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): November 1, 2020

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

Delaware	001-33650	22-2343568
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

110 Allen Road, Second Floor, Basking Ridge, NJ 07920
(Address of Principal Executive Offices)(Zip Code)

(908) 842-0100
Registrant's Telephone Number

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	CLBS	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

☐ Emerging growth company

☐ If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

The information in Item 7.01 is incorporated by reference.

Item 5.02 Departure of Directors or Principal Officers; Election of Officers; Appointment of Principal Officers; Compensatory Arrangements of Certain Officers

(d) Effective November 1, 2020, Anne Whitaker was appointed as a Class I Director to the Board of Directors (the "Board") of Caladrius Biosciences, Inc. (the "Company"). Ms. Whitaker will also serve as a member of the Compensation Committee and of the Science & Technology Committee of the Board.

Ms. Whitaker is currently the CEO of Aerami Therapeutics (formerly Dance Biopharm Holdings, Inc.), a private life science company pursuing the treatment of chronic diseases with its inhaled therapies. Prior to Aerami, she served as the CEO and President of KNOW Bio, LLC, a privately held life science company, and the founding CEO of its subsidiary, Novoclem Therapeutics, Inc. Previously, Ms. Whitaker was Executive Vice President and Company Group Chairman at Bausch Health, where she was responsible for overseeing its Global Branded Pharmaceutical Business. Prior to that, Anne served as President and Chief Executive Officer of Synta Pharmaceuticals. Ms. Whitaker also served as President of the North American Region and CEO of Sanofi US at Sanofi SA (Euronext Paris: SAN---FR), where she oversaw all pharmaceutical and consumer healthcare operations for the region and held several commercial leadership roles at GlaxoSmithKline. Ms. Whitaker holds a Bachelor of Science degree in chemistry from the University of North Alabama.

As a non-employee director, Ms. Whitaker is entitled to receive cash compensation and grants of stock options or other equity awards in accordance with the arrangements in effect for non-employee directors of the Company and its committees. In connection with her appointment to the Company's Board, Ms. Whitaker received a grant of 79,470 restricted stock units of the Company's common stock, with an aggregate value of $120,000, with one-third of the shares vesting annually on each of the first, second and third anniversaries of the grant date.

There are no arrangements or understandings between Ms. Whitaker and any other person pursuant to which she was selected as a member of the Board. The Company is not aware of any transaction in which Ms. Whitaker has an interest requiring disclosure under Item 404(a) of Regulation S-K. On November 2, 2020, the Company issued a press release announcing the appointment of Ms. Whitaker to the Board. A copy of this press release is filed as Exhibit 99.2 to this current report.

Item 7.01 Regulation FD Disclosure.

On November 5, 2020, the Company issued a press release in connection with its financial results for the third quarter ended September 30, 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 November 5, 2020 at 4:30 p.m. Eastern Time.

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, or otherwise subject to the liabilities of that Section. The information in this Item 7.01, including Exhibit 99.1 attached hereto, shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, except as otherwise expressly stated in such filing.

Item 9.01. Financial Statement and Exhibits.

Exhibit No.	Description
99.1	Press release regarding earnings release, dated November 5, 2020
99.2	Press release regarding new director, November 2, 2020

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CALADRIUS BIOSCIENCES, INC.

By: /s/ David J. Mazzo
Name: David J. Mazzo, PhD
Title: President and Chief Executive Officer

Dated: November 5, 2020

Exhibit 99.1

Caladrius Biosciences Provides Corporate Update and Reports 2020 Third Quarter Financial Results

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

BASKING RIDGE, N.J. (November 5, 2020) – Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company"), a clinical-stage biopharmaceutical company dedicated to the development of cellular therapies designed to reverse disease, provides a corporate update and reports financial results for the three and nine months ended September 30, 2020.

"Amid the continuing global impact of COVID-19, our team continues to rise to the occasion, addressing a multitude of challenges tied to the pandemic," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius. "To date in 2020, we have extended our cash runway through the end of 2021, while continuing to deliver on a number of key initiatives in support of our clinical programs including the initiation of our study of CLBS119 for the treatment of COVID-19 induced lung damage and finalizing preparations for the start to our newly-named Phase 2b FREEDOM Study of CLBS16 in coronary microvascular dysfunction."

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

Product Development and Financing Highlights

HONEDRA® (formerly CLBS12) development in Japan continues to progress

The Company's open-label, registration-eligible study in Japan of HONEDRA® (formerly CLBS12), continues to progress toward enrollment completion, although enrollment has been slowed by the impact of the COVID-19 pandemic in Japan. HONEDRA® is a SAKIGAKE-designated product candidate for the treatment of critical limb ischemia ("CLI"); a disease with limited treatment options - most of which have minimal impact - and a higher combined incidence and mortality rate than all cancers but lung cancer. As previously reported, the Buerger's Disease (an "orphan-sized" type of CLI) cohort has concluded with 4 out of 7 (~60%) patients achieving a positive outcome, an outstandingly positive result for these patients who normally see continued progression leading to amputation. The Company remains encouraged by the patient pre-screening pipeline that has been identified for the arteriosclerosis obliterans ("ASO") cohort, which is the primary arm of the study, and anticipates trial enrollment to conclude in the first quarter of 2021, leading to top line data for the full study in late 2021 or early 2022.

CLBS14 remains poised to enter a single confirmatory phase 3 clinical trial

The Company's Phase 3 protocol for its RMAT-designated product candidate, CLBS14, for the treatment of no-option refractory angina ("NORDA") remains ready to initiate pending sufficient funding to run the program to completion. Based on an abundance of very strong data from previous Phase 1, 2, and 3 studies, Caladrius remains confident in the potential for clinical success once the program is executed.

CLBS16 to be studied in Phase 2b trial for the treatment of coronary microvascular dysfunction

Caladrius recently completed and announced the 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. Data from the Phase 2a trial showed a positive therapeutic effect with a statistically significant improvement in angina frequency, coronary flow reserve, Canadian Cardiovascular Society Angina Class and Seattle Questionnaire score, as well as an acceptable safety profile. The Company is committed to raising awareness of this growing women's health crisis and plans to initiate a rigorous Phase 2b FREEDOM trial, with the first patient expected to be enrolled by the

end of 2020. The double-blind, randomized, placebo-controlled Phase 2b trial will evaluate the efficacy and safety of delivering autologous CD34+ cells (CLBS16) in subjects with CMD and without obstructive coronary artery disease.

CLBS119 for the repair of COVID-19-induced lung damage in COVID-19 survivors

Caladrius is committed to helping patients and communities combat the public health crisis of COVID-19 by leveraging its proprietary CD34+ cell technology to potentially repair COVID-19-induced lung damage. COVID-19 appears to damage the vasculature of the lungs and Caladrius believes the repair of that vasculature will prove necessary for patients to achieve a full recovery. Experience to date indicates that a large portion of COVID-19 survivors who required ventilatory support will suffer long-term, debilitating lung damage. While many developmental therapies responding to the COVID-19 pandemic are appropriately targeting the SARS-CoV-2 virus itself, or the manifestations of the acute phase of the illness, Caladrius is unaware of a therapy that has demonstrated the ability to repair COVID-19-induced lung damage. With consistent clinical and pre-clinical evidence that CD34+ cells can repair multiple organs, including models of severe lung inflammation, the Company sought and received FDA authorization for its investigational new drug ("IND") application for the study of CLBS119, a CD34+ cell therapy for the repair of COVID-19-induced lung damage. The planned 10-12-patient open-label, proof-of-concept clinical trial, is designed to evaluate the safety and efficacy of a single administration of CLBS119 for the treatment and repair of COVID-19-induced lung damage in adults. The study was recently initiated and patients who are experiencing hypoxia due to prior infection with SARS-CoV-2 and who require supplemental oxygen are now being screened for participation at NYU Langone Health.

Secures new capital to support cash runway through the end of 2021

As previously disclosed, in July 2020, Caladrius raised $2.0 million in a private placement priced at the market under Nasdaq rules. Caladrius has now successfully raised approximately $30 million in net proceeds year-to-date in 2020.

Third Quarter 2020 Financial Highlights

Research and development expenses were approximately $3.0 million for both the three months ended September 30, 2020 and the three months ended September 30, 2019. Research and development in both periods focused on the advancement of our ischemic repair platform. More specifically, R&D expense comprised (i) costs associated with investigational new drug application and planning for commencement of a pilot study of CLBS119, (ii) execution expenses for our ongoing registration-eligible study for CLBS12 in critical limb ischemia in Japan, and (iii) expenses for both the completion of our ESCaPE-CMD study of CLBS16 in coronary microvascular dysfunction and planning for the follow on Phase 2b study.

General and administrative expenses were approximately $2.3 million for the three months ended September 30, 2020, compared to $2.1 million for the three months ended September 30, 2019, representing an increase of 12%.

Overall, net losses were $5.3 million for the three months ended September 30, 2020, compared to $4.9 million for the three months ended September 30, 2019.

Balance Sheet Highlights

As of September 30, 2020, Caladrius had cash, cash equivalents and marketable securities of $40.3 million. Based on existing programs and projections, the Company remains confident that its current cash balances will fund its operations through 2021.

Conference Call

Caladrius will hold a conference call on Thursday, November 5, 2020, at 4:30 p.m. ET 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: +1-833-467-0024
International: 469-333-9553
Conference ID / Passcode: 5872349
Please dial-in at least 10 minutes before the conference call starts.

For those unable to participate in the live conference call, a replay will be accessible approximately two hours after the call has concluded until November 12, 2020, by dialing 855-859-2056 (domestic) or 404-537-3406 (international) and referencing conference ID/passcode: 5872349. A webcast audio 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: HONEDRA® (formerly CLBS12), recipient of SAKIGAKE designation and eligible for early conditional approval in Japan for the treatment of critical limb ischemia ("CLI") based on the results of an ongoing clinical trial; CLBS14, a Regenerative Medicine Advanced Therapy ("RMAT") designated therapy for which the Company has finalized with the U.S. Food and Drug Administration (the "FDA") a protocol for a Phase 3 confirmatory trial in subjects with no-option refractory disabling angina ("NORDA"); CLBS16, the subject of a recently completed positive Phase 2a clinical trial in the U.S. for the treatment of coronary microvascular dysfunction ("CMD"); and CLBS119, an emergent CD34+ stem cell therapy responding to the COVID-19 pandemic and the potentially permanent damage the virus inflicts on the lungs of many patients. For more information on the company, please visit www.caladrius.com.

Safe Harbor for Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements reflect management's current expectations, as of the date of this press release, and involve certain risks and uncertainties. All statements other than statements of historical fact contained in this press release are forward-looking statements including, without limitation, all statements related to the intended use of net proceeds from financings as well as any expectations of revenues, expenses, cash flows, earnings or losses from operations, cash required to maintain current and planned operations, capital or other financial items; any statements of the plans, strategies and objectives of management for future operations; any plans or expectations with respect to product research, development and commercialization, including regulatory approvals; any other statements of expectations, plans, intentions or beliefs; and any statements of assumptions underlying any of the foregoing. Without limiting the foregoing, the words "plan," "project," "forecast," "outlook," "intend," "may," "will," "expect," "likely," "believe," "could," "anticipate," "estimate," "continue" or similar expressions or other variations or comparable terminology are intended to identify such forward-looking statements, although some forward-looking statements are expressed differently. Factors that could cause future results to differ materially from the recent results or those projected in forward-looking statements include the "Risk Factors" described in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 5, 2020 and in the Company's other periodic filings with the SEC. The Company's further development is highly dependent on, among other things, future medical and research developments and market acceptance, which are outside of its control. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this Press Release. Caladrius does not intend, and disclaims any obligation, to update or revise any forward-looking information contained in this Press Release or with respect to the matters described herein, except as required by law.

Contact:

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- Tables to Follow -

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

	Three Months Ended Sept 30,		Nine Months Ended Sept 30,	
	2020	2019	2020	2019
(in thousands, except per share data)	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Statement of Operations Data:				
Research and development	$ 3,029	$ 3,004	$ 6,346	$ 8,030
General and administrative	2,321	2,068	7,353	6,980
Total operating expenses	**5,350**	**5,072**	**13,699**	**15,010**
Operating loss	**(5,350)**	**(5,072)**	**(13,699)**	**(15,010)**
Investment income, net	25	175	118	611
Net loss before benefit from income taxes and noncontrolling interests	**(5,325)**	**(4,897)**	**(13,581)**	**(14,399)**
Benefit from income taxes	—	—	(10,872)	—
Net loss	**(5,325)**	**(4,897)**	**(2,709)**	**(14,399)**
Less - net income attributable to noncontrolling interests	2	1	10	6
Net loss attributable to Caladrius Biosciences, Inc. common stockholders	**$ (5,327)**	**$ (4,898)**	**$ (2,719)**	**$ (14,405)**
Basic and diluted loss per share attributable to Caladrius Biosciences, Inc. common stockholders	**$ (0.29)**	**$ (0.47)**	**$ (0.19)**	**$ (1.40)**
Weighted average common shares outstanding	**18,597**	**10,411**	**14,116**	**10,279**

	Sept 30, 2020 (unaudited)	December 31, 2019
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 40,269	$ 25,157
Total assets	42,019	27,153
Total liabilities	4,532	6,600
Total equity	37,487	20,553

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Exhibit 99.2

Caladrius Biosciences Appoints Industry Veteran, Anne Whitaker, to Board of Directors

BASKING RIDGE, N.J. (November 2, 2020) – Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company"), a clinical-stage biopharmaceutical company dedicated to the development of cellular therapies designed to reverse, not manage, disease, today announced the appointment of Anne Whitaker to its Board of Directors. Ms. Whitaker is a seasoned healthcare executive bringing to Caladrius 28 years of experience in the life science industry, including senior leadership roles with large pharmaceutical, biotech and specialty pharma companies, and with a proven track record of building and leading high performance teams to successfully commercialize pharmaceuticals, consumer products and medical devices.

"It is with great pleasure that we welcome Anne Whitaker to the Board of Directors," said Gregory B. Brown, MD, Caladrius' Board Chairman. "Anne brings a wealth of experience to Caladrius gained over a distinguished career in executive roles in the life sciences industry. Her knowledge and experience in business strategy, business development, regulatory affairs, leadership and organizational development and commercialization will be invaluable to the Company as we continue to advance Caladrius' clinical programs through late-stage development and commercialization."

"Anne is an accomplished leader, and we are delighted to welcome her to the Board," said David J. Mazzo, PhD, President and Chief Executive Officer of Caladrius. "She brings a deep understanding of our industry and keen strategic insights that will bring an important perspective to the Board."

Ms. Whitaker is currently the CEO of Aerami Therapeutics (formerly Dance Biopharm Holdings, Inc.), a private life science company reimaging the treatment of chronic diseases with their inhaled therapies. Prior to Aerami, Anne served as the CEO and President of KNOW Bio, LLC, a privately held life science company, and the founding CEO of its subsidiary, Novoclem Therapeutics, Inc., from February 2017 until April 2018 where she oversaw the raise of >$12M in seed capital and signed technology partnerships with multiple partners to advance the company's nitric oxide platform. Previously, Anne was Executive Vice President and Company Group Chairman at Bausch Health, where she was responsible for overseeing its Global Branded Pharmaceutical Business. Prior to that, Anne served as President and Chief Executive Officer of Synta Pharmaceuticals. She also served as President of the North American Region and CEO of Sanofi US at Sanofi SA (Euronext Paris: SAN---FR), where she oversaw all pharmaceutical and consumer healthcare operations for the region and held several commercial leadership roles at GlaxoSmithKline.

Ms. Whitaker also serves as an independent director on the board of Cree, Inc. (Nasdaq: CREE) an LED and semiconductor company, Mallinckrodt plc (NYSE: MKN), a specialty pharmaceutical company, and UDG Healthcare plc (London Exchange: UDGHC), a pharmaceutical services company. She also serves on the Board of Trustees for the University of North Alabama, her alma mater. She has previously served on the board of Vectura, Plc (London

Exchange: VEC-GB), Synta Pharmaceuticals, Inc. (Nasdaq: SNTA) now Madrigal Pharmaceuticals, Inc. (Nasdaq: MDGL), Novoclem Therapeutics, Inc., KNOW Bio, LLC, and Foundation Board for the North Carolina School of Mathematics and Science. In addition to her public company board work and private company CEO role, she is an active industry advisor to private equity and venture capital funds in the U.S. and Europe.

"It's an honor to be appointed to Caladrius' Board of Directors and I'm excited for the opportunity to provide additional perspectives and insights at such an important time in the Company's evolution," said Ms. Whitaker. "Caladrius' CD34+ cell therapy technology has the potential to revolutionize the treatment of ischemic diseases and I look forward to working with the Company's very talented and dedicated team to create value for patients and shareholders."

Ms. Whitaker holds a Bachelor of Science degree in chemistry from the University of North Alabama.

About Caladrius Biosciences

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