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): February 25, 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 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 February 25, 2021, 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, 2020. 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 February 25, 2021 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 Exhibits 99.1 and 99.2 attached hereto, shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, except as otherwise expressly stated in such filing.

Item 9.01. Financial Statement and Exhibits.

Exhibit No.	Description
99.1	Press release, dated February 25, 2021
99.2	Caladrius Biosciences, Inc. Corporate Presentation, February 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: February 25, 2021

Exhibit 99.1

Caladrius Biosciences Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Business Update

Company demonstrates resilience despite COVID-19 challenges: Financial situation secure and development programs progressing

Conference call begins today at 4:30 p.m. (ET)

BASKING RIDGE, N.J. (February 25, 2021) – 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, provides a corporate update and reports financial results for the three and twelve months ended December 31, 2020.

"Despite the continued headwinds of the global pandemic, we are pleased to report continued progress of our development programs as well as an improved financial situation during the fourth quarter and full year of 2020, which reflect the resiliency, creativity and strength of our team and the growing optimism associated with our CD34+ cell technology-based clinical programs," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius. "We ended 2020 in a strong financial and strategic position and have set the stage for key clinical enrollment milestones this year.

"Importantly, we have continued the operational momentum into 2021 with an even further strengthened balance sheet, giving us the confidence and means to expand program development and execute on our business priorities," Dr. Mazzo concluded.

Product Development and Financing Highlights

CLBS16 for the treatment of coronary microvascular dysfunction

Caladrius reported in May 2020 the compelling positive results of its ESCaPE-CMD Phase 2a study of CLBS16 for the treatment of coronary microvascular dysfunction ("CMD"), a disease that continues to be underdiagnosed and potentially afflicts millions annually - a vast majority of whom are female - with no current treatment options. The Company is committed to raising awareness of this growing women's health crisis and finding an effective treatment for it. Consequently, Caladrius recently initiated a rigorous 105-subject Phase 2b clinical trial (the FREEDOM trial), which, to our knowledge, is the first controlled regenerative medicine trial in CMD, and, which is currently recruiting and treating patients and is targeted to complete enrollment by the end of 2021 with top line data anticipated for the third quarter of 2022. This double-blind, randomized, placebo-controlled Phase 2b trial will evaluate the efficacy and safety of delivering autologous CD34+ cells in subjects with CMD and without obstructive coronary artery disease. In support of the FREEDOM trial, the Company is engaging with the American Heart Association for a variety of initiatives around Heart Health Month (February) and the "Go Red for Women" campaign to help raise awareness of CMD.

HONEDRA® (CLBS12) for the treatment of critical limb ischemia

The Company's open-label, registration-eligible study of SAKIGAKE-designated HONEDRA® in Japan for the treatment of critical limb ischemia ("CLI") and Buerger's Disease (an orphan-sized subset of CLI) has shown strong results to date. The initial responses observed in the subjects who have reached an endpoint in this study are consistent with a therapeutic effect and safety profile reported by previously published clinical trials in Japan and the USA. Although the study's enrollment has been slowed by the pandemic's impact in Japan, the Company is encouraged by the patient pre-screening pipeline and hopes to conclude trial enrollment during the second quarter of 2021. While the final outcome of the trial will depend on all data from all subjects, the data to date is very encouraging (~60% of

subjects in the completed Buerger's Disease cohort have reached a positive "CLI-free" endpoint, despite a natural history of such patients predicting continuing disease progression to amputation).

CLBS201 for the treatment of pre-dialysis chronic kidney disease

Our most recently proposed development program, CLBS201, is designed to assess the safety and efficacy of CD34+ cell therapy as a treatment for chronic kidney disease ("CKD") in patients not yet requiring dialysis. 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. Caladrius plans to file an IND for this program in the second quarter of 2021 and to initiate a Phase 1/2 proof-of-concept study of CLBS201 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.

OLOGO™ for the treatment of no option refractory disabling angina ("NORDA")

We acquired the rights to data and regulatory filings for a CD34+ cell therapy program for NORDA that had been advanced to Phase 3 by a previous sponsor. Based on the clinical evidence from the completed studies that a single administration of OLOGO™ reduces mortality, improves angina and increases exercise capacity in patients with otherwise untreatable angina, this product received Regenerative Medicine Advanced Therapy ("RMAT") designation from the FDA. We remain in discussion with the FDA regarding the size and scope of a phase 3 trial which, in combination with previously filed Phase 1, 2 and 3 data, will be considered for the registration of OLOGO™. Notably, the RMAT designation affords the product a 6-month review time for a biologics license application ("BLA"), once submitted.

Closed on an additional $90.0 million in funding

In January 2021, the Company announced that it had closed on a $25.0 million capital raise through the sale of its common stock to several institutional and accredited investors in a private placement priced at-the-market under Nasdaq rules. In February 2021, the Company announced that it closed a $65.0 million capital raise through the sale of its common stock to several institutional and accredited investors in two registered direct offerings priced at-the-market under Nasdaq rules.

Fourth Quarter and Full Year 2020 Financial Highlights

Research and development expenses for the fourth quarter of 2020 were $2.9 million, a 5% increase compared with $2.8 million for the fourth quarter of 2019, and $9.3 million for the year ended December 31, 2020 compared to $10.8 million for the year ended December 31, 2019, representing a decrease of approximately 14%. Research and development in both the current year and prior year periods focused on the advancement of our ischemic repair platform and related to:

- Expenses associated with exploration of our concept program, CLBS119, a CD34+ cell therapy for repair of COVID-19 induced lung damage targeting patients with severe SARS-CoV-2 infection that required ventilatory support due to respiratory failure (this program has since been indefinitely postponed due to the continuous evolution of the targeted patient population);
- Ongoing expenses for HONEDRA® in critical limb ischemia in Japan, whereby we continue to focus spending on patient enrollment and Japanese NDA preparation (enrollment completion is now targeted for 2Q21 based on the impact of the COVID-19 pandemic in Japan);
- Expenses associated with the proof-of-concept study for CLBS16 in coronary microvascular dysfunction, for which study enrollment was completed in the second quarter of 2019 and full

results reported in May 2020 and continuing efforts to advance CLBS16 into a Phase 2b study (the FREEDOM trial) in the second half of 2020; and

- Expenses associated with the ongoing dialogue with FDA regarding design and execution of confirmatory Phase 3 study of OLOGO™ in NORDA.

General and administrative expenses, which focus on general corporate related activities, were $2.5 million for the three months ended December 31, 2020, compared to $2.3 million for the three months ended December 31, 2019, and $9.9 million for the year ended December 31, 2020, compared to $9.3 million for the year ended December 31, 2019, representing an increase of 6%.

Overall, net losses were $8.1 million and $19.4 million for the years ended December 31, 2020 and 2019, respectively.

Balance Sheet Highlights

As of December 31, 2020, Caladrius had cash, cash equivalents and marketable securities of $34.6 million and, following the previously mentioned capital raises in January and February 2021, the Company has cash, cash equivalents and marketable securities of approximately $116 million as of February 25, 2021. Based on existing programs and projections, the Company remains confident that its current cash balances will fund its operations for the next several years, notably, through study completion for the Phase 2b for CLBS16, through the registration-eligible study completion for HONEDRA® and through the Phase 1/2 Proof-of-Concept study for CLBS201 while still providing capital to explore additional pipeline expansion opportunities.

Conference Call

Caladrius will hold a conference call on Thursday, February 25, 2021, at 4:30 p.m. Eastern time to discuss the financial results, provide a business update and answer questions. To join the conference call, please refer to the dial-in information provided below. The conference call will also be webcast live under the Investors section on the Company's website at www.caladrius.com.

Dial-in information:
U.S. Toll-Free: 866-595-8403
International: 706-758-9979
Conference ID / Passcode: 7372695

Please dial-in at least 10 minutes before the conference call starts.

For those unable to participate in the live conference call, an audio replay will be available approximately two hours after the call has concluded until March 4, 2021, by dialing 855-859-2056 (domestic) or 404-537-3406 (international) and referencing conference ID / passcode: 7372695. A webcast recording of the call will also be archived for 90 days under the Investors section of the Company's website at www.caladrius.com.

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: 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"); HONEDRA® (CLBS12), recipient of SAKIGAKE designation and eligible for early conditional approval in Japan for the treatment of critical limb ischemia ("CLI") and Buerger's Disease based on the results of an ongoing clinical trial; CLBS201, designed to assess the safety and efficacy of CD34+ cell therapy as a

treatment for chronic kidney disease (“CKD”) and OLOGO™ (CLBS14), a Regenerative Medicine Advanced Therapy (“RMAT”) designated therapy for which the Company is in discussion with the U.S. Food and Drug Administration (the “FDA”) to finalize a Phase 3 protocol of reduced size and scope for a 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 the completion of the private placement, the satisfaction of customary closing conditions related to the private placement and the intended use of net proceeds from the private placement 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; market and other conditions; 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

- Tables to Follow -

\

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
(in thousands, except per share data)	(unaudited)	(unaudited)		
Statement of Operations Data:				
Research and development	$ 2,907	$ 2,767	$ 9,253	$ 10,797
General and administrative	2,539	2,316	9,892	9,295
Total operating expenses	**5,446**	**5,083**	**19,145**	**20,092**
Operating loss	**(5,446)**	**(5,083)**	**(19,145)**	**(20,092)**
Investment income, net	15	129	132	740
Net loss before benefit from income taxes and noncontrolling interests	**(5,431)**	**(4,954)**	**(19,013)**	**(19,352)**
Benefit from income taxes	—	—	(10,872)	—
Net loss	**(5,431)**	**(4,954)**	**(8,141)**	**(19,352)**
Less - net (loss) income attributable to noncontrolling interests	(1)	3	9	9
Net loss attributable to Caladrius Biosciences, Inc. common shareholders	**$ (5,430)**	**$ (4,957)**	**$ (8,150)**	**$ (19,361)**
Basic and diluted loss per share attributable to Caladrius Biosciences, Inc. common shareholders	**$ (0.28)**	**$ (0.47)**	**$ (0.53)**	**$ (1.88)**
Weighted average common shares outstanding	**19,396**	**10,460**	**15,440**	**10,325**

	December 31, 2020	December 31, 2019
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 34,573	$ 25,157
Total assets	36,002	27,153
Total liabilities	3,760	6,600
Total equity	32,242	20,553

# # #

Exhibit 99.2

caladrius
BIOSCIENCES

Developing Regenerative Therapies that Reverse Chronic Disease

David J. Mazzo, PhD
President & Chief Executive Officer

February 25, 2021 | Nasdaq: CLBS

Forward-looking statement

This Investor Presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements reflect management's current expectations, as of the date of this presentation, and involve certain risks and uncertainties. All statements other than statements of historical fact contained in this Investor Presentation are forward-looking statements. The Company's actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors. Factors that could cause future results to differ materially from the recent results or those projected in forward-looking statements include the "Risk Factors" described in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on February 25, 2021 and in the Company's other periodic filings with the SEC. The Company's further development is highly dependent on, among other things, future medical and research developments and market acceptance, which are outside of its control. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this Investor Presentation. Caladrius does not intend, and disclaims any obligation, to update or revise any forward-looking information contained in this Investor Presentation or with respect to the matters described herein.

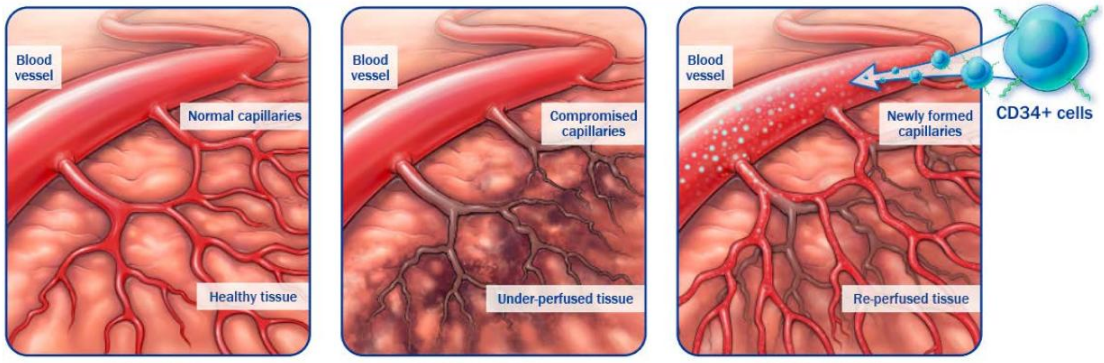
Caladrius investment highlights

- CD34+ cell therapy platform yielding a multi-product development pipeline with 2 clinical programs having regenerative medicine “breakthrough” designation
- Proprietary field-leading technology in lucrative global indications backed by a strong IP portfolio
- Multiple potential value creating events in the next 12-24 months based on milestones across the pipeline
- Strong balance sheet; ~116 million in cash & cash equivalents (2/25/2021) with no debt and cash runway projected to fund operations for several years
- 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 action



NORMAL MICROVASCULATURE | **COMPROMISED MICROVASCULATURE** | **AUGMENTED MICROVASCULATURE**

- Naturally occurring endothelial progenitor cells that re-establish blood flow to under-perfused tissues[1,2]
- 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

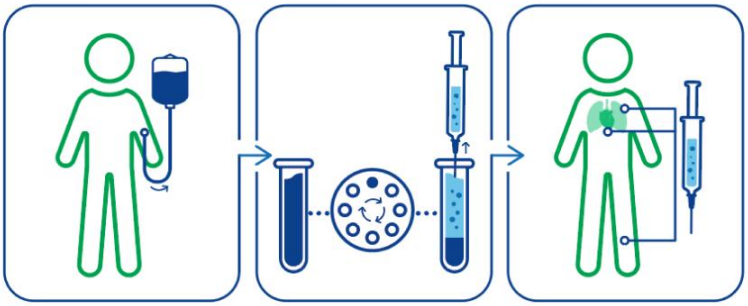
CD34+ cell therapy is extensively studied/clinically validated

- 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 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/scaled

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 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 TARGETS
CLBS16 CORONARY MICROVASCULAR DYSFUNCTION	FREEDOM PHASE 2B TRIAL (**USA**; ONGOING)	- Complete enrollment: **4Q2021** - Top-line data: **3Q2022**
HONEDRA® (CLBS12) ***SAKIGAKE DESIGNATED*** CRITICAL LIMB ISCHEMIA + BUERGER'S DISEASE	REGISTRATION ELIGIBLE TRIAL (**JAPAN**; ONGOING)	- Complete enrollment: **2Q2021** - Top-line data: **2Q2022** - J-NDA submission: **2H2022** - Approval:**1H2023**
CLBS201 CHRONIC KIDNEY DISEASE	PHASE 1/2 (**USA**; CLINICAL INITIATION PENDING)	- File IND: **2Q2021** - Initiate enrollment: **2-3Q2021** - Complete enrollment: **4Q2021** - Top-line data: **3Q2022**
OLOGO™ (CLBS14) * ***RMAT DESIGNATED*** NO-OPTION REFRACTORY DISABLING ANGINA	PHASE 3 (**USA**; INITIATION PENDING)	- Complete development: **Pending FDA discussions completion**

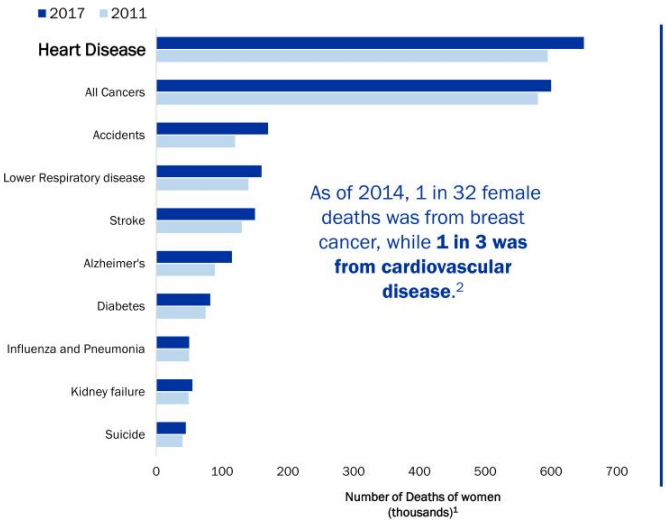
[1] Products are distinct and not interchangeable [2] Timing subject to COVID-19 pandemic influence

CLBS16

Coronary Microvascular Dysfunction

(USA)

CD34+ cell therapy targets unmet needs in cardiovascular diseases



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

- The International Study of Comparative Health 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 patients[3]
  - Significantly elevated risk of all-cause mortality[4]
- 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, 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

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 (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 CMD[5]

Applicable CMD population in the U.S. potentially treatable by CLBS16 ranges from ~415,000 to ~1.6 million patients[6]

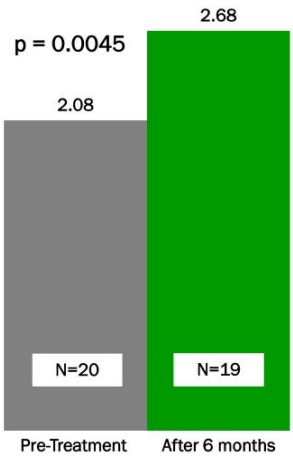
[1] Kunadian V, et al. European Heart Journal. 2020; 0:1-21
[2] Cleveland Clinic/AHA (American Heart Association)
[3] Farrehi PM, et al. Am J Manag Care. 2002;8:643–648
[4] Bradley SM, et al. J Am Coll Cardiol. 2014;63:417–426
[5] Marinescu MA, et al. JACC Cardiovasc Imaging. 2015;8:210-220
[6] Tunstall-Pedoe H. (ed.) WHO, Geneva, 2003, pp. 244, Swiss Fr 45, ISBN: 92-4-156223-4.

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

Endpoints	▪ Therapeutic effect and the evaluation of adverse events; including changes from baseline to 6 months for coronary flow reserve, angina frequency, CCS angina class, quality of life
Study Size	▪ 20 subjects (U.S. centers - Cedars Sinai, Los Angeles & Mayo Clinic, Rochester)
Dose	▪ Up to 300 x 10^6 CD34+ cells
Mode of administration	▪ Single intracoronary infusion
Timing	▪ Positive complete results presented at SCAI Scientific Sessions (May 2020)

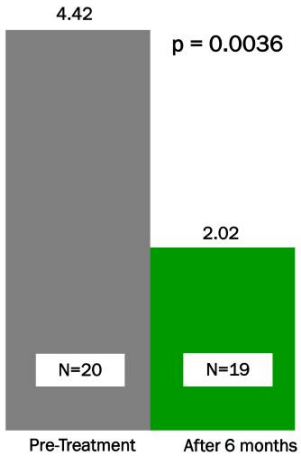
CLBS16 ESCaPE-CMD results are unique and compelling

Coronary Flow Reserve [1]



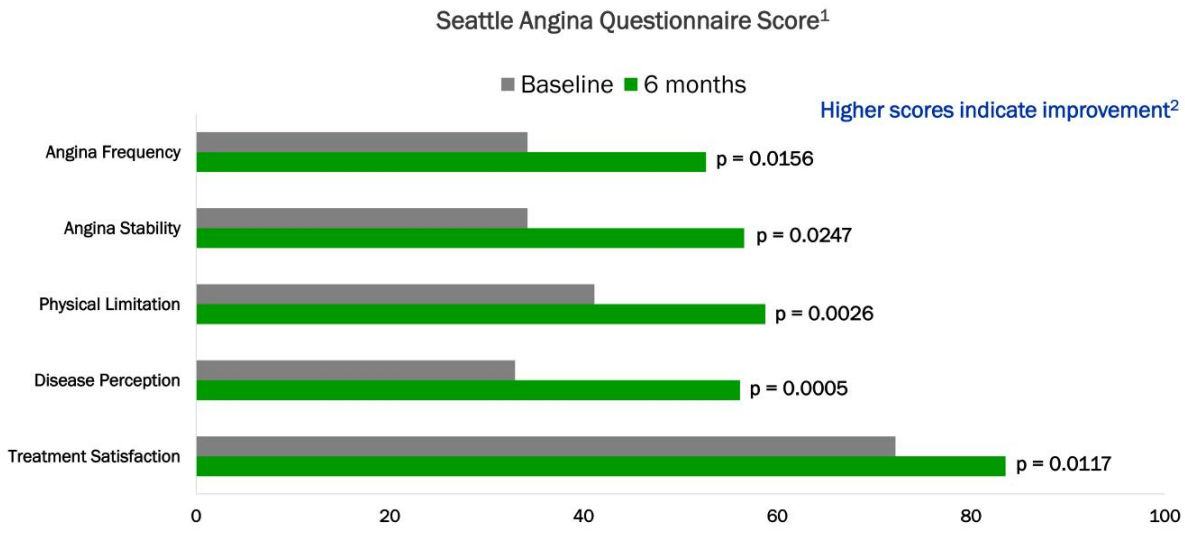
- CFR ≤2.5 indicates CMD
  - CFR of 2 = 3-4 x increase in MACE at 3 years[1]
- CFR ≥2.5 is in "normal" range
- Results after a single intracoronary administration of CLBS16

Daily Angina Frequency [2]



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

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

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 death
- Supports microvascular repair mechanism of CD34+ cells
- Phase 2b FREEDOM trial initiated 4Q2020; top-line data anticipated 3Q2022
  - Double blind, placebo-controlled, randomized

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

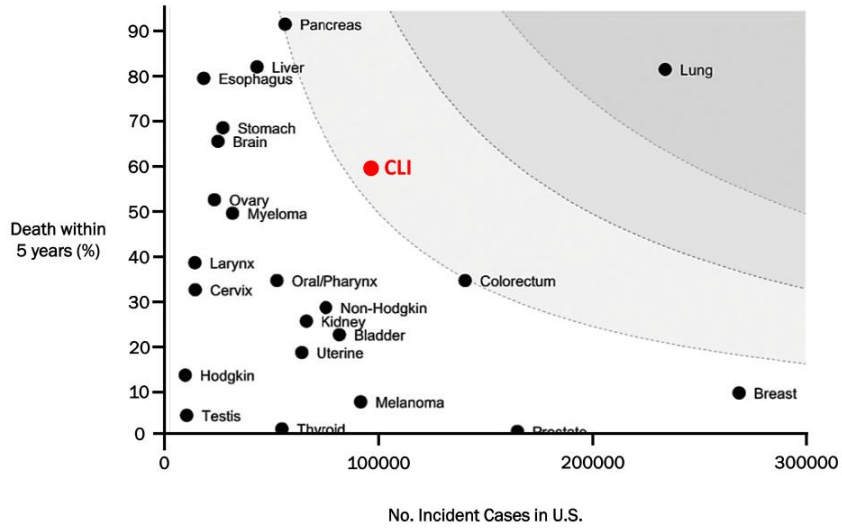
Endpoints	▪ Change from baseline in angina frequency [Baseline to 3 and 6 months] ▪ Change from baseline in total exercise time [Baseline to 6 months] ▪ Change from baseline in health-related quality of life [Baseline to 3 and 6 months] ▪ Change from baseline in peak coronary flow reserve [Baseline to 6 months]
Study Size	▪ 105 subjects (~10 sites in the USA)
Dose	▪ 1 x 10^6 to 300 x 10^6 CD34+ cells or placebo
Mode of administration	▪ Single intracoronary infusion
Timing	▪ Study initiated 4Q2020 ▪ Complete Enrollment: Year- End 2021 ▪ 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 CLI 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 cancers



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

HONEDRA® targets patients based on the Rutherford Scale

CLI amputation rates increase with increasing Rutherford score (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: Mild to severe claudication

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

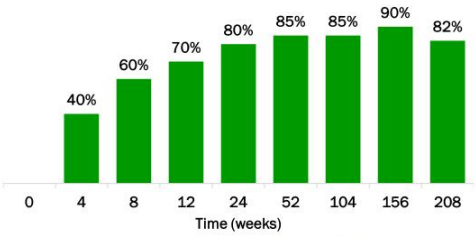
[1] Reinecke H., European Heart Journal, 2015 Apr 14;36(15):932-8

Single treatment of CD34+ cells reversed CLI (Phase 2 data)

Actual CLI Patient Laser Doppler Image

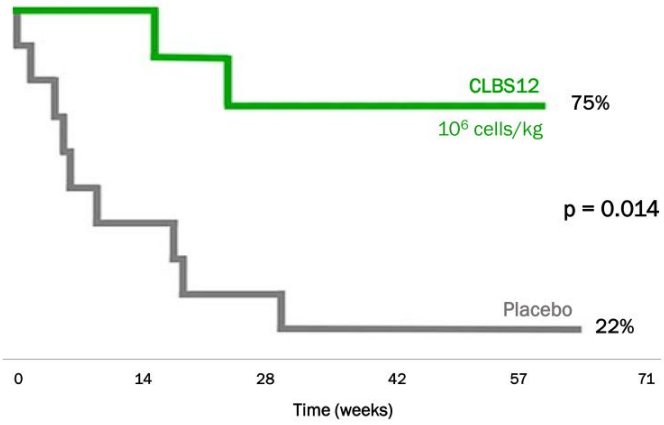
Pre-treatment Post-treatment (week 12)

% 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 independently)
Study Size	▪ 30 subjects with no-option CLI + 7 Buerger's Disease pts.; all Rutherford category 4 or 5; recruited across 12 centers in Japan
Dose	▪ 10^6 cells/kg of HONEDRA® to the most seriously affected limb (target limb)
Control/Comparator	▪ Standard of Care: wound care plus drugs approved in Japan ▪ Including antimicrobials, antiplatelets, anticoagulants and vasodilators
Mode of administration	▪ Intramuscular, 20 injections in affected lower limb in a single treatment
Timing	▪ Enrollment completion/results target : 2Q2021/2Q2022, respectively ▪ Early approval target: 1H2023 ▪ Timing subject to COVID-19 pandemic influence

Extraordinary HONEDRA® results in Buerger's Disease (JPN)

- Surgery not viable; existing pharmacotherapies do not prevent amputation[1]
- Cohort enrollment complete
- Results will contribute to the efficacy evaluation of the full study population

Approximately 60% of patients achieved CLI-free status

(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

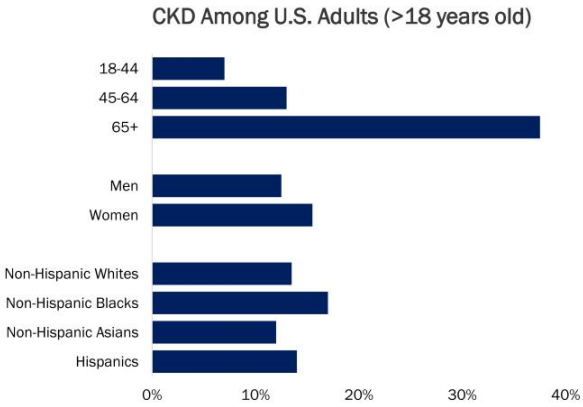
CLBS201

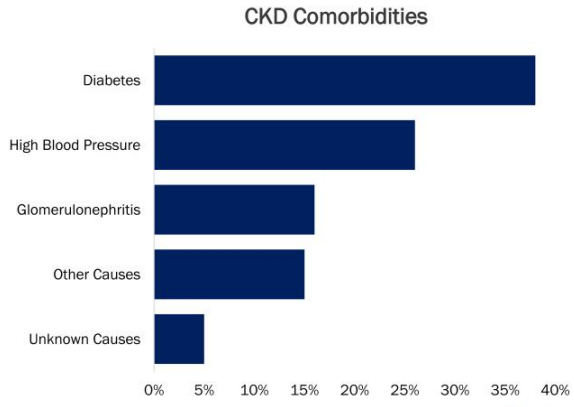
Chronic Kidney Disease

(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

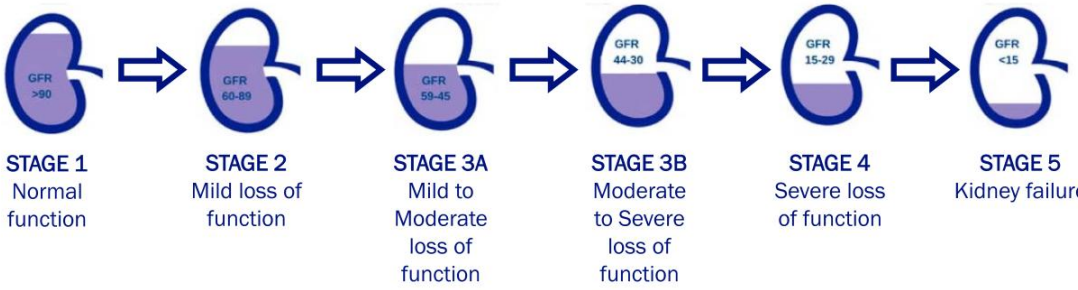




Centers for Disease Control and Prevention. Chronic Kidney Disease in the United States, 2019. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2019.

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 creatinine)
- 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, ~15 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 failure

[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 diabetes[1]
- The pathophysiology of CKD denotes compromised renal microvasculature[2]
- 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.*

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 (stage 3b/4 CKD patients)
Dose	▪ 10^6 cells/kg administered as a one-time infusion
Design	▪ Placebo-controlled with a total of 12-months follow-up
Mode of administration	▪ Single intra-arterial injection into each renal artery
Timing	▪ Initiation target: 2Q2021 ▪ Top-line data target: 3Q2022


OLOGO™
(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: OLOGO™ (CLBS14)

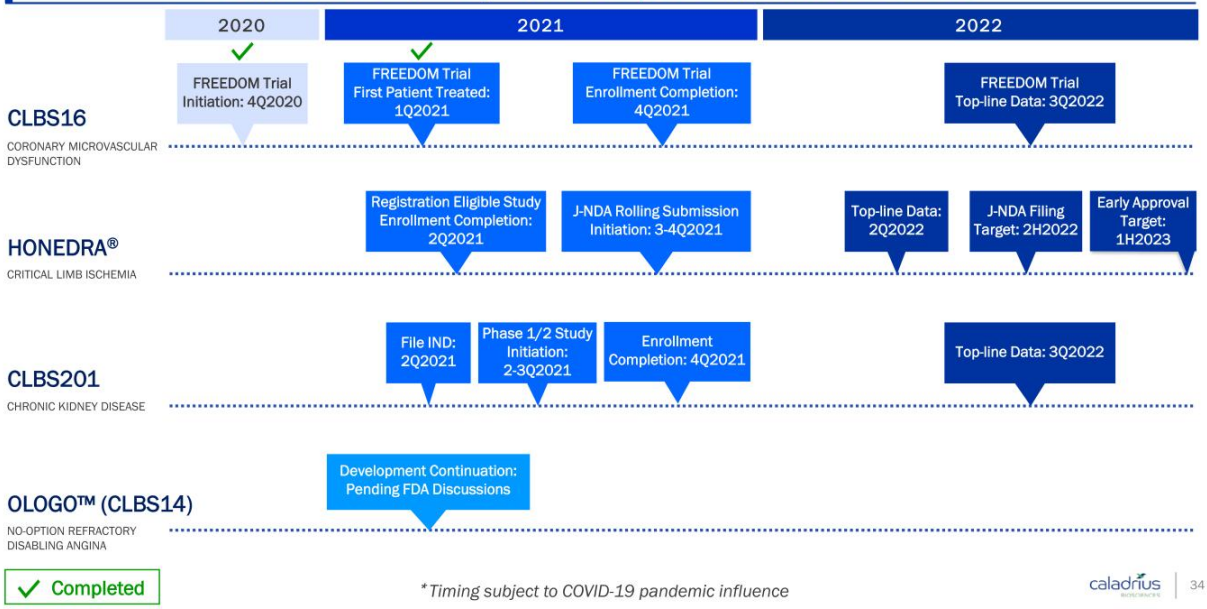
- Phase 2 and partial Phase 3[1-5] clinical data (blinded, randomized, placebo-controlled; $n_{(total)}$= 303) show:
  - Statistically significant increase in exercise capacity (FDA primary endpoint)
  - Statistically significant reduction in angina
  - Statistically significant reduction in mortality
  - 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

OLOGO™ (CLBS14) Phase 3 study; initial FDA agreement

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% of patients complete 6-month follow-up
Study Size	▪ ~400 subjects (~200 active, ~150 placebo, ~50 SOC with cross-over to open label treatment at 6 months)
Dose	▪ 10^5 cells/kg body weight (studied in Phase 2)
Control/Comparator	▪ Placebo control (blinded) ▪ Standard-of-care (unblinded)
Mode of administration	▪ Intramyocardial injection guided by mapping catheter (NOGA)
Timing	▪ Target initiation: Pending completion of ongoing discussions with FDA regarding orphan designation status, combination product definition and Phase 3 size/scope reductions

Caladrius timeline of key development milestones*



*Timing subject to COVID-19 pandemic influence

Caladrius key financial information

Cash & Investments: As of February 25, 2021[1]	~$116 million
Full Year Ended December 31, 2020 Operating Cash Burn:[2]	$19.7 million
Cash Runway Based on Current Plan:	Sufficient capital to fund operations beyond multiple key data readouts (>2023)
Debt as of February 25, 2021:	$0
Common Shares Outstanding: As of February 25, 2021[3]	59.5 million shares
Options Outstanding as of February 25, 2021: Exercise Price: $1.43 - $3.50 = 192,000 shares Exercise Price: > $3.50 = 765,000 shares	1.0 million shares
Warrants Outstanding as of February 25, 2021[4]: Weighted Average Exercise Price: $2.84	21.4 million shares

[1] Includes $25.0 million in gross proceeds from January 2021 Private Placement, $1.8 million from warrant exercises in January 2021 and $65.0 million in gross proceeds from February 2021 Registered Direct Offerings
[2] Excludes $10.9 million in net proceeds from sale of New Jersey NOLs
[3] Includes 12.5 million shares from January 2021 Private Placement, ~0.8 million shares from from warrant exercises in January 2021 and 26.5 million shares from February 2021 Registered Direct Offerings
[4] Includes ~6.3 million warrants from January 2021 Private Placement less ~0.8 million warrants exercised in January 2021 plus ~13.3 million warrants from February 2021 Registered Direct Offerings

Caladrius investment highlights

- CD34+ cell therapy platform yielding a multi-product development pipeline with 2 clinical programs having regenerative medicine “breakthrough” designation
- Proprietary field-leading technology in lucrative global indications backed by a strong IP portfolio
- Multiple potential value creating events in the next 12-24 months based on milestones across the pipeline
- Strong balance sheet; ~116 million in cash & cash equivalents (2/25/2021) with no debt and cash runway projected to fund operations for several years
- Seasoned management with noteworthy domain expertise along with big pharma and emerging biotech experience

caladrius

BIOSCIENCES

Developing Regenerative Therapies that Reverse Chronic Disease

Investor Relations Contact:
John D. Menditto
Tel: (908) 842-0084
jmenditto@caladrius.com

February 25, 2021 | Nasdaq: CLBS