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): March 5, 2020

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 2.02 Results of Operations and Financial Condition.

The information in Item 7.01 is incorporated by reference.

Item 7.01 Regulation FD Disclosure.

On March 5, 2020, Caladrius Biosciences, Inc. (the "Company") issued a press release in connection with its financial results for the fourth quarter and fiscal year ended December 31, 2019. 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.

The Company will conduct a conference call to review its financial results on March 5, 2020 at 4:30 p.m. Eastern Time.

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 Exhibits 99.1 and 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 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 March 5, 2020
99.2	Caladrius Biosciences, Inc. Corporate Presentation, March 2020

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: March 5, 2020

Exhibit 99.1

Caladrius Biosciences Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Business Update

CLBS16 ESCaPE-CMD data presented at American Heart Association 2019 Scientific Sessions demonstrated highly statistically significant improvement in coronary flow reserve and angina symptoms

CLBS12 registration eligible trial in Japan targeted to complete enrollment in 1H2020; Data to date continues to corroborate previously published positive results

CLBS14 is poised to commence a single confirmatory phase 3 study as agreed with FDA pending finalization of funding

Existing capital provides runway through 2Q 2021

Conference call begins today at 4:30 p.m. Eastern time

BASKING RIDGE, N.J. (March 5, 2020) - Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company"), a clinical-stage biopharmaceutical company dedicated to the development of cellular therapies designed to reverse, not manage, cardiovascular disease, announces financial results for the three and twelve months ended December 31, 2019.

"I am pleased with the Company's many achievements throughout 2019 as we made significant progress advancing our CD34+ technology-based clinical programs while maintaining strict financial controls," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius. "Notably, in November at the American Heart Association Scientific Sessions 2019, we reported the data for those patients (17 of 20) who, at that time, had completed their six-month follow-up visit in our ESCaPE-CMD study of CLBS16. The results showed highly statistically significant improvement in coronary flow reserve ("CFR") correlating with angina symptom relief for patients with coronary microvascular dysfunction ("CMD") after a single administration of CLBS16. To our knowledge, this is the first therapy to show the ability to durably increase CFR and potentially reverse CMD after a single administration. We look forward to reporting the full study data in the first half of 2020 in an appropriate forum. In Japan, enrollment continues to progress for the study of CLBS12 in critical limb ischemia ("CLI"), and we anticipate completing enrollment in the first half of 2020. Current data in both the no-option CLI and Buerger's Disease cohorts of that study (the latter cohort has been fully enrolled and data are available in our corporate presentation) remain corroborative of previously published results, which we believe are an indication of a high probability of clinical success of the trial. We continue to anticipate top line data for the full study in early 2021 leading to an earliest possible approval in Japan in late 2021 or early 2022. Finally, we have completed all preparatory measures for the initiation of the single confirmatory phase 3 study agreed with U.S. Food and Drug Administration (the "FDA") to conclude development of CLBS14 in no-option refractory disabling angina (NORDA) and are awaiting finalization of a funding plan before commencing the trial.

"We are excited about what lies ahead in 2020 and expect to build on this momentum as we continue to advance our clinical development pipeline and strive to achieve a number of important development milestones throughout the balance of the year," concluded Dr. Mazzo.

Fourth Quarter and Full Year 2019 Financial Highlights

Research and development expenses for the fourth quarter of 2019 were $2.8 million, an 84% increase compared with $1.5 million for the fourth quarter of 2018, and $10.8 million for 2019, a 42% increase compared with $7.6 million for 2018. Research and development in both the current year and prior year periods focused on the advancement of our ischemic repair platform and related to:

- ongoing registration-eligible study expenses for CLBS12 in critical limb ischemia in Japan, whereby we continue to focus spending on our patient enrollment;
- ongoing Phase 2 proof-of-concept study expenses for CLBS16 in coronary microvascular dysfunction, for which study enrollment was completed in the second quarter of 2019; and
- expenses associated with preparation of our confirmatory Phase 3 study of CLBS14 in NORDA. In late 2019, we projected that the Phase 3 study would cost approximately $70 million in external expenses over the next several years to complete, and as a result, we elected to postpone the initiation of the study until we have confidence that we can access sufficient capital to allow us to complete the study uninterrupted

General and administrative expenses, which focus on general corporate related activities, were approximately $2.3 million for both the fourth quarters of 2019 and 2018, and $9.3 million for 2019, a slight decline compared to $9.4 million in 2018.

The net loss for the fourth quarter of 2019 was $5.0 million, or $0.47 per share, compared with $3.6 million, or $0.36 per share, for the fourth quarter of 2018. The net loss for 2019 was $19.4 million, or $1.88 per share, compared with $16.2 million, or $1.67 per share, for 2018.

Balance Sheet Highlights

As of December 31, 2019, Caladrius had cash, cash equivalents and marketable securities of $25.2 million. Based on existing programs and projections, the Company remains confident that its cash balances will fund its operations through at least the second quarter of 2021.

Conference Call

Caladrius' management will host a conference call for the investment community later today, March 5, 2020, at 4:30 p.m. (ET) to discuss the financial results, provide a company update and answer questions.

Shareholders and other interested parties may participate on the conference call by dialing (866) 595-8403 (U.S.) or (706) 758-9979 (International), using the conference ID code: 4155934. The live webcast will be accessible via the Events page listed under the Investor section of the Company's website at www.caladrius.com/investors/news-events/events.

For those unable to participate on the live conference call, an audio replay will be available approximately two hours after the conclusion of the call until 11:59 p.m. ET on March 12, 2020. To access the replay, please dial (855) 859-2056 (U.S.) or (404) 537-3406 (International) and provide the conference ID code: 4155934.

A webcast replay of the conference call will remain available on the Company's website for 90 days.

About Caladrius Biosciences
Caladrius Biosciences, Inc. is a clinical-stage biopharmaceutical company dedicated to the development of cellular therapies designed to reverse, not manage, cardiovascular disease. We are developing a first in-class cell therapy product that is based on the notion that our body contains finely tuned mechanisms for self-repair. Our technology leverages and enables these mechanisms in the form of specific cells, using formulations and modes of delivery unique to each medical indication.

Our leadership team collectively has decades of biopharmaceutical development experience and world-recognized scientific achievement in the field of cardiovascular disease, among other fields. Our goal is to build a broad portfolio of novel and versatile products that address important unmet medical needs and bring these products to market to benefit patients, the medical community and our shareholders. Our current product candidates include three developmental treatments for ischemic diseases based on our CD34+ cell therapy platform: CLBS12, recipient

of SAKIGAKE designation (a Japanese regulatory status that is similar in certain respects to "breakthrough therapy" designation granted by the U.S. Food and Drug Administration (the "FDA") to eligible investigational treatments) and eligible for early conditional approval in Japan for the treatment of critical limb ischemia ("CLI") based on the results of an ongoing clinical trial; CLBS16, in a Phase 2 proof-of-concept clinical trial in the U.S. for the treatment of coronary microvascular dysfunction ("CMD"); and CLBS14, an RMAT designated therapy for which we have finalized with the FDA a protocol for a Phase 3 confirmatory trial in subjects with no-option refractory disabling angina ("NORDA"). 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 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 5, 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.

Contact:

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W2O Group
Christiana Pascale
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Email: cpascale@w2ogroup.com

- Tables to Follow -

Caladrius Biosciences, Inc.
Selected Financial Data (unaudited)
(in thousands, except per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
(in thousands, except per share data)	(unaudited)	(unaudited)		
Statement of Operations Data:				
Research and development	$ 2,767	$ 1,507	$ 10,797	$ 7,594
General and administrative	2,316	2,288	9,295	9,393
Total operating expenses	**5,083**	**3,795**	**20,092**	**16,987**
Operating loss	**(5,083)**	**(3,795)**	**(20,092)**	**(16,987)**
Investment income, net	129	239	740	824
Interest expense	—	—	—	(5)
Net loss	**(4,954)**	**(3,556)**	**(19,352)**	**(16,168)**
Less - net income (loss) attributable to noncontrolling interests	3	1	9	(1)
Net loss attributable to Caladrius Biosciences, Inc. common stockholders	**$ (4,957)**	**$ (3,557)**	**$ (19,361)**	**$ (16,167)**
Basic and diluted loss per share attributable to Caladrius Biosciences, Inc. common stockholders	**$ (0.47)**	**$ (0.36)**	**$ (1.88)**	**$ (1.67)**
Weighted average common shares outstanding	**10,460**	**9,853**	**10,325**	**9,689**

	December 31, 2019	December 31, 2018
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 25,157	$ 43,053
Total assets	27,153	44,580
Total liabilities	6,600	7,126
Total equity	20,553	37,454

# # #

Exhibit 99.2

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BIOSCIENCES

Advancing Restorative Therapies to Treat Ischemic Disease

David J. Mazzo, PhD
President and Chief Executive Officer

March 5, 2020 | Nasda

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's curre expectations, as of the date of this presentation, and involve certain risks and uncertainties. A statements other than statements of historical fact contained in this Investor Presentation a forward-looking statements. The Company's actual results could differ materially from thos anticipated in these forward-looking statements as a result of various factors. Factors that cou cause future results to differ materially from the recent results or those projected in forward-lookir statements include the "Risk Factors" described in the Company's Annual Report on Form 10-K file with the Securities and Exchange Commission ("SEC") on March 14, 2019, as subsequently amende on March 19, 2019, and in the Company's other periodic filings with the SEC. The Company's furth development is highly dependent on, among other things, future medical and research developmen and market acceptance, which are outside of its control. You are cautioned not to place undu reliance on forward-looking statements, which speak only as of the date of this Investor Presentatio Caladrius does not intend, and disclaims any obligation, to update or revise any forward-lookir information 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 wit two programs with cell therapy “breakthrough” designation
- Proprietary field-leading technology in multi-billion dollar global indications 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 with big pharma and emerging biotech experience
- Strong balance sheet; $25.2 million in cash (December 31, 2019) with no d and cash runway projected through 2Q 2021

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 a
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 boar

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

Carl Pepine, MD
University of Florida, Gaines

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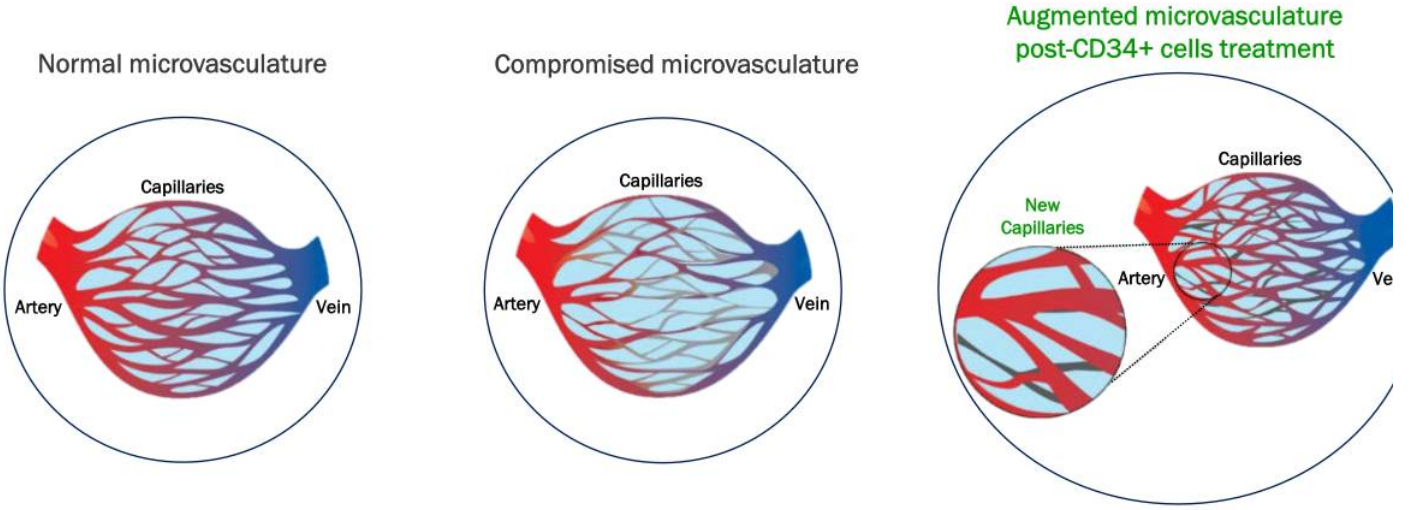
CD34+ cell therapy platform technology overview

CD34+ cells have a well characterized mechanism of acti



- 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

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CD34+ cell therapy is extensively studied/clinically valida

- CD34+ cells were clinically studied in multiple ischemic disease indications by numerous investigators across many sites and countrie
- Consistent and compelling results of rigorous clinical studies compris >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

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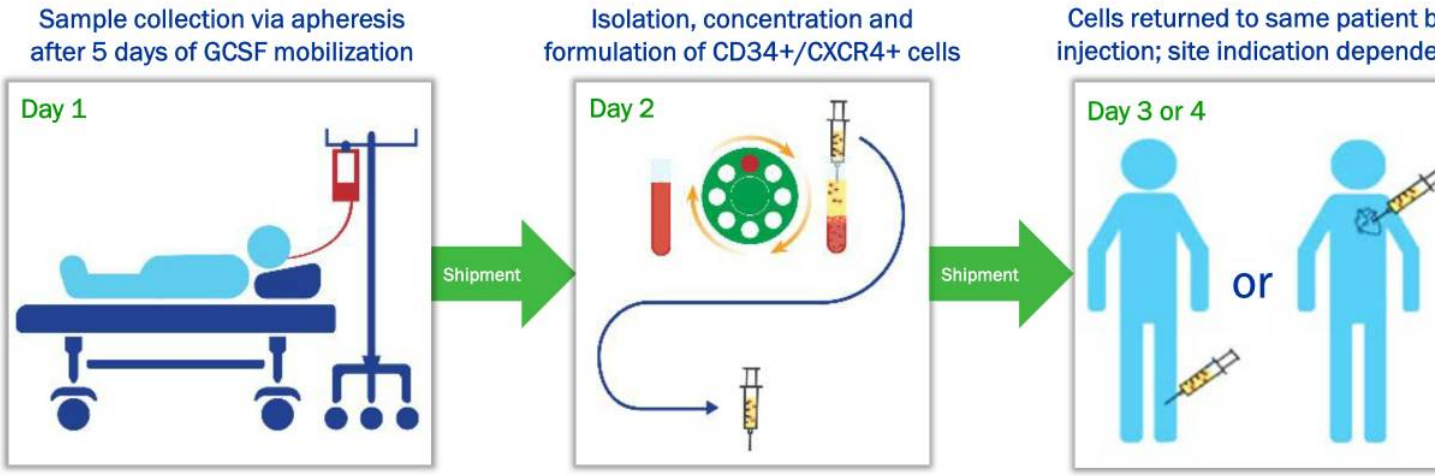
Caladrius CD34 process is simple/fast/economical/scale



- 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 proper

Fundamental protection to 2031+

9
U.S. patents granted

27
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 trial *(Japan; ongoing)*	2021
CLBS16	CMD	Phase 2 *(USA; start target mid 2020)*	TBD
CLBS14	NORDA	Phase 3 confirmatory *(USA; initiation pending funding)*	TBD

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

*Products are distinct and not interchangeab

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CLBS12

Critical Limb Ischemia

(Japan)

SAKIGAKE designated – Japan

Advanced Therapeutic Medicinal Product (ATMP) designated - EU

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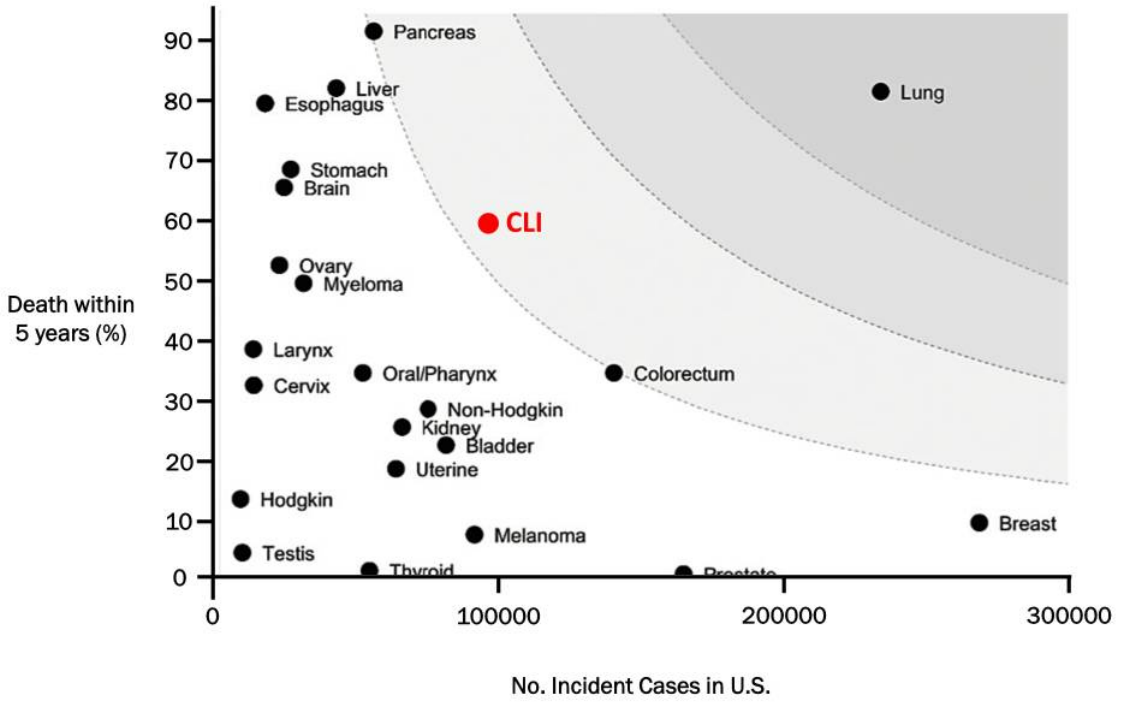
Indication: Critical Limb Ischemia (CLI)

- 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 patient
with R4 or R5 disease

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

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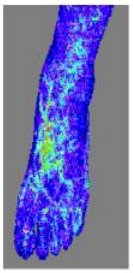
Single treatment of CD34+ cells reversed CLI

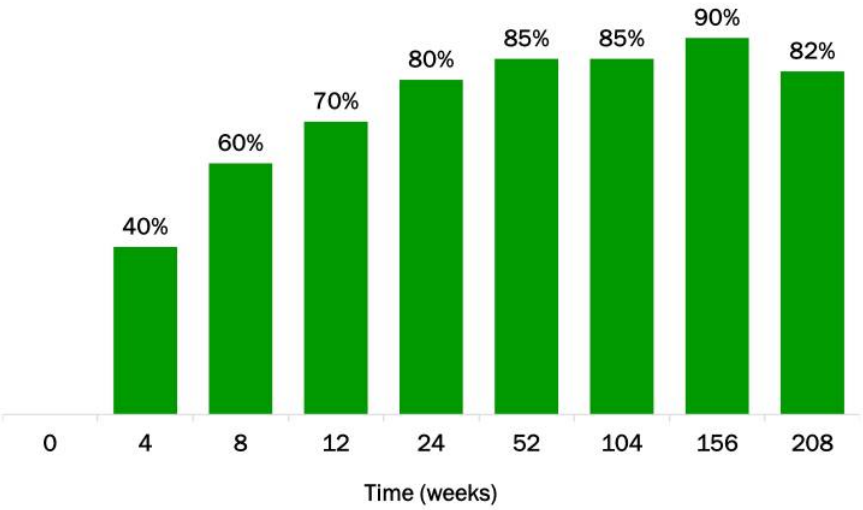
Actual CLI Patient Laser Doppler Image

Pre-treatment

Post-treatment (week 12)



% of Patients (CLI + BD) Achieving CLI-free Status



~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

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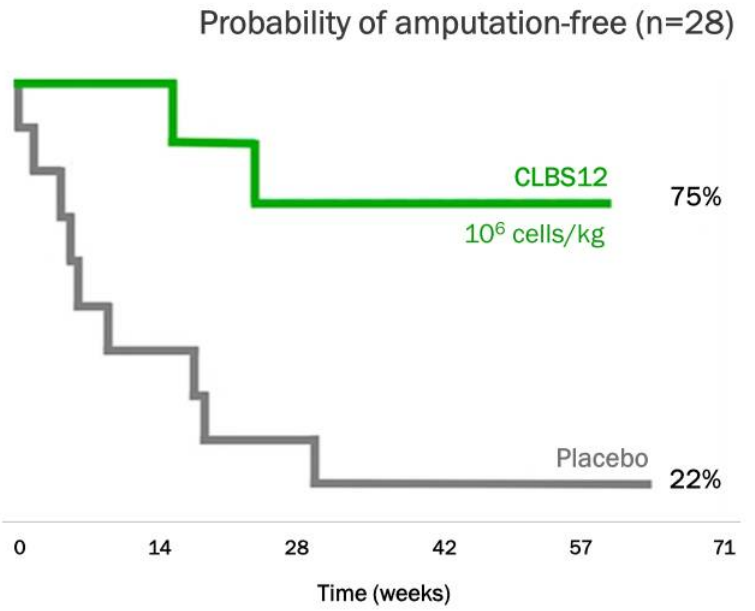
Single treatment of CD34+ cells increased amputation-free surv



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 independe
Study Size	▪ 30 subjects with no-option CLI + 7 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 vasodilato
Mode of administration	▪ Intramuscular, 20 injections in affected lower limb in a single treatment
Timing/Costs	▪ Results expected end 2020/early 2021 ▪ Earliest possible commercialization 2021 ▪ Study funded to completion in current budget projections

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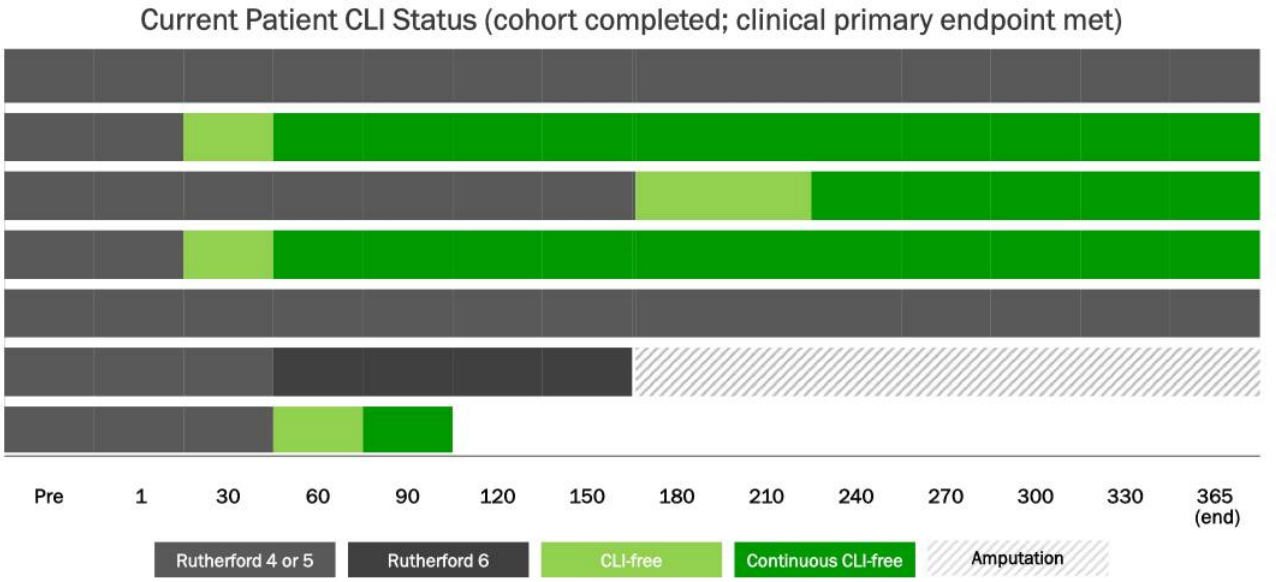
Extraordinary CLBS12 results in Buerger's Disease (Japan



- Natural evolution of Buerger's Disease is continual deterioration for all patients
- Surgery is not viable and existing pharmacotherapies do not prevent amputation[1]
- CLBS12 treatment resulted in 57% 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

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CLBS16

Coronary Microvascular Dysfunction

(USA)

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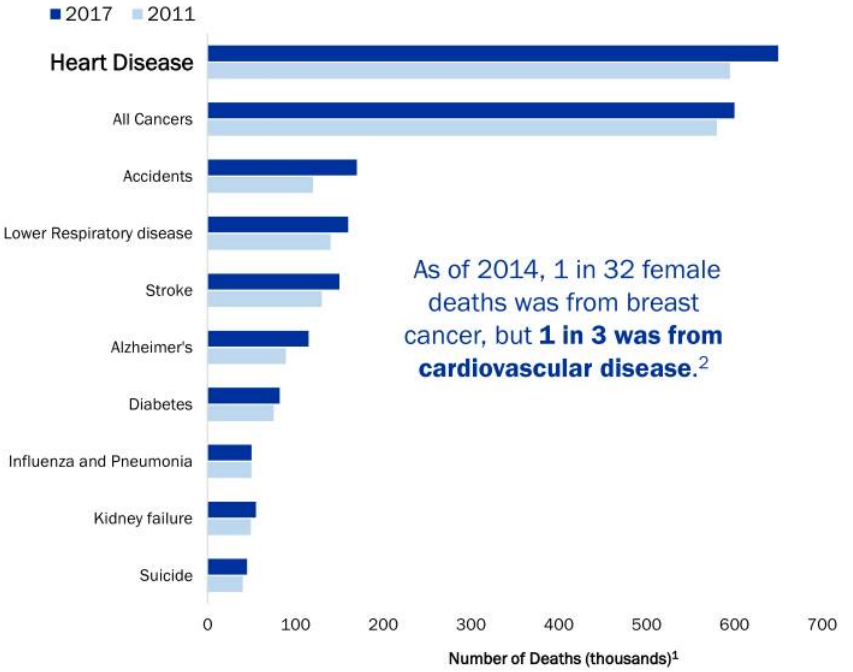
Heart disease: still a major unmet medical need globally



ISCHEMIA Trial[3] results validate the nee treatments that go beyond large vess interventions

- The International Study of Comparative He Effectiveness with Medical and Invasive Approaches (ISCHEMIA) was funded by th National Heart, Lung, and Blood Institute
- The study enrolled 5,179 patients at 320 in 37 countries

Conclusion:
Interventional heart procedures *do no* reduce the overall rate of heart attack or death compared with medicines and lifestyle changes alone.

[1] 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, Link to article.
[2] Kochanek, KD., et al. (2016). Deaths: final data for 2014. National vital statistics reports: from the Centers for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System, 65(4), 1-122.
[3] ISCHEMIA Study Results, AHA Scientific Sessions November 2019. https://ischemiatrial.org/ischemia-study-results#slides

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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

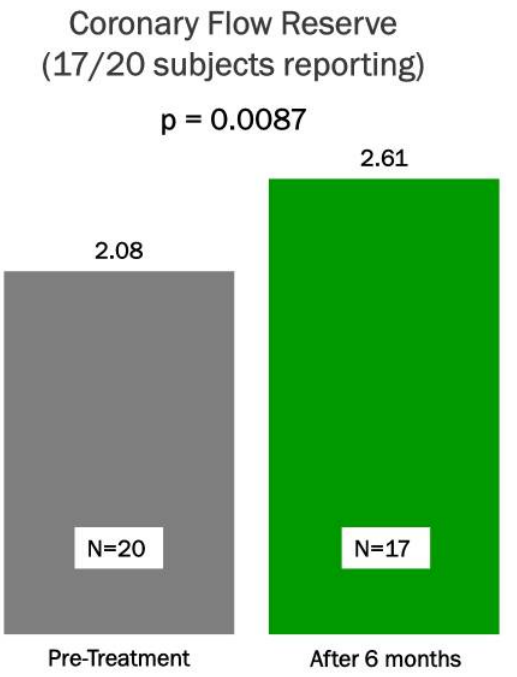
[1] Coronary Microvascular Disease. (2015, July 31). In American Heart Association
[2] R. David Anderson, John W. Petersen, Puja K. Mehta, et al., Journal of Interventional Cardiology, 2019: 8
[3] Loffler and Bourque, Curr Cardiol Rep. 2016 Jan; 18(1): 1
[4] Kenkre, T.S. et al., Circ: CV Qual & Outcomes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

ESCaPE-CMD: CLBS16 interventional, proof-of-concept tri

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

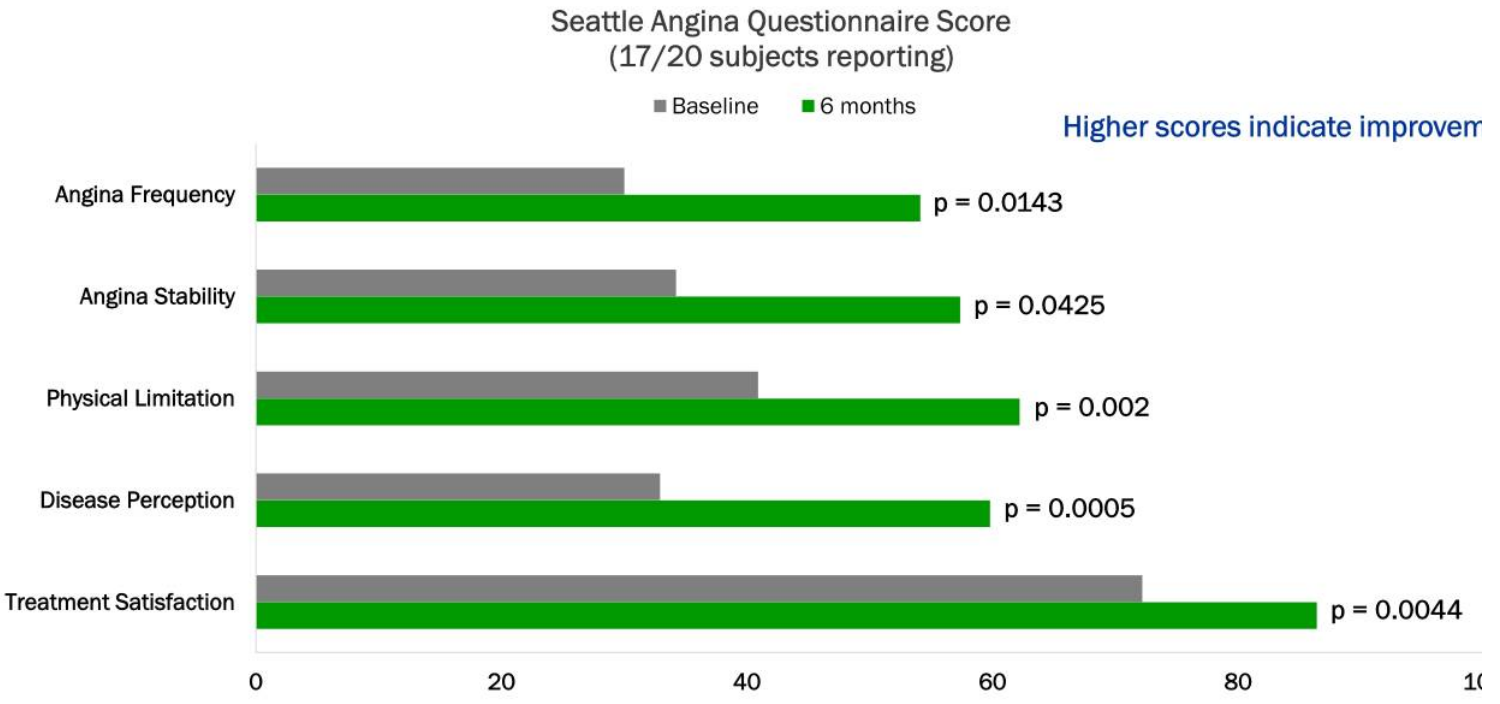
CLBS16 ESCaPE-CMD results are unique and compelling

- 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 compelling



[1]Spertus, J.A. et al, JACC Vol. 25, No. 2 February 1995: 333-341

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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 rever CMD after a single administration
- No evidence of cell related adverse events
- Expected to lead to a decreased risk of adverse cardiovascular outcomes, including CV-related death, associated with CMD
- Supports microvascular repair mechanism of CD34+ cells across all indicatio
- Represents a potential breakthrough for the treatment of CMD, a condition th affects millions in the U.S. and that disproportionately afflicts women
- Full data release pending presentation/publication in a medical meeting/jou

CLBS14

No Option Refractory Disabling Angina

(USA)

Regenerative Medicine Advanced Therapy (RMAT) designated - USA

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BIO

Indication: No Option Refractory Disabling Angina (NORDA

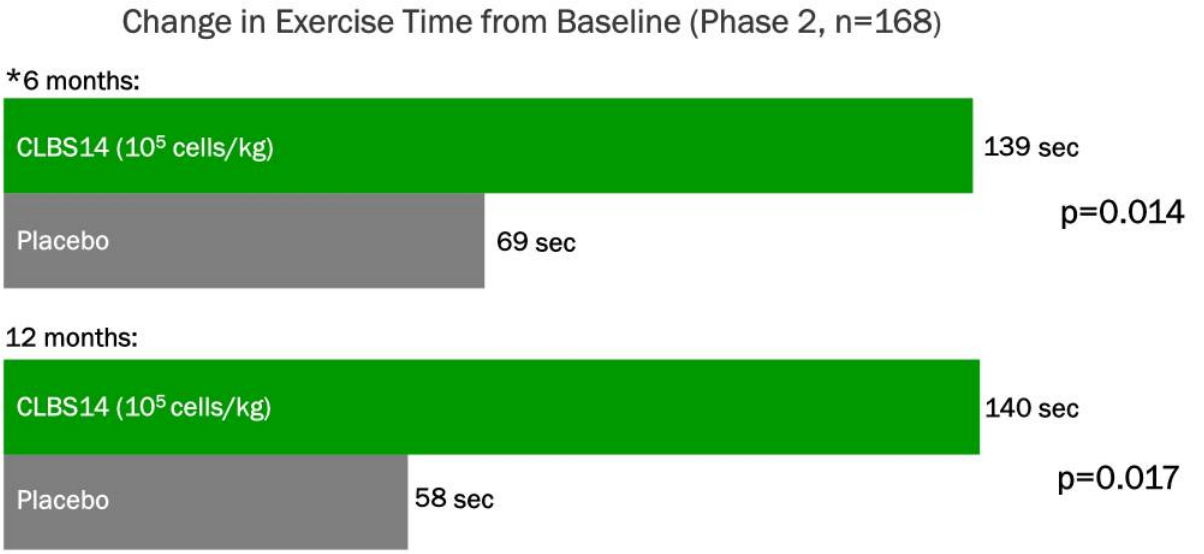
- Recurring angina results from chronically impaired cardiac blood supp
- The condition persists even after bypass surgery, angioplasty, stentin and available pharmacotherapy; no current treatment options
- NORDA patients experience very frequent disabling chest pain at rest with minimal activity
- Cardiac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

Our solution: CLBS14

- Clinical data from double-blind, randomized, placebo-controlled clinical trials, including big pharma sponsored Phase 2 and partial Phase 3[1,2,3]
- 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 exercise t



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

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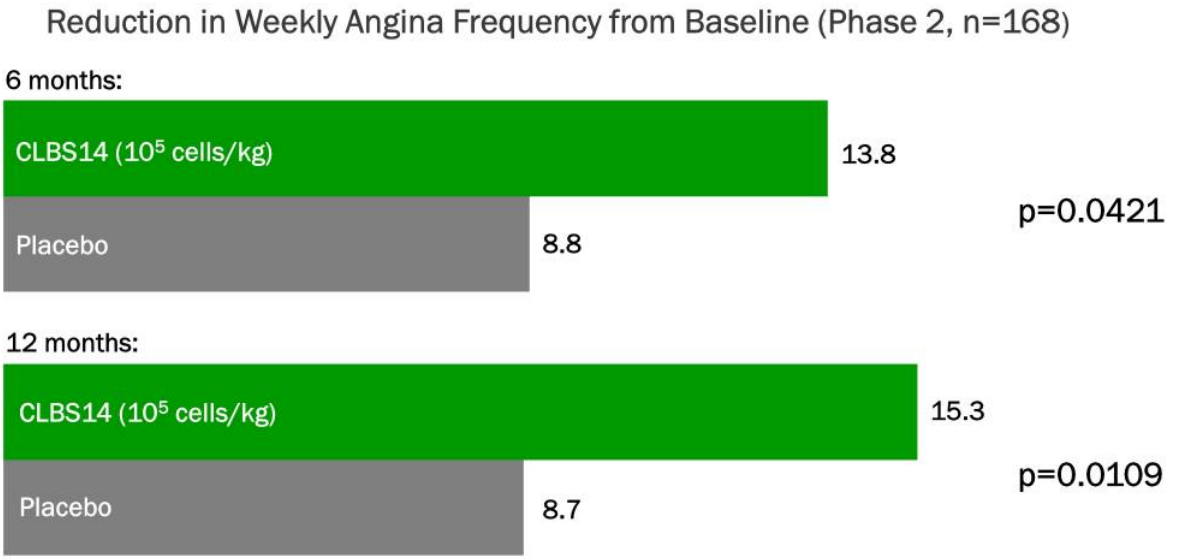
CLBS14 single treatment significantly reduced angina freque



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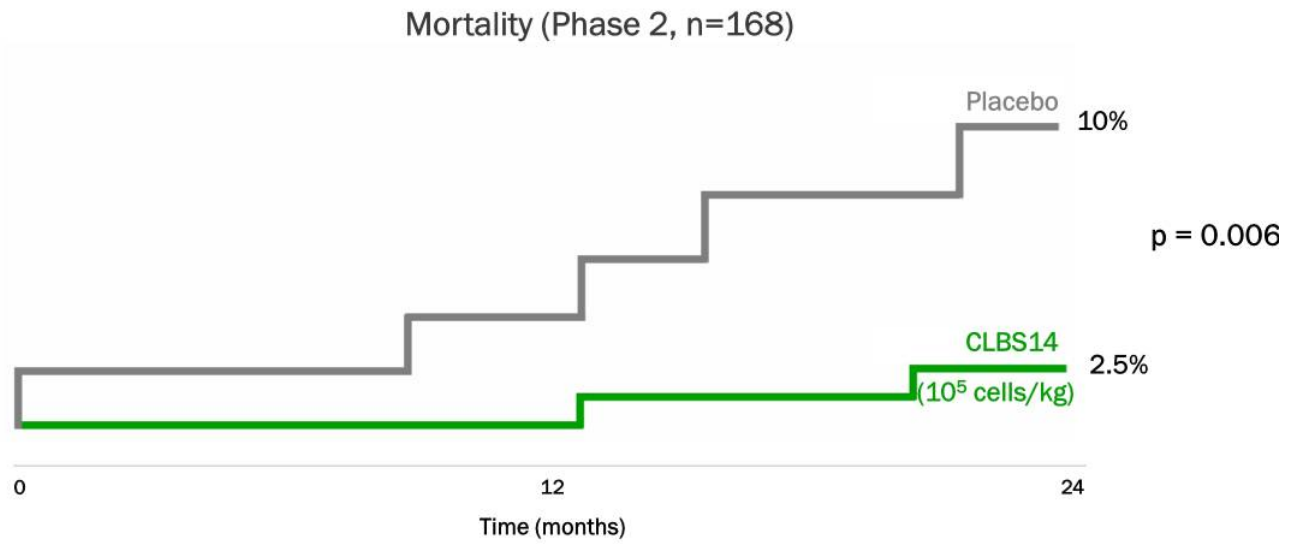
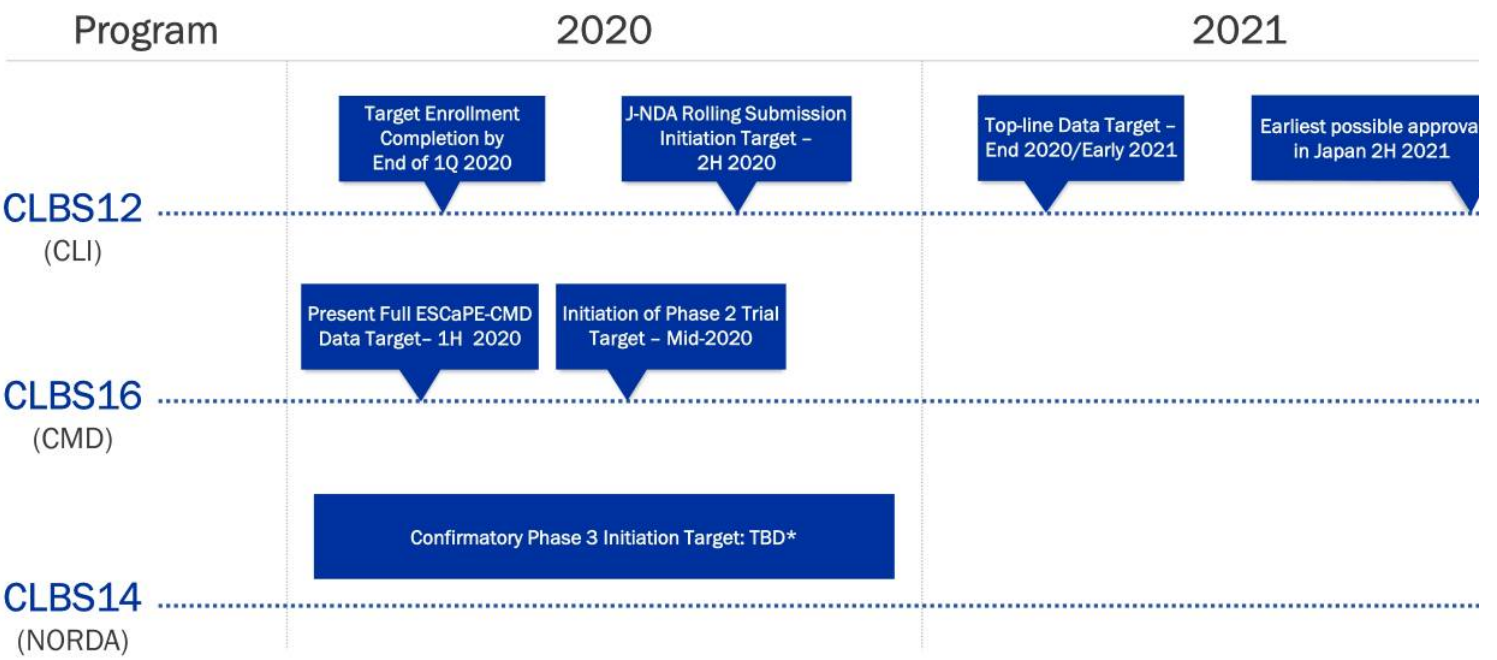
CLBS14 single treatment significantly improved survival



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 50% patients complete 6-month follow-up
Study Size	▪ ~400 subjects (~200 active, ~150 placebo, ~50 SOC with cross-over to o 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



**Pending funding*

Caladrius key financial information

Cash & Investments as of December 31, 2019:	$25.2 million
Twelve Months Ended December 31, 2019 Operating Cash Burn:	$18.9 million
Cash Runway Based on Current Plan:	through 2Q 2021
Debt:	$0
Common Shares Outstanding as of December 31, 2019:	10.5 million shares
Options Outstanding as of December 31, 2019: Exercise Price < $5.00 = 647,000 shares Exercise Price > $5.00 = 397,000 shares	1.0 million shares

Caladrius investment case summary

- CD34+ cell therapy platform company with an advanced clinical pipeline wit two programs with cell therapy “breakthrough” designation
- Proprietary field-leading technology in multi-billion dollar global indications 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 with big pharma and emerging biotech experience
- Strong balance sheet; $25.2 million in cash (December 31, 2019) with no d and cash runway projected through 2Q 2021

caladrius

BIOSCIENCES

Thank you!

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March 5, 2020 | Nasda