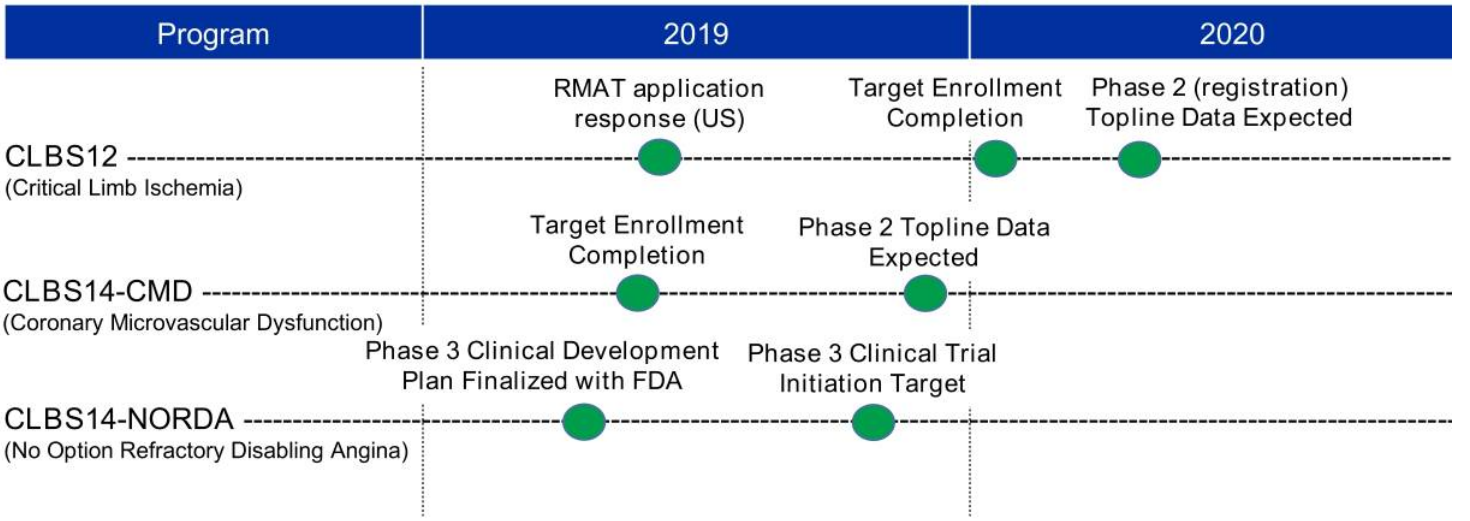
[3] Povsic, T.J., et al, JACC Cardiovasc Interv, 2016 9(15) pp.1576-85

# Multi-product pipeline based on proprietary technology platforms



# Timeline of key development milestones by project



## Key CLBS financial information

| | |
|---|---|
| Cash & Investments at December 31, 2018 | $43m |
| 2018 Operating Cash Burn | $20m |
| Cash Runway Based on Current Plan<br>(Including CLBS14-NORDA Clinical Initiation Costs) | through May 2020 |
| Debt | $0 |
| Common Shares Outstanding at December 31, 2018 | ~9.9m shares |
| Options Outstanding:<br>Exercise Price < $5.00 = 476,000 shares<br>Exercise Price < $10.00 = 139,000 shares<br>Exercise Price > $10.00 = 403,000 shares | ~1m shares |

## Caladrius Biosciences: Uniquely positioned for near-term success

- Late-stage therapeutics development company
  - Three principal development programs; 2 designated “breakthroug
    - CLBS12*, CLBS14-CMD, CLBS14-NORDA*
- Financially stable and debt-free
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  - Key regulatory and data milestones across the pipeline

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BIOSCIENCES

NASDAQ: CLBS

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