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 18, 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, Second 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	CLBS	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

o Emerging growth company

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.

Item 7.01 Regulation FD Disclosure.

On November 16, 2019, Caladrius Biosciences, Inc. (the "Company") issued a press release in connection with its presentation at the American Heart Association Scientific Sessions in Philadelphia, PA on the same date. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 7.01 by reference.

A copy of a slide presentation that Caladrius Biosciences, Inc. (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 Item 7.01, including Exhibit 99.1 and Exhibit 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, or otherwise subject to the liabilities of that Section. The information in this Item 7.01, including Exhibit 99.1 and Exhibit 99.2 attached hereto, shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, except as otherwise expressly stated in such filing.

Item 9.01. Financial Statement and Exhibits.

Exhibit No.	Description
99.1	Press release, dated November 16, 2019
99.2	Caladrius Biosciences, Inc. Corporate Presentation, November 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.

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

Dated: November 18, 2019

Exhibit 99.1

Caladrius Biosciences Reports Positive Results for CLBS16 from the ESCaPE-CMD Trial at American Heart Association Scientific Sessions 2019

Single administration of CLBS16 durably improves heart function and symptoms with no cell-related adverse events

CLBS16 cell therapy shows promise as a significant advancement in treatment of Coronary Microvascular Dysfunction (CMD), a condition that disproportionately afflicts women

PHILADELPHIA (November 16, 2019) - Caladrius Biosciences, Inc. (Nasdaq: CLBS), a late-stage biopharmaceutical company focused on developing treatments for select cardiovascular diseases, along with researchers from Cedars-Sinai (Los Angeles), Mayo Clinic (Rochester, Minn.) and The Christ Hospital (Cincinnati), today presented results from the ESCaPE-CMD trial of Caladrius's autologous CD34+ cell therapy, CLBS16, at the American Heart Association Scientific Sessions 2019. Data showed highly statistically significant improvement in coronary flow reserve correlating with symptom relief for patients with coronary microvascular dysfunction after a single intracoronary injection of CLBS16. The results for patients who have completed the six-month follow-up to date (17 of 20) were presented, with the results from the remaining patients expected by the end of 2019.

"CLB16 represents a potential breakthrough for the treatment of CMD, a condition that affects millions in the U.S. and that disproportionately afflicts women. This is the first time that a therapy has shown the ability to durably increase coronary flow reserve and potentially reverse CMD after a single dose. These reported results clearly support the premise that manageable cell-based tissue regeneration is possible in patients with CMD," said David J. Mazzo, Ph.D., President and CEO of Caladrius. "The reported results from the ESCaPE-CMD trial bring us one step closer to realizing the promise of CD34+ cell therapy to augment microvasculature in the heart enabling the restoration of health rather than simply management of disease."

Trial investigators observed that patients experienced a highly statistically significant (p=0.0087) increase in coronary flow reserve after a single intracoronary administration of CLBS16. The trial also evaluated changes from baseline to six months in chest pain frequency, Canadian Cardiovascular Society angina classification and Seattle Angina Questionnaire scores. A single administration of CLBS16 resulted in statistically significant improvements in all these measures of patient symptoms and function.

"Coronary microvascular dysfunction is becoming increasingly recognized as a major health problem that disproportionately affects women. Unfortunately, there are no currently available therapies that directly target this condition. The reported data from this study provide objective evidence that CD34+ cell therapy results in long-lasting improvement in microvascular function, something that has not been shown with any other therapy to date," said Timothy D. Henry, M.D., Medical Director of the Carl and Edyth Lindner Center for Research at The Christ Hospital Health Network. "The CLBS16 program has demonstrated real promise and I am looking forward to seeing Caladrius further develop this new therapeutic option for CMD patients."

The ESCaPE-CMD [1] trial is an interventional, proof-of-concept study designed to evaluate the effect of Caladrius's autologous CD34+ cell therapy (CLBS16) on CMD symptoms and indicators while also evaluating treatment

[1]Funding for the Phase 2 ESCaPE-CMD study came, in part, from a $1.9 million grant from the National Institutes of Health under award number R44 HL135889. The content of this press release is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

tolerance. The key endpoint was measurement of the change from baseline of coronary flow reserve, a direct measure of microvascular function, at six months following a single injection of CLBS16. The trial completed enrollment of the targeted 20 patients in May of 2019. The study's three principal investigators are Dr. C. Noel Bairey Merz, Cedars-Sinai, Dr. Timothy D. Henry, The Christ Hospital, and Dr. Amir Lerman, Mayo Clinic. All patients received a single infusion of their own GCSF-mobilized CD34+ cells formulated as CLBS16.

"CMD patients often are frustrated and in despair due to unresolved symptoms even after exhausting all other available therapies. These data indicate that the naturally-occurring CD34+ repair cell could provide a durable improvement in symptoms and reduced risk of adverse cardiovascular outcomes," said Douglas W. Losordo, M.D., FACC, FAHA, Chief Medical Officer at Caladrius. "We are extremely encouraged by these results from the trial and look forward to advancing the development of CLBS16 expeditiously with the goal of one day soon helping the large and underserved population of patients suffering from CMD."

Results from the six-month follow-up of the remaining treated patients will be available by year-end 2019.

About Coronary Microvascular Dysfunction
Coronary microvascular dysfunction is a type of non-obstructive coronary artery disease that causes decreased blood flow to the heart muscle that affects approximately 8.3 million[2,3] people in the U.S. With common symptoms such as recurring, debilitating chest pain, tiredness, and shortness of breath, many CMD patients are undiagnosed because of the absence of large vessel obstruction. Due to a misunderstanding of the disease, patients, the majority of whom are women, often go years without proper treatment. When a diagnosis of CMD is missed, patients are untreated and remain at high risk of heart attack and/or cardiovascular-related death.

About Caladrius Biosciences
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 Japan and advanced therapy medicinal product classification (ATMP) in Europe, eligible for early conditional approval for the treatment of critical limb ischemia in Japan based on an ongoing clinical trial; CLBS16, subject of the proof-of-concept ESCaPE-CMD clinical trial in the U.S.A. for the treatment of coronary microvascular dysfunction; and CLBS14, a Phase 3 ready clinical program in no option refractory disabling angina and recipient of a RMAT designation in the U.S.A. For more information on the company, please visit www.caladrius.com

Safe Harbor for 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 including, without limitation, all statements related to any expectations of revenues, expenses, cash flows, earnings or losses from operations, cash required to maintain current and planned operations, capital or other financial items; any statements of the plans, strategies and objectives of management for future operations; any plans or expectations with respect to product research, development and commercialization, including regulatory approvals; any other statements of expectations, plans, intentions or beliefs; and any statements of assumptions underlying any of the foregoing. Without limiting the foregoing, the words "plan," "project," "forecast," "outlook," "intend," "may," "will," "expect," "likely," "believe," "could," "anticipate," "estimate," "continue" or similar expressions or other variations or comparable terminology are intended to identify such forward-looking statements, although some forward-looking statements

[2]Mittal, S.R.; Indian Heart Journal, Volume 66, 2014, Pages 678-681
[3]Cleveland Clinic/AHA (American Heart Association)

are expressed differently. 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 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 Press Release. Caladrius does not intend, and disclaims any obligation, to update or revise any forward-looking information contained in this Press Release or with respect to the matters described herein.

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BIOSCIENCES

Advancing Restorative Therapies to Treat Ischemic Disease

David J. Mazzo, PhD
President and Chief Executive Officer

November 2019 |

Forward-looking statement

This Investor Presentation contains forward-looking statements within the meaning of the Priva Securities Litigation Reform Act of 1995. Forward-looking statements reflect management current expectations, as of the date of this presentation, and involve certain risks ar uncertainties. All statements other than statements of historical fact contained in this Invest Presentation are forward-looking statements. The Company's actual results could diff materially from those anticipated in these forward-looking statements as a result of variou factors. Factors that could cause future results to differ materially from the recent results or thos projected in forward-looking statements include the "Risk Factors" described in the Company Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") o March 14, 2019, as subsequently amended on March 19, 2019, and in the Company's oth periodic filings with the SEC. The Company's further development is highly dependent o among other things, future medical and research developments and market acceptance, whic are outside of its control. You are cautioned not to place undue reliance on forward-lookin statements, which speak only as of the date of this Investor Presentation. Caladrius does n intend, and disclaims any obligation, to update or revise any forward-looking informatio contained in this Investor Presentation or with respect to the matters described herein.

Presentation contents

- Investment case summary
- Management team introduction
- CD34+ cell therapy platform technology overview
- Pipeline description and individual program summaries
- Financial overview
- Milestone timeline
- Conclusion

Caladrius investment case summary

- CD34+ cell therapy platform company with an advanced clinical pipeline two programs with cell therapy “breakthrough” designation
- Proprietary field-leading technology in multi-billion dollar global indicatio backed by a strong IP portfolio
- Multiple potential value creating events in the next 12 months based on development milestones across the pipeline
- Seasoned management team with noteworthy domain expertise along w big pharma and emerging biotech experience
- Strong balance sheet; $29.2 million in cash (September 30, 2019) with r debt and cash runway projected into 2021

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Caladrius management team

David J. Mazzo, PhD

President and
Chief Executive Officer

RegadoBiosciences
CHUGAI
Schering-Plough
Hoechst
RHÔNE-POULENC RORER

Douglas Losordo, MD

EVP, Global Head of R&D
and Chief Medical Officer

Baxter
Northwestern Medicine
Feinberg School of Medicine
Tufts University | School of Medicine

Joseph Talamo, CPA

Senior VP and
Chief Financial Officer

(OSI) pharmaceuticals
Bristol-Myers Squibb
KPMG

Todd Girolamo, JD

Senior VP, General Counsel
and Corporate Secretary

100 years CAHILL
Thelen Reid & Priest LLP
Attorneys At Law
OPPENHEIMER
CIBC

John Mendit

Vice President, IR
Corporate Communic

Argos Therapeutics
medco
NOVART

Note: Select experience is shown above. For a comprehensive bio, please visit: www.caladrius.com

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Esteemed cardiovascular disease scientific advisory board

C. Noel Bairey Merz, MD
Cedars-Sinai, Los Angeles

C. Michael Gibson, MD
Harvard Medical School

Timothy Henry, MI
The Christ Hospital, Cincinn

Thomas Povsic, MD, PhD
Duke Clinical Research Institute

Richard Schatz, MD
Scripps Clinic, San Diego

Christopher White,
Ochsner Health, New Orlea

Joseph Wu, MD, PhD
Stanford Cardiovascular Institute

Andreas Zeiher, MD
Goethe University, Frankfurt

Zan Fleming, MD
Executive Chairman, Kinexu

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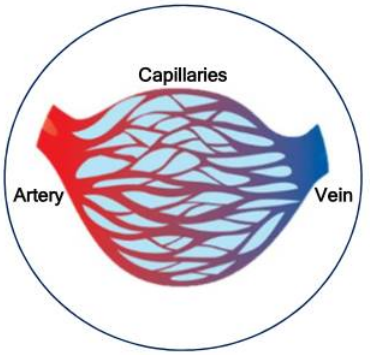
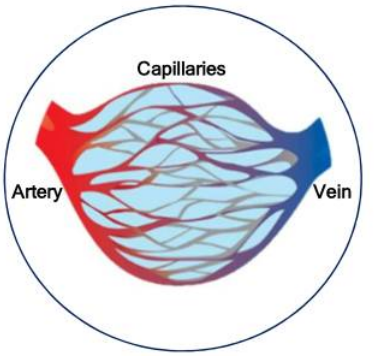
CD34+ cell therapy platform technology overview

CD34+ cells have a well characterized mechanism of action

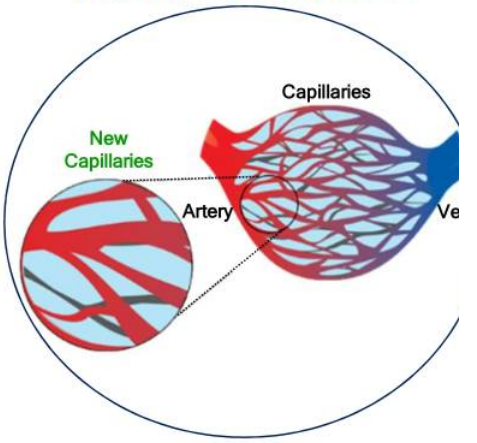
Normal microvasculature



Compromised microvasculature



Augmented microvasculature post-CD34+ cells treatment



- Naturally occurring vascular repair (endothelial progenitor) cell
- Provokes restorative angiogenesis of the microvasculature
- CD34+ cells reestablish blood flow to under-perfused tissues[1,2]

[1]Mackie, A.R. et al., Tex Heart Inst J 2011, 38(5), 474-485
[2]Kocher, A.A. et al., *Nat Med* 2001, 440-436

CD34+ cell therapy is extensively studied/clinically validated

- CD34+ cells were clinically studied in multiple ischemic disease indications by numerous investigators across many sites and countries

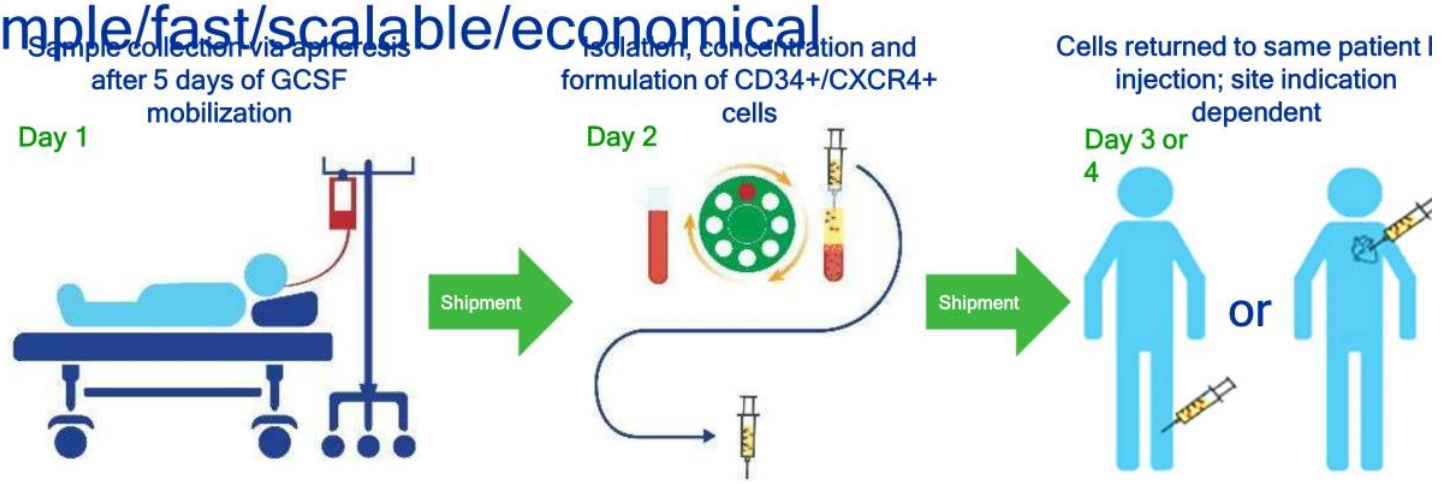
- Consistent and compelling results of rigorous clinical studies comprising >1,000 patients have been published in peer reviewed journals[1,2,3,4]

- Single treatment has elicited durable therapeutic effect

- No cell-related adverse events reported to date

[1] Povsic, T. et al. *JACC Cardiovasc Interv*, 2016, 9 (15) 1576-1585
[2] Losordo, D.W. et al. *Circ Cardiovasc Interv*, 2012; 5:821-830
[3] Velagapudi P, et al, *Cardiovas Revasc Med*, 2018, 20(3):215-219
[4] Henry T.D., et al. *European Heart Jour*2018, 2208-2216

Caladrius CD34 process is simple/fast/scalable/economical



- GCSF mobilization eliminates need for surgical bone marrow aspiration
- No genetic manipulation or *ex vivo* expansion of cells
- Four days or less from donation to treatment
- Cost-of-goods an order of magnitude less expensive than CAR-T therapies

Caladrius CD34 technology has robust intellectual property

Fundamental protection to 2031+

9
U.S. patents granted

23
Foreign patents granted

Key Claims

- Pharmaceutical composition of non-expanded CD34+/CXCR4+ stem cells
- Therapeutic concentration range
- Stabilizing serum
- Repair of injury caused by vascular insufficiency

Caladrius innovative CD34+ cell therapy pipeline*

Product	Indication	Development Stage	Commercializati Target
CLBS12	CLI	Registration eligible Phase 2 *(Japan; ongoing)*	2021
CLBS16	CMD	Proof-of-concept *(USA; ongoing)*	TBD
CLBS14 *funding)*	NORDA	Phase 3 confirmatory *(USA; initiation pending*	TBD

CLI = Critical Limb Ischemia
CMD = Coronary Microvascular Dysfunction
NORDA = No Option Refractory Disabling Angina

*Products are distinct and n
interchangeab

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CLBS12
Critical Limb Ischemia
(Japan)
SAKIGAKE designated - Japan
Advanced Therapeutic Medicinal Product (ATMP) designated - EU
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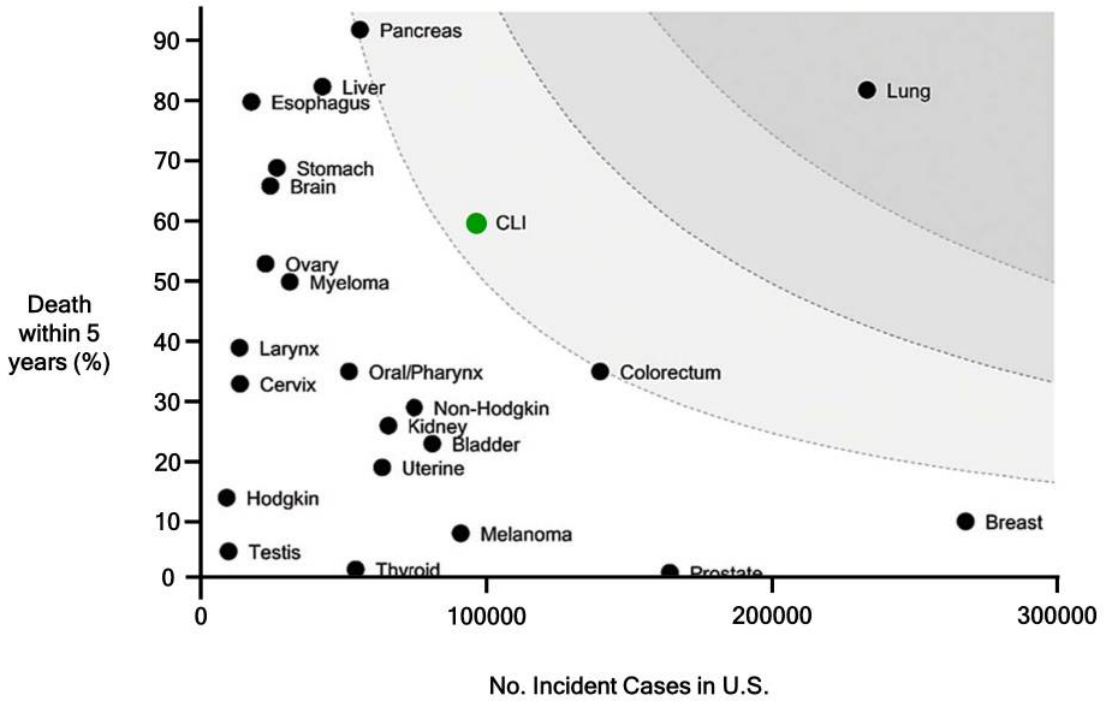
Indication: Critical Limb Ischemia (CLI)

- Severe arterial obstruction impeding blood flow in the lower extremities
  - Often found as a co-morbidity in diabetes patients
  - Includes severe rest pain and non-healing ulcers
- Buerger's disease (inflammation in small and medium arteries) also causes CLI; exacerbated by a history of heavy smoking
- Patients with no-option CLI have persistent symptoms even after bypass surgery, angioplasty, stenting and available pharmacotherapy
- CLI patients are at high risk of amputation and increased risk of death
- Multi-billion dollar global commercial opportunity

CLI: higher mortality rate than most cancers



Mustapha, J. A., Katzen, B. T., et al. (2019, May). Endovascular Today, 18(5), 80-82

CLI amputation rates increase with disease severity[1]

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

CLBS12 targets patients with R4 or R5 disease

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

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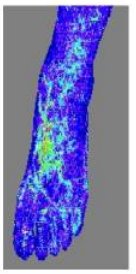
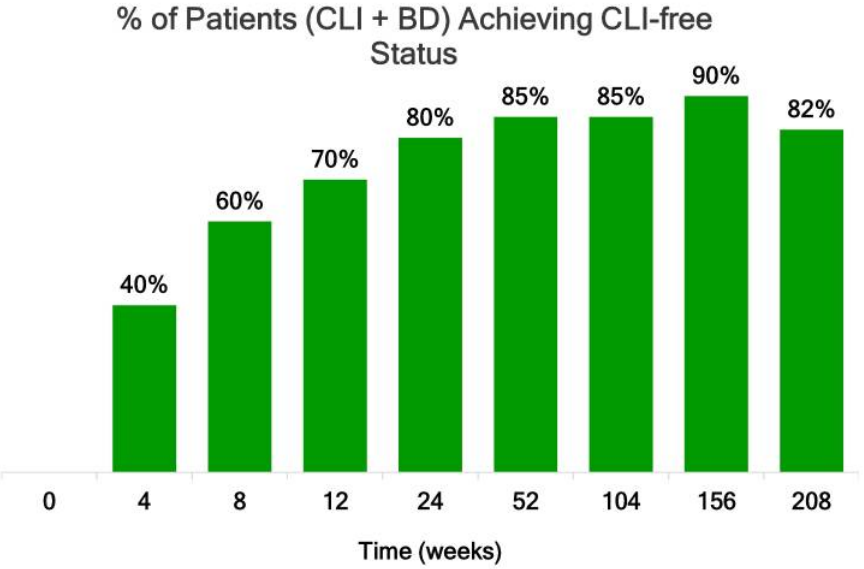
Single treatment of CD34+ cells reversed CLI

Actual CLI Patient Laser Doppler Image

Pre-treatment

Post-treatment (week 12)

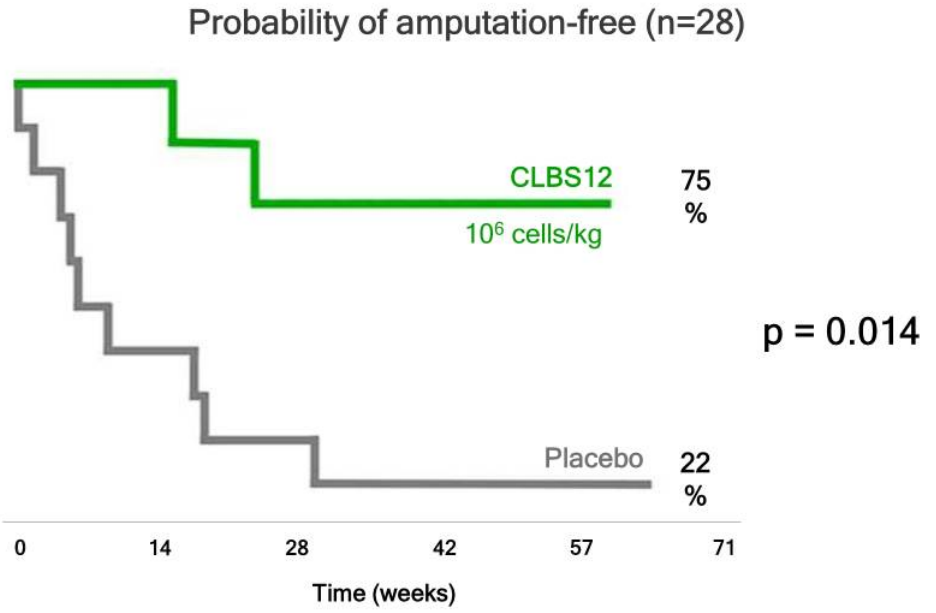




~80% of patients achieved sustainable remission within 6 months of a single treatment; durable for at least 4 years

Kinoshita et al, Atherosclerosis 224 (2012) 440-445

Single treatment of CD34+ cells increased amputation-free survival

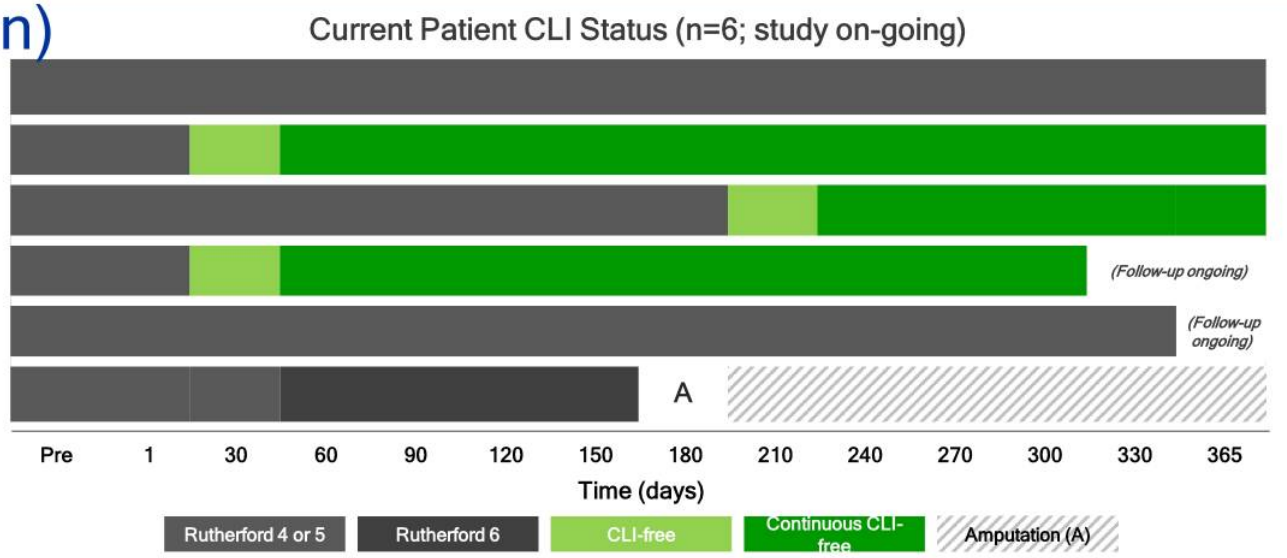


Losordo, D.W. et al, Circulation 2012; 5(6):821-830

CLBS12 registration-eligible study (Japan)

Primary Endpoint	▪ Continuous CLI-free (2 consecutive monthly visits, adjudicated independently)
Study Size	▪ 30 subjects with no-option CLI + 5 Buerger's Disease pts.; all R4 or R5 12 centers in Japan
Dose	▪ 10^6 cells/kg (CLBS12) per affected limb (studied in previous trial)
Control/Comparator	▪ Standard of Care: wound care plus drugs approved in Japan ▪ Including antimicrobials, antiplatelets, anticoagulants and vasodilators
Mode of administration	▪ Intramuscular, 20 injections in affected lower limb in a single treatment
Timing/Costs	▪ Results expected by year end 2020; earliest possible commercializatio 2021 ▪ Study funded to completion in current budget projections

Extraordinary CLBS12 results in Buerger's Disease (Japan)



- Natural evolution of Buerger's Disease is continual deterioration for all patients
- Surgery is not viable and existing pharmacotherapies do not prevent amputation[1]
- To date, CLBS12 treatment has resulted in 50% of patients achieving a positive outcome

[1] Cacione DG, et al, Pharm. treatment of Buerger's Disease, Cochrane Database of Systematic Reviews, 2016, (3) CD011033


CLBS16
Coronary
Microvascular
Dysfunction
(USA)
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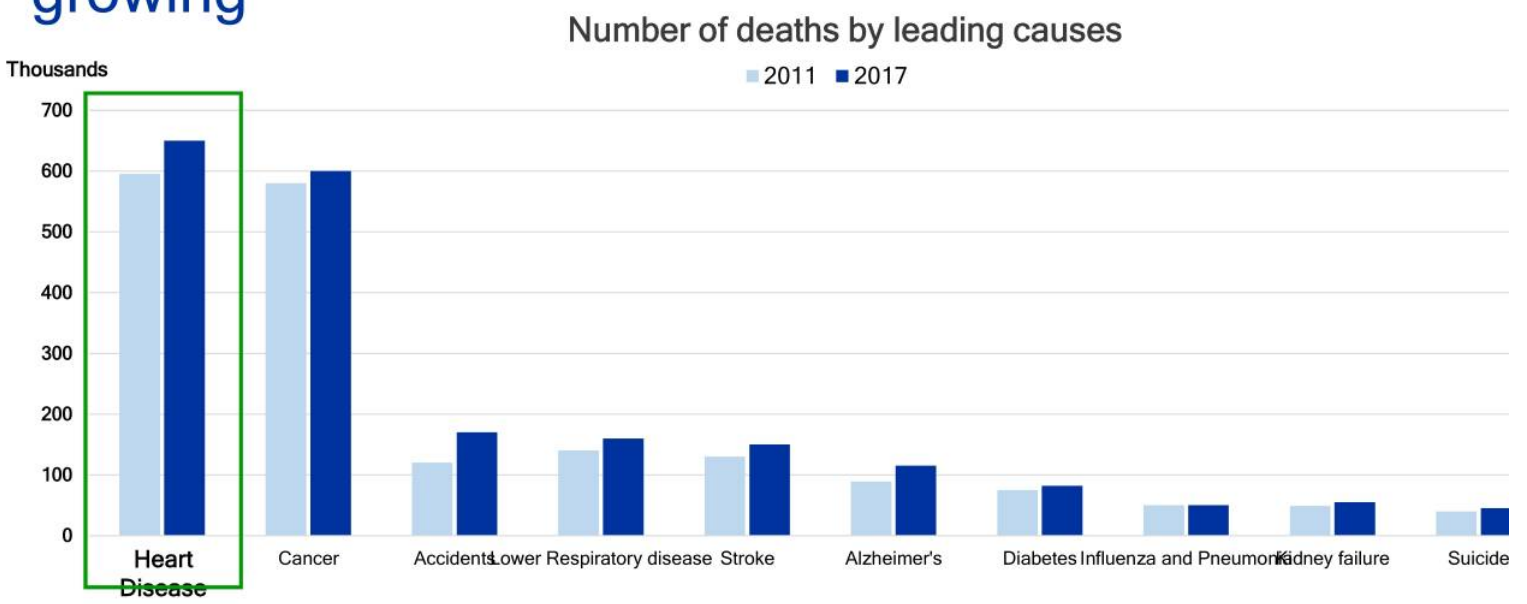
Heart disease: No. 1 cause of death in the U.S. and growing



Source: Centers for Disease Control and Prevention as cited in McKay, Betsy. "Heart-Failure Deaths Rise, Contributing to Worsening Life Expectancy." The Wall Street Journal, 30 Oct. 2019, www.wsj.com/articles/heart-failure-deaths-rise-contributing-to-worsening-life-expectancy-11572411901.

Indication: Coronary Microvascular Dysfunction (CMD)

- Deficient heart microvasculature without obstructive vessel disease
- Causes frequent, debilitating chest pain that is not treatable by stents or bypass; responds poorly or not at all to available medications
- Afflicts women more frequently, especially younger women[1,2]
- Results in poor prognosis for patients with the condition[3]
  - Significantly elevated risk of all-cause mortality in women[4]
- Quantitatively diagnosed using Coronary Flow Reserve (CFR)
  - CFR is the ratio of maximal to resting coronary blood flow[5]
- Multi-billion dollar global commercial opportunity

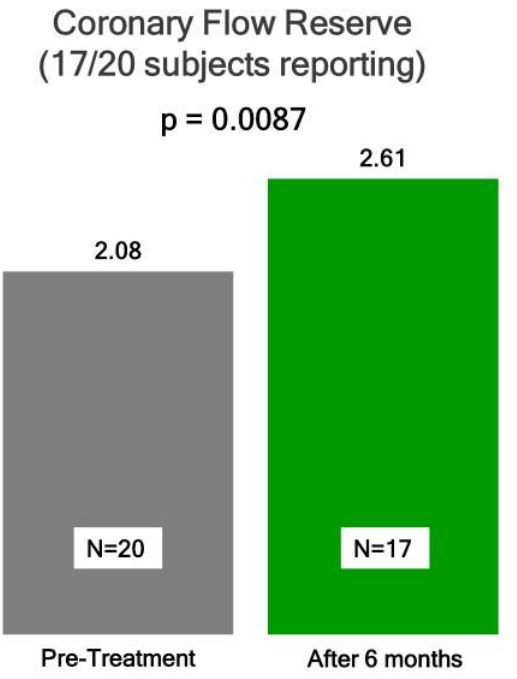
[1] Coronary Microvascular Disease. (2015, July 31). In American Heart Association
[2] R. David Anderson, John W. Petersen, Puja K. Mehta, et al., Journal of Interventional Cardiology, 2019: 8
[3] Loffler and Bourque, Curr Cardiol Rep. 2016 Jan; 18(1): 1
[4] Kenkre, T.S. et al., Circ: CV Qual & Outcomes 2017, 10(12) 1-9
[5] Collins, P., British heart journal (1993) 69(4), 279-281

ESCaPE-CMD: CLBS16 interventional, proof-of-conce trial

Endpoints	▪ Therapeutic effect and the evaluation of adverse events; including cha from baseline to 6 months for coronary flow reserve, endothelial-deper microvascular function, time to angina; other CV metrics
Study Size	▪ 20 subjects (U.S. centers - Cedars Sinai, Los Angeles & Mayo Clinic, Rochester)
Dose	▪ Up to 300 x 10^6 CD34+ cells
Mode of administration	▪ Single intracoronary infusion
Timing/Cost	▪ Positive results reported at AHA on Nov. 16, 2019 (17/20 subjects) ▪ Full results expected by early 1Q 2020 ▪ Study funded to completion in current budget projections (including NIH grant)

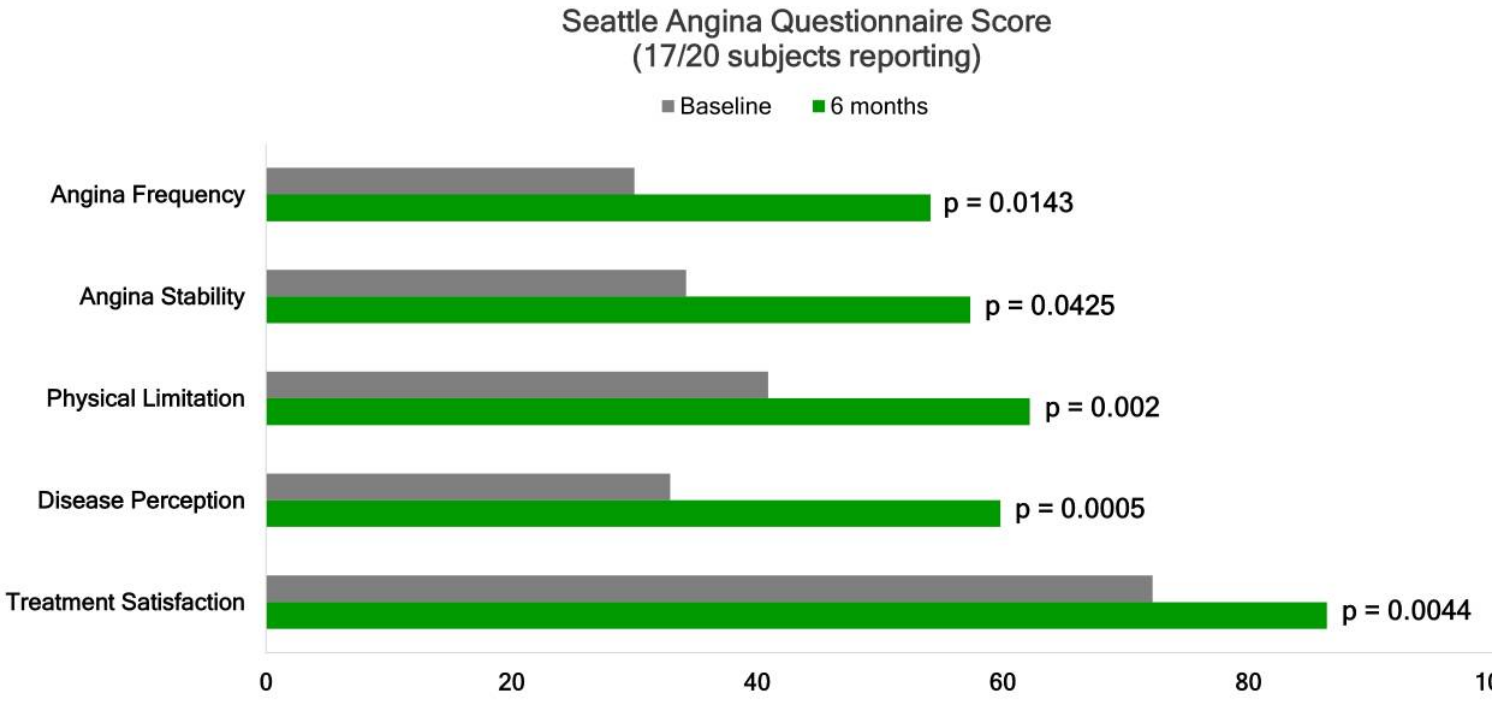
CLBS16 ESCaPE-CMD results are unique and compe

- CFR≤2.5 indicates CMD
- CFR≥2.5 is in “normal” range
- Results after a single intracoronary administration of CLBS16



Bairey Merz, C. N., AHA 2019 Scientific Sessions

CLBS16 ESCaPE-CMD results are unique and compe



ESCaPE-CMD CLBS16 reported results summary

- Statistically significant improvement in heart function and symptoms
- First therapy to show the ability to durably increase CFR and potentially reverse CMD after a single administration
- No evidence of cell related adverse events
- Expected to lead to a decreased risk of adverse cardiovascular outcome including CV-related death, associated with CMD
- Supports microvascular repair mechanism of CD34+ cells across all indications
- Represents a potential breakthrough for the treatment of CMD, a conditi that affects millions in the U.S. and that disproportionately afflicts women

CLBS14

No Option Refractory Disabling Angina

(USA)

Regenerative Medicine Advanced Therapy (RMAT) designated - USA

Indication: No Option Refractory Disabling Angina (NORDA)

- Recurring angina results from chronically impaired cardiac blood supply
- The condition persists even after bypass surgery, angioplasty, stenting and available pharmacotherapy; no current treatment options
- NORDA patients experience very frequent disabling chest pain at rest or with minimal activity
- Cardiac microcirculation deficiency is the remaining treatment targ
- Multi-billion-dollar global commercial opportunity

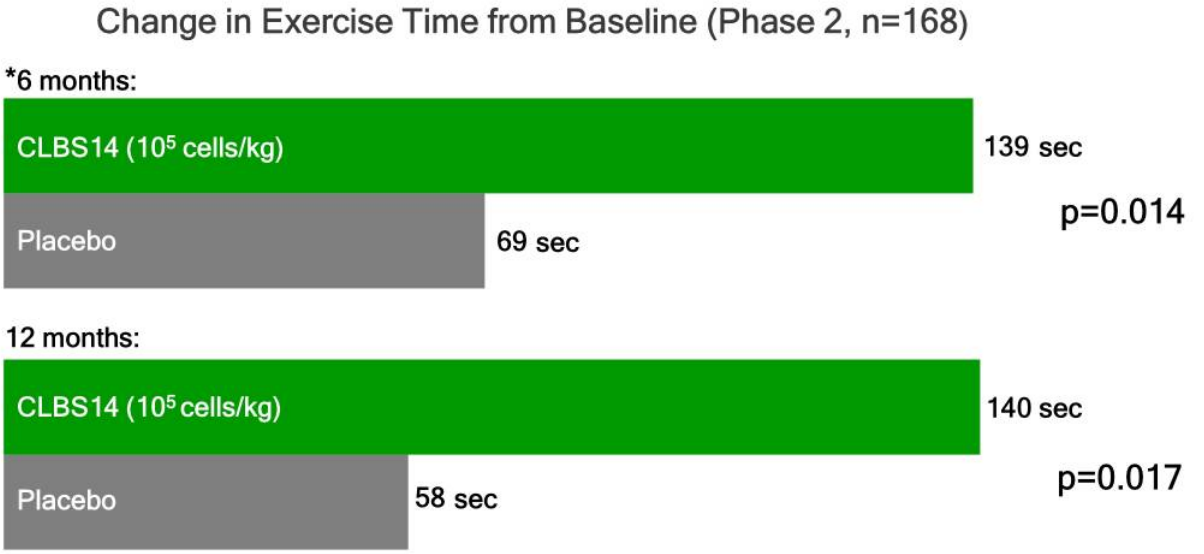
Our solution: CLBS14

- Clinical data from double-blind, randomized, placebo-controlled clir trials, including big pharma sponsored Phase 2 and partial Phase 3[1,2,3,4,5]

- Published results demonstrate:
  - Statistically significant improvement in exercise capacity
  - Statistically significant reduction in angina
  - Statistically significant reduction in mortality
  - Pristine cell safety profile

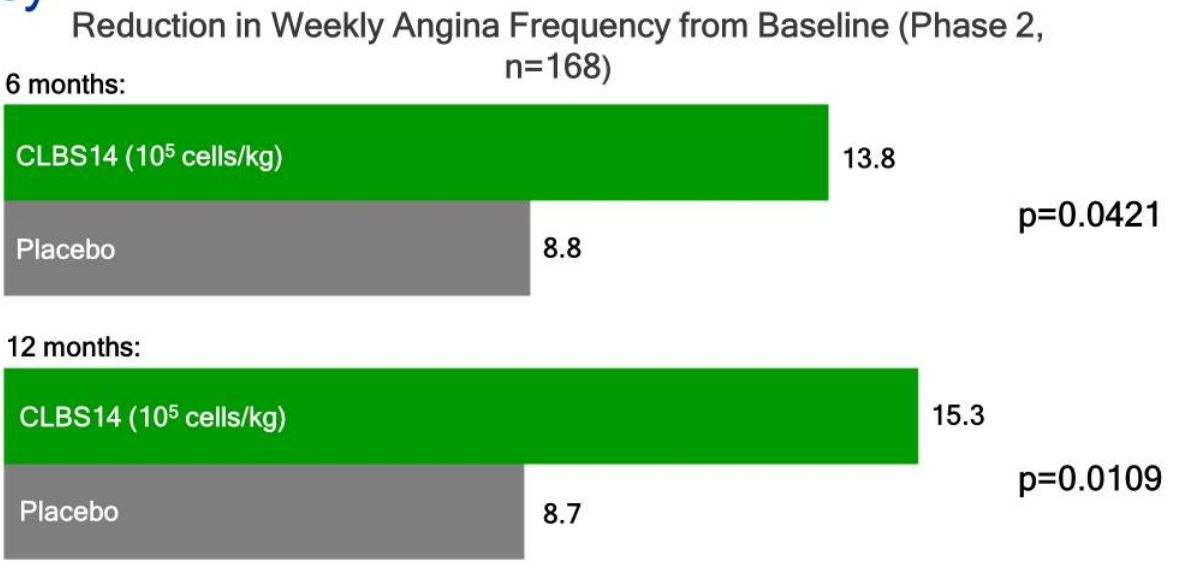
[1] Losordo, D.W., et al, Circulation 2007, 115(25): 3165-72.
[2] Losordo, D.W., et al, Circ Res 2011, 109(4): 428-36
[3] Povsic, T.J., et al, JACC Cardiovasc Interv, 2016 9(15): 1576-85
[4] Povsic, T. J. et al, European Heart Journal, 2018 39(23), 2208-2216
[5] Velagapudi P, et al, *Cardiovas Revasc Med*, 2018, 20(3):215-219

CLBS14 single treatment significantly improved exercis time

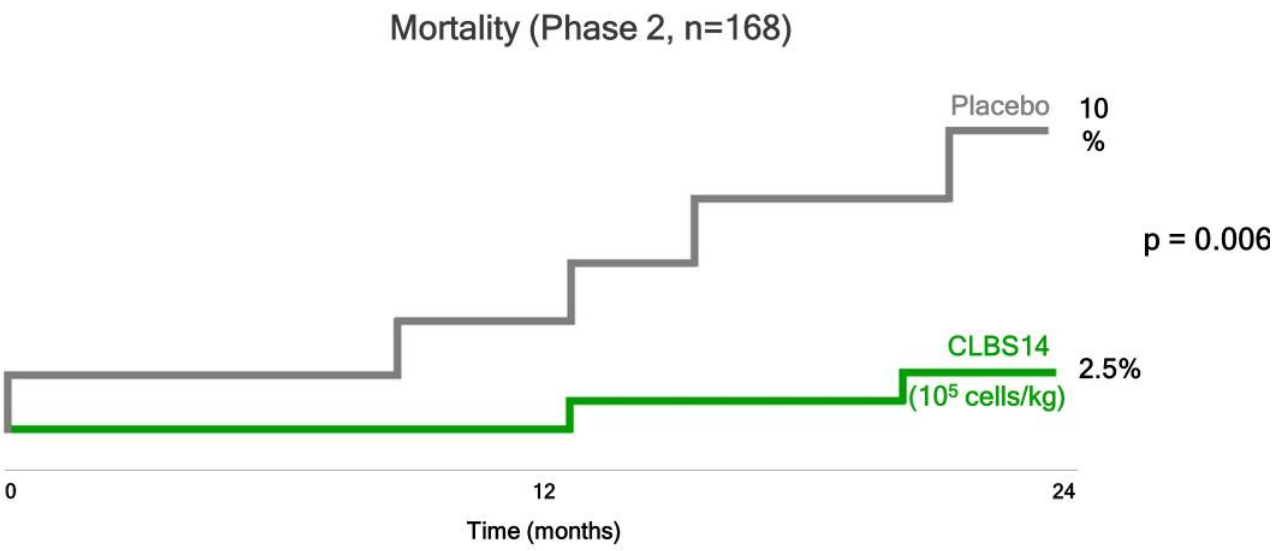


**Change in exercise time from baseline at 6 months will be the Phase 3 primary endpo*

CLBS14 single treatment significantly reduced angina frequency



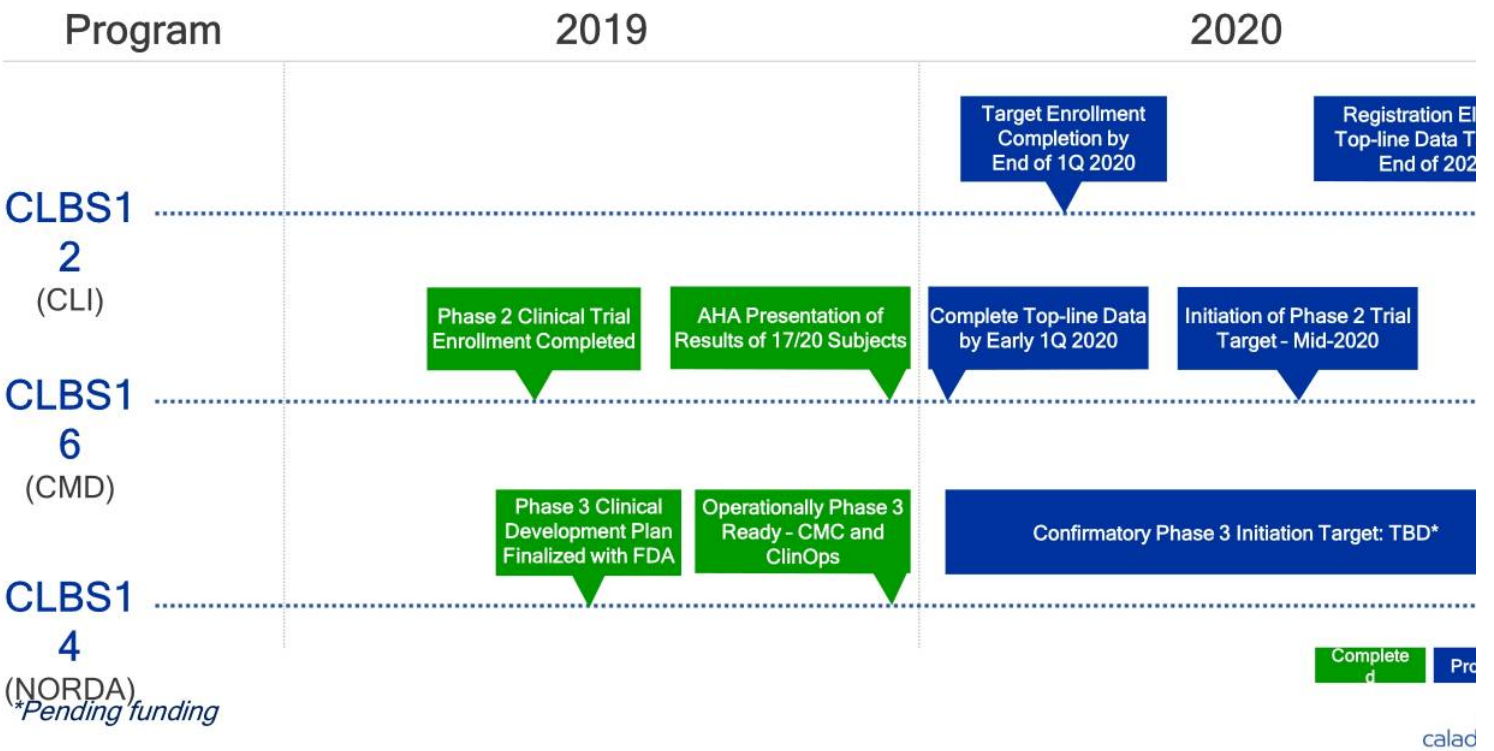
CLBS14 single treatment significantly improved surviva



CLBS14 Phase 3 confirmatory registration study (U.S.)

Primary Endpoint	▪ Change in exercise time from baseline at month 6 (studied in Phase 2
Timing	▪ 39 months from first-patient-in to top-line data; interim analysis after 5 of patients complete 6-month follow-up
Study Size	▪ ~400 subjects (~200 active, ~150 placebo, ~50 SOC with cross-over t open label treatment at 6 months)
Dose	▪ 10^5 cells/kg body weight (studied in Phase 2)
Control/Comparator	▪ Placebo control (blinded) ▪ Standard-of-care (unblinded)
Mode of administration	▪ Intramyocardial injection guided by mapping catheter (NOGA)
Timing/Costs	▪ External costs: ~$70 million over a 3-4 years period ▪ Target initiation: Upon acquisition of sufficient capital that provides confidence that the study could be funded through completion

Caladrius timeline of key development milestones



Caladrius key financial information

Cash & Investments as of September 30, 2019:	$29.2 million
Nine Months Ended September 30, 2019 Operating Cash Burn:	$14.7 million
Cash Runway Based on Current Plan:	Through 1Q 2021
Debt:	$0
Common Shares Outstanding as of September 30, 2019:	10.4 million shares
Options Outstanding as of September 30, 2019: Exercise Price < $5.00 = 647,000 shares Exercise Price > $5.00 = 448,000 shares	1.1 million shares

Caladrius investment case summary

- CD34+ cell therapy platform company with an advanced clinical pipeline two programs with cell therapy “breakthrough” designation
- Proprietary field-leading technology in multi-billion dollar global indicatio backed by a strong IP portfolio
- Multiple potential value creating events in the next 12 months based on development milestones across the pipeline
- Seasoned management team with noteworthy domain expertise along w big pharma and emerging biotech experience
- Strong balance sheet; $29.2 million in cash (September 30, 2019) with r debt and cash runway projected into 2021

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caladrius

BIOSCIENCES

Thank you!

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November 2019 |