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): January 11, 2021

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.

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.

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, January 2021

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: January 11, 2021

Exhibit 99.1

caladrius
BIOSCIENCES

Developing Regenerative Therapies that Reverse Chronic Disease

David J. Mazzo, PhD
President & Chief Executive Officer

January 11, 2021 | 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 refl management's current expectations, as of the date of this presentation, and involve cert risks and uncertainties. All statements other than statements of historical fact containec this Investor Presentation are forward-looking statements. The Company's actual resu could differ materially from those anticipated in these forward-looking statements as a res of various factors. Factors that could cause future results to differ materially from the rec results or those projected in forward-looking statements include the "Risk Facto described in the Company's Annual Report on Form 10-K filed with the Securities a Exchange Commission ("SEC") on March 5, 2020 and in the Company's other periodic fili with the SEC. The Company's further development is highly dependent on, among ot things, future medical and research developments and market acceptance, which outside of its control. You are cautioned not to place undue reliance on forward-look statements, which speak only as of the date of this Investor Presentation. Caladrius does intend, and disclaims any obligation, to update or revise any forward-looking informat contained in this Investor Presentation or with respect to the matters described herein.

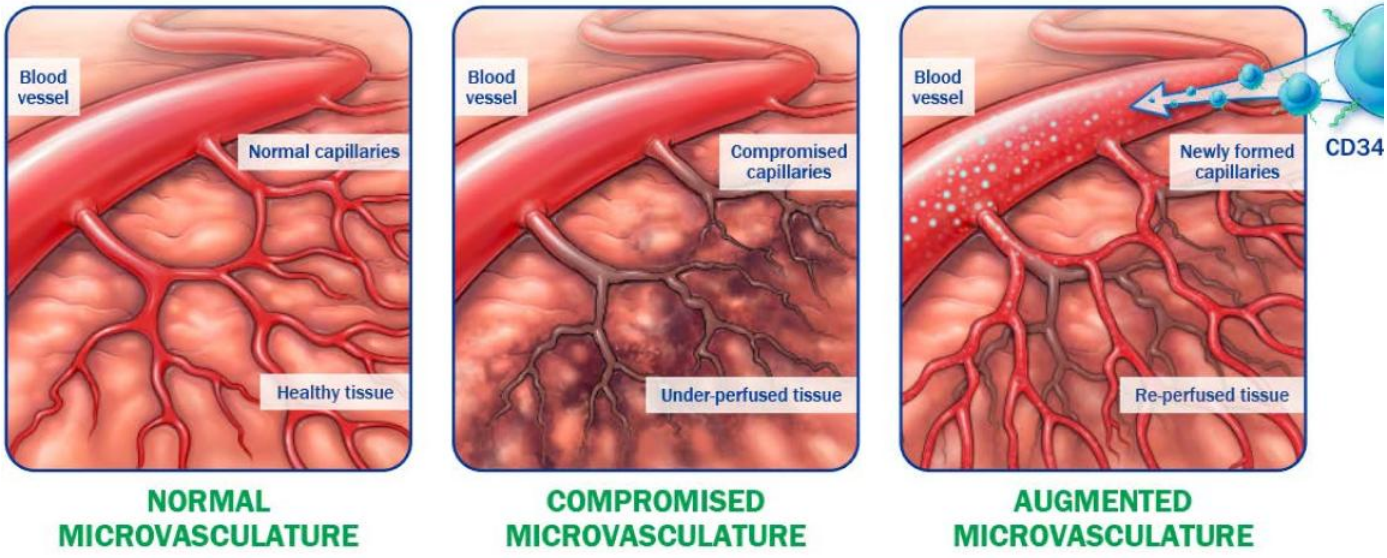
Caladrius investment highlights

- CD34+ cell therapy platform yielding a multi-product development pipeline
  2 clinical programs having regenerative medicine “breakthrough” designat
- Proprietary field-leading technology in lucrative global indications backed b
  strong IP portfolio
- Multiple potential value creating events in the next 12-24 months based o
  milestones across the pipeline
- Strong balance sheet; ~$40.3 million in cash & cash equivalents (9/30/2
  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 tiss
- Possess pre-programmed pro-angiogenic and anti-inflammatory tissue repair properties[3,4]

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

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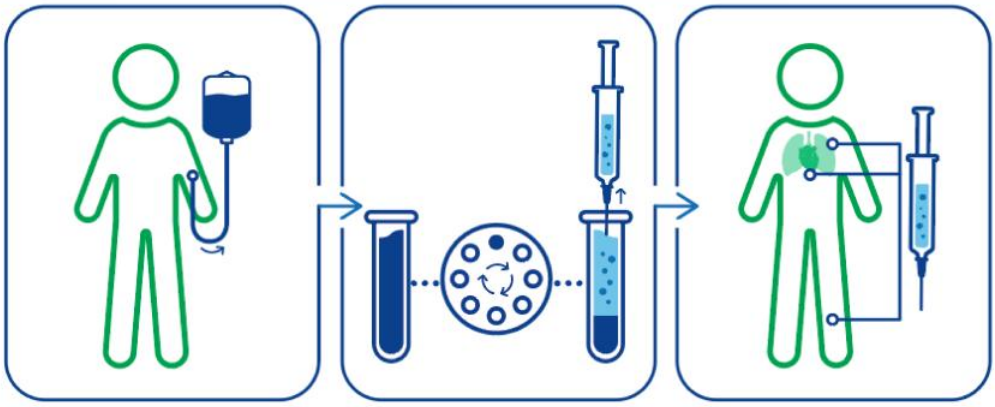
CD34+ cell therapy is extensively studied/clinically valida

- CD34+ cells have been studied clinically in a variety of ischemic disea indications by numerous investigators across many sites and countrie
- CD34+ cells repeatedly demonstrated vascular repair in multiple orga
- Consistent and compelling results of rigorous clinical studies comprisi >1,000 patients have been published in peer reviewed journals[1-4]
- 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, *Cardiovas 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



DAY 1
Sample **COLLECTION** via apheresis

DAY 2
Isolation, concentration and **FORMULATION** of CD34+/CXCR4+ cells

DAY 3 OR 4
Sample returned for ADMINISTRATION to the **SAME PATIENT** by injection; site indication dependent

- 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 prope

Patent protection to 2031+

9
U.S. patents granted

28
Foreign patents granted

Key Claims

- Pharmaceutical composition of non-expanded CD34+/CXCR4+ stem ce
- 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 TAR
CLBS16 CORONARY MICROVASCULAR DYSFUNCTION	FREEDOM PHASE 2B TRIAL (USA; ONGOING)	- Complete enrollment: - Top-line data: 3Q2022
HONEDRA® (CLBS12) *SAKIGAKE DESIGNATED CRITICAL LIMB ISCHEMIA + BUERGER'S DISEASE	REGISTRATION ELIGIBLE TRIAL (JAPAN; ONGOING)	- Complete enrollment: - Top-line data: 2Q2022 - J-NDA submission: 2H - Approval:1H2023
CLBS201 CHRONIC KIDNEY DISEASE	PHASE 1/2 (USA; CLINICAL INITIATION PENDING)	- File IND: 2Q2021 - Initiate enrollment: 2- - Complete enrollment: - Top-line data: 3Q2022
CLBS14 * RMAT DESIGNATED NO-OPTION REFRACTORY DISABLING ANGINA	PHASE 3 (USA; INITIATION PENDING)	- Complete developmer FDA discussions comp

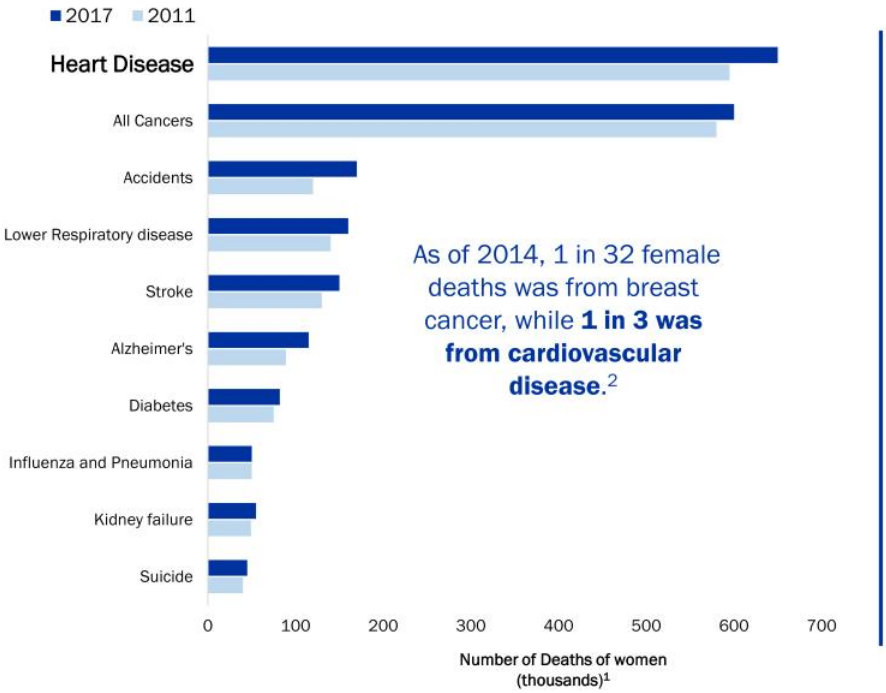
[1] Products are distinct and not interchangeable [2] Timing subject to COVID-19 pandemic influence

CLBS16

Coronary Microvascular Dysfunction

(USA)

CD34+ cell therapy targets unmet needs in cardiovascular disea



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

ISCHEMIA Trial[3] results underscore the for treatments beyond large vesse interventions

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

Conclusion:
Interventional heart procedures ***do*** reduce the overall rate of heart atta or death compared with medicines a 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 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 patients[3]
  - Significantly elevated risk of all-cause mortality[4]
- Clinically diagnosed based on symptoms ***and*** demonstrated absence of larg 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, 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

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CMD represents a large unmet medical need

- ~112 million people globally are affected by angina[1]
- ~8.3 million people in the U.S. suffering from coronary artery disease (C
- 10% - 30% of angina patients have no significant CAD on invasive corona angiography[3,4]
- 50% - 65% of patients with angina without obstructive CAD are believed t have CMD[5]

Applicable CMD population in the U.S. potentially treatable l 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

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

Endpoints	▪ Therapeutic effect and the evaluation of adverse events; including chang from baseline to 6 months for coronary flow reserve, angina frequency, C angina class, quality of life
Study Size	▪ 20 subjects (U.S. centers - Cedars Sinai, Los Angeles & Mayo Clinic, Roch
Dose	▪ Up to 300 x 10^6 CD34+ cells
Mode of administration	▪ Single intracoronary infusion
Timing	▪ Positive complete results presented at SCAI Scientific Sessions (May 202

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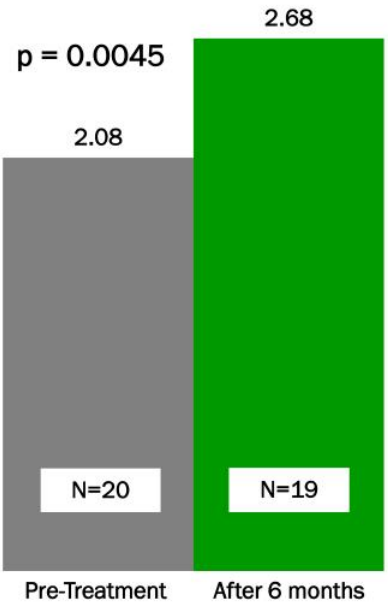
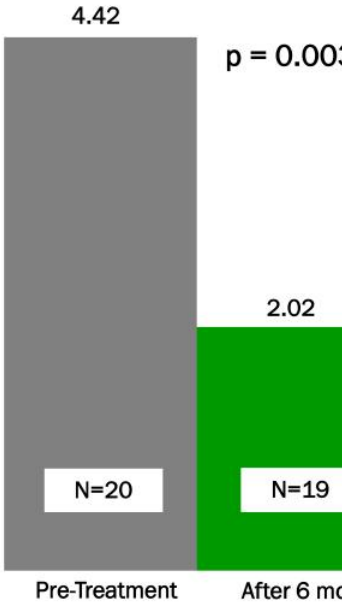
CLBS16 ESCaPE-CMD results are unique and compelling

Coronary Flow Reserve [1]



- CFR ≤2.5 indicates CMD
  - CFR of 2 = 3-4 x increase in MACE at 3 years[1]
- CFR ≥2.5 is in "normal" range
- Results after a single intracoronary administration of CLBS16

Daily Angina Frequenc



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

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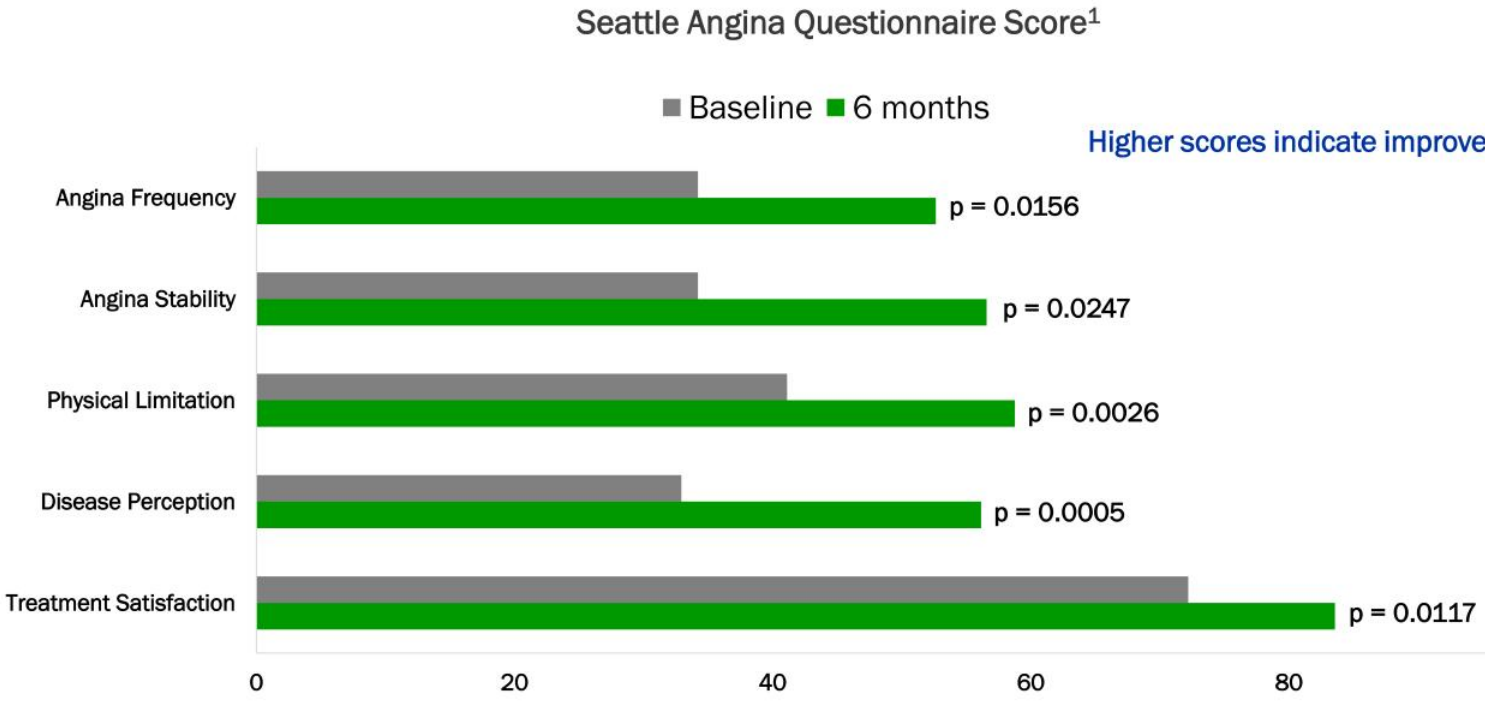
CLBS16 ESCaPE-CMD results are unique and compelling



[1] Henry, D. T., SCAI 2020 Scientific Sessions
[2] Spertus, J.A. et al, JACC Vol. 25, No. 2 February 1995: 333-341

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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 3Q2
  - Double blind, placebo-controlled, randomized

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

Endpoints	▪ 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	▪ 105 subjects (~10 sites in the USA)
Dose	▪ Up to 300 x 10^6 CD34+ cells vs. placebo
Mode of administration	▪ Single intracoronary infusion
Timing	▪ Study initiated 4Q2020 ▪ Top-line Data Target: 3Q2022

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HONEDRA®

(CLBS12)

Critical Limb Ischemia

(Japan)

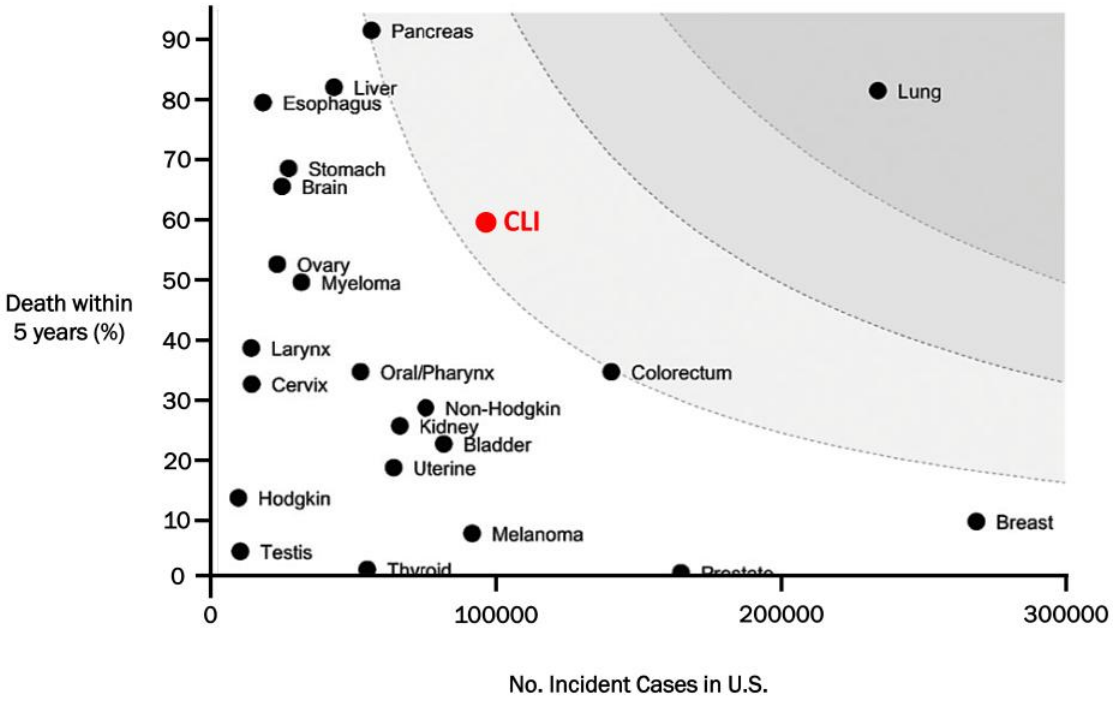
SAKIGAKE designated – Japan

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 cance



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

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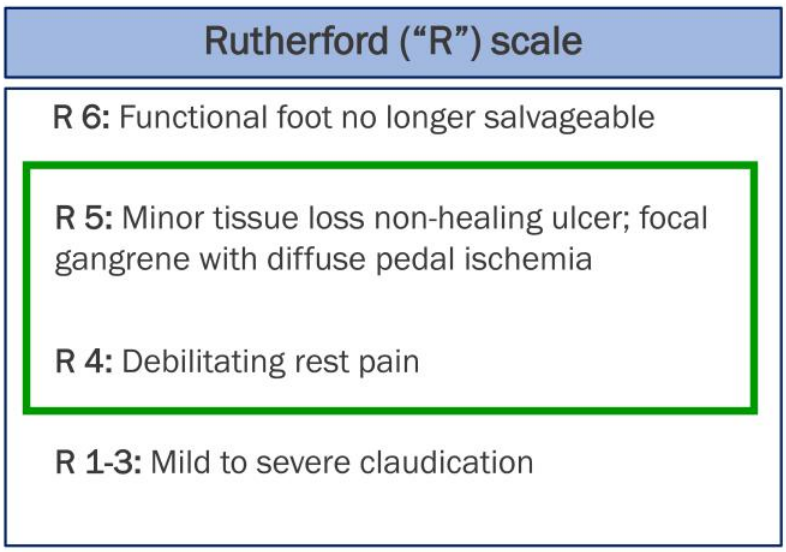
HONEDRA® targets patients based on the Rutherford Sca

CLI amputation rates increase with increasing Rutherford score (disease severity



HONEDRA® targets patie
with **R4** or **R5** disease

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

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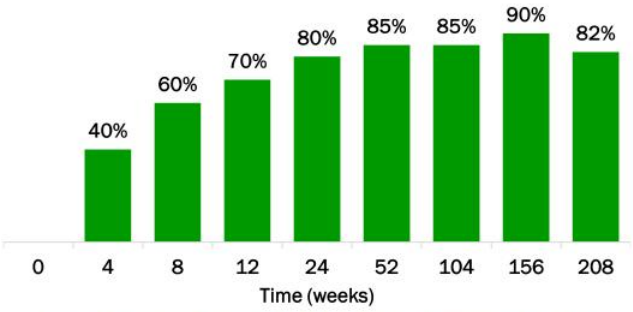
Single treatment of CD34+ cells reversed CLI (Phase 2 d

Actual CLI Patient Laser Doppler Image

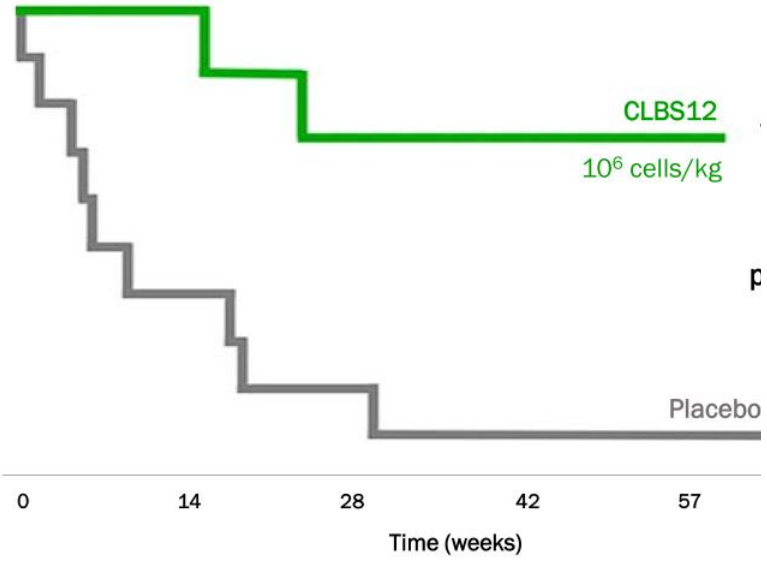
Pre-treatment Post-treatment (week 12)

% 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	▪ 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 of HONEDRA® per affected limb (studied in previous trial)
Control/Comparator	▪ Standard of Care: wound care plus drugs approved in Japan ▪ Including antimicrobials, antiplatelets, anticoagulants and vasodilat
Mode of administration	▪ Intramuscular, 20 injections in affected lower limb in a single treatment
Timing	▪ Enrollment completion/results target : 2Q2021/2Q2022, respectively ▪ Early approval targeted for 1H2023 ▪ Timing subject to COVID-19 pandemic influence

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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 statu

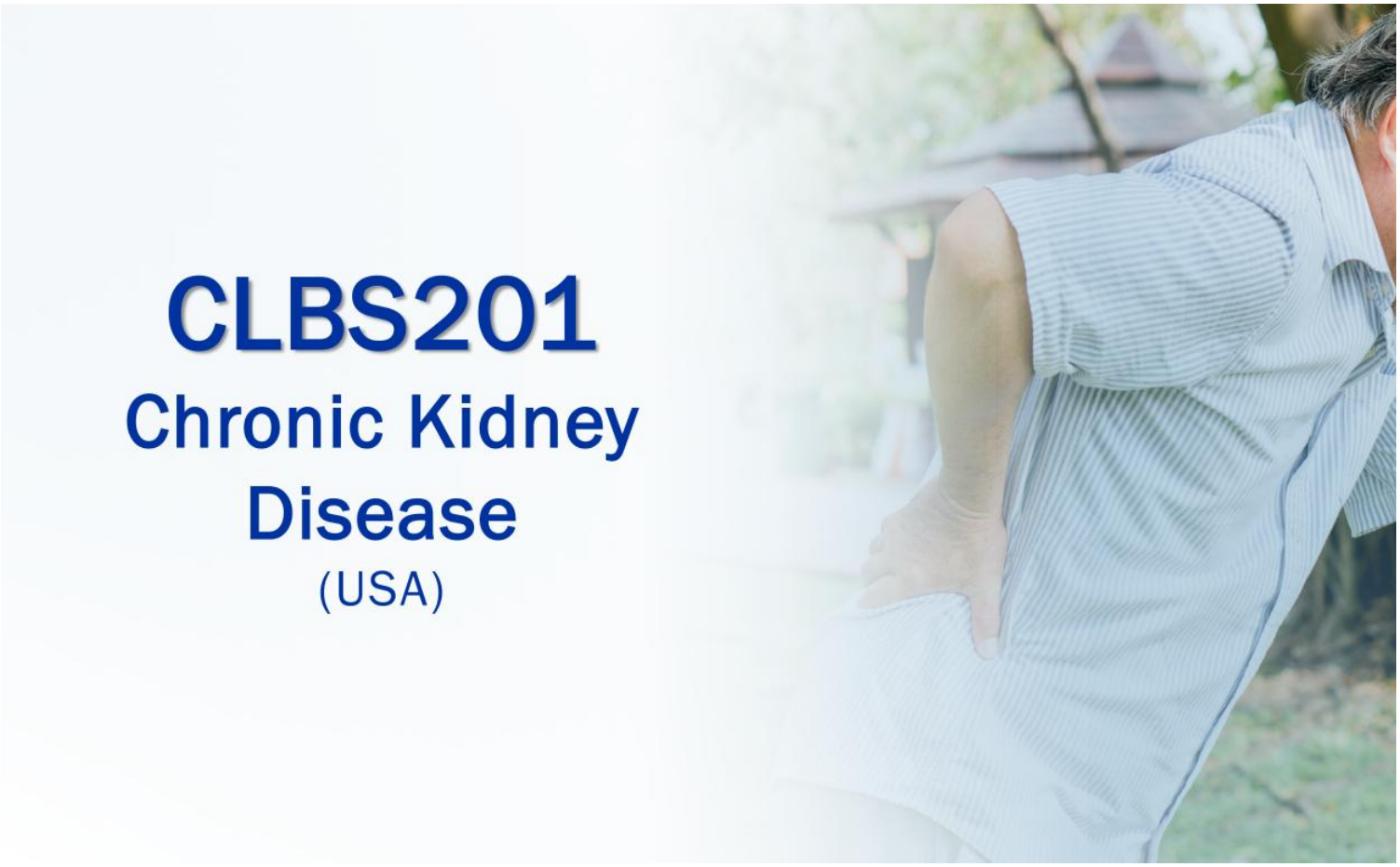
(Natural patient evolution is continual deterioration for all patients)

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

CLBS201

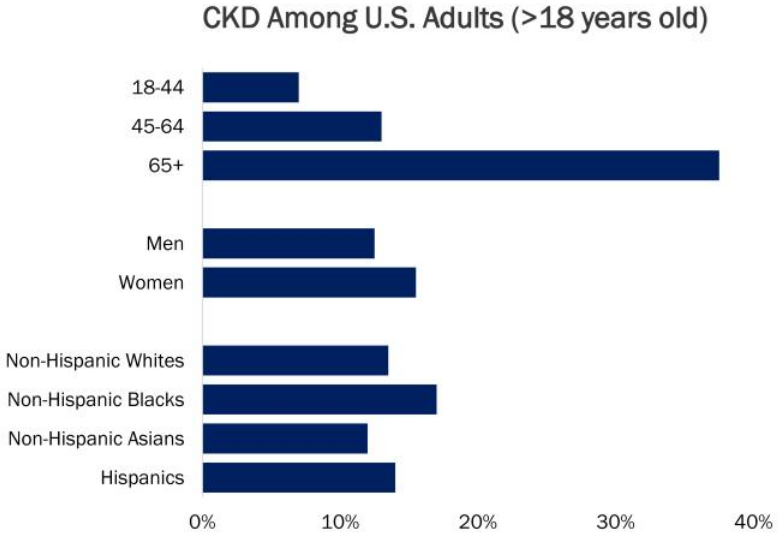
Chronic Kidney Disease

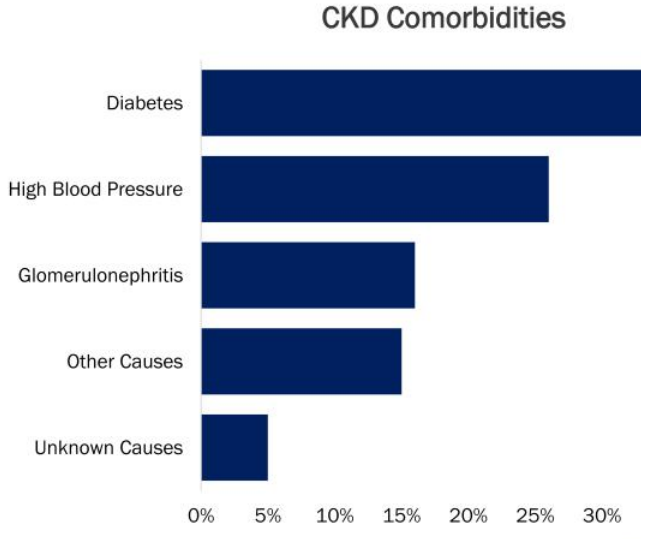
(USA)



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

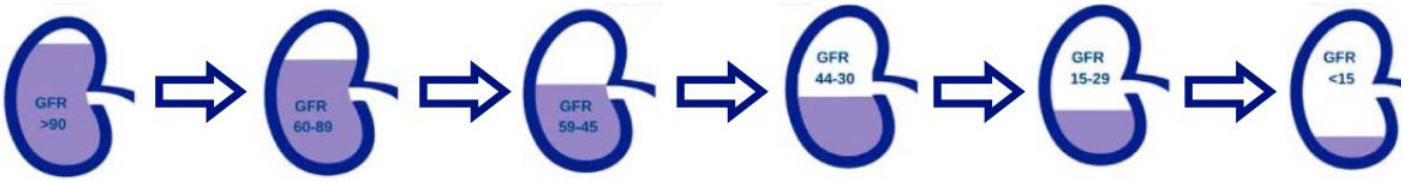




Centers for Disease Control and Prevention. Chronic Kidney Disease in the United States, 2019. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2019.

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 4[2]



STAGE 1 Normal function

STAGE 2 Mild loss of function

STAGE 3A Mild to Moderate loss of function

STAGE 3B Moderate to Severe loss of function

STAGE 4 Severe loss of function

STAGE 5 Kidney fail

[1] 2020 Dallas Nephrology Associates
[2] Centers for Disease Control and Prevention. Chronic Kidney Disease Surveillance System—United States.

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Scientific rationale for CLBS201 trial

- CKD is often associated with progressive microvasculature damage and loss, resu from its common comorbidities of hypertension and diabetes[1]
- The pathophysiology of CKD denotes compromised renal microvasculature[2]
- Preclinical studies show that microcirculation replenishment improves kidney func
- CD34+ cells are promoters of new capillary growth, improving the microvasculatur

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 prev

[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.*

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 treatm
- 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 3[1-5] 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, *Cardiovas Revasc Med*, 2018, 20(3):215-219

CLBS14 Phase 3 study; initial FDA proposed design

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 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	▪ Target initiation: Pending completion of ongoing discussions with FDA regarding orphan designation status, combination product definition and Phase 3 size/scope reductions

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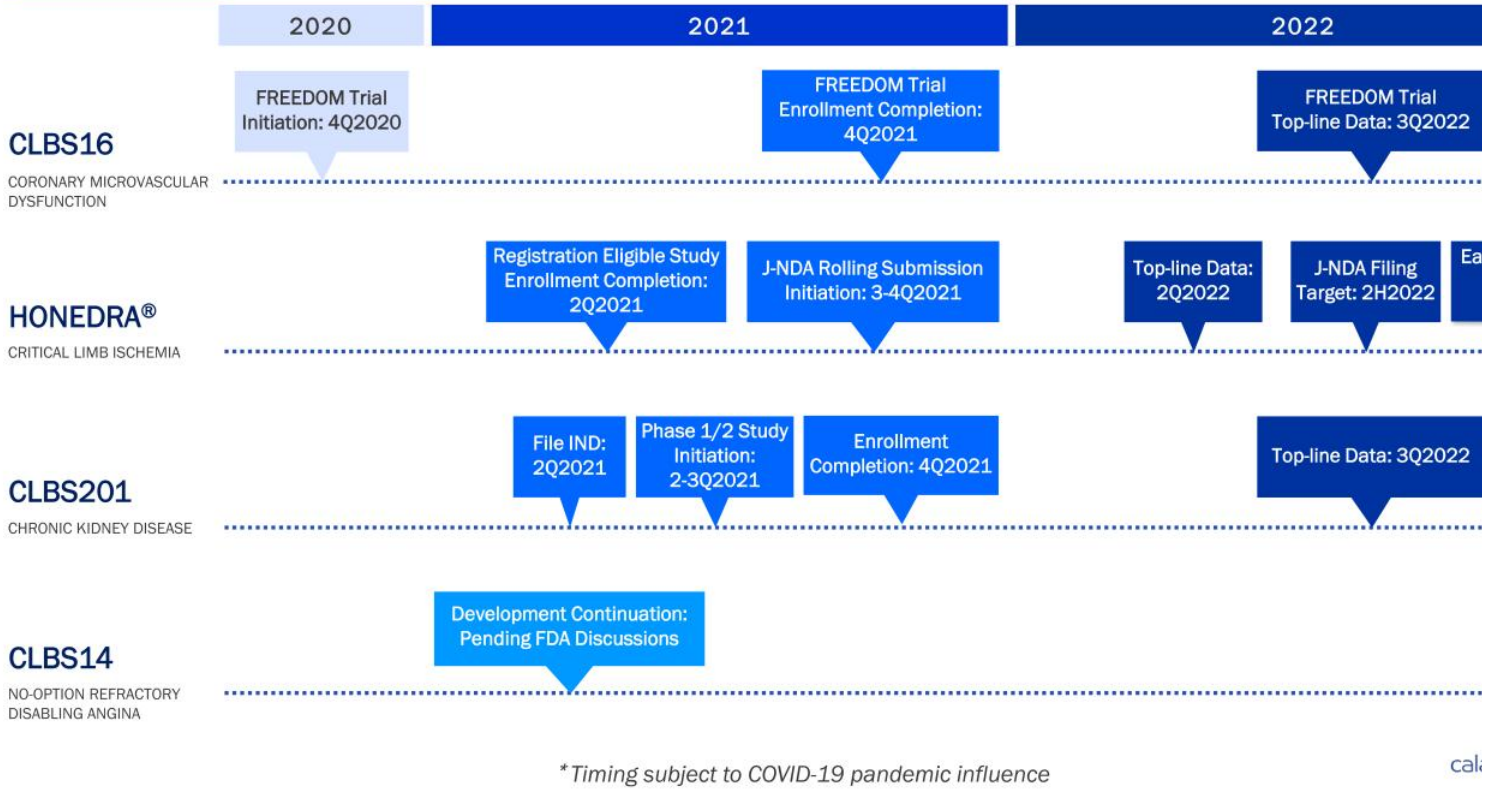
Caladrius timeline of key development milestones*



*Timing subject to COVID-19 pandemic influence

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” designat
- Proprietary field-leading technology in lucrative global indications backed b
  strong IP portfolio
- Multiple potential value creating events in the next 12-24 months based o
  milestones across the pipeline
- Strong balance sheet; ~$40.3 million in cash & cash equivalents (9/30/2
  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

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BIOSCIENCES

Developing Regenerative Therapies that Reverse Chronic Disease

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