

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): December 14, 2020

CALADRIUS BIOSCIENCES, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-33650
(Commission
File Number)

22-2343568
(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:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- 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).

Emerging growth company

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.

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, 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.

On December 14, 2020, the Company issued a press release providing a year end 2020 development portfolio update. A copy of the press release is furnished as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated into this Item 7.01 by reference.

This information 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, December 2020
99.2	Press release, dated December 14, 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: December 14, 2020



caladrius

BIOSCIENCES

*Developing Regenerative Therapies
that Reverse Chronic Disease*

David J. Mazzo, PhD
President & Chief Executive Officer

December 2020 | Nasdaq: CLBS

Forward-looking statement

This Investor Presentation contains forward-looking statements within the meaning of 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 recorded 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, 2020 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.

cal

Caladrius investment highlights



CD34+ cell therapy platform yielding a multi-product development pipeline
2 clinical programs having regenerative medicine “breakthrough” designation



Proprietary field-leading technology in lucrative global indications backed by
strong IP portfolio



Multiple potential value creating events in the next 12-18 months based on
milestones across the pipeline



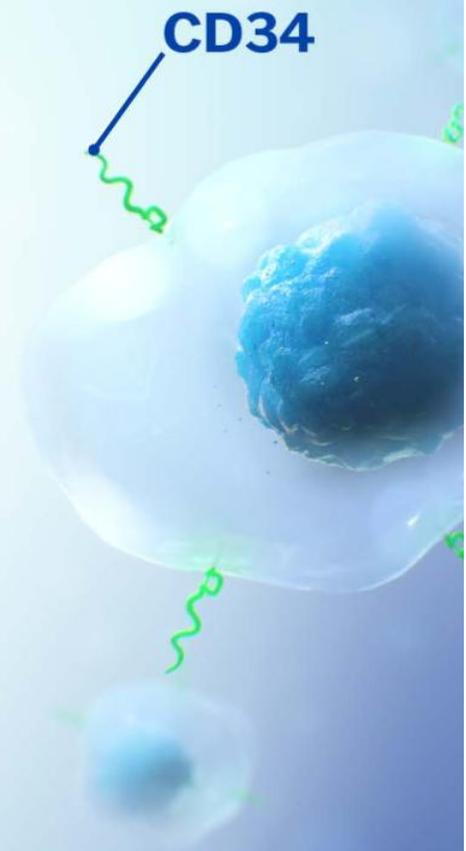
Strong balance sheet; ~\$40.3 million in cash & cash equivalents (9/30/2020)
with no debt and cash runway projected to fund operations through 2021



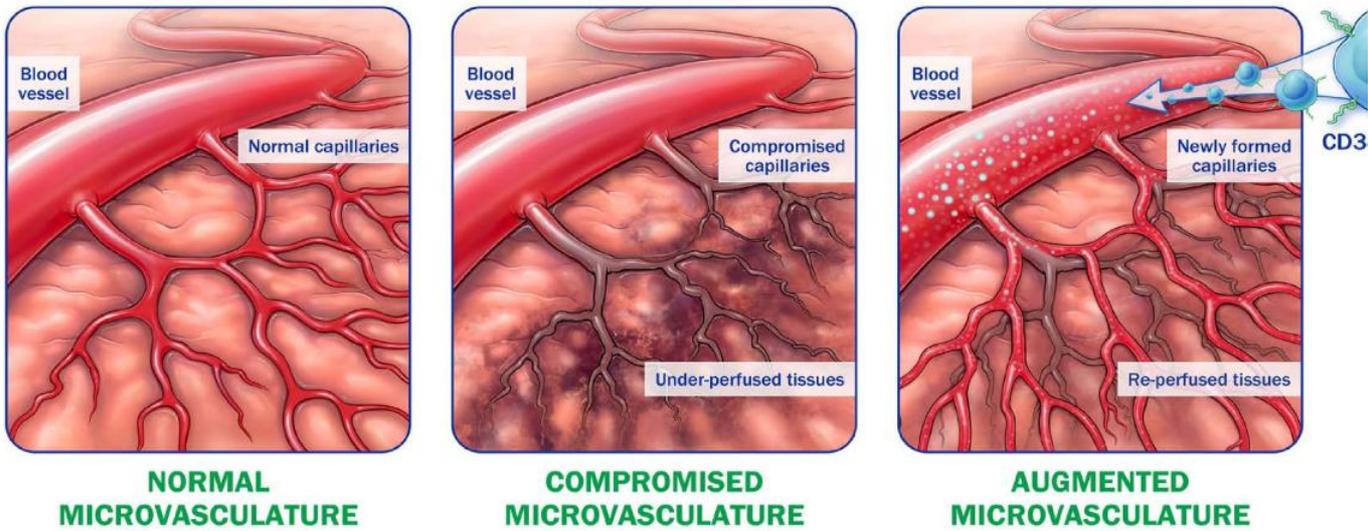
Seasoned management with noteworthy domain expertise along with
big pharma and emerging biotech experience

CD34+ Cell Therapy

Technology Overview



CD34+ cells have a well characterized mechanism of act



- Naturally occurring endothelial progenitor cells that re-establish blood flow to under-perfused tissues
- Possess pre-programmed pro-angiogenic and anti-inflammatory tissue repair properties^{3,4}

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

³Abd-Allah et al., *Cytotherapy* 2015, 17: 443-53
⁴Lo, B.C. et al., *Am J Respir Cell Mol Biol* 2017, 57: 651-61

CD34+ cell therapy is extensively studied/clinically validated

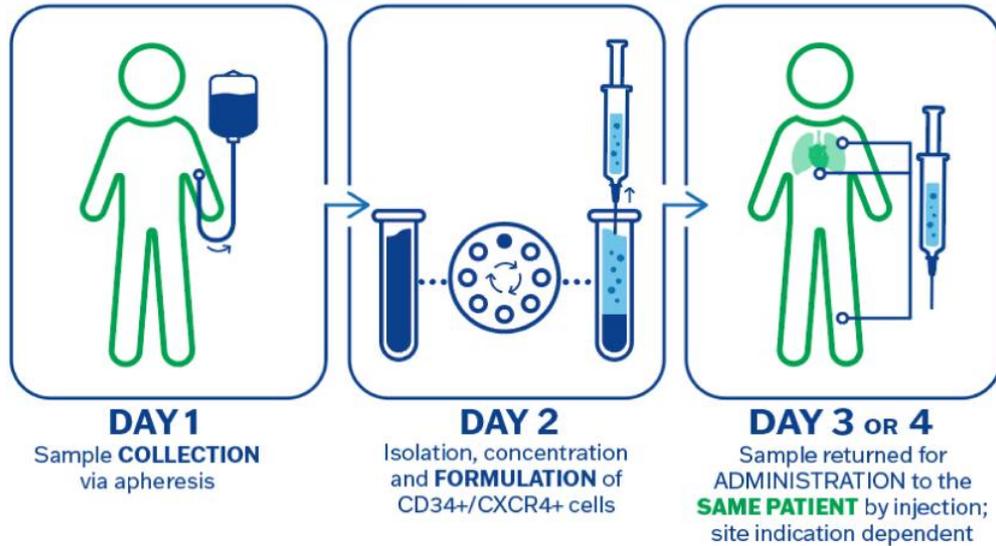
- CD34+ cells have been studied clinically in a variety of ischemic disease indications by numerous investigators across many sites and countries
- CD34+ cells repeatedly demonstrated vascular repair in multiple organs
- Consistent and compelling results of rigorous clinical studies comprising >1,000 patients have been published in peer reviewed journals¹⁻⁴
- A 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. *Cardiovasc Revasc Med*, 2018, 20(3):215-219
⁴ Henry T.D., et al. *European Heart Jour* 2018, 2208-2216

Caladrius' CD34+ cell process is rapid/economical/scale

GCSF-induced mobilization of patient's CD34+ cells from the bone marrow to the peripheral circulation



- Drug induced 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

Patent protection to 2031+

9

U.S. patents
granted

28

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^{1,2}

PRODUCT/INDICATION	DEVELOPMENT STAGE	KEY MILESTONE TARGET
CLBS16 CORONARY MICROVASCULAR DYSFUNCTION	FREEDOM PHASE 2B TRIAL (USA; ONGOING)	- Complete enrollment: - Top-line data: 3Q2021
HONEDRA® (CLBS12) *SAKIGAKE DESIGNATED CRITICAL LIMB ISCHEMIA + BUERGER'S DISEASE	REGISTRATION ELIGIBLE TRIAL (JAPAN; ONGOING)	- Complete enrollment: - Top-line data: 1/2Q22 - J-NDA submission: 1/22 - Approval: 2H2022/1H23
CLBS201 CHRONIC KIDNEY DISEASE	PHASE 1/2 (USA; CLINICAL INITIATION PENDING)	- File IND: 2Q2021 - Initiate enrollment: 2-3Q21 - Complete enrollment: - Top-line data: 3Q2021
CLBS14 *RMAT DESIGNATED NO-OPTION REFRACTORY DISABLING ANGINA	PHASE 3 (USA; INITIATION PENDING)	- Complete developer FDA discussions complete
CLBS119 COVID-19-INDUCED LUNG DAMAGE	PILOT (USA; RE-INITIATION PENDING)	- Continued Development target patient optimization

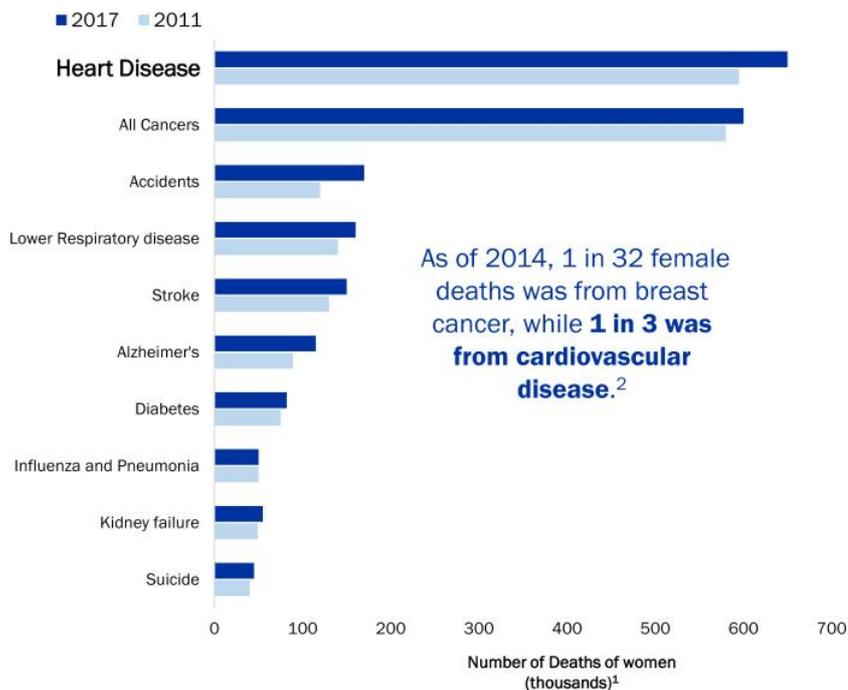
¹ Products are distinct and not interchangeable

² Timing subject to COVID-19 pandemic influence

CLBS16
Coronary Microvascular
Dysfunction
(USA)



CD34+ cell therapy targets unmet needs in cardiovascular disease



As of 2014, 1 in 32 female deaths was from breast cancer, while **1 in 3 was from cardiovascular disease.**²

ISCHEMIA Trial³ results underscore the need for treatments beyond large vessel interventions

- The International Study of Comparative Effectiveness with Medical and Invasive Approaches (ISCHEMIA) enrolled 5,179 patients at 320 sites in 37 countries

Conclusion:

Interventional heart procedures *do not* 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>

Indication: coronary microvascular dysfunction (CMD)

- Deficient heart microvasculature *without large vessel obstructive disease*
- Causes frequent, debilitating chest pain; not treatable by stents or bypass; responds poorly or not at all to available pharmacotherapies
- Afflicts women more frequently (2:1 to 3:1), especially younger women^{1,2}
- Results in poor prognosis for patients³
 - Significantly elevated risk of all-cause mortality⁴
- Clinically diagnosed based on symptoms *and* demonstrated absence of large vessel obstructive disease
- Quantitatively diagnosed using Coronary Flow Reserve (CFR)⁵

¹ Coronary Microvascular Disease. (2015, July 31). In American Heart Association

² R. David Anderson, John W. Petersen, Pujja 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

CMD represents a large unmet medical need

- ~112 million people globally are affected by angina¹
- ~8.3 million people in the U.S. suffering from coronary artery disease (CAD)²
- 10% - 30% of angina patients have no significant CAD on invasive coronary angiography^{3,4}
- 50% - 65% of patients with angina without obstructive CAD are believed to have CMD⁵

Applicable CMD population in the U.S. potentially treatable by CLBS16 ranges from ~415,000 to ~1.6 million patients

¹ Kunadian V, et al. European Heart Journal. 2020; 0:1-21

² Cleveland Clinic/AHA (American Heart Association)

³ Farrehi PM, et al. Am J Manag Care. 2002;8:643-648

⁴ Bradley SM, et al. J Am Coll Cardiol. 2014;63:417-426

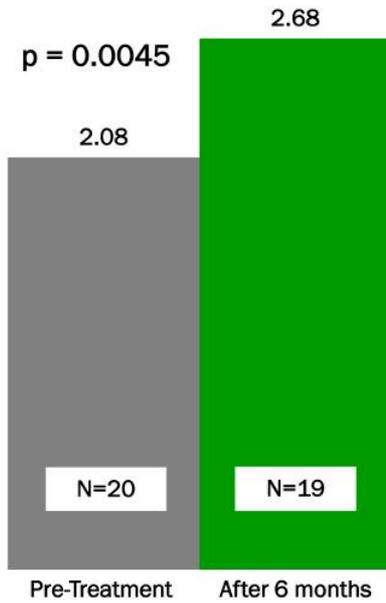
⁵ Marinescu MA, et al. JACC Cardiovasc Imaging. 2015;8:210-220

ESCaPE-CMD: Phase 2a interventional, proof-of-concept

Endpoints	<ul style="list-style-type: none">Therapeutic effect and the evaluation of adverse events; including change from baseline to 6 months for coronary flow reserve, angina frequency, Cangina class, quality of life
Study Size	<ul style="list-style-type: none">20 subjects (U.S. centers - Cedars Sinai, Los Angeles & Mayo Clinic, Roch
Dose	<ul style="list-style-type: none">Up to 300×10^6 CD34+ cells
Mode of administration	<ul style="list-style-type: none">Single intracoronary infusion
Timing	<ul style="list-style-type: none">Positive complete results presented at SCAI Scientific Sessions (May 202

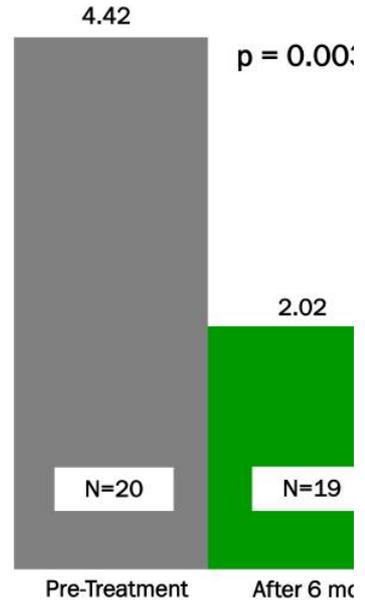
CLBS16 ESCaPE-CMD results are unique and compelling

Coronary Flow Reserve ¹



- CFR ≤ 2.5 indicates CMD
 - CFR of 2 = 3-4 x increase in MACE at 3 years¹
- CFR ≥ 2.5 is in “normal” range
- Results after a single intracoronary administration of CLBS16

Daily Angina Frequency



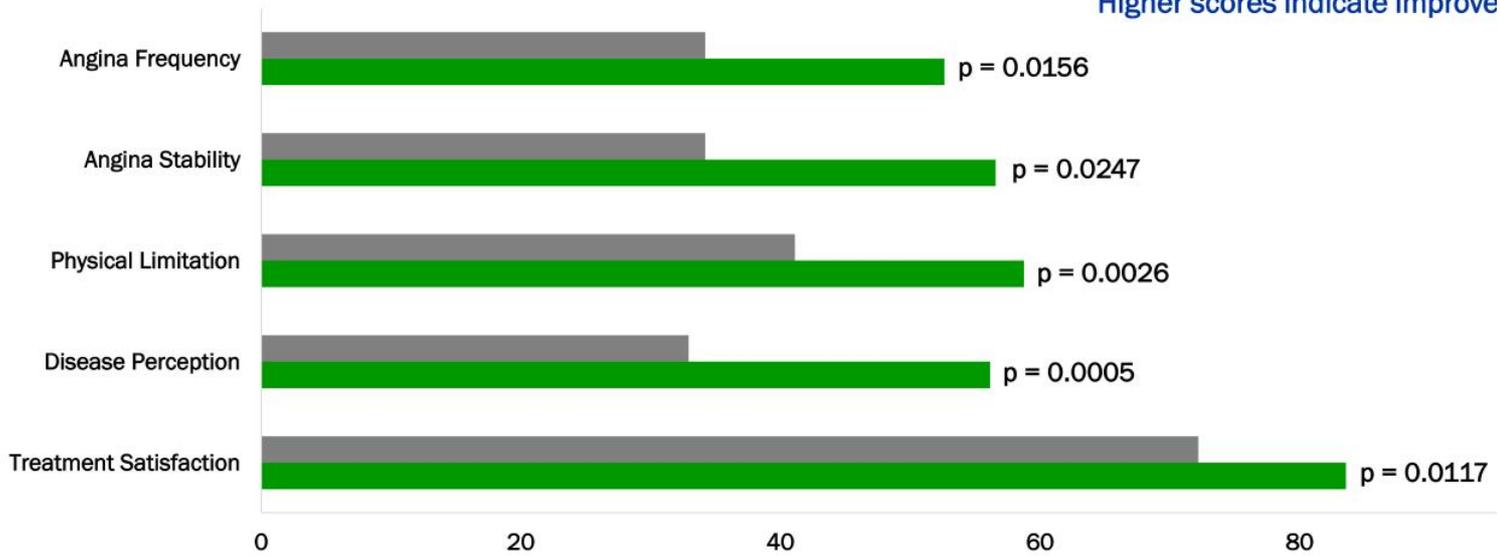
¹ Murthy et al, Circulation, 2014
² Henry, D. T., SCAI 2020 Scientific Sessions

CLBS16 ESCaPE-CMD results are unique and compelling

Seattle Angina Questionnaire Score¹

■ Baseline ■ 6 months

Higher scores indicate improve



¹ Henry, D. T., SCAI 2020 Scientific Sessions

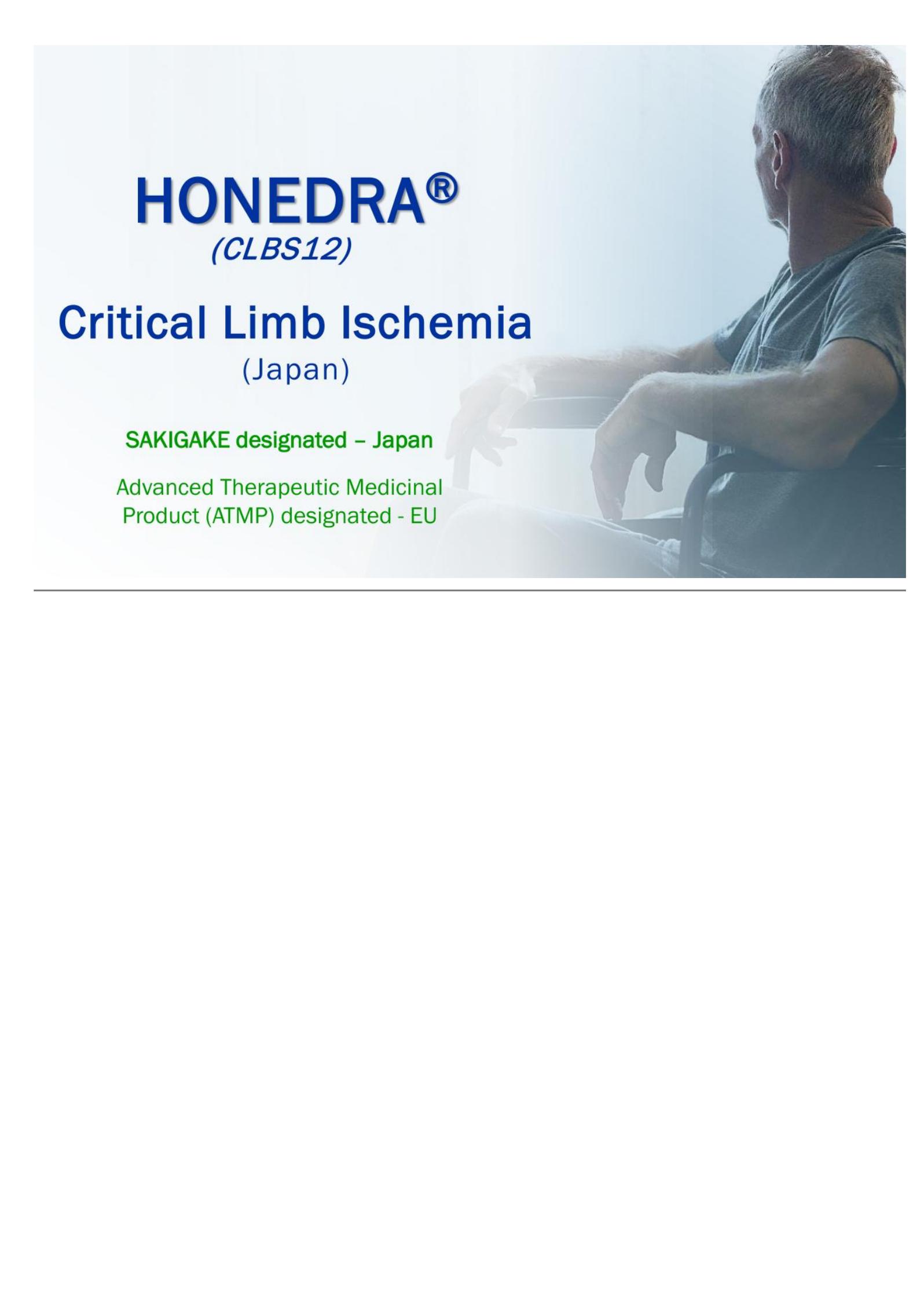
² Spertus, J.A. et al, JACC Vol. 25, No. 2 February 1995: 333-341

CLBS16: ESCaPE-CMD summary and next step

- Statistically significant improvement in heart function and symptoms
- No evidence of cell related adverse events
- First therapy to potentially reverse CMD after a single administration; a potential breakthrough in the treatment of CMD
 - Expected to lead to a decreased risk of MACE, including CV-related de
- Supports microvascular repair mechanism of CD34+ cells
- Phase 2b FREEDOM trial initiated 4Q2020; top-line data anticipated 3Q21
 - Double blind, placebo-controlled, randomized

FREEDOM trial: Phase 2b double-blind, placebo-controlled

Endpoints	<ul style="list-style-type: none">▪ Change from baseline in angina frequency [Baseline to 3 and 6 months]▪ Change from baseline in total exercise time [Baseline to 6 months]▪ Change from baseline in health-related quality of life [Baseline to 3 and 6 months]▪ Change from baseline in peak coronary flow reserve [Baseline to 6 months]
Study Size	<ul style="list-style-type: none">▪ 105 subjects (~10 sites in the USA)
Dose	<ul style="list-style-type: none">▪ Up to 300×10^6 CD34+ cells; placebo cross-over to treatment (frozen cells) at 6 months
Mode of administration	<ul style="list-style-type: none">▪ Single intracoronary infusion, retrograde infusion arm included
Timing	<ul style="list-style-type: none">▪ Study initiated 4Q2020▪ Top-line Data Target: 3Q2022



HONEDRA®
(CLBS12)

Critical Limb Ischemia (Japan)

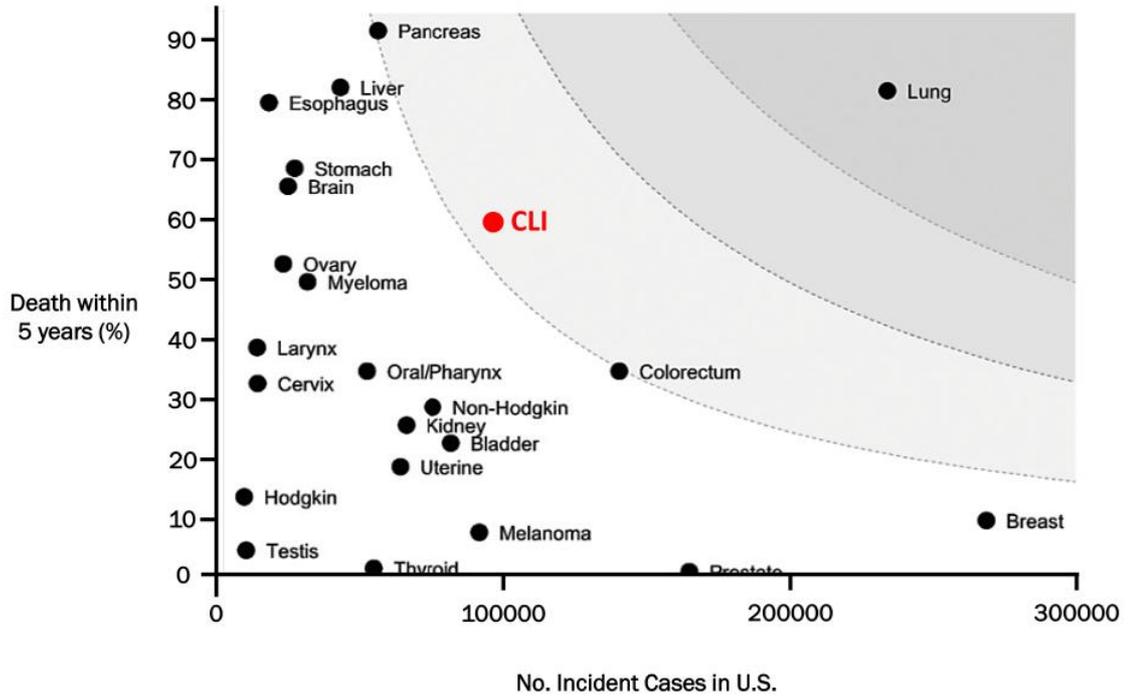
SAKIGAKE designated – Japan

Advanced Therapeutic Medicinal
Product (ATMP) designated - EU

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) a form of associated with a history of heavy smoking (orphan population)
- 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-hundred-million-dollar opportunity in Japan

CLI: higher mortality rate and incidence than most cancer



HONEDRA[®] targets patients based on the Rutherford Scale

CLI amputation rates increase with increasing Rutherford score (disease severity)

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: Mild to severe claudication

HONEDRA[®] targets patients with R4 or R5 disease

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

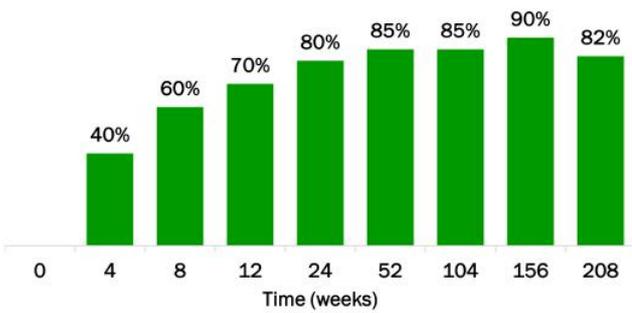
Single treatment of CD34+ cells reversed CLI (Phase 2 d

Actual CLI Patient Laser Doppler Image

Pre-treatment Post-treatment (week 12)

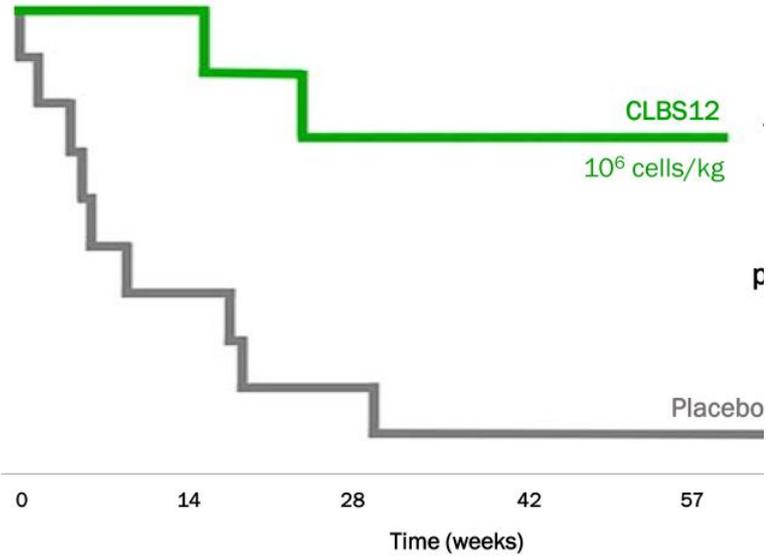


% of Patients (CLI + BD) Achieving CLI-free Status (China; n=27)¹



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

Probability of Amputation-Free Survival (USA; n=28)²



¹ Kinoshita et al, Atherosclerosis 224 (2012) 440-445
² Losordo, D.W. et al, Circulation 2012; 5(6):821-830

HONEDRA[®] registration-eligible study (Japan)

Primary Endpoint	<ul style="list-style-type: none">Continuous CLI-free (2 consecutive monthly visits, adjudicated independent)
Study Size	<ul style="list-style-type: none">30 subjects with no-option CLI + 7 Buerger's Disease pts.; all R4 or R5; 12 centers in Japan
Dose	<ul style="list-style-type: none">10⁶ cells/kg of HONEDRA[®] per affected limb (studied in previous trial)
Control/Comparator	<ul style="list-style-type: none">Standard of Care: wound care plus drugs approved in Japan<ul style="list-style-type: none">Including antimicrobials, antiplatelets, anticoagulants and vasodilators
Mode of administration	<ul style="list-style-type: none">Intramuscular, 20 injections in affected lower limb in a single treatment
Timing	<ul style="list-style-type: none">Enrollment completion : results target: 1Q2021 : 1/2Q2022, respectivelyEarly approval targeted for 2H2022/1H2023Timing subject to COVID-19 pandemic influence

cal

Extraordinary HONEDRA® results in Buerger's Disease (JI

- Surgery not viable; existing pharmacotherapies do not prevent amputa
- Cohort enrollment complete
- Results will contribute to the efficacy evaluation of the full study popul

Approximately 60% of patients achieved CLI-free stati

(Natural patient evolution is continual deterioration for all patients,

CLBS201

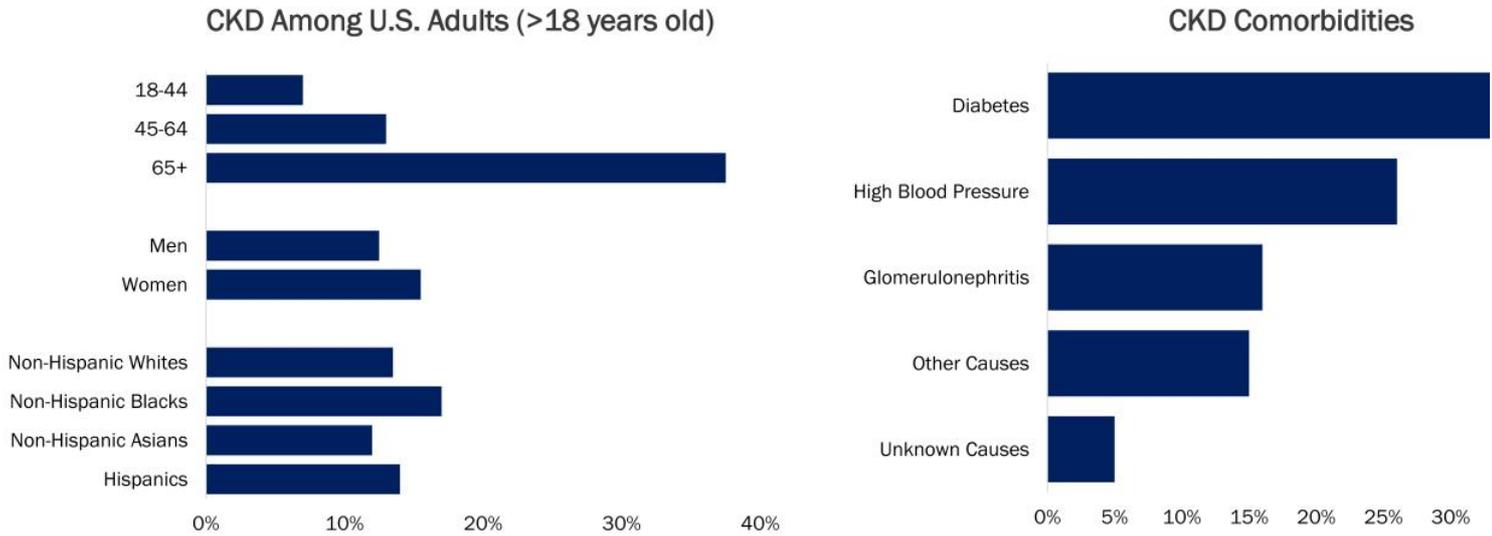
Chronic Kidney Disease

(USA)



CKD: risk factors and comorbidities

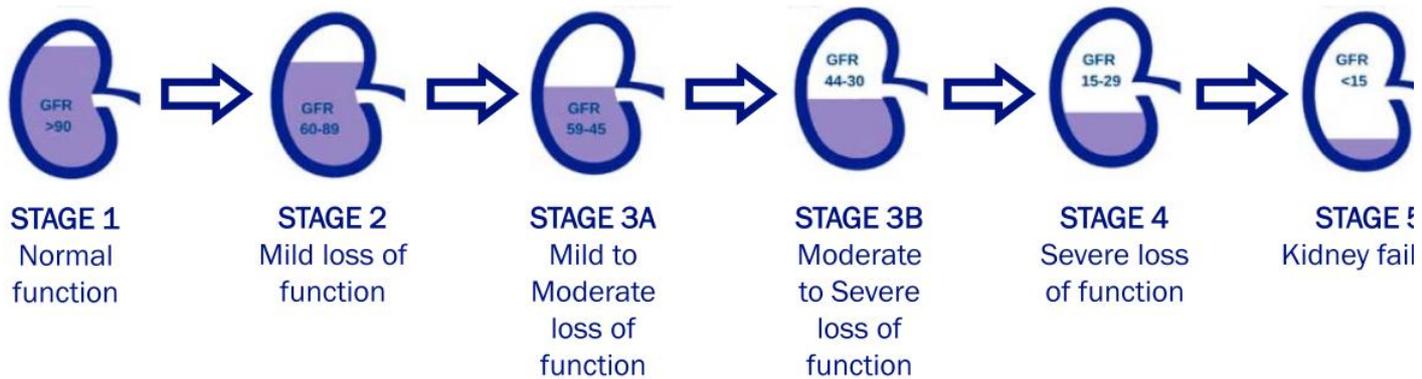
- An aging population is at greatest risk of chronic kidney disease with diabetes and hypertension being typical comorbidities
 - 1 in 3 adults are diabetic and 1 in 5 adults are hypertensive



Centers for Disease Control and Prevention. Chronic Kidney Disease in the United States, 2019. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2019.

CKD: multiple stages progressing toward kidney failure

- The stages of CKD are determined by glomerular filtration rate (GFR)¹
- GFR is measured to determine the level of creatinine in the blood (serum creatinin
- As kidney function worsens, the level of creatinine increases and GFR decreases
- In 2015-2016, 14%-15% of U.S. adults had evidence of CKD stages 1-4; of these, to 18 million had evidence of CKD stage 3 or 4²



¹ 2020 Dallas Nephrology Associates

² Centers for Disease Control and Prevention. Chronic Kidney Disease Surveillance System—United States.

Scientific rationale for CLBS201 trial

- CKD is often associated with progressive microvasculature damage and loss, resulting from its common comorbidities of hypertension and diabetes¹
- The pathophysiology of CKD denotes compromised renal microvasculature²
- Preclinical studies show that microcirculation replenishment improves kidney function
- CD34+ cells are promoters of new capillary growth, improving the microvasculature

CLBS201 clinical strategy

- To demonstrate that regeneration of the kidney microcirculation using CD34+ cell therapy will safely improve or stabilize kidney function [as measured by GFR]
- To show that progression to kidney failure and hemodialysis can be slowed or prevented

¹ Chade AR. (2017) Small Vessels, Big Role: Renal Microcirculation and Progression of Renal Injury. *Hypertension*; 69(4):551-563.

² Zuk, Anna & Bonventre, Joseph. (2016). *Annual Review of Medicine*. 67. 293-307. [10.1146/annurev-med-050214-013407](https://doi.org/10.1146/annurev-med-050214-013407).

CLBS201: Planned Phase 1/2 proof-of-concept study

Primary Endpoint ■ Percent change in eGFR compared to baseline, assessed at 6 months

Study Size ■ ~40 subjects

Dose ■ 10^6 cells/kg administered as a one-time infusion

Design ■ Open-label with 12-months total follow-up

Mode of administration ■ Single intra-arterial injection into each renal artery

Timing ■ Initiation target: 2Q2021
 ■ Top-line data target: 3Q2022

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
- Persists even after bypass surgery, angioplasty, stenting and pharmacotherapy; no current treatment
- NORDA patients experience very frequent disabling chest pain at rest or with minimal activity
- Cardiac microcirculation deficiency is the remaining treatment target
- Multi-billion-dollar global commercial opportunity

Treatment: CLBS14

- Phase 2 and partial Phase 3¹⁻⁵ clinical data (blinded, randomized, placebo-controlled; n_(total) = 303)
 - Statistically significant increase in exercise capacity (FDA primary endpoint)
 - 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

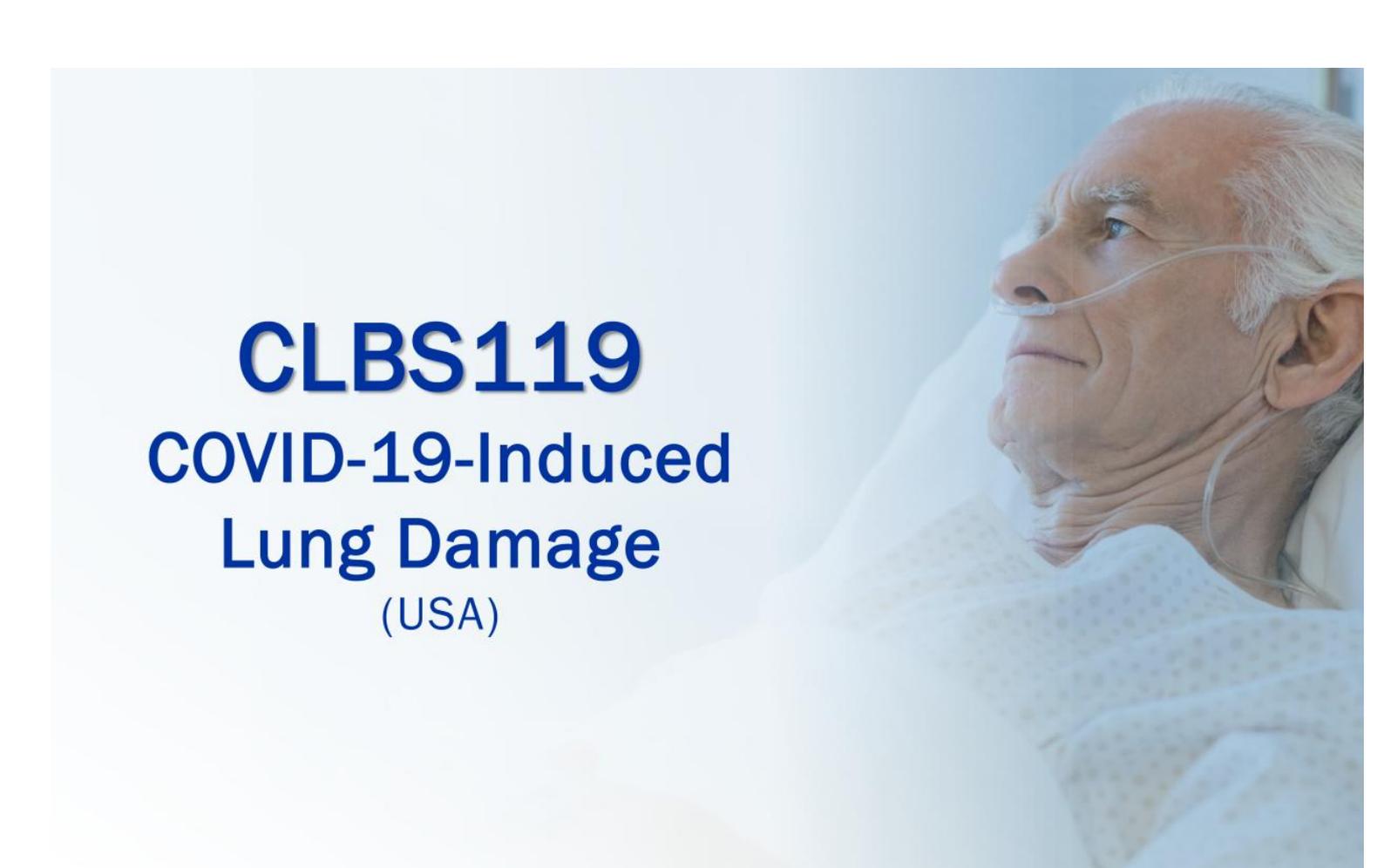
⁴ Povsic, T. J. et al, *European Heart Journal*, 2018 39(23), 2208-2216

⁵ Velagapudi P, et al, *Cardiovasc Revasc Med*, 2018, 20(3):215-219

CLBS14 Phase 3 study; initial FDA proposed design

Primary Endpoint	<ul style="list-style-type: none">Change in exercise time from baseline at month 6 (studied in Phase 2)
Timing	<ul style="list-style-type: none">39 months from first-patient-in to top-line data; interim analysis after 50 patients complete 6-month follow-up
Study Size	<ul style="list-style-type: none">~400 subjects (~200 active, ~150 placebo, ~50 SOC with cross-over to label treatment at 6 months)
Dose	<ul style="list-style-type: none">10^5 cells/kg body weight (studied in Phase 2)
Control/Comparator	<ul style="list-style-type: none">Placebo control (blinded)Standard-of-care (unblinded)
Mode of administration	<ul style="list-style-type: none">Intramyocardial injection guided by mapping catheter (NOGA)
Timing	<ul style="list-style-type: none">Target initiation: Pending completion of ongoing discussions with FDA regarding orphan designation status, combination product definition and Phase 3 size/scope reductions

cal:



CLBS119
COVID-19-Induced
Lung Damage
(USA)

Indication: repair of COVID-19-induced lung damage

- Early evidence suggested that severe lung damage due to COVID-19 leads to long term disability and possibly death as a result of inflammation and vascular damage¹⁻³
 - Many COVID-19 pneumonia survivors have some lung damage visible in CT scans⁴
- SARS epidemic data suggest that SARS-CoV-2 targets lung CD34+ cells and loss of these contributes to the incomplete recovery of some COVID-19 patients with severe lung damage
- As a result of acute COVID-19 treatment regimens improving significantly throughout 2020 leading to decreased use of ventilatory support and a dearth of patients with chronic hypoxemia coupled with the emergence of several potential effective vaccines, we have suspended the execution of the current CLBS119 clinical trial

Continued development of CLBS119 is predicated on the identification of an underserved treatable population with a stable profile

¹ Varga Z, et al., *Lancet*. 2020;395(10234):1417-1418

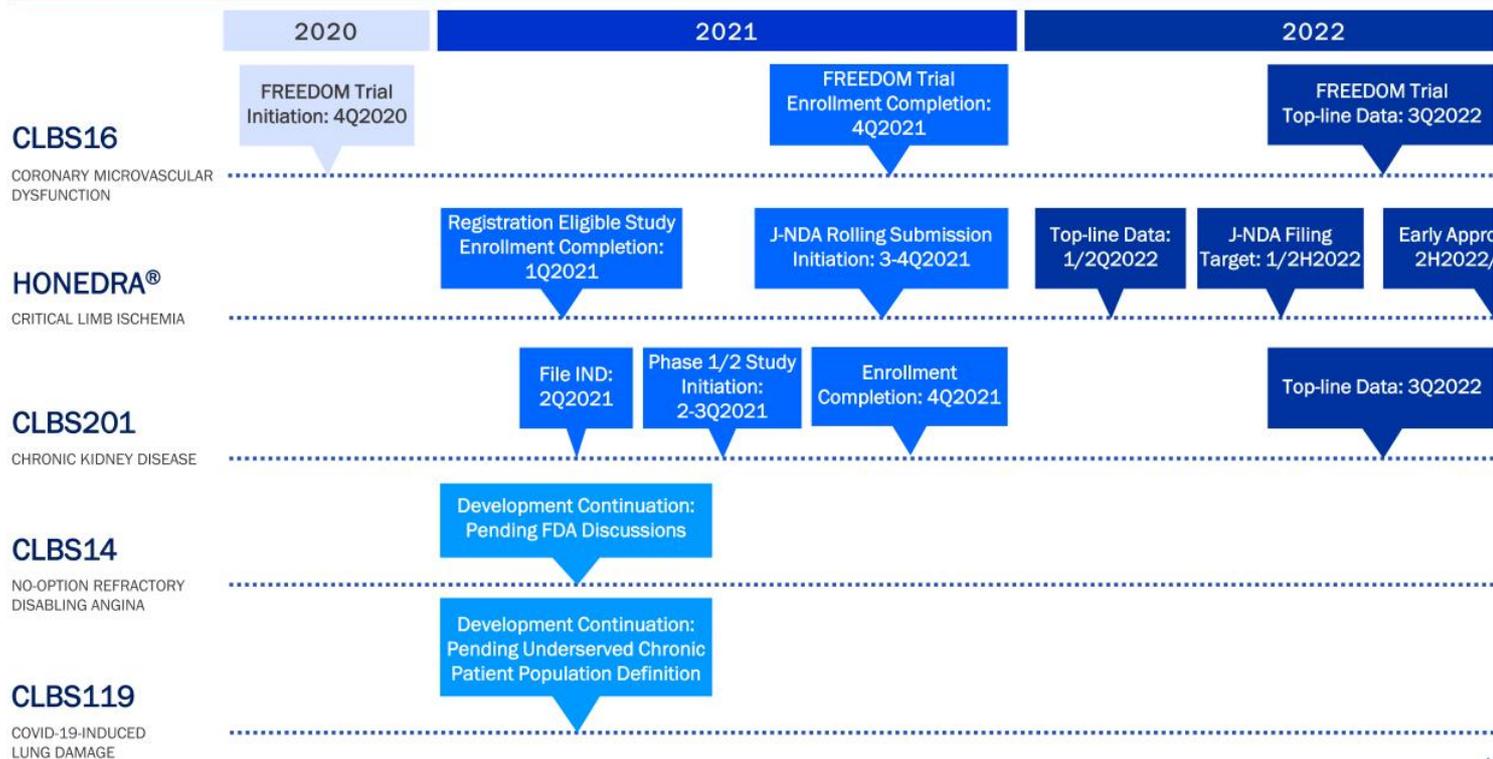
² Lo, et al, *Am J Respir Cell Mol Biol*, 2017. 57(6): p. 651-661

³ Abd-Allah SH., et al, *Cytotherapy*, 2015. 17(4): p. 443-453

⁴ Yuhui Wang, et al, *Radiology*, March 19, 2020

⁵ Chen Y, et al. *J Exp Med*. 2007;204(11):2529-2536

Caladrius timeline of key development milestones*



*Timing subject to COVID-19 pandemic influence

cal

Caladrius key financial information

Cash & Investments: As of September 30, 2020	\$40.3 million
Nine Months Ended September 30, 2020 Operating Cash Burn: ¹	\$14.1 million
Cash Runway Based on Current Plan:	Through 2021
Debt as of September 30, 2020:	\$0
Common Shares Outstanding: As of September 30, 2020	19.4 million shares
Options Outstanding as of November 30, 2020: Exercise Price: \$1.80 - \$3.50 = 197,000 shares Exercise Price: > \$3.50 = 767,000 shares	1.0 million shares
Warrants Outstanding as of November 30, 2020 : Weighted Average Exercise Price: \$2.18	2.6 million shares

¹ Excludes \$10.9 million in net proceeds from sale of New Jersey NOLs

Caladrius investment highlights



CD34+ cell therapy platform yielding a multi-product development pipeline
2 clinical programs having regenerative medicine “breakthrough” designation



Proprietary field-leading technology in lucrative global indications backed by
strong IP portfolio



Multiple potential value creating events in the next 12-18 months based on
milestones across the pipeline



Strong balance sheet; ~\$40.3 million in cash & cash equivalents (9/30/2020)
with no debt and cash runway projected to fund operations through 2021



Seasoned management with noteworthy domain expertise along with
big pharma and emerging biotech experience

A photograph of a middle-aged man and woman smiling warmly at the camera. They are outdoors in a bright, natural setting, possibly a field or park. The man is on the left, wearing a light-colored scarf and a grey shirt. The woman is on the right, wearing a light-colored top. The background is softly blurred, showing greenery and a bright sky.

caladrius

BIOSCIENCES

*Developing Regenerative Therapies
that Reverse Chronic Disease*

Investor Relations Contact:

John D. Menditto

Tel: (908) 842-0084

jmenditto@caladrius.com

December 2020 | Nasdaq: CLBS

Caladrius Biosciences Provides Year-End 2020 Strategic Portfolio Update

Program strategy and prioritization supports projection of available capital through 2021

BASKING RIDGE, N.J. (December 14, 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 disease, today announced that the Company has completed its year-end strategic portfolio product review to optimize the development strategy and priority of each of its programs for 2021 and beyond.

“The Company evaluated its current and proposed development programs in the context of multiple variables, including macro considerations, COVID-19 pandemic headwinds and financial limitations,” stated David J. Mazzo, Ph.D. President and CEO of Caladrius. “The result is a business and development plan for 2021 that will ensure that our available capital will fund the Company through 2021.” The Company has determined the following development strategy for each program (listed in order of highest to lowest priority).

CLBS16

If the compelling positive results of the open label ESCaPE-CMD phase 2a trial reported in May 2020 can be replicated in subsequent larger blinded trials, CLBS16 could become the first therapy to reverse coronary microvascular dysfunction (“CMD”) with a single treatment for the up to 1.6 million CMD patients in the U.S. alone. The Phase 2b FREEDOM trial, which is currently recruiting patients, is targeted to complete enrollment by the end of 2021 and we hope to have top-line data in the third quarter of 2022. “This 105 subject trial will be the centerpiece of Caladrius’ clinical development efforts in 2021 and is expected to provide critical information on safety, therapeutic effect, optimal mode of administration and product processing that would be key to discussions with FDA in determining the next development step in the most rapid path to potential approval,” stated Dr. Mazzo.

HONEDRA® (CLBS12)

Of the Company’s pipeline programs, the COVID-19 pandemic has most negatively impacted the registration-eligible trial in Japan of our SAKIGAKE-designated product, HONEDRA. The trial to assess HONEDRA as a treatment for critical limb ischemia and Buerger’s Disease (“BD”) saw enrollment come to a halt from February 2020 through October 2020 as a result of virus mitigation measures implemented by the Japanese government. We re-initiated enrollment in November 2020 and now target completion of enrollment by the end of the first quarter of 2021, assuming no further COVID-19 impact. The data reported to date for the trial for the completed BD cohort continues to encourage us of future success when the trial is completed. Approximately 60% (4 of 7) of BD patients achieved the study’s primary endpoint of “CLI-free”. This is a remarkable result considering that BD patients typically experience continued disease progression leading to ultimate amputation. With study enrollment expected to be completed in the first quarter of 2021 and full trial data expected in the first quarter of 2022, we are targeting a

Japanese NDA filing early in the second half of 2022. Based on the SAKIGAKE designation that stipulates a 6 months review period, HONEDRA could have an approval decision in Japan as early as late 2022 or early 2023. HONEDRA could represent a commercial market opportunity of several hundred million dollars in Japan alone and the Company plans to commercialize the product through a partnership with a Japanese pharmaceutical company to maximize its commercial success.

CLBS201

Our newest proposed development program, CLBS201, is designed to assess the safety and efficacy of CD34+ cell therapy as a treatment for chronic kidney disease (“CKD”). Based on a wealth of published preclinical and early clinical data, it appears that the innate ability of CD34+ cells to promote the growth of new microvasculature could be a means to attenuate the progression of the disease or even reverse the course of CKD. We plan to file an IND for this program in the second quarter 2021 and to initiate a phase 1/2 proof-of-concept study of CLBS12 in a moderate to severe CKD population shortly thereafter. Chronic Kidney Disease remains a largely unmet medical need, especially as the general population ages and the incidence of diabetes and hypertension increases.

CLBS14

Our development program for CLBS14 in No-option Refractory Disabling Angina (“NORDA”) remains the subject of much discussion with the U.S. Food and Drug Administration (“FDA”). Previously, we announced that we had reached agreement with FDA on a phase 3 confirmatory protocol to complete development of the product in the U.S. That program design, consisting of 400 patients divided among treatment, placebo and standard-of-care arms, was projected to cost approximately \$70 million and take approximately 39 months from first patient treated to top-line data. The challenges for Caladrius to finance such a trial, especially in the midst of the COVID-19 pandemic, are substantial and we have, therefore, re-engaged the FDA to ascertain if a less costly path to development could be available. The pursuit of registration of CLBS14 is now dependent on these discussions with the FDA and a positive outcome of the FDA’s decisions regarding orphan designation status, combination product definition and phase 3 size and scope reductions. We hope to obtain clarity on the development plan for CLBS14 during the first half of 2021, recognizing that our timeline remains constrained by FDA responsiveness.

CLBS119

CLBS119 for the treatment of COVID induced lung damage was conceived and launched as a development program in the early days of the COVID-19 pandemic based on the then available characterization of the disease, its available treatments and the anticipated treatable patient population. Fortunately for patients, acute COVID-19 treatment regimens improved significantly throughout 2020 leading to decreased use of ventilatory support. This fact, coupled with the recent approval of an effective vaccine and the anticipated approval of additional effective vaccines in the near future, has changed dramatically the profile and prognosis of COVID-19 patients with chronic lung debilitation and led to a dearth of patients with long-term hypoxia. (Receiving ventilatory support and demonstrating chronic hypoxia are inclusion criteria for enrollment in our CLBS119 pilot clinical trial.) As a result, despite recruiting patients for almost 2 months, no patients have been enrolled in the CLBS119 pilot trial. “Given these recent developments, and in recognition of the fact that the characterization of the COVID-19 patient suffering long-term effects continues to evolve, we have suspended execution of the

current pilot study of CLBS119,” said Dr. Mazzo. “Future development of CLBS119 will be predicated on the identification of an underserved treatable population with a stable profile.”

About Caladrius Biosciences

Caladrius Biosciences, Inc. is a clinical-stage biopharmaceutical company dedicated to the development of cellular therapies designed to reverse disease. We are developing first-in-class cell therapy products based on the finely tuned mechanisms for self-repair that exist in the human body. Our technology leverages and enables these mechanisms in the form of specific cells, using formulations and modes of delivery unique to each medical indication.

The Company’s current product candidates include: HONEDRA® (formerly CLBS12), recipient of SAKIGAKE designation 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; CLBS14, a Regenerative Medicine Advanced Therapy (“RMAT”) designated therapy for which the Company has finalized with the U.S. Food and Drug Administration (the “FDA”) a protocol for a Phase 3 confirmatory trial in subjects with no-option refractory disabling angina (“NORDA”); CLBS16, the subject of both a recently completed positive Phase 2a study and a newly initiated Phase 2b study in the U.S. for the treatment of coronary microvascular dysfunction (“CMD”); and CLBS119, an emergent CD34+ stem cell therapy responding to the COVID-19 pandemic and the potentially permanent damage the virus inflicts on the lungs of many patients. 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 the intended use of net proceeds from financings as well as 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, 2020 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, except as required by law.

Contact:

Investors:
Caladrius Biosciences, Inc.
John Menditto
Vice President, Investor Relations and Corporate Communications
Phone: +1-908-842-0084
Email: jmenditto@caladrius.com

Media:
W2O Group
Christiana Pascale
Phone: +1-212-257-6722
Email: cpascale@w2ogroup.com

###