

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED September 30, 2021

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Transition Period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 001-33650

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

Delaware  
(State or other jurisdiction of incorporation or organization)

22-2343568  
(I.R.S. Employer Identification No.)

110 Allen Road, 2nd Floor, Basking Ridge, New Jersey  
(Address of principal executive offices)

07920  
(zip code)

Registrant's telephone number, including area code: 908-842-0100

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

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  
Yes  No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding as of November 4, 2021
Common stock, \$0.001 par value per share	59,779,855 shares

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report (this "Quarterly Report") contains "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995, as well as historical information. When used in this Quarterly Report, statements that are not statements of current or historical fact may be deemed to be forward-looking statements, including, without limitation, all statements related to 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. We remind readers that forward-looking statements are merely predictions and therefore inherently subject to uncertainties and other factors and involve known and unknown risks that could cause the actual results, performance, levels of activity or our achievements or industry results, to be materially different from any future results, performance, levels of activity or our achievements or industry results expressed or implied by such forward-looking statements. Factors that could cause our actual results to differ materially from anticipated results expressed or implied by forward-looking statements include, among others:

- our ability to obtain sufficient capital or strategic business arrangements to fund our operations and expansion plans, including meeting our financial obligations under various licensing and other strategic arrangements, the funding of our clinical trials for product candidates, and the commercialization of the relevant technology;
- our ability to build and maintain the management and human resources infrastructure necessary to support the growth of our business;
- whether a market is established for our cell-based products and services and our ability to capture a meaningful share of this market;
- scientific, regulatory and medical developments beyond our control;
- our ability to obtain and maintain, as applicable, appropriate governmental licenses, accreditations or certifications or to comply with healthcare laws and regulations or any other adverse effect or limitations caused by government regulation of our business;
- whether any of our current or future patent applications result in issued patents, the scope of those patents and our ability to obtain and maintain other rights to technology required or desirable for the conduct of our business; and our ability to commercialize products without infringing upon the claims of third-party patents;
- whether any potential strategic or financial benefits of various licensing agreements will be realized;
- the results of our development activities;
- our ability to complete our other planned clinical trials (or initiate other trials) in accordance with our estimated timelines due to delays associated with enrolling patients due to the novelty of the treatment, the size of the patient population and the need of patients to meet the inclusion criteria of the trial or otherwise;
- the extent to which the COVID-19 coronavirus may impact our business, including our clinical trials and financial condition; and
- other factors discussed in "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on February 25, 2021 (our "2020 Form 10-K").

The factors discussed herein, including those risks described in "Item 1A. Risk Factors" and elsewhere in our 2020 Form 10-K and in our other periodic filings with the SEC, which are available for review at [www.sec.gov](http://www.sec.gov), could cause actual results and developments to be materially different from those expressed or implied by such statements. All forward-looking statements attributable to us are expressly qualified in their entirety by these and other factors. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date they were made. Except as required by law, we undertake no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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## PART I. FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS

(In thousands, except share data)

	September 30, 2021	December 31, 2020
<b>ASSETS</b>	<b>(Unaudited)</b>	
Cash and cash equivalents	\$ 12,772	\$ 16,512
Marketable securities	87,377	18,061
Prepaid and other current assets	1,958	758
Total current assets	102,107	35,331
Property and equipment, net	70	57
Other assets	361	614
Total assets	\$ 102,538	\$ 36,002
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Liabilities</b>		
Accounts payable	\$ 768	\$ 1,020
Accrued liabilities	3,304	2,486
Total current liabilities	4,072	3,506
Other long-term liabilities	53	254
Total liabilities	4,125	3,760
<b>Commitments and Contingencies</b>		
<b>Stockholders' Equity</b>		
Preferred stock, authorized, 20,000,000 shares Series B convertible redeemable preferred stock liquidation value, 0.001 share of common stock, \$0.01 par value; 825,000 shares designated; issued and outstanding, 10,000 shares at September 30, 2021 and December 31, 2020, respectively	—	—
Common stock, \$0.001 par value, authorized 500,000,000 shares; issued 59,790,935 and 19,389,413 shares at September 30, 2021 and December 31, 2020, respectively; and outstanding, 59,779,855 and 19,378,333 shares at September 30, 2021 and December 31, 2020, respectively	60	19
Additional paid-in capital	545,601	458,748
Treasury stock, at cost; 11,080 shares at September 30, 2021 and December 31, 2020	(708)	(708)
Accumulated deficit	(446,222)	(425,550)
Accumulated other comprehensive loss	(64)	(13)
Total Caladrius Biosciences, Inc. stockholders' equity	98,667	32,496
<b>Noncontrolling interests</b>	(254)	(254)
Total stockholders' equity	98,413	32,242
Total liabilities and stockholders' equity	\$ 102,538	\$ 36,002

See accompanying notes to consolidated financial statements.

**CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(Unaudited)**

(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
<b>Operating Expenses:</b>				
Research and development	\$ 4,125	\$ 3,029	\$ 13,530	\$ 6,346
General and administrative	2,843	2,321	8,671	7,353
Total operating expenses	6,968	5,350	22,201	13,699
Operating loss	(6,968)	(5,350)	(22,201)	(13,699)
<b>Other income (expense):</b>				
Investment income, net	41	25	111	118
Other expense, net	—	—	(90)	—
Total other income (expense)	41	25	21	118
Net loss before benefit from income taxes and noncontrolling interests	(6,927)	(5,325)	(22,180)	(13,581)
Benefit from income taxes	—	—	(1,508)	(10,872)
Net loss	<u>\$ (6,927)</u>	<u>\$ (5,325)</u>	<u>\$ (20,672)</u>	<u>\$ (2,709)</u>
Less - net income attributable to noncontrolling interests	—	2	—	10
Net loss attributable to Caladrius Biosciences, Inc. common stockholders	<u>\$ (6,927)</u>	<u>\$ (5,327)</u>	<u>\$ (20,672)</u>	<u>\$ (2,719)</u>
<b>Basic and diluted loss per share</b>				
Caladrius Biosciences, Inc. common stockholders	\$ (0.12)	\$ (0.29)	\$ (0.38)	\$ (0.19)
<b>Weighted average common shares outstanding</b>				
Basic and diluted shares	59,614	18,597	53,811	14,116

See accompanying notes to consolidated financial statements.

**CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**  
**(Unaudited)**  
(In thousands)

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>	<b>2021</b>	<b>2020</b>
Net loss	\$ (6,927)	\$ (5,325)	\$ (20,672)	\$ (2,709)
Other comprehensive loss:				
Available for sale securities - net unrealized loss	(47)	(14)	(51)	(14)
Total other comprehensive loss	(47)	(14)	(51)	(14)
Comprehensive loss	(6,974)	(5,339)	(20,723)	(2,723)
Comprehensive income attributable to noncontrolling interests	—	2	—	10
Comprehensive loss attributable to Caladrius Biosciences, Inc. common stockholders	<u>\$ (6,974)</u>	<u>\$ (5,341)</u>	<u>\$ (20,723)</u>	<u>\$ (2,733)</u>

See accompanying notes to consolidated financial statements.

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**CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF EQUITY**  
**(Unaudited)**  
(In thousands)

	Series B Convertible Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Treasury Stock	Total Caladrius Biosciences, Inc. Stockholders' Equity	Non-Controlling Interest in Subsidiary	Total Equity
	Shares	Amount	Shares	Amount							
<b>Balance at June 30, 2021</b>	10	\$ —	59,529	\$ 60	\$ 544,893	\$ (17)	\$ (439,295)	\$ (708)	\$ 104,933	\$ (254)	\$ 104,679
Net loss	—	—	—	—	—	—	(6,927)	—	(6,927)	—	(6,927)
Unrealized loss on marketable securities	—	—	—	—	—	(47)	—	—	(47)	—	(47)
Share-based compensation	—	—	262	—	708	—	—	—	708	—	708
<b>Balance at September 30, 2021</b>	10	\$ —	59,791	\$ 60	\$ 545,601	\$ (64)	\$ (446,222)	\$ (708)	\$ 98,667	\$ (254)	\$ 98,413

	Series B Convertible Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Treasury Stock	Total Caladrius Biosciences, Inc. Stockholders' Equity	Non-Controlling Interest in Subsidiary	Total Equity
	Shares	Amount	Shares	Amount							
<b>Balance at December 31, 2020</b>	10	\$ —	19,389	\$ 19	\$ 458,748	\$ (13)	\$ (425,550)	\$ (708)	\$ 32,496	\$ (254)	\$ 32,242
Net loss	—	—	—	—	—	—	(20,672)	—	(20,672)	—	(20,672)
Unrealized loss on marketable securities	—	—	—	—	—	(51)	—	—	(51)	—	(51)
Share-based compensation	—	—	535	—	1,391	—	—	—	1,391	—	1,391
Net proceeds from issuances of common stock and warrants	—	—	39,860	41	85,438	—	—	—	85,479	—	85,479
Proceeds from option exercises	—	—	7	—	24	—	—	—	24	—	24
<b>Balance at September 30, 2021</b>	10	\$ —	59,791	\$ 60	\$ 545,601	\$ (64)	\$ (446,222)	\$ (708)	\$ 98,667	\$ (254)	\$ 98,413

	Series B Convertible Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Treasury Stock	Total Caladrius Biosciences, Inc. Stockholders' Equity	Non-Controlling Interest in Subsidiary	Total Equity
	Shares	Amount	Shares	Amount							
<b>Balance at June 30, 2020</b>	10	\$ —	15,585	\$ 16	\$ 449,302	\$ (7)	\$ (414,792)	\$ (708)	\$ 33,811	\$ (255)	\$ 33,556
Net loss	—	—	—	—	—	—	(5,327)	—	(5,327)	2	(5,325)
Unrealized loss on marketable securities	—	—	—	—	—	(5)	—	—	(5)	—	(5)
Share-based compensation	—	—	(25)	—	229	—	—	—	229	—	229
Net proceeds from issuances of common stock and warrants	—	—	3,847	3	9,029	—	—	—	9,032	—	9,032
<b>Balance at September 30, 2020</b>	10	\$ —	19,407	\$ 19	\$ 458,560	\$ (12)	\$ (420,119)	\$ (708)	\$ 37,740	\$ (253)	\$ 37,487

	Series B Convertible Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Treasury Stock	Total Caladrius Biosciences, Inc. Stockholders' Equity	Non-Controlling Interest in Subsidiary	Total Equity
	Shares	Amount	Shares	Amount							
<b>Balance at December 31, 2019</b>	10	\$ —	10,529	\$ 11	\$ 438,911	\$ 2	\$ (417,400)	\$ (708)	\$ 20,816	\$ (263)	\$ 20,553
Net loss	—	—	—	—	—	—	(2,719)	—	(2,719)	10	(2,709)
Unrealized loss on marketable securities	—	—	—	—	—	(14)	—	—	(14)	—	(14)
Share-based compensation	—	—	81	—	942	—	—	—	942	—	942
Net proceeds from issuances of common stock and warrants	—	—	8,797	8	18,707	—	—	—	18,715	—	18,715
<b>Balance at September 30, 2020</b>	10	\$ —	19,407	\$ 19	\$ 458,560	\$ (12)	\$ (420,119)	\$ (708)	\$ 37,740	\$ (253)	\$ 37,487

See accompanying notes to consolidated financial statements.

**CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(Unaudited)**  
(In thousands)

	<b>Nine Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (20,672)	\$ (2,709)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	1,639	1,090
Depreciation and amortization	47	46
Accretion on marketable securities	1,925	172
Changes in operating assets and liabilities:		
Prepaid and other current assets	(1,199)	(174)
Other assets	252	387
Accounts payable, accrued liabilities and other liabilities	367	(2,068)
Net cash used in operating activities	<u>(17,641)</u>	<u>(3,256)</u>
<b>Cash flows from investing activities:</b>		
Purchase of marketable securities	(137,329)	(21,819)
Sale of marketable securities	66,035	13,646
Purchase of property and equipment	(60)	(14)
Net cash used in investing activities	<u>(71,354)</u>	<u>(8,187)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from exercise of options	24	—
Tax withholding payments on net share settlement equity awards	(248)	(148)
Net proceeds from issuance of common stock	85,479	18,715
Net cash provided by financing activities	<u>85,255</u>	<u>18,567</u>
Net (decrease) increase in cash and cash equivalents	(3,740)	7,124
Cash and cash equivalents at beginning of period	16,512	14,032
Cash and cash equivalents at end of period	<u>\$ 12,772</u>	<u>\$ 21,156</u>

See accompanying notes to consolidated financial statements.

## CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES

### NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

#### **Note 1 – The Business**

##### **Overview**

Caladrius Biosciences, Inc. (“we,” “us,” “our,” “Caladrius” or the “Company”) is a clinical-stage biopharmaceutical company dedicated to the development of treatments and reversal of severe diseases. The Company is developing what are intended to be first-in-class therapeutics based on the characteristics of naturally occurring CD34+ cells and their ability to stimulate the growth of new microvasculature. Its technology is intended to leverage these cells to enable the body’s natural repair mechanisms using formulations unique to each medical indication.

The Company’s leadership team has decades of collective biopharmaceutical development experience. Its goal is to develop and commercialize products that address important unmet medical needs based on a broad and versatile portfolio of candidates. The Company’s current product candidates include:

- XOWNA® (CLBS16), the subject of both a recently completed positive Phase 2a study (ESCaPE-CMD) and a newly initiated Phase 2b (FREEDOM Trial) study in the United States 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 a clinical trial being executed in Japan. Additionally, CLBS12 was the recipient of orphan drug designation in March 2021 from the U.S. Food and Drug Administration (“FDA”) for Buerger’s disease; and
- CLBS201, designed to assess the safety and efficacy of CD34+ cell therapy as a treatment for patients with chronic kidney disease related to type 2 diabetes (diabetic kidney disease or “DKD”).

##### ***Ischemic Repair (CD34 Cell Technology)***

The CD34+ cell was discovered as a result of the deliberate search for a cell capable of stimulating the development and/or repair of blood vessels. All tissues in the body maintain their function by replacing cells over time. In addition to the maintenance function, the body must also be capable of building new blood vessels after injury. A CD34+ cell is an endothelial progenitor cell that has the ability to stimulate new blood vessel formation at the level of the microvasculature. No other native cell discovered to date has demonstrated this same capability.

The Company’s proprietary cell technology using autologous (a patient’s own naturally occurring) CD34+ cells has led to the development of therapeutic product candidates designed to address diseases and conditions caused by ischemia. Ischemia occurs when the supply of oxygenated blood to healthy tissue is restricted. Through the administration of CD34+ cells, the Company seeks to promote the development and formation of new microvasculature and thereby increase blood flow to the impacted area. The Company believes that a number of conditions caused by underlying ischemic injury can be improved through our CD34+ cell technology including but not limited to Buerger’s disease, CLI, CMD, and DKD.

##### ***XOWNA® for Treatment of Coronary Microvascular Dysfunction***

In 2017, with the assistance of a \$1.9 million grant from the National Institutes of Health (Award Number R44HL135889), the Company initiated its program for XOWNA® for the treatment of CMD, a disease that afflicts as many as 1.5 million patients in the U.S. alone, with no current targeted treatment options. That study, the ESCaPE-CMD Trial, was a Phase 2a proof-of-concept open label study that enrolled patients at the Mayo Clinic in Rochester, MN and Cedars-Sinai Medical Center in Los Angeles, CA. Those data showed a positive therapeutic effect with a statistically significant improvement in angina frequency, coronary flow reserve, Canadian Cardiovascular Society Angina Class and Seattle Angina Questionnaire scores, as well as an acceptable safety profile. The full data set from that study was presented at the SCAI 2020 Scientific Sessions Virtual Conference on May 14, 2020 by Dr. Timothy Henry, FACC, of the Christ Hospital in Cincinnati, Ohio. In December 2020, the Company commenced enrollment in its Phase 2b FREEDOM Trial of XOWNA®, a double-blind, randomized and placebo-controlled clinical trial designed to further evaluate the efficacy and safety of intracoronary delivery of autologous CD34+ cells in subjects with CMD and without obstructive coronary artery disease. While early enrollment proceeded to plan with the first patient treated in January 2021, the impact of the COVID-19 pandemic contributed to a general slowing of enrollment. Protocol amendments to the initial FREEDOM Trial protocol, as agreed to by the FDA, were implemented with the goal of enhancing breadth and speed of subject enrollment. Actual improvement in enrollment rate will be assessed during the fourth quarter of 2021. As part of program optimization, the Company convened an advisory board meeting of key opinion leaders in the fields

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of cardiology, drug development, and payer access and reimbursement in mid-October 2021 with the objective of assuring the most efficient and effective development program for XOWNA<sup>®</sup>.

### ***CLBS201 for Treatment of Diabetic Kidney 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. Based on these observations, the Company proposed an initial development plan for CLBS201 contemplating an adaptive design. However, after multiple conversations with key opinion leaders in the fields of nephrology and drug development, the Company has elected to move forward with a Phase 1, open-label, proof-of-concept trial evaluating CLBS201 dosed via intra-renal artery injections in subjects with DKD. This new protocol, pending approval of the Institutional Review Board (the "IRB"), is expected to include six subjects in total with the first two subjects sequentially dosed and followed for a two-week safety observation period. Clearance by the independent Data Safety Monitoring Board overseeing the study will then permit the treatment of the next four patients, with all patients being followed for safety and therapeutic effect. A key read-out of data will occur at the six-month follow-up visit for all patients. The Company projects enrollment of this study will begin in the first quarter of 2022. A key criterion for continued development of CLBS201 will be its ability to demonstrate a therapeutic effect that will make it competitive in the field of DKD treatment, i.e., kidney function regeneration, as indicated by increased glomerular filtration rate.

### ***HONEDRA<sup>®</sup> for Treatment of Critical Limb Ischemia***

The Company's randomized, open-label, registration-eligible study of HONEDRA<sup>®</sup> in Japan for the treatment of CLI and Buerger's disease continues to demonstrate positive trends in both safety and efficacy. These data remain consistent with the efficacy and safety from previously published clinical trials in Japan. The HONEDRA<sup>®</sup> study's enrollment, however, has been significantly curtailed by the COVID-19 pandemic's impact in Japan, including the States of Emergency in Japan that have persisted for much of the past 18 months. Due to the significant and continued operational and financial burden incurred as a result of these COVID-19 delays, coupled with the unpredictability of the timing of site enrollment re-initiation, the Company is suspending further enrollment and focusing its efforts on consummating a partnership with a Japanese company that could complete the study enrollment of the three remaining no-option CLI subjects and/or explore the possibility of submitting the existing data to Japan's Pharmaceuticals and Medical Devices Agency ("PMDA") under the SAKIGAKE designation, which allows for accelerated approval of innovative medical products. Also, as previously noted, in March 2021 CLBS12 was awarded an orphan designation in the U.S. by FDA as a potential treatment for Buerger's disease. However, based on a recent response from the FDA regarding a development plan for U.S. registration, the Company has decided not to pursue U.S. development in Buerger's disease at this time.

### ***Additional Out-licensing Opportunities***

The Company's broad intellectual property portfolio of cell therapy assets includes notable programs available for out-licensing in order to continue their clinical development. The Company's current long-term strategy focuses on advancing its therapies through development with the ultimate objective of obtaining market authorizations and entering commercialization, either alone or with partners, to provide treatment options to patients suffering from life-threatening medical conditions. The Company believes that it is well-positioned to realize potentially meaningful value increases within its own proprietary pipeline if it is successful in advancing its product candidates to their next significant development milestones.

### ***Coronavirus Considerations***

In December 2019, a novel strain of coronavirus (SARS-CoV-2), which causes COVID-19, was reported to have surfaced in China. In March 2020, the World Health Organization declared the outbreak of COVID-19 to be a pandemic, and the world's economies began to experience pronounced effects. Despite the FDA approval of multiple COVID-19 vaccines in late 2020, there remains uncertainty around the extent and duration of disruption and any future related financial impact cannot reasonably be estimated at this time. In response to the COVID-19 pandemic, the Company has implemented universal work from home as well as stringent social distancing and other hygiene policies for employees when they must be in the office. The Company's clinical study of HONEDRA<sup>®</sup> in Japan has experienced significant delays in enrollment due to the "State of Emergency" in effect in Japan for most of 2020 and reimplemented in Japan on January 7, 2021 through March 21, 2021 covering Tokyo and other regions in response to an increased number of COVID-19 patients. Due to reported increases in COVID-19 cases and a low rate of vaccination in Japan, a "State of Emergency" was renewed on April 25, 2021 through May 11, 2021 and then

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reimplemented in Tokyo from July 12, 2021 through September 30, 2021. We expect that COVID-19 in Japan will continue to negatively impact enrollment of the HONEDRA<sup>®</sup> clinical trial.

### ***Basis of Presentation***

The accompanying unaudited Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the SEC for interim financial information. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, the accompanying Consolidated Financial Statements of the Company and its subsidiaries, which are unaudited, include all normal and recurring adjustments considered necessary to present fairly the Company's financial position as of September 30, 2021, and the results of its operations and its cash flows for the periods presented. The unaudited consolidated financial statements herein should be read together with the historical consolidated financial statements of the Company for the years ended December 31, 2020 and 2019 included in our 2020 Form 10-K. Operating results for the three and nine months ended September 30, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021.

### ***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements. Estimates also affect the reported amount of expenses during the reporting period. The Company bases its estimates on historical experience and other assumptions believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. The Company makes critical estimates and assumptions in determining stock-based awards values. Accordingly, actual results could differ from those estimates and assumptions.

### ***Principles of Consolidation***

The Consolidated Financial Statements include the accounts of Caladrius Biosciences, Inc. and its wholly owned and majority owned subsidiaries and affiliates. All intercompany activities have been eliminated in consolidation.

### **Note 2 – Summary of Significant Accounting Policies**

In addition to the policies below, the Company's significant accounting policies are described in Note 2 of the Notes to Consolidated Financial Statements included in its 2020 Form 10-K. There were no changes to these policies during the three and nine months ended September 30, 2021.

### ***Concentration of Risks***

The Company is subject to credit risk from its portfolio of cash, cash equivalents and marketable securities. Under its investment policy, the Company limits amounts invested in such securities by credit rating, maturity, industry group, investment type and issuer, except for securities issued by the U.S. government. Cash is held at major banks in the United States. Therefore, the Company is not exposed to any significant concentrations of credit risk from these financial instruments. The goals of the Company's investment policy, in order of priority, are as follows: safety and preservation of principal and diversification of risk, liquidity of investments sufficient to meet cash flow requirements, and a competitive after-tax rate of return.

### ***Share-Based Compensation***

The Company expenses all share-based payment awards to employees, directors, and consultants, including grants of stock options, warrants, and restricted stock, over the requisite service period based on the grant date fair value of the awards. Consultant awards are remeasured each reporting period through vesting. For awards with performance-based vesting criteria, the Company estimates the probability of achievement of the performance criteria and recognizes compensation expense related to those awards expected to vest. The Company determines the fair value of option awards using the Black-Scholes option-pricing model which uses both historical and current market data to estimate the fair value. This method incorporates various assumptions such as the risk-free interest rate, expected volatility, expected dividend yield and expected life of the options or

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warrants. The fair value of the Company's restricted stock and restricted stock units is based on the closing market price of the Company's common stock on the date of grant.

### ***New Accounting Pronouncements***

In October 2019, the FASB issued ASU 2019-12, which affects general principles within Topic 740, Income Taxes. The amendments of ASU 2019-12 are meant to simplify and reduce the cost of accounting for income taxes. For public business entities, the amendments in this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The Company determined that the adoption of this new accounting guidance did not have a material impact on its consolidated financial statements and footnote disclosures.

### **Note 3 – Available-for-Sale Securities**

The following table is a summary of available-for-sale securities recorded in cash and cash equivalents or marketable securities in our Consolidated Balance Sheets (in thousands):

	September 30, 2021				December 31, 2020			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities	\$ 60,903	\$ 3	\$ (61)	\$ 60,845	\$ 8,406	\$ —	\$ (7)	\$ 8,399
Money market funds	9,600	—	—	9,600	7,591	—	—	7,591
Municipal debt securities	26,539	—	(7)	26,532	14,753	—	(6)	14,747
<b>Total</b>	<b>\$ 97,042</b>	<b>\$ 3</b>	<b>\$ (68)</b>	<b>\$ 96,977</b>	<b>\$ 30,750</b>	<b>\$ —</b>	<b>\$ (13)</b>	<b>\$ 30,737</b>

Estimated fair values of available-for-sale securities are generally based on prices obtained from commercial pricing services. The following table summarizes the classification of the available-for-sale securities in our Consolidated Balance Sheets (in thousands):

	September 30, 2021	December 31, 2020
Cash equivalents	\$ 9,600	\$ 12,676
Marketable securities	87,377	18,061
<b>Total</b>	<b>\$ 96,977</b>	<b>\$ 30,737</b>

The following table summarizes our portfolio of available-for-sale securities by contractual maturity (in thousands):

	September 30, 2021	
	Amortized Cost	Estimated Fair Value
Less than one year	\$ 96,979	\$ 96,914
Greater than one year	63	63
<b>Total</b>	<b>\$ 97,042</b>	<b>\$ 96,977</b>

### **Note 4 – Income (Loss) Per Share**

For the three and nine months ended September 30, 2021 and 2020, the Company incurred net losses and therefore no common stock equivalents were utilized in the calculation of diluted loss per share as they are anti-dilutive. At September 30, 2021 and 2020, the Company excluded the following potentially dilutive securities (in thousands):

	September 30,	
	2021	2020
Stock Options	2,142	1,105
Warrants	21,357	2,638
Restricted Stock Units	798	348

**Note 5 – Fair Value Measurements**

The fair value of financial assets and liabilities that are being measured and reported are defined as the exchange price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the principal market at the measurement date (exit price). The Company is required to classify fair value measurements in one of the following categories:

Level 1 inputs are defined as quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2 inputs are defined as inputs other than quoted prices included within Level 1 that are observable for the assets or liabilities, either directly or indirectly.

Level 3 inputs are defined as unobservable inputs for the assets or liabilities. Financial assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of the fair value of assets and liabilities and their placement within the fair value hierarchy levels.

The following table sets forth by level within the fair value hierarchy the Company's financial assets that were accounted for at fair value on a recurring basis as of September 30, 2021 and December 31, 2020 (in thousands).

	September 30, 2021				December 31, 2020			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Marketable securities - available for sale	\$ —	\$ 87,377	\$ —	\$ 87,377	\$ —	\$ 18,061	\$ —	\$ 18,061
	\$ —	\$ 87,377	\$ —	\$ 87,377	\$ —	\$ 18,061	\$ —	\$ 18,061

**Note 6 – Accrued Liabilities**

Accrued liabilities as of September 30, 2021 and December 31, 2020 were as follows (in thousands):

	September 30, 2021	December 31, 2020
Salaries, employee benefits and related taxes	\$ 1,811	\$ 1,716
Operating lease liabilities — current	297	370
Other	1,196	400
Total	\$ 3,304	\$ 2,486

**Note 7 – Operating Leases**

The Company has operating leases for two offices with terms that expire in 2022 and 2023. The Company estimates its incremental borrowing rate, at lease commencement, to determine the present value of lease payments, since most of the Company's leases do not provide an implicit rate of return. The Company recognizes lease expense on a straight-line basis over the lease term. For lease agreements entered into or reassessed after the adoption of Topic 842, the Company elected to account for non-lease components associated with its leases and lease components as a single lease component. Each of the Company's leases include options for the Company to extend the lease term and/or sub-lease space in whole or in part.

Operating lease liabilities and right-of-use assets were recorded in the following captions of our balance sheet were as follows (in thousands):

	September 30, 2021	December 31, 2020
<b>Right-of Use Assets:</b>		
Other assets	\$ 322	\$ 574
<b>Total Right-of-Use Asset</b>	<b>\$ 322</b>	<b>\$ 574</b>
<b>Operating Lease Liabilities:</b>		
Accrued liabilities	\$ 297	\$ 370
Other long-term liabilities	53	254
<b>Total Operating Lease Liabilities</b>	<b>\$ 350</b>	<b>\$ 624</b>

As of September 30, 2021, the weighted average remaining lease term for our operating leases was 1.1 years, and the weighted average discount rate for our operating leases was 9.625%. Future minimum lease payments under the lease agreements as of September 30, 2021 were as follows (in thousands):

Years ended	Operating Leases
2021	104
2022	239
2023	27
Total lease payments	370
Less: Amounts representing interest	(20)
Present value of lease liabilities	<u>\$ 350</u>

## **Note 8 – Stockholders' Equity**

### **Equity Issuances**

#### **Purchase Agreement**

In March 2019, the Company and Lincoln Park Capital Fund, LLC (“Lincoln Park”) entered into a purchase agreement (the “Purchase Agreement”) and a registration rights agreement (the “Registration Rights Agreement”), pursuant to which the Company has the right to sell to Lincoln Park shares of the Company’s common stock having an aggregate value of up to \$26.0 million, subject to certain limitations and conditions set forth in the Purchase Agreement (the “Offering”). As consideration for entering into the Purchase Agreement, the Company issued to Lincoln Park an additional 181,510 shares of common stock as commitment shares.

Pursuant to the Purchase Agreement, Lincoln Park purchased 250,000 shares of common stock, at a price of \$4.00 per share, for a total gross purchase price of \$1.0 million (the “Initial Purchase”) upon commencement. Thereafter, as often as every business day from and after one business day following the date of the Initial Purchase and over the 36-month term of the Purchase Agreement the Company has the right, from time to time, at its sole discretion and subject to certain conditions, to direct Lincoln Park to purchase up to 100,000 shares of common stock, with such amount increasing as the closing sale price of the common stock increases; provided Lincoln Park’s obligation under any single such purchase will not exceed \$2.5 million, unless the Company and Lincoln Park mutually agree to increase the maximum amount of such single purchase (each, a “Regular Purchase”). If the Company directs Lincoln Park to purchase the maximum number of shares of common stock it then may sell in a Regular Purchase, then in addition to such Regular Purchase, and subject to certain conditions and limitations in the Purchase Agreement, the Company may direct Lincoln Park in an “accelerated purchase” to purchase an additional amount of common stock that may not exceed the lesser of (i) 300% the number of shares purchased pursuant to the corresponding Regular Purchase or (ii) 30% of the total number of shares of the Company’s common stock traded during a specified period on the applicable purchase date as set forth in the Purchase Agreement. Under certain circumstances and in accordance with the Purchase Agreement, the Company may direct Lincoln Park to purchase shares in multiple accelerated purchases on the same trading day.

The Company controls the timing and amount of any sales of its common stock to Lincoln Park. There is no upper limit on the price per share that Lincoln Park must pay for its common stock under the Purchase Agreement, but in no event will shares

be sold to Lincoln Park on a day the closing price is less than the floor price specified in the Purchase Agreement. In all instances, the Company may not sell shares of its common stock to Lincoln Park under the purchase agreement if it would result in Lincoln Park beneficially owning more than 9.99% of its common stock.

The Purchase Agreement does not limit the Company's ability to raise capital from other sources at the Company's sole discretion, except that (subject to certain exceptions) the Company may not enter into any Variable Rate Transaction (as defined in the Purchase Agreement, including the issuance of any floating conversion rate or variable priced equity-like securities) during the 36 months after the date of the Purchase Agreement. The Company has the right to terminate the Purchase Agreement at any time, at no cost to the Company.

As of September 30, 2021, the Company had not made any sales of common stock to Lincoln Park under the Purchase Agreement other than the Initial Purchase.

#### Common Stock Sales Agreement

In February 2018, the Company entered into a common stock sales agreement with H.C. Wainwright & Co., LLC ("HCW") as sales agent, which was subsequently amended in August 2018 (the "Sales Agreement"), in connection with an "at the market offering" under which the Company from time to time could offer and sell shares of its common stock having an aggregate offering price of not more than \$25.0 million.

The Company provided HCW with customary indemnification rights, and HCW was entitled to a commission at a fixed commission rate equal to 3.0% of the gross proceeds per share sold.

On February 12, 2021, the Company suspended the use of the at-the-market transactions facility and terminated the continuous offering pursuant to the Sales Agreement.

As of the termination of the Sales Agreement on February 12, 2021, the Company had sold an aggregate of 3,784,912 shares of its common stock pursuant to the Sales Agreement for net proceeds of \$9.5 million. During the nine months ended September 30, 2021, the Company had not issued any shares under the Sales Agreement.

#### At The Market Offering Agreement

On June 4, 2021, the Company entered into an At The Market Offering Agreement (the "ATM Agreement") with HCW, as sales agent, in connection with an "at the market offering" under which the Company from time to time may offer and sell shares of its common stock, having an aggregate offering price of up to \$50.0 million. During the nine months ended September 30, 2021, the Company had not issued any shares under the ATM Agreement.

#### Registered Direct Offerings

In February 2021, the Company entered into a Securities Purchase Agreement (the "Institutional Purchase Agreement") with certain institutional investors (the "Institutional Purchasers"). Pursuant to the terms of the Institutional Purchase Agreement, the Company sold to the Institutional Purchasers in a registered direct offering an aggregate of 24,906,134 shares of its common stock and warrants to purchase an aggregate of 12,453,067 shares of its common stock at a combined purchase price equal to \$2.45 per share and associated warrant. Each warrant features an exercise price equal to \$2.90 per share, is exercisable immediately upon issuance and will expire five years from the issuance date. Additionally, in a concurrent non-brokered registered direct offering, the Company entered into a Securities Purchase Agreement (the "Additional Purchase Agreement") with certain accredited investors (the "Additional Purchasers"). Pursuant to the terms of the Additional Purchase Agreement, the Company sold to the Additional Purchasers an aggregate of 1,632,652 shares of its common stock and warrants to purchase an aggregate of 816,326 shares of its common stock at a combined purchase price equal to \$2.45 per share and associated warrant. Each warrant features an exercise price equal to \$2.90 per share, is exercisable immediately upon issuance and will expire five years from the issuance date. In connection with the registered direct offerings, the Company received gross proceeds of approximately \$65.0 million.

#### Private Placement

In January 2021, the Company entered into a securities purchase agreement (the "January Private Placement") with certain investors (the "January Purchasers"). Pursuant to the terms of the January Private Placement, the Company agreed to sell to the January Purchasers an aggregate of 12,500,000 shares of its common stock at a purchase price equal to \$2.00 per share, along with warrants to purchase an aggregate of 6,250,000 shares of its common stock. In connection with the January Private Placement, the Company received gross proceeds of \$25.0 million. Each warrant is exercisable for one share of common stock and features an exercise price equal to \$2.90 per share. The warrants are exercisable immediately upon issuance and will expire five and one-half years from the issuance date.

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***Warrant Exercises***

In January 2021, the Company issued 801,148 shares of common stock for net proceeds of \$1.8 million in connection with warrant exercises associated with the April 23, 2020 securities purchase agreement and the May 25, 2020 securities purchase agreement.

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## Stock Options and Warrants

The following table summarizes the activity for stock options and warrants for the nine months ended September 30, 2021:

	Stock Options				Warrants			
	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (In Thousands)	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (In Thousands)
Outstanding at December 31, 2020	963,700	\$ 14.64	5.86	\$ —	2,638,355	\$ 2.18	4.98	\$ —
Changes during the period:								
Granted	1,314,790	1.32			19,519,393	2.90		
Exercised	(7,250)	3.28			(801,148)	2.19		
Forfeited	(19,492)	1.92			—	—		
Expired	(109,549)	34.12			—	—		
Outstanding at September 30, 2021	2,142,199	\$ 5.63	8.26	\$ —	21,356,600	\$ 2.84	4.63	\$ —
Vested at September 30, 2021 or expected to vest in the future	2,126,167	\$ 5.65	8.26	\$ —	21,356,600	\$ 2.84	4.63	\$ —
Vested at September 30, 2021	1,122,583	\$ 9.26	7.04	\$ —	21,356,600	\$ 2.84	4.63	\$ —

## Restricted Stock

During the nine months ended September 30, 2021 and 2020, the Company issued restricted stock for services as follows (\$ in thousands):

	Nine Months Ended September 30,	
	2021	2020
Number of restricted stock issued	612,950	156,184
Value of restricted stock issued	\$ 878	\$ 512

The vesting terms of restricted stock issuances are generally between one to four years.

## Restricted Stock Units

During the nine months ended September 30, 2021 and 2020, the Company issued restricted stock units for services as follows (\$ in thousands, except share data):

	Nine Months Ended September 30,	
	2021	2020
Number of restricted stock units issued	458,245	246,383
Value of restricted stock units issued	\$ 729	\$ 743

The weighted average estimated fair value of restricted stock issued for services in the nine months ended September 30, 2021 and 2020 was \$1.59 and \$3.02 per share, respectively. The fair value of the restricted stock units was determined using the Company's closing stock price on the date of issuance. The vesting terms of restricted stock unit issuances are generally one year, or upon the achievement of performance-based milestones.

## Note 9 – Share-Based Compensation

### Share-Based Compensation

We utilize share-based compensation in the form of stock options, restricted stock, and restricted stock units. The following table summarizes the components of share-based compensation expense for the three and nine months ended September 30, 2021 and 2020 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	\$ 523	\$ 58	\$ 643	\$ 24
General and administrative	250	171	996	83
Total share-based compensation expense	\$ 773	\$ 229	\$ 1,639	\$ 1,09

Total compensation cost related to non-vested awards not yet recognized and the weighted-average periods over which the awards were expected to be recognized at September 30, 2021 were as follows (in thousands):

	Stock Options	Restricted Stock Units	Restricted Stock
Unrecognized compensation cost	\$ 915	\$ 277	\$ 673
Expected weighted-average period in years of compensation cost to be recognized	1.82	1.23	1.88

Total fair value of shares vested and the weighted average estimated fair values of shares granted for the nine months ended September 30, 2021 and 2020 were as follows (in thousands):

	Stock Options	
	Nine Months Ended September 30, 2021	2020
Total fair value of shares vested	\$ 757	\$ 535
Weighted average estimated fair value of shares granted	\$ 0.91	\$ 2.12

### Valuation Assumptions

The fair value of stock options and warrants at the date of grant was estimated using the Black-Scholes option pricing model. The expected volatility is based upon historical volatility of the Company's stock. The expected term for the options is based upon observation of actual time elapsed between date of grant and exercise of options for all employees. The expected term for the warrants is based upon the contractual term of the warrants.

### Note 10 – Research Funding

#### California Institute of Regenerative Medicine Grant Award

In February 2017, the California Institute for Regenerative Medicine ("CIRM") awarded the Company funds of up to \$12.2 million to support The Sanford Project: T-Rex Study, a prospective, randomized, placebo-controlled, double-blind Phase 2 clinical trial to evaluate the safety and efficacy of CLBS03 as a treatment for recent-onset type 1 diabetes. The funding is based upon the achievement of certain milestones related to the proportion of subjects enrolled in California, as well as manufacturing and development costs incurred in California. Based on the actual number of subjects enrolled in California, the total amount of funding was revised to \$8.6 million, of which \$8.2 million has been received through the grant project period completion. The Company received \$5.7 million in initial funding in May 2017, a \$1.9 million milestone payment in December 2017, a \$0.3 million progress payment in March 2018, and a \$0.2 million progress payment in May 2019, of which the total was amortized over the estimated award period through July 2020 as a reduction to the related research and development expenses, with the final true up payment of \$46 thousand received in September 2020 and recorded as a reduction to the related research and development expenses. During the three and nine months ended September 30, 2021, the Company amortized and recognized \$0.0 million and \$0.0 million in credits, respectively, to research and development related to CIRM funds received. During the three and nine months ended September 30, 2020, the Company amortized and recognized \$0.3 million and \$1.6 million in credits, respectively, to research and development related to CIRM funds received.

### Note 11 – Income Taxes

In assessing the realizability of deferred tax assets, including the net operating loss carryforwards ("NOLs"), the Company assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to utilize its existing deferred tax assets. Based on its assessment, the Company has provided a full valuation allowance against its net deferred tax assets as their future utilization remains uncertain at this time.

As of December 31, 2020, the Company had approximately \$264 million of federal NOLs available to offset future taxable income expiring from 2030 through 2036. As of December 31, 2020, the Company had State NOLs available in New Jersey of \$99 million, California of \$70 million, and New York City of \$13 million to offset future taxable income expiring from 2030 through 2040. In accordance with Section 382 of the Internal Revenue code, the usage of the Company's NOLs could be limited in the event of a change in ownership. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period when those temporary differences become deductible.

The Company performed an analysis and determined that they did not have an ownership change of greater than 50% over a 3-year testing period. The last ownership change was determined to be on June 3, 2015. Based on a market capitalization of \$125 million and using an applicable federal rate of 2.5%, the annual limitation would be approximately \$3.0 million. Post change losses generated after June 3, 2015 would not be subject to 382 limitations.

The Company applies the FASB's provisions for uncertain tax positions. The Company utilizes the two-step process to determine the amount of recognized tax benefit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the consolidated financial statements is the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the relevant tax authority. The Company recognizes interest and penalties associated with uncertain tax positions as a component of income tax expense.

As of September 30, 2021, management does not believe the Company has any material uncertain tax positions that would require it to measure and reflect the potential lack of sustainability of a position on audit in its financial statements. The Company will continue to evaluate its uncertain tax positions in future periods to determine if measurement and recognition in its financial statements is necessary. The Company does not believe there will be any material changes in its unrecognized tax positions over the next year.

For years prior to 2017, the federal statute of limitations is closed for assessing tax. The Company's state tax returns remain open to examination for a period of three to four years from date of filing.

In February 2021, the Company received preliminary approval from the New Jersey Economic Development Authority ("NJEDA") to participate in the Technology Business Tax Certificate Transfer Program (the "Program"). The Program permits qualified companies to sell a percentage of their New Jersey net operating losses ("NJ NOLs") to unrelated profitable corporations. On April 12, 2021, the Company received final approval from NJEDA to sell a portion of our NJ NOLs, which were subsequently sold to a qualifying and approved buyer pursuant to the Program for net proceeds of \$1.4 million. The \$1.5 million of our NJ NOL related tax benefits ("NJ NOL Tax Benefits") have been recorded as a benefit from income taxes and the loss on sale of \$0.1 million recorded in other income (expense) in the consolidated financial statements.

## **Note 12 – Contingencies**

### ***Contingencies***

From time to time, the Company is subject to legal proceedings and claims, either asserted or unasserted, that arise in the ordinary course of business. While the outcome of pending claims cannot be predicted with certainty, the Company does not believe that the outcome of any pending claims will have a material adverse effect on the Company's financial condition or operating results.

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## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Cautionary Note Regarding Forward-Looking Statements" herein and under "Risk Factors" in our 2020 Form 10-K. The following discussion should be read in conjunction with our consolidated financial statements and related notes thereto included elsewhere in this Quarterly Report and in our 2020 Form 10-K.

### Overview

Caladrius Biosciences, Inc. ("we," "us," "our," "Caladrius" or the "Company") is a clinical-stage biopharmaceutical company dedicated to the development of treatments and reversal of severe diseases. We are developing what are intended to be first-in-class therapeutics based on the characteristics of naturally occurring CD34+ cells and their ability to stimulate the growth of new microvasculature. Our technology is intended to leverage these cells to enable the body's natural repair mechanisms using formulations unique to each medical indication.

Our leadership team has decades of collective biopharmaceutical development experience. Our goal is to develop and commercialize products that address important unmet medical needs based on a broad and versatile portfolio of candidates. Our current product candidates include:

- XOWNA® (CLBS16), the subject of both a recently completed positive Phase 2a study (ESCaPE-CMD) and a newly initiated Phase 2b (FREEDOM Trial) study in the United States 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 a clinical trial being executed in Japan. Additionally, CLBS12 was the recipient of orphan drug designation in March 2021 from the U.S. Food and Drug Administration ("FDA") for Buerger's disease; and
- CLBS201, designed to assess the safety and efficacy of CD34+ cell therapy as a treatment for patients with chronic kidney disease related to type 2 diabetes (diabetic kidney disease or "DKD").

### Ischemic Repair (CD34 Cell Technology)

The CD34+ cell was discovered as a result of the deliberate search for a cell capable of stimulating the development and/or repair of blood vessels. All tissues in the body maintain their function by replacing cells over time. In addition to the maintenance function, the body must also be capable of building new blood vessels after injury. A CD34+ cell is an endothelial progenitor cell that has the ability to stimulate new blood vessel formation at the level of the microvasculature. No other native cell discovered to date has demonstrated this same capability.

Our proprietary cell technology using autologous (a patient's own naturally occurring) CD34+ cells has led to the development of therapeutic product candidates designed to address diseases and conditions caused by ischemia. Ischemia occurs when the supply of oxygenated blood to healthy tissue is restricted. Through the administration of CD34+ cells, we seek to promote the development and formation of new microvasculature and thereby increase blood flow to the impacted area. We believe that a number of conditions caused by underlying ischemic injury can be improved through our CD34+ cell technology including but not limited to Buerger's disease, CLI, CMD, and DKD.

#### **XOWNA® for Treatment of Coronary Microvascular Dysfunction**

In 2017, with the assistance of a \$1.9 million grant from the National Institutes of Health (Award Number R44HL135889), we initiated our program for XOWNA® for the treatment of CMD, a disease that afflicts as many as 1.5 million patients in the United States alone, with no current targeted treatment options. That study, the ESCaPE-CMD Trial, was a Phase 2a proof-of-concept open label study that enrolled patients at the Mayo Clinic in Rochester, MN and Cedars-Sinai Medical Center in Los Angeles, CA. Those data showed a positive therapeutic effect with a statistically significant improvement in angina frequency, coronary flow reserve, Canadian Cardiovascular Society Angina Class and Seattle Angina Questionnaire scores, as well as an acceptable safety profile. The full data set from that study was presented at the SCAI 2020 Scientific Sessions Virtual Conference on May 14, 2020 by Dr. Timothy Henry, FACC, of the Christ Hospital in Cincinnati, Ohio. In December 2020, we commenced enrollment in our Phase 2b FREEDOM Trial of XOWNA®: a double-blind, randomized and placebo-controlled clinical trial designed to further evaluate the efficacy and safety of intracoronary delivery of autologous CD34+ cells in subjects with CMD and without obstructive coronary artery disease. While early enrollment proceeded to plan with the first patient treated in January 2021, the impact of the COVID-19 pandemic contributed to a general slowing of enrollment. Protocol

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amendments to the initial FREEDOM Trial protocol, as agreed to by the FDA, were implemented with the goal of enhancing breadth and speed of subject enrollment. Actual improvement in enrollment rate will be assessed during the fourth quarter of 2021. There can be no assurance that there will be an improvement in enrollment in the near future or at all. As part of program optimization, we convened an advisory board meeting of key opinion leaders in the fields of cardiology, drug development, and payer access and reimbursement in mid-October 2021 with the objective of assuring the most efficient and effective development program for XOWNA®.

### ***CLBS201 for Treatment of Diabetic Kidney 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. Based on these observations, we proposed an initial development plan for CLBS201 contemplating an adaptive design. However, after multiple conversations with key opinion leaders in the fields of nephrology and drug development, we have elected to move forward with a Phase 1, open-label, proof-of-concept trial evaluating CLBS201 dosed via intra-renal artery injections in subjects with DKD. This new protocol, pending approval of the Institutional Review Board (the "IRB") is expected to include six subjects in total with the first two subjects sequentially dosed and followed for a two-week safety observation period. Clearance by the independent Data Safety Monitoring Board overseeing the study will then permit the treatment of the next four patients, with all patients being followed for safety and therapeutic effect. A key read-out of data will occur at the six-month follow-up visit for all patients. We project enrollment of this study will begin in the first quarter of 2022. A key criterion for continued development of CLBS201 will be its ability to demonstrate a therapeutic effect that will make it competitive in the field of DKD treatment, i.e. kidney function regeneration, as indicated by increased glomerular filtration rate. There can be no assurance that we will be able to enroll patients in this study during the first quarter of 2022 or at all.

### ***HONEDRA® for Treatment of Critical Limb Ischemia***

Our randomized, open-label, registration-eligible study of HONEDRA® in Japan for the treatment of CLI and Buerger's disease continues to demonstrate positive trends in both safety and efficacy. These data remain consistent with the efficacy and safety from previously published clinical trials in Japan. The HONEDRA® study's enrollment, however, has been significantly curtailed by the COVID-19 pandemic's impact in Japan, including the States of Emergency in Japan that have persisted for much of the past 18 months. Due to the significant and continued operational and financial burden incurred as a result of these COVID-19 delays, coupled with the unpredictability of the timing of site enrollment re-initiation, we are suspending further enrollment and focusing our efforts on consummating a partnership with a Japanese company that could complete the study enrollment of the three remaining no-option CLI subjects and/or explore the possibility of submitting the existing data to Japan's Pharmaceuticals and Medical Devices Agency ("PMDA") under the SAKIGAKE designation, which allows for accelerated approval of innovative medical products. There can be no assurance that the PMDA will accept the existing data under SAKIGAKE designation. Also, as previously noted, in March 2021 CLBS12 was awarded an orphan designation in the U.S. by FDA as a potential treatment for Buerger's disease. However, based on a recent response from the FDA regarding a development plan for U.S. registration, we have decided not to pursue U.S. development in Buerger's disease at this time.

### ***Additional Out-licensing Opportunities***

Our broad intellectual property portfolio of cell therapy assets includes notable programs available for out-licensing in order to continue their clinical development. Our current long-term strategy focuses on advancing our therapies through development with the ultimate objective of obtaining market authorizations and entering commercialization, either alone or with partners, to provide treatment options to patients suffering from life-threatening medical conditions. We believe that we are well-positioned to realize potentially meaningful value increases within our own proprietary pipeline if we are successful in advancing our product candidates to their next significant development milestones.

### ***Coronavirus Considerations***

In December 2019, a novel strain of coronavirus (SARS-CoV-2), which causes COVID-19, was reported to have surfaced in China. In March 2020, the World Health Organization declared the outbreak of COVID-19 to be a pandemic, and the world's economies began to experience pronounced effects. Despite the FDA approval of multiple COVID-19 vaccines in late 2020, there remains uncertainty around the extent and duration of disruption and any future related financial impact cannot reasonably be estimated at this time. In response to the COVID-19 pandemic, we have implemented universal work from home as well as stringent social distancing and other hygiene policies for employees when they must be in the office. Our clinical study of HONEDRA® in Japan has experienced significant delays in enrollment due to the "State of Emergency" in effect in Japan for most of 2020 and reimplemented in Japan on January 7, 2021 through March 21, 2021 covering Tokyo and other regions in response to an increased number of COVID-19 patients. Due to reported large increases in COVID-19 cases and a low rate of vaccinations in Japan, a "State of Emergency" was renewed on April 25, 2021 through May 11, 2021 and then reimplemented

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in Tokyo from July 12, 2021 through September 30, 2021. We expect that COVID-19 in Japan will continue to negatively impact enrollment of the HONEDRA® clinical trial.

## Results of Operations

### *Three Months Ended September 30, 2021 Compared to Three Months Ended September 30, 2020*

Overall, net losses were \$6.9 million for the three months ended September 30, 2021, compared to \$5.3 million for the three months ended September 30, 2020.

#### Operating Expenses

For the three months ended September 30, 2021, operating expenses totaled \$7.0 million, compared to \$5.4 million for the three months ended September 30, 2020, representing an increase of 30%. Operating expenses comprised the following:

- Research and development expenses were approximately \$4.1 million for the three months ended September 30, 2021, compared to \$3.0 million for the three months ended September 30, 2020, representing an increase of \$1.1 million or 36%. This increase was primarily due to an increase in expenses associated with the enrollment of our XOWNA® Phase 2b study (the FREEDOM Trial). Research and development in both periods focused on the advancement of our ischemic repair platform and related to:
  - expenses associated with our XOWNA® Phase 2b study (the FREEDOM Trial) which commenced in the fourth quarter of 2020 with the first patient in the study treated in January 2021;
  - ongoing registration-eligible study expenses for HONEDRA® in critical limb ischemia in Japan which focused on patient enrollment completion. The study's enrollment has been significantly curtailed by the COVID-19 pandemic's impact in Japan, including the States of Emergency that have persisted there for over 18 months. Due to the significant and continued operational and financial burden incurred as a result of these COVID-19 delays, coupled with the complete unpredictability of the timing of site enrollment re-initiation, we will focus our efforts on consummating a partnership with a Japanese company in order to complete the study enrollment as well as to explore the possibility of submitting the existing data to PMDA under the SAKIGAKE designation;
  - expenses associated with the preparation of our filing of an IND for the clinical study of CLBS201 for treatment of diabetic kidney disease. A Phase 1, open-label, proof-of-concept trial is being planned and is expected to include six subjects in total with projected enrollment commencing in the first quarter of 2022.
  
- General and administrative expenses were approximately \$2.8 million for the three months ended September 30, 2021, compared to \$2.3 million for the three months ended September 30, 2020, representing an increase of 22%. This increase was primarily due to an increase in Directors and Officers insurance premiums and strategic consulting expenses. Our general and administrative expenses focus on general corporate-related activities.

Historically, to minimize our use of cash, we have used a variety of equity and equity-linked instruments to compensate employees, consultants and other service providers. The use of these instruments has resulted in charges to the results of operations, which have been significant in the past.

#### Other Income (Expense)

Total other income (expense) is comprised of investment income on cash, cash equivalents and marketable securities.

### *Nine Months Ended September 30, 2021 Compared to Nine Months Ended September 30, 2020*

Overall, net losses were \$20.7 million for the nine months ended September 30, 2021, compared to \$2.7 million for the nine months ended September 30, 2020.

#### Operating Expenses

For the nine months ended September 30, 2021, operating expenses totaled \$22.2 million compared to \$13.7 million for the nine months ended September 30, 2020, representing an increase of 62%. Operating expenses comprised the following:

- Research and development expenses were approximately \$13.5 million for the nine months ended September 30, 2021, compared to \$6.3 million for the nine months ended September 30, 2020, representing an increase of \$7.2 million or 113%. This increase was primarily due to an increase in expenses associated with the enrollment of our XOWNA® Phase 2b study (the
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FREEDOM Trial). Research and development in both periods focused on the advancement of our ischemic repair platform and related to:

- expenses associated with our XOWNNA<sup>®</sup> Phase 2b study (the FREEDOM Trial) which commenced in the fourth quarter of 2020 with the first patient in the study treated in January 2021;
  - ongoing registration-eligible study expenses for HONEDRA<sup>®</sup> in critical limb ischemia in Japan which focused on patient enrollment completion. The study's enrollment has been significantly curtailed by the COVID-19 pandemic's impact in Japan, including the States of Emergency that have persisted there for over 18 months. Due to the significant and continued operational and financial burden incurred as a result of these COVID-19 delays, coupled with the complete unpredictability of the timing of site enrollment re-initiation, we will focus our efforts on consummating a partnership with a Japanese company in order to complete the study enrollment as well as to explore the possibility of submitting the existing data to PMDA under the SAKIGAKE designation;
  - expenses associated with the preparation of our filing of an IND for the clinical study of CLBS201 for treatment of diabetic kidney disease. A Phase 1, open-label, proof-of-concept trial is being planned and is expected to include six subjects in total with projected enrollment commencing in the first quarter of 2022.
- General and administrative expenses were approximately \$8.7 million for the nine months ended September 30, 2021, compared to \$7.4 million for the nine months ended September 30, 2020, representing an increase of 18%. This increase was primarily due to an increase in Directors and Officers insurance premiums and strategic consulting expenses. Our general and administrative expenses focus on general corporate-related activities.

Historically, to minimize our use of cash, we have used a variety of equity and equity-linked instruments to compensate employees, consultants and other service providers. The use of these instruments has resulted in charges to the results of operations, which have been significant in the past.

#### **Other Income (Expense)**

Total other income (expense) is comprised of investment income on cash, cash equivalents and marketable securities and a loss on sale of \$0.1 million related to the sale of our NJ NOLs.

#### **Income Tax Benefit**

In April 2020, we received final approval from the New Jersey Economic Development Authority ("NJEDA") under the Technology Business Tax Certificate Transfer Program ("Program") to sell a percentage of our NJ NOLs. We subsequently sold a portion of our NJ NOLs to a qualifying and approved buyer pursuant to the Program for net proceeds of \$10.9 million.

In April 2021, we received final approval from the NJEDA under the Program to sell a portion of our NJ NOLs, which were subsequently sold to a qualifying and approved buyer pursuant to the Program for net proceeds of \$1.4 million. The \$1.5 million of our NJ NOL Tax Benefits have been recorded as a benefit from income taxes and the loss on sale of \$0.1 million recorded in other income (expense).

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## Analysis of Liquidity and Capital Resources

As of September 30, 2021, we had cash, cash equivalents and marketable securities of approximately \$100.1 million, working capital of approximately \$98.0 million, and stockholders' equity of approximately \$98.7 million.

During the nine months ended September 30, 2021, we met our immediate cash requirements through existing cash balances. Additionally, we used equity and equity-linked instruments to pay for services and compensation.

Net cash used in or provided by, operating, investing and financing activities were as follows (in thousands):

	Nine Months Ended September 30,	
	2021	2020
Net cash used in operating activities	\$ (17,641)	\$ (3,256)
Net cash used in investing activities	(71,354)	(8,187)
Net cash provided by financing activities	85,255	18,567

### Operating Activities

Our cash used in operating activities during the nine months ended September 30, 2021 was \$17.6 million, which is comprised of (i) our net loss of \$20.7 million, adjusted for non-cash expenses totaling \$3.6 million (which includes adjustments for equity-based compensation, depreciation and amortization, and amortization/accretion of marketable securities), and (ii) changes in operating assets and liabilities using approximately \$0.6 million.

Our cash used in operating activities during the nine months ended September 30, 2020 was \$3.3 million, which is comprised of (i) our net loss of \$2.7 million, adjusted for non-cash expenses totaling \$1.3 million (which includes adjustments for equity-based compensation, depreciation and amortization, and amortization/accretion of marketable securities), and (ii) changes in operating assets and liabilities using approximately \$1.9 million.

### Investing Activities

Our cash used in investing activities during the nine months ended September 30, 2021 totaled \$71.4 million and was primarily due to net purchases of marketable securities (net of sales of marketable securities).

Our cash used in investing activities during the nine months ended September 30, 2020 totaled \$8.2 million and was primarily due to net purchases of marketable securities (net of sales of marketable securities).

### Financing Activities

Our cash provided by financing activities during the nine months ended September 30, 2021 primarily consisted of (i) net proceeds of \$23.1 million through the issuance of common shares and warrants in our January 2021 private placement, (ii) net proceeds of \$1.8 million in connection with warrant exercises, (iii) net proceeds of \$60.6 million through the issuance of common shares and warrants in both of our February 2021 registered direct offerings, which was partially offset by tax withholding-related payments on net share settlement equity awards to employees.

Our cash provided by financing activities during the nine months ended September 30, 2020 primarily consisted of (i) net proceeds of \$4.5 million through the issuance of common shares and warrants in our April 2020 registered direct offering, (ii) net proceeds of \$3.8 million through the issuance of common shares and warrants in our May 2020 registered direct offering, and (iii) net proceeds of \$1.9 million through the issuance of common shares and warrants in our July 2020 private placement offering, and (iv) net proceeds of \$8.4 million through the issuance of common shares under our common stock sales agreement with H.C. Wainwright, which was partially offset by tax withholding-related payments on net share settlement equity awards to employees.

## Liquidity and Capital Requirements Outlook

To meet our short and long-term liquidity needs, we expect to use existing cash balances and a variety of other means. Other sources of liquidity could include additional potential issuances of debt or equity securities in public or private financings, partnerships and/or collaborations and/or sale of assets. Our history of operating losses and liquidity challenges may make it difficult for us to raise capital on acceptable terms or at all. The demand for the equity and debt of biopharmaceutical companies like ours is dependent upon many factors, including the general state of the financial markets. During times of extreme market volatility, capital may not be available on favorable terms, if at all. Our inability to obtain such additional capital could materially and adversely affect our business operations. We will also continue to seek, as appropriate, grants for scientific and clinical studies from various governmental agencies and foundations, and other sources of non-dilutive funding.

We believe that our cash on hand will enable us to fund operating expenses for at least the next 12 months following the issuance of our financial statements.

On June 4, 2021, we entered into an At The Market Offering Agreement (the “ATM Agreement”) with H.C. Wainwright & Co., LLC (“HCW”), as sales agent, in connection with an “at the market offering” under which we from time to time may offer and sell shares of our common stock, having an aggregate offering price of up to \$50.0 million. As of September 30, 2021, we had not issued any shares under the ATM Agreement.

In February 2021, we received preliminary approval from the NJEDA to participate in the Program. The Program permits qualified companies to sell a percentage of their NJ NOLs to unrelated profitable corporations. On April 12, 2021, we received final approval from NJEDA to sell \$1.5 million of our NJ NOLs, which was subsequently sold to a qualifying and approved buyer pursuant to the Program for net proceeds of \$1.4 million.

In February 2021, we entered into a Securities Purchase Agreement (the “Institutional Purchase Agreement”) with certain institutional investors (the “Institutional Purchasers”). Pursuant to the terms of the Institutional Purchase Agreement, we sold to the Institutional Purchasers in a registered direct offering an aggregate of 24,906,134 shares of our common stock and warrants to purchase an aggregate of 12,453,067 shares of our common stock at a combined purchase price equal to \$2.45 per share and associated warrant. Each warrant features an exercise price equal to \$2.90 per share, is exercisable immediately upon issuance and will expire five years from the issuance date. Additionally, in a concurrent non-brokered registered direct offering, we entered into a Securities Purchase Agreement (the “Additional Purchase Agreement”) with certain accredited investors (the “Additional Purchasers”). Pursuant to the terms of the Additional Purchase Agreement, we sold to the Additional Purchasers an aggregate of 1,632,652 shares of our common stock and warrants to purchase an aggregate of 816,326 shares of our common stock at a combined purchase price equal to \$2.45 per share and associated warrant. Each warrant features an exercise price equal to \$2.90 per share, is exercisable immediately upon issuance and will expire five years from the issuance date. The closing of the offerings occurred on February 17, 2021. In connection with the registered direct offerings, we received gross proceeds of approximately \$65.0 million.

On February 12, 2021, we suspended the use of the at-the-market transactions facility (the “ATM”) and terminated the continuous offering pursuant to the Common Stock Sales Agreement (“Sales Agreement”) entered into in February 2018 with HCW. As of termination date of February 12, 2021, we had sold an aggregate of 3,784,912 shares of our common stock pursuant to the Sales Agreement for aggregate gross proceeds of \$9.5 million.

In January 2021, we entered into a Securities Purchase Agreement (the “January Purchase Agreement”) with certain institutional and accredited investors (the “January Purchasers”), pursuant to which the Company issued and sold to the January Purchasers in a private placement an aggregate of (i) 12,500,000 shares of common stock, and (ii) warrants exercisable for up to an aggregate of 6,250,000 shares of common stock at a combined offering price of \$2.00 per share of common stock and associated warrant. The warrants have an exercise price of \$2.90 per share. Each warrant will be immediately exercisable and will expire five and one-half years from the issuance date. The closing of the offering occurred on January 25, 2021. We received gross proceeds of \$25.0 million in connection with the private placement, before deducting placement agent fees and related offering expenses.

In March 2019, we and Lincoln Park Capital Fund, LLC (“Lincoln Park”) entered into a purchase agreement (the “Purchase Agreement”) and a registration rights agreement (the “Registration Rights Agreement”), pursuant to which we have the right to sell to Lincoln Park shares of our common stock having an aggregate value of up to \$26.0 million, subject to certain limitations and conditions set forth in the Purchase Agreement (the “Offering”). As consideration for entering into the Purchase Agreement, we issued to Lincoln Park an additional 181,510 shares of common stock as commitment shares. Pursuant to the Purchase Agreement, Lincoln Park purchased 250,000 shares of common stock, at a price of \$4.00 per share, for a total gross purchase price of \$1.0 million (the “Initial Purchase”) upon commencement. Thereafter, as often as every business day from and after one business day following the date of the Initial Purchase and over the 36-month term of the Purchase Agreement, we have the right, from time to time, at our sole discretion and subject to certain conditions, to direct Lincoln Park to purchase up to 100,000 shares of common stock, with such amount increasing as the closing sale price of the common stock increases; provided Lincoln Park’s obligation under any single such purchase will not exceed \$2,500,000, unless we and Lincoln Park mutually agree to increase the maximum amount of such single purchase (each, a “Regular Purchase”). If we direct Lincoln Park to purchase the maximum number of shares of common stock it then may sell in a Regular Purchase, then in addition to such Regular Purchase, and subject to certain conditions and limitations in the Purchase Agreement, we may direct Lincoln Park in an “accelerated purchase” to purchase an additional amount of common stock that may not exceed the lesser of (i) 300% the number of shares purchased pursuant to the corresponding Regular Purchase or (ii) 30% of the total number of shares of our common stock traded during a specified period on the applicable purchase date as set forth in the Purchase Agreement. Under certain circumstances and in accordance with the Purchase Agreement, we may direct Lincoln Park to purchase shares in multiple accelerated purchases on the same trading day. As of September 30, 2021, we had not made any sales of common stock to Lincoln Park under the Purchase Agreement other than the Initial Purchase.

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While we continue to seek capital through a number of means, there can be no assurance that additional financing will be available on acceptable terms, if at all, and our negotiating position in capital generating efforts may worsen as existing resources are used. Additional equity financing may be dilutive to our stockholders; debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate as a business; our stock price may not reach levels necessary to induce option or warrant exercises; and asset sales may not be possible on terms we consider acceptable. If we are unable to access capital necessary to meet our long-term liquidity needs, we may have to delay the expansion of our business or raise funds on terms that we currently consider unfavorable.

### **Seasonality**

We do not believe that our operations are seasonal in nature.

### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements.

### **Critical Accounting Policies and Estimates**

There have been no material changes in our critical accounting policies and estimates during the three and nine months ended September 30, 2021, compared to those reported in our 2020 Form 10-K.

## **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Not applicable.

## **ITEM 4. CONTROLS AND PROCEDURES**

### **(a) Disclosure Controls and Procedures**

Disclosure controls and procedures are the controls and other procedures we have designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the “Exchange Act”) is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports that we file under the Exchange Act is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well-designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Due to the inherent limitations of control systems, not all misstatements may be detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Controls and procedures can only provide reasonable, not absolute, assurance that the above objectives have been met.

As of September 30, 2021, we carried out an evaluation, with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15(e) and 15d-15(e) of the Exchange Act. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective, at the reasonable assurance level, in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms and is accumulated and communicated to management, including the principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

### **(b) Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15, that occurred during our last quarter to which this Quarterly Report relates that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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**PART II**

**OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

There are no material changes to the disclosures previously reported in our 2020 Form 10-K.

**ITEM 1A. RISK FACTORS**

There have been no material changes to the risk factors previously reported in our 2020 Form 10-K. See the risk factors set forth in our 2020 Annual Report on Form 10-K under the caption "Item 1 A - Risk Factors."

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

The Exhibit Index appearing immediately after the signature page to this Form 10-Q is incorporated herein by reference.

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**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 thereunto duly authorized.

November 4, 2021

**CALADRIUS BIOSCIENCES, INC.**

By: /s/ David J. Mazzo, PhD

Name: David J. Mazzo, PhD

Title: President and Chief Executive Officer

(Principal Executive Officer, Principal Financial Officer  
and Principal Accounting Officer)

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**CALADRIUS BIOSCIENCES, INC.**  
**FORM 10-Q**

**Exhibit Index**

<a href="#">31.1</a>	*	Certification of Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
<a href="#">32</a>	**	Certification of Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS		XBRL Instance Document
101.SCH		XBRL Taxonomy Extension Schema
101.CAL		XBRL Taxonomy Extension Calculation Linkbase
101.DEF		XBRL Taxonomy Extension Definition Linkbase
101.LAB		XBRL Taxonomy Extension Label Linkbase
101.PRE		XBRL Taxonomy Extension Presentation Linkbase

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\* Filed herewith.

\*\* Furnished herewith.

**CERTIFICATIONS UNDER SECTION 302**

I, David J. Mazzo, PhD, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Caladrius Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2021

/s/ David J. Mazzo, PhD

Name: David J. Mazzo, PhD

Title: President and Chief Executive Officer

(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Caladrius Biosciences, Inc. (the "Company") for the quarter ended September 30, 2021 filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David J. Mazzo, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition of the Company as of the dates presented and the results of operations of the Company for the periods presented.

Dated: November 4, 2021

/s/ David J. Mazzo, PhD

David J. Mazzo, PhD

President and Chief Executive Officer (Principal Executive Officer,  
Principal Financial Officer and Principal Accounting Officer)

The foregoing certification is being furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and is not being filed as part of the Form 10-Q or as a separate disclosure document.