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

August 5, 2021
Date of Report (date of earliest event reported)

CALADRIUS BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-33650**	**22-2343568**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

110 Allen Road, Second Floor, Basking Ridge, NJ 07920
(Address of Principal Executive Offices)(ZipCode)
(908) 842-0100
Registrant's telephone number, including area code

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 (see General Instruction A.2. below):

☐ 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

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 August 5, 2021, Caladrius Biosciences, Inc. (the "Company") issued a press release in connection with its financial results for the second quarter ended June 30, 2021. 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 August 5, 2021 at 4:30 p.m. Eastern Time.

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 99.2 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.

	Description
99.1	Press release, dated August 5, 2021
99.2	Caladrius Biosciences, Inc. Corporate Presentation, August 5, 2021

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: August 5, 2021

Exhibit 99.1

Caladrius Biosciences Reports Second Quarter 2021 Financial Results and Provides Business Update

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

BASKING RIDGE, N.J. (August 5, 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 six months ended June 30, 2021.

"The second quarter and first six months of 2021 have proven to be operationally and financially positive for Caladrius. Despite the continuing challenges presented by the COVID-19 pandemic, we continued to advance and expand our clinical pipeline while also adding a large amount of additional capital to our balance sheet," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius. "Most notably, we are seeing steady progress with site activation for our Phase 2b FREEDOM Trial of CLBS16 for the treatment of coronary microvascular dysfunction, as we continue to increase outreach activities to potential subjects in order to accelerate enrollment. In addition, a Phase 2 proof-of-concept clinical trial of CLBS201, designed to assess the safety and efficacy of CD34+ cell therapy as a treatment for patients with pre-dialysis diabetic kidney disease, is on track for a planned initiation in the second half of 2021. Lastly, even though our registration-eligible study of HONEDRA® in critical limb ischemia and Buerger's disease continues to be greatly impacted by the Japanese government-issued states of emergency tied to the COVID-19 pandemic, we have managed to treat patients and remain optimistic that the few remaining patients needed to complete enrollment will be treated by year end."

Product Development and Financing Highlights

CLBS16 for the treatment of coronary microvascular dysfunction

Caladrius reported in May 2020 the compelling 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. To this end, we have partnered with the American Heart Association on a number of activities designed to educate people about CMD and to encourage them to discuss the condition with their physician. Caladrius recently initiated, and is currently treating patients in, a rigorous 105-subject Phase 2b clinical trial (the FREEDOM Trial) which, to our knowledge, is the first controlled regenerative medicine trial in CMD.

Investigator and subject response to the FREEDOM Trial has been favorable and early enrollment proceeded according to plan. However, the continued impact of the COVID-19 pandemic, including the resurgence of cases occurring in select areas throughout the United States, has contributed to a general slowing of enrollment. In addition, further work with investigators and prospective subject feedback led the Company to propose to the FDA amendments to the FREEDOM Trial protocol to enhance the breadth and speed of subject enrollment. These changes included expanding the techniques that are acceptable for diagnosing CMD. Nevertheless, given the uncertainty that persists surrounding the future impact of the COVID-19 pandemic on potential patient recruitment and the accessibility of investigator sites, the Company now projects enrollment completion for the FREEDOM Trial to occur in the third quarter of 2022 with final data (based on the 6 month assessment of all subjects) expected by the second quarter of 2023.

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 positive therapeutic effect and safety profile reported by previously published clinical trials in Japan and the U.S. The study's enrollment continues to be almost stopped by the pandemic's impact in Japan, however, the Company is encouraged that less than a handful of patients are needed to reach study completion, the exact date of which is impossible to predict given the continuing impact of COVID-19 on clinical trials in Japan. While the final outcome of the trial will depend on all data from all subjects, the data to date is 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 that predicts continuing disease progression to amputation). In the U.S., the Company was pleased to report that the U.S. Food and Drug Administration ("FDA") granted orphan designation to CLBS12 as a treatment for Buerger's disease,

however, any decisions regarding potential development in the U.S. will be made after further discussion with FDA on the requirements for registration.

CLBS201 for the treatment of diabetic kidney disease

The Company has prepared an initial development plan for the clinical study of CLBS201, a CD34+ investigational product for administration via the renal arteries to slow the deterioration, or, ideally, reverse the decline of renal function in patients with diabetic kidney disease ("DKD") who, although still pre-dialysis, exhibit rapidly progressing stage 3b disease. Progressive kidney failure is associated with attrition of the microcirculation of the kidney. Pre-clinical studies in kidney disease and injury models have demonstrated that protection or replenishment of the microcirculation results in improved kidney function. A Phase 2 proof of concept, randomized, placebo-controlled study for the stage 3b chronic kidney disease patient population is planned to initiate in the second half of 2021. The protocol, pending final central institutional review board approval, calls for a six-subject open-label treatment run-in arm in which patients will be treated sequentially, to be completed, evaluated and cleared for continuation by the study's data safety monitoring board prior to initiating the 40-patient randomized, placebo-controlled, double blinded portion of the trial. The Company is projecting that safety data from the six-subject run-in arm will be completed by the end of the second quarter of 2022.

OLOGO™ for the treatment of no option refractory disabling angina

Caladrius acquired the rights to data and regulatory filings for a CD34+ cell therapy program for no option refractory disabling angina ("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. Discussions with the FDA have resulted in a rejection of the Company's efforts to reduce the FDA requirement of a 400-patient Phase 3 study for registration (including an arm of 50 standard of care patients and an arm of 150 placebo patients), despite data showing that the NORDA population is orphan in size. Because enrollment of a study of this magnitude and design is projected to take many years, if executable at all, the Company has decided not to pursue a Phase 3 program for OLOGO™ on its own, but will continue to seek a partner to execute the study and advance the program.

Sufficient capital to fund operations beyond multiple key data readouts anticipated in 2023

As previously disclosed, in January 2021, Caladrius raised $25.0 million 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 and warrants to several institutional and accredited investors in two registered direct offerings priced at-the-market under Nasdaq rules. In addition, in May 2021, the Company received $1.4 million in non-dilutive funding as an approved participant of the Technology Business Tax Certificate Transfer Program (the "Program") sponsored by the New Jersey Economic Development Authority (NJEDA). The Program enables qualifying New Jersey-based biotechnology or technology companies to sell a percentage of their New Jersey net operating losses ("NOLs") and research and development tax credits to unrelated qualifying corporations.

Second Quarter 2021 Financial Summary

Research and development expenses were approximately $4.3 million for the three months ended June 30, 2021, compared to $1.8 million for the three months ended June 30, 2020, representing an increase of 138%. Research and development in both periods focused on the advancement of our ischemic repair platform and related to:

- Expenses associated with efforts to advance the FREEDOM Trial where the first patient was dosed in the first quarter of 2021;
- Expenses associated with the planning and preparation of an IND and Phase 2 proof-of-concept protocol for CLBS201 as a treatment for diabetic kidney disease; and
- Ongoing expenses for HONEDRA® in critical limb ischemia and Buerger's disease in Japan for which we continue to focus spending on patient enrollment and Japanese NDA preparation.

General and administrative expenses were approximately $2.8 million for the three months ended June 30, 2021, compared to $2.5 million for the three months ended June 30, 2020, representing an increase of 14%.

Overall, net losses were $5.7 million for the three months ended June 30, 2021, compared to net income of $6.6 million for the three months ended June 30, 2020.

Balance Sheet Highlights

As of June 30, 2021, we had cash, cash equivalents and marketable securities of approximately $106.1 million. 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 FREEDOM Trial, through the registration-eligible study completion for HONEDRA® and through the Phase 2 proof-of-concept study for CLBS201, while still potentially providing capital to explore additional pipeline expansion opportunities.

Conference Call

Caladrius will hold a live conference call today, August 5, 2021, at 4:30 p.m. (ET) to discuss financial results, provide a business update and answer questions. To join the conference call, please refer to the dial-in information provided below. A live webcast of the call will also be available under the Investors & News section of the Caladrius website, https://ir.caladrius.com, and will be available for replay for 90 days after the conclusion of the call.

Dial-in information:
U.S. Toll-Free: 844-369-8774
International: 862-298-0844

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

For those unable to participate on the live conference call, an audio replay will be available that day starting at 7:30 p.m. (ET) until August 19, 2021, by dialing 877-481-4010 (U.S. Toll-Free) or 919-882-2331 (International) and by entering the replay passcode: 42180.

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 (www.freedom-trial.com) in the U.S. for the treatment of coronary microvascular dysfunction ("CMD"); CLBS12 (HONEDRA® in Japan), recipient of orphan designation for Buerger's Disease in the U.S. and, in Japan, recipient of a SAKIGAKE designation and eligible for early conditional approval 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 diabetic kidney disease ("DKD"); and OLOGO™ (CLBS14), a Regenerative Medicine Advanced Therapy ("RMAT") designated phase 3 ready therapy for 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, 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 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 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:

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- Tables to Follow –

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

	Three Months Ended Jun 30,		Six Months Ended Jun 30,	
	2021	2020	2021	2020
(in thousands, except per share data)	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Statement of Operations Data:				
Research and development	$ 4,329	$ 1,818	$ 9,405	$ 3,317
General and administrative	2,818	2,474	5,828	5,032
Total operating expenses	**7,147**	**4,292**	**15,233**	**8,349**
Operating loss	**(7,147)**	**(4,292)**	**(15,233)**	**(8,349)**
Investment income, net	47	22	70	93
Other expense, net	(90)	—	(90)	—
Net loss before benefit from income taxes and noncontrolling interests	**(7,190)**	**(4,270)**	**(15,253)**	**(8,256)**
Benefit from income taxes	(1,508)	(10,872)	(1,508)	(10,872)
Net (loss) income	**(5,682)**	**6,602**	**(13,745)**	**2,616**
Less - net income attributable to noncontrolling interests	—	4	—	8
Net (loss) income attributable to Caladrius Biosciences, Inc. common shareholders	**$ (5,682)**	**$ 6,598**	**$ (13,745)**	**$ 2,608**
Basic and diluted (loss) income per share attributable to Caladrius Biosciences, Inc. common shareholders	**$ (0.10)**	**$ 0.50**	**$ (0.27)**	**$ 0.22**
Weighted average common shares outstanding	**59,510**	**13,151**	**50,862**	**11,880**

	June 30, 2021	December 31, 2020
	(unaudited)	
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$106,090	$34,573
Total assets	108,614	36,002
Total liabilities	3,935	3,760
Total equity	104,679	32,242

# # #

Exhibit 99.2

caladrius
BIOSCIENCES

Developing Regenerative Therapies that Reverse Chronic Disease

David J. Mazzo, PhD
President & Chief Executive Officer

August 5, 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.

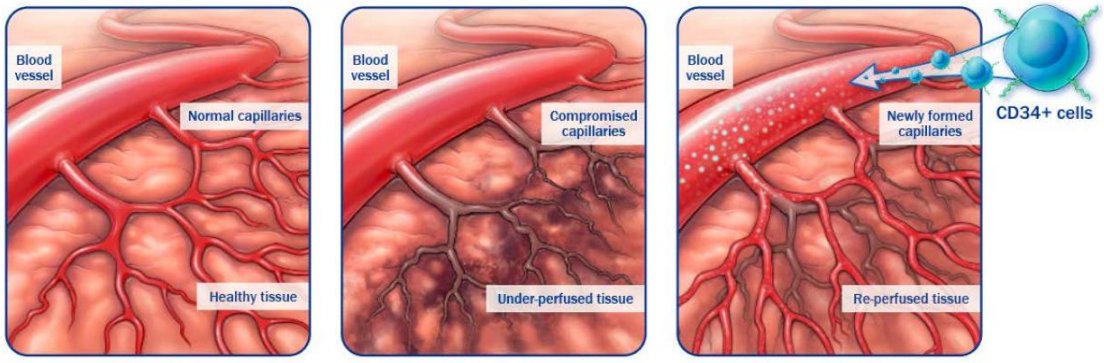
Caladrius investment highlights

- 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; ~$106 million in cash & investments (6/30/2021) 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]

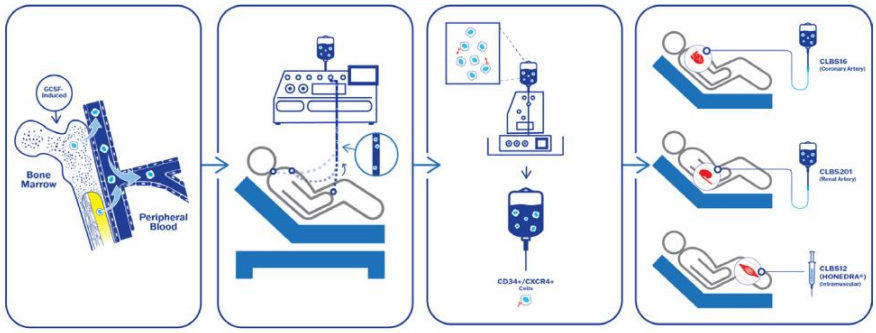
[1]Mackie, A.R. et al., *Tex Heart Inst J* 2011, 38(5), 474-485
[2]Kocher, A.A. et al., *Nat Med* 2001, 440-436
[3]Abd-Allah et al., *Cytotherapy 2015*, 17: 443-53
[4]Lo , B.C. et al., *Am J Respir Cell Mol Biol* 2017, 57: 651-61

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



DAY -5 TO 0
GCSF-induced mobilization of patient's CD34+ cells from the bone marrow to the peripheral circulation

DAY 1
Sample collection via apheresis at one of several access points at an outpatient center

DAY 2
ISOLATION, concentration and formulation of CD34+/CXCR4+ cells

DAY 3 OR 4
CD34+ cells returned to the **SAME PATIENT**; route of administration is indication-specific

- 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

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+ 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: **3Q2022** - Top-line data: **2Q2023**
HONEDRA® (CLBS12) ***SAKIGAKE DESIGNATED (JAPAN)*** CRITICAL LIMB ISCHEMIA + BUERGER'S DISEASE	REGISTRATION ELIGIBLE TRIAL (**JAPAN**; ONGOING)	- Complete enrollment: **TBD** - Top-line data: **~2022** - J-NDA filing: **1H2023** - Approval:**~2023**
CLBS201 DIABETIC KIDNEY DISEASE	PHASE 2 (**USA**; INITIATION PENDING)	<u>6-patient run-in arm:</u> - Initiate enrollment: **2H2021** - Top-line data: **2Q2022** <u>40-patient randomized arm:</u> - To follow Data and Safety Monitoring Board clearance of the run-in arm

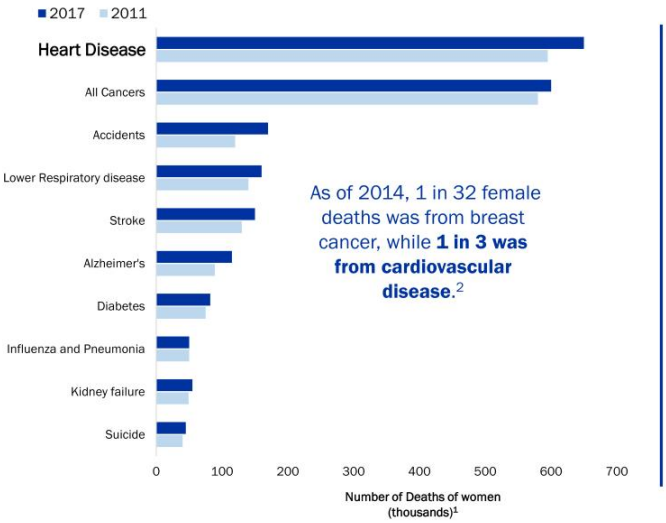
[1] Products are distinct and not interchangeable [2] Timing subject to COVID-19 pandemic influence

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]

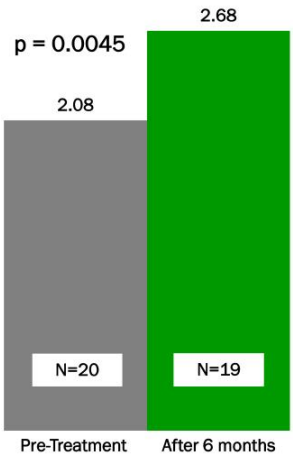
[1] Kunadian V, et al. European Heart Journal. 2020; 0:1-21
[2] Cleveland Clinic/AHA (American Heart Association)
[3] Farrehi PM, et al. Am J Manag Care. 2002;8:643–648
[4] Bradley SM, et al. J Am Coll Cardiol. 2014;63:417–426
[5] Marinescu MA, et al. JACC Cardiovasc Imaging. 2015;8:210-220
[6] Tunstall-Pedoe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

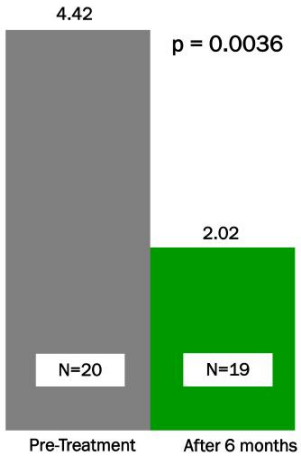
CLBS16 ESCaPE-CMD results are unique and compelling

Coronary Flow Reserve [1]



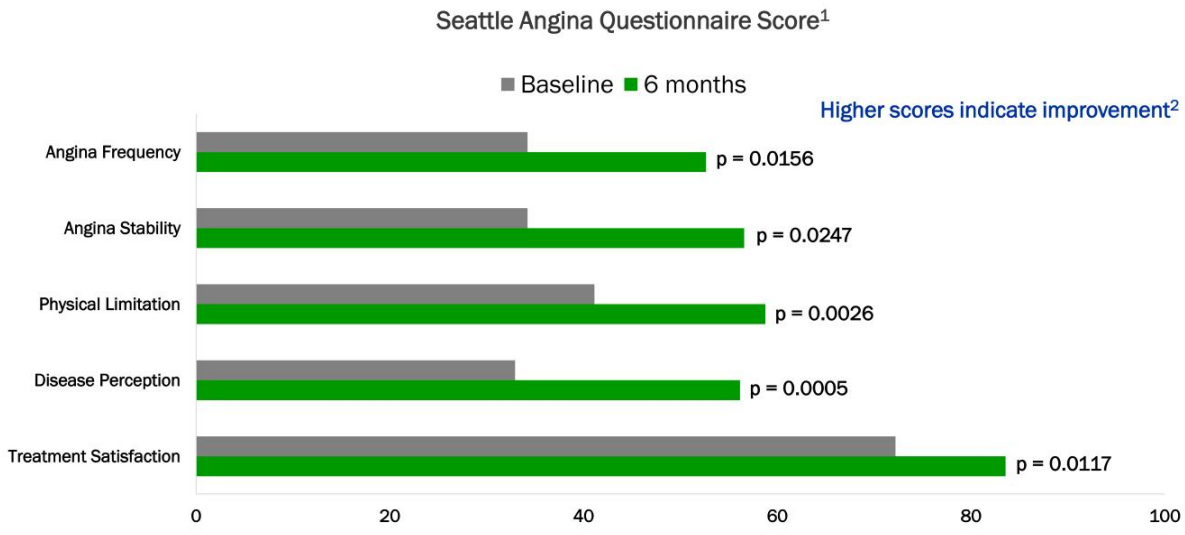
- CFR ≤2.5 indicates CMD
  - CFR of 2 = 3-4 x increase in MACE at 3 years[1]
- CFR ≥2.5 is in "normal" range
- Results after a single intracoronary administration of CLBS16

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

- 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

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

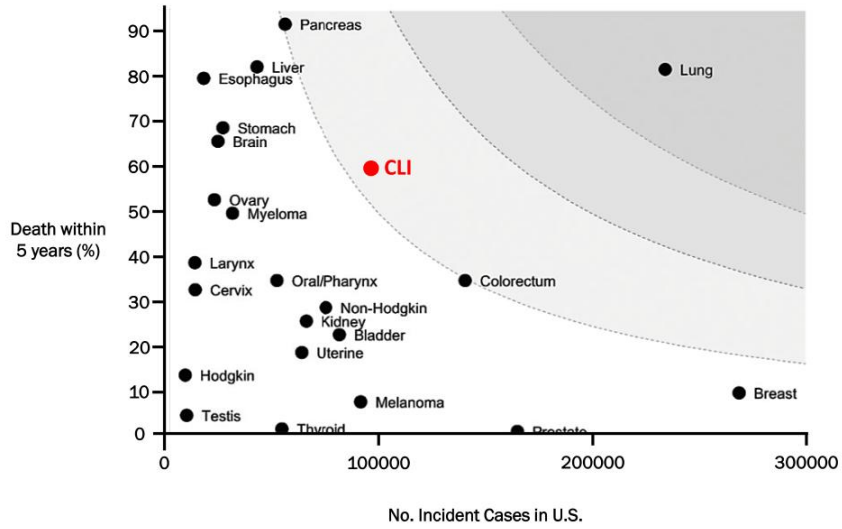
Endpoints	▪ Change from baseline in angina frequency [Baseline to 3 and 6 months] ▪ Change from baseline in total exercise time [Baseline to 6 months] ▪ Change from baseline in health-related quality of life [Baseline to 3 and 6 months] ▪ Change from baseline in peak coronary flow reserve [Baseline to 6 months]
Study Size	▪ 105 subjects (~15 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 **(Assuming no further COVID-19 impact)**	▪ Study initiated 4Q2020 ▪ Complete Enrollment: 3Q2022 ▪ Top-line Data Target: 2Q2023


HONEDRA®
(CLBS12)
Critical Limb Ischemia
(Japan)
SAKIGAKE designated – Japan
Orphan Drug designated
(Buerger's disease) - USA
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

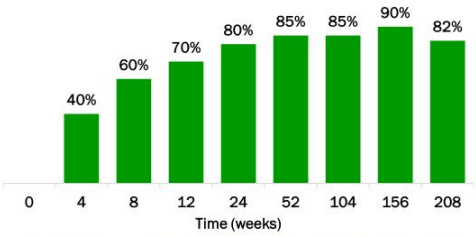
[1] Reinecke H., European Heart Journal, 2015 Apr 14;36(15):932-8

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

Actual CLI Patient Laser Doppler Image

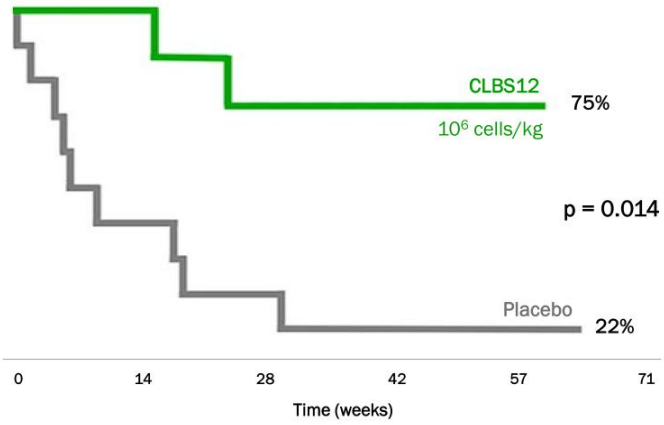
Pre-treatment Post-treatment (week 12)

% of Patients (CLI + BD) Achieving CLI-free Status (Japan; 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	▪ Up to 10^6 cells/kg of HONEDRA® (CLBS12) 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 : TBD (COVID-19 impact dependent) ▪ Earliest approval target: ~2023

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

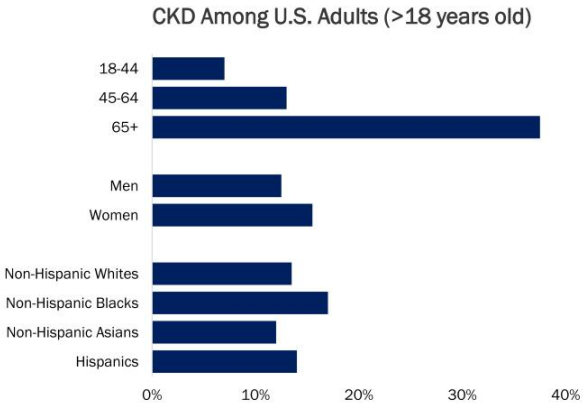
CLBS201

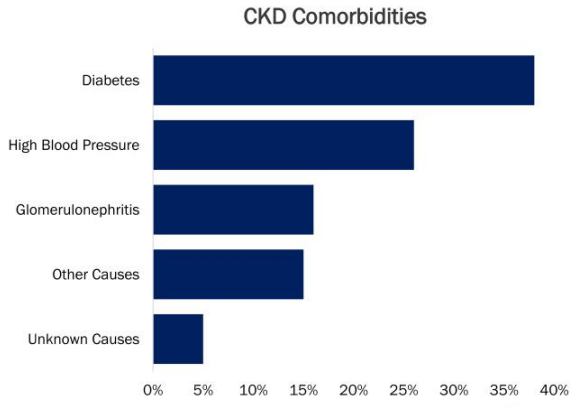
Diabetic Kidney Disease

(USA)

Chronic kidney disease: risk factors and comorbidities

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

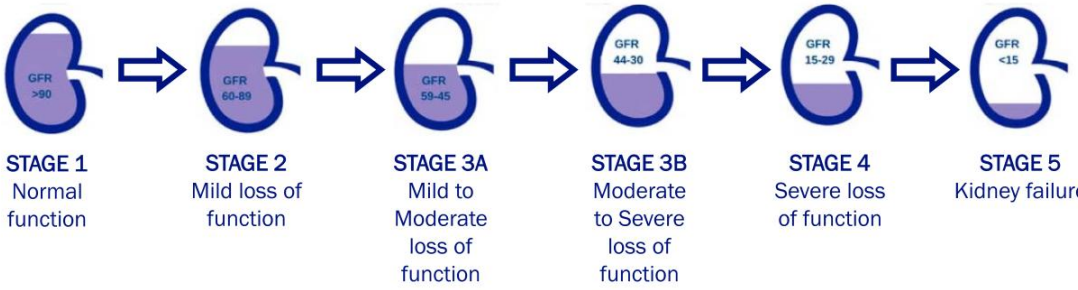




Centers for Disease Control and Prevention. Chronic Kidney Disease in the United States, 2019. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2019.

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

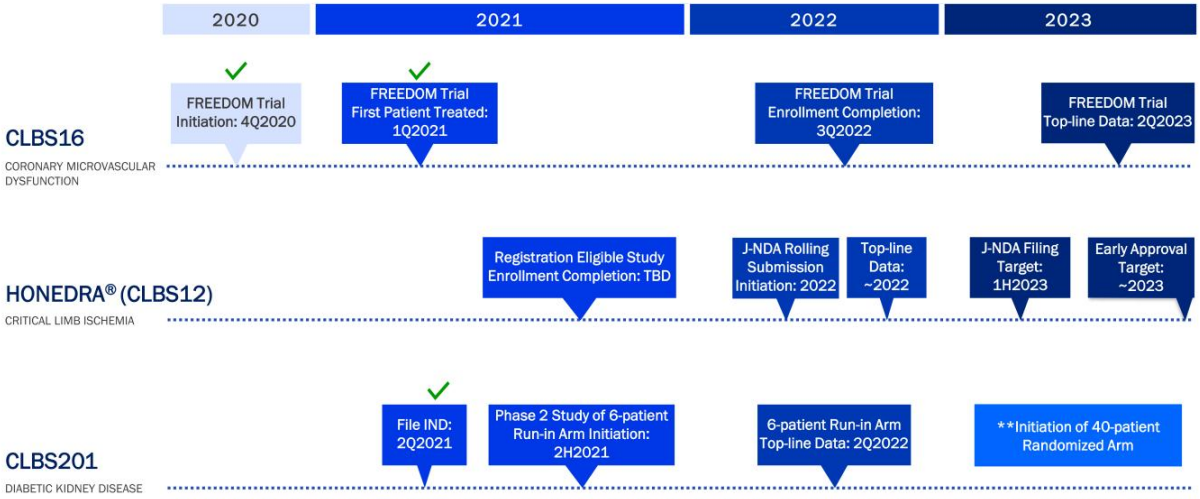
- To demonstrate that regeneration of the kidney microcirculation using CD34+ cell therapy will safely improve or stabilize kidney function [as measured by GFR]
- To show that progression to kidney failure and hemodialysis can be slowed or prevented

[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 2 proof-of-concept study

Primary Endpoint	▪ Change in eGFR compared to baseline, assessed at 6 months
Study Size	▪ 6 patient open-label run-in arm (safety) followed by ~40 subjects (stage 3b diabetic kidney disease) randomized arms
Dose	▪ $1x10^6$ – $300x10^6$ cells, half per kidney, 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	<u>6-patient run-in arm:</u> ▪ Initiation target: 3Q2021 ▪ Top-line data target: 2Q2022 <u>40-patient randomized arm:</u> ▪ To follow Data and Safety Monitoring Board (DSMB) clearance of the run-in arm

Caladrius timeline of key development milestones*



✓ Completed

*Timing subject to COVID-19 pandemic influence

**Contingent on DSMB clearance of run-in arm

Caladrius key financial information

Cash & Investments: As of June 30, 2021	$106 million
Six months ended June 30, 2021 Operating Cash Burn[1]:	$14.0 million
Cash Runway Based on Current Plan:	Sufficient capital to fund operations beyond multiple key data readouts (>2023)
Debt as of June 30, 2021:	$0
Common Shares Outstanding: As of June 30, 2021	59.5 million shares
Options Outstanding as of June 30, 2021: Exercise Price: $1.48 - $3.50 = 346,000 shares Exercise Price: > $3.50 = 659,000 shares	1.0 million shares
Warrants Outstanding as of June 30, 2021: Weighted Average Exercise Price: $2.84	21.4 million shares

[1] Excludes $1.4 million in net proceeds from sale of New Jersey NOLs

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; ~$106 million in cash & investments (6/30/2021) 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

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August 5, 2021 | Nasdaq: CLBS