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 March 31, 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	22-2343568
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
110 Allen Road, 2nd Floor, Basking Ridge, New Jersey	07920
(Address of principal executive offices)	(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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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 May 6, 2021**
Common stock, $0.001 par value per share	59,498,958 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*, 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 I. FINANCIAL STATEMENTS

CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)

	March 31, 2021	December 31, 2020
ASSETS	**(Unaudited)**	
Cash and cash equivalents	$ 28,744	$ 16,512
Marketable securities	82,767	18,061
Prepaid and other current assets	2,522	758
Total current assets	114,033	35,331
Property and equipment, net	41	57
Other assets	533	614
Total assets	$ 114,607	$ 36,002
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities		
Accounts payable	$ 2,315	$ 1,020
Accrued liabilities	2,123	2,486
Total current liabilities	4,438	3,506
Other long-term liabilities	155	254
Total liabilities	4,593	3,760
Commitments and Contingencies		
Stockholders' Equity		
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 March 31, 2021 and December 31, 2020, respectively	—	—
Common stock, $0.001 par value, authorized 500,000,000 shares; issued 59,510,038 and 19,389,413 shares at March 31, 2021 and December 31, 2020, respectively; and outstanding, 59,498,958 and 19,378,333 shares at March 31, 2021 and December 31, 2020, respectively	60	19
Additional paid-in capital	544,601	458,748
Treasury stock, at cost; 11,080 shares at March 31, 2021 and December 31, 2020	(708)	(708)
Accumulated deficit	(433,613)	(425,550)
Accumulated other comprehensive loss	(72)	(13)
Total Caladrius Biosciences, Inc. stockholders' equity	110,268	32,496
Noncontrolling interests	(254)	(254)
Total stockholders' equity	110,014	32,242
Total liabilities and stockholders' equity	$ 114,607	$ 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 March 31,	
	2021	**2020**
Operating Expenses:		
Research and development	$ 5,076	$ 1,499
General and administrative	3,010	2,558
Total operating expenses	8,086	4,057
Operating loss	(8,086)	(4,057)
Other income:		
Investment income, net	23	71
Total other income	23	71
Net loss	$ (8,063)	$ (3,986)
Less - net income attributable to noncontrolling interests	—	4
Net loss attributable to Caladrius Biosciences, Inc. common stockholders	$ (8,063)	$ (3,990)
Basic and diluted loss per share		
Caladrius Biosciences, Inc. common stockholders	$ (0.19)	$ (0.38)
Weighted average common shares outstanding		
Basic and diluted shares	42,117	10,623

See accompanying notes to consolidated financial statements.

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

	Three Months Ended March 31, 2021	Three Months Ended March 31, 2020
Net loss	$ (8,063)	$ (3,986)
Other comprehensive loss:		
Available for sale securities - net unrealized loss	(59)	(2)
Total other comprehensive loss	(59)	(2)
Comprehensive loss	(8,122)	(3,988)
Comprehensive income attributable to noncontrolling interests	—	4
Comprehensive loss attributable to Caladrius Biosciences, Inc. common stockholders	$ (8,122)	$ (3,992)

See accompanying notes to consolidated financial statements.

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 Income (Loss)	Accumulated Deficit	Treasury Stock	Total Caladrius Biosciences, Inc. Stockholders' Equity	Non-Controlling Interest in Subsidiary	Total Equity
	Shares	Amount	Shares	Amount							
Balance at December 31, 2020	10	$ —	19,389	$ 19	$ 458,748	$ (13)	$ (425,550)	$ (708)	$ 32,496	$ (254)	$ 32,242
Net loss	—	—	—	—	—	—	(8,063)	—	(8,063)	—	(8,063)
Unrealized loss on marketable securities	—	—	—	—	—	(59)	—	—	(59)	—	(59)
Share-based compensation	—	—	273	—	413	—	—	—	413	—	413
Net proceeds from issuance of common stock and warrants	—	—	39,841	41	85,416	—	—	—	85,457	—	85,457
Proceeds from option exercises	—	—	7	—	24	—	—	—	24	—	24
Balance at March 31, 2021	10	$ —	59,510	$ 60	$ 544,601	$ (72)	$ (433,613)	$ (708)	$ 110,268	$ (254)	$ 110,014

	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							
Balance at December 31, 2019	10	$ —	10,529	$ 11	$ 438,911	$ 2	$ (417,400)	$ (708)	$ 20,816	$ (263)	$ 20,553
Net loss	—	—	—	—	—	—	(3,990)	—	(3,990)	4	(3,986)
Unrealized loss on marketable securities	—	—	—	—	—	(2)	—	—	(2)	—	(2)
Share-based compensation	—	—	110	—	419	—	—	—	419	—	419
Balance at March 31, 2020	10	$ —	10,639	$ 11	$ 439,330	$ —	$ (421,390)	$ (708)	$ 17,243	$ (259)	$ 16,984

See accompanying notes to consolidated financial statements.

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

	Three Months Ended March 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (8,063)	$ (3,986)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	597	567
Depreciation and amortization	16	15
Accretion on marketable securities	323	19
Changes in operating assets and liabilities:		
Prepaid and other current assets	(1,763)	354
Other assets	81	233
Accounts payable, accrued liabilities and other liabilities	834	(1,443)
Net cash used in operating activities	(7,975)	(4,241)
Cash flows from investing activities:		
Purchase of marketable securities	(75,911)	—
Sale of marketable securities	10,821	11,104
Purchases of property and equipment	—	(2)
Net cash (used in) provided by investing activities	(65,090)	11,102
Cash flows from financing activities:		
Proceeds from exercise of options	24	—
Tax withholding payments on net share settlement equity awards	(184)	(148)
Net proceeds from issuance of common stock	85,457	—
Net cash provided by (used in) financing activities	85,297	(148)
Net increase in cash and cash equivalents	12,232	6,713
Cash and cash equivalents at beginning of period	16,512	14,032
Cash and cash equivalents at end of period	$ 28,744	$ 20,745

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 and commercialization of cellular therapies designed to reverse disease and/or promote the regeneration of damaged tissue. The Company is developing 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 leverages 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: CLBS16, the subject of both a recently completed positive Phase 2a study and a newly initiated Phase 2b (FREEDOM) study in the U.S. for the treatment of coronary microvascular dysfunction ("CMD"); HONEDRA® (CLBS12), recipient of SAKIGAKE designation and eligible for early conditional approval in Japan for the treatment of critical limb ischemia ("CLI") and Buerger's disease based on the results of an ongoing clinical trial and recipient of orphan drug designation in March 2021 from the U.S. Food and Drug Administration ("FDA") for Buerger's disease; CLBS201, designed to assess the safety and efficacy of CD34+ cell therapy as a treatment for patients with pre-dialysis diabetic kidney disease ("DKD") and OLOGO™ (CLBS14), a Regenerative Medicine Advanced Therapy ("RMAT") designated Phase 3 ready therapy for treatment of no-option refractory disabling angina ("NORDA").

Ischemic Repair (CD34 Cell Technology)

The CD34+ cell was discovered as a result of the deliberate search for a stem 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 a stem 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 CLI, CMD, DKD and NORDA.

HONEDRA® for Treatment of Critical Limb Ischemia

The Company's randomized and open-label, registration-eligible study of HONEDRA® in Japan for the treatment of CLI has shown strong results to date. The initial responses observed in the subjects who have reached an endpoint in this open label study are consistent with a positive therapeutic effect and safety profile as reported by previously published clinical trials in Japan. The study's enrollment continues to be slowed by the COVID-19 pandemic's impact in Japan, however, the Company is encouraged by the patient pre-screening pipeline and continues to make progress towards study completion, the exact date of which is impossible to predict given the continuing impact of COVID-19 on clinical trials like ours in Japan. While the final outcome of the trial will depend on all data from all subjects, data, to date, are very encouraging.

CLBS16 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 CLBS16 for the treatment of CMD, a disease that afflicts millions of patients with no current targeted treatment options. That study, the ESCaPE-CMD trial, was a Phase 2a proof-of-concept study that enrolled patients at the Mayo Clinic in Rochester, MN and Cedars-Sinai Medical Center in Los Angeles, CA. That data set showed a positive therapeutic effect with a statistically significant improvement in angina frequency, coronary flow reserve, Canadian Cardiovascular Society Angina Class and Seattle Questionnaire score, as well as an acceptable safety profile. The 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 CLBS16 as a therapy for CMD. The first patient in the study was subsequently treated in January 2021 at The Christ Hospital Health Network in Cincinnati, Ohio. This 105-patient double-blind randomized and placebo-controlled clinical trial (FREEDOM Trial) is 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. To the Company's knowledge, this is the first controlled regenerative medicine trial in CMD.

CLBS201 for Treatment of Diabetic Kidney Disease

The Company has prepared an initial development plan for the clinical study of CLBS201, a CD34+ investigational product for administration into the renal arteries to slow the deterioration or reverse the decline of renal function in patients with diabetic kidney disease ("DKD") who, although at a pre-dialysis stage, exhibit rapidly progressive disease. Progressive kidney failure is associated with attrition of the microcirculation of the kidney. Pre-clinical studies in kidney disease and injury models have demonstrated that protection or replenishment of the microcirculation results in improved kidney function. A Phase 2 proof of concept, randomized, placebo-controlled study is planned for initiation in the second half of 2021.

OLOGO™ for Treatment of No Option Refractory Disabling Angina

The Company acquired the rights to data and regulatory filings for a CD34+ cell therapy program for refractory angina that had been advanced to Phase 3 by a previous sponsor.

Based on the clinical evidence from the completed studies that a single administration of OLOGO™ reduces mortality, improves angina and increases exercise capacity in patients with otherwise untreatable angina, this product received Regenerative Medicine Advanced Therapy (“RMAT”) designation from the FDA. The Company continues to seek an agreement with the FDA on the design of a Phase 3 study of appropriate and practical size and scope which, in combination with previously filed Phase 1, 2 and 3 data, will be considered for the registration of OLOGO™. Notably, the RMAT designation affords the product a 6-month review time for a biologics license application ("BLA"), once submitted.

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 be reasonably estimated at this time. In response to the 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® in Japan has experienced significant delays in enrollment due to the “State of Emergency” that was in effect for most of 2020 in response to COVID-19, and which was re-implemented on January 7, 2021 through March 21, 2021, and again on April 25, 2021 through May 11, 2021 covering Tokyo and other regions. This most recent reinstatement of the “State of Emergency” continues negatively to impact enrollment of the on-going 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 March 31, 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 months ended March 31, 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 months ended March 31, 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 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 June 2016, the FASB issued ASU 2016-13, Financial Instruments—Credit Losses, which will require companies to present assets held at amortized cost and available for sale debt securities net of the amount expected to be collected. The guidance requires the measurement of expected credit losses to be based on relevant information from past events, including historical experiences, current conditions and reasonable and supportable forecasts that affect collectability. The guidance was effective for fiscal years and interim periods beginning after December 15, 2019 and adopted January 1, 2020. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

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):

	March 31, 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	$ 59,937	$ —	$ (61)	$ 59,876	$ 8,406	$ —	$ (7)	$ 8,399
Money market funds	18,044	—	—	18,044	7,591	—	—	7,591
Municipal debt securities	29,016	—	(12)	29,004	14,753	—	(6)	14,747
Total	$ 106,997	$ —	$ (73)	$ 106,924	$ 30,750	$ —	$ (13)	$ 30,737

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):

	March 31, 2021	December 31, 2020
Cash and cash equivalents	$ 24,157	$ 12,676
Marketable securities	82,767	18,061
Total	$ 106,924	$ 30,737

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

	March 31, 2021	
	Amortized Cost	Estimated Fair Value
Less than one year	$ 106,997	$ 106,924
Greater than one year	—	—
Total	$ 106,997	$ 106,924

Note 4 – Income (Loss) Per Share

For the three months ended March 31, 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 March 31, 2021 and 2020, the Company excluded the following potentially dilutive securities (in thousands):

	March 31,	
	2020	2020
Stock Options	1,022	1,280
Warrants	21,357	30
Restricted Stock Units	798	313

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 March 31, 2021, and December 31, 2020 (in thousands).

	March 31, 2021				December 31, 2020			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Marketable securities - available for sale	$ —	$ 82,767	$ —	$ 82,767	$ —	$ 18,061	$ —	$ 18,061
	$ —	$ 82,767	$ —	$ 82,767	$ —	$ 18,061	$ —	$ 18,061

Note 6 – Accrued Liabilities

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

	March 31, 2021	December 31, 2020
Salaries, employee benefits and related taxes	$ 1,119	$ 1,716
Operating lease liabilities - current	381	370
Other	623	400
Total	$ 2,123	$ 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):

	March 31, 2021	December 31, 2020
Right-of Use Assets:		
Other assets	$ 492	$ 574
Total Right-of-Use Asset	$ 492	$ 574
Operating Lease Liabilities:		
Accrued liabilities	$ 381	$ 370
Other long-term liabilities	155	254
Total Operating Lease Liabilities	$ 536	$ 624

As of March 31, 2021, the weighted average remaining lease term for our operating leases was 1.6 years, and the weighted average discount rate for our operating leases was 9.625%. Future minimum lease payments under the lease agreements as of March 31, 2021 were as follows (in thousands):

Years ended	Operating Leases
2021	312
2022	239
2023	27
Total lease payments	578
Less: Amounts representing interest	(42)
Present value of lease liabilities	$ 536

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 March 31, 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 may offer and sell shares of its common stock having an aggregate offering price of not more than $25.0 million. In March 2019, subsequent to the filing of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 (the "2018 Form 10-K"), the aggregate market value of its outstanding common stock held by non-affiliates was approximately $52.8 million. Pursuant to General Instruction I.B.6 of Form S-3, since the aggregate market value of the Company's outstanding common stock held by non-affiliates was below $75.0 million at the time of its 2018 Form 10-K filing, the aggregate amount of securities that the Company was permitted to offer and sell at such time was reduced to $17.6 million (or a maximum of 4.8 million shares), which was equal to one-third of the aggregate market value of its common stock held by non-affiliates at such time.

Subject to the terms and conditions of the Sales Agreement, HCW will use commercially reasonable efforts consistent with its normal trading and sales practices to sell the shares from time to time, based upon the Company's instructions, including any price, time or size limits specified by the Company. The Company has provided HCW with customary indemnification rights, and HCW will be entitled to a commission at a fixed commission rate equal to 3.0% of the gross proceeds per share sold. The Company has no obligation to sell any of the shares and may at any time suspend sales under the Sales Agreement or terminate the Sales Agreement. The Sales Agreement will terminate upon the sale of all of the shares under the Sales Agreement unless terminated earlier by either party as permitted under the Sales Agreement.

On February 12, 2021, the Company 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 H.C. Wainwright & Co., LLC (“HCW”). The Company will no longer make any sales of its common stock pursuant to the Sales Agreement unless and until a new prospectus supplement is filed with the Securities and Exchange Commission.

As of 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 three months ended March 31, 2021, the Company had not issued any shares under the Sales 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.

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.

Stock Options and Warrants

The following table summarizes the activity for stock options and warrants for the three months ended March 31, 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	155,150	1.60			19,519,393	2.90		
Exercised	(7,250)	3.28			(801,148)	2.19		
Forfeited	(7,017)	2.20			—	—		
Expired	(82,359)	6.54			—	—		
Outstanding at March 31, 2021	1,022,224	$ 13.48	6.67	$ —	21,356,600	$ 2.84	4.98	$ —
Vested at March 31, 2021 or expected to vest in the future	996,573	$ 13.77	6.60	$ —	21,356,600	$ 2.84	4.98	$ —
Vested at March 31, 2021	765,479	$ 17.08	5.87	$ —	21,356,600	$ 2.80	4.98	$ —

Restricted Stock

During the three months ended March 31, 2021 and 2020, the Company issued restricted stock for services as follows ($ in thousands):

	Three Months Ended March 31,	
	2021	**2020**
Number of restricted stock issued	300,450	156,184
Value of restricted stock issued	$ 478	$ 512

Restricted Stock Units

During the three months ended March 31, 2021 and 2020, the Company issued restricted stock units for services as follows ($ in thousands, except share data):

	Three Months Ended March 31,	
	2021	**2020**
Number of restricted stock units issued	458,245	195,320
Value of restricted stock units issued	$ 729	$ 623

The weighted average estimated fair value of restricted stock issued for services in the three months ended March 31, 2021 and 2020 was $1.59 and $3.19 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 months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Research and development	$ 96	$ 125
General and administrative	501	442
Total share-based compensation expense	$ 597	$ 567

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 March 31, 2021 were as follows (in thousands):

	Stock Options	Restricted Stock Units	Restricted Stock
Unrecognized compensation cost	$ 395	$ 537	$ 575
Expected weighted-average period in years of compensation cost to be recognized	1.82	1.39	2.21

Total fair value of shares vested and the weighted average estimated fair values of shares granted for the three months ended March 31, 2021 and 2020 were as follows (in thousands):

	Stock Options	
	Three Months Ended March 31,	
	2021	2020
Total fair value of shares vested	$ 397	$ 502
Weighted average estimated fair value of shares granted	1.08	2.16

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 T-Rex Study. 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 months ended March 31, 2021 and March 31, 2020, the Company amortized and recognized $0.0 million and $0.7 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 March 31, 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.

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.

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 and commercialization of cellular therapies designed to reverse disease and/or promote the regeneration of damaged tissue. We are developing 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 leverages 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: CLBS16, the subject of both a recently completed positive Phase 2a study and a newly initiated Phase 2b (FREEDOM) study in the U.S. for the treatment of coronary microvascular dysfunction (“CMD”); HONEDRA® (CLBS12), recipient of SAKIGAKE designation and eligible for early conditional approval in Japan for the treatment of critical limb ischemia (“CLI”) and Buerger’s disease based on the results of an ongoing clinical trial and recipient of orphan drug designation in March 2021 from the U.S. Food and Drug Administration ("FDA") for Buerger's disease; CLBS201, designed to assess the safety and efficacy of CD34+ cell therapy as a treatment for patients with pre-dialysis diabetic kidney disease (“DKD”) and OLOGO™ (CLBS14), a Regenerative Medicine Advanced Therapy (“RMAT”) designated Phase 3 ready therapy for treatment of no-option refractory disabling angina (“NORDA”).

Ischemic Repair (CD34 Cell Technology)

The CD34+ cell was discovered as a result of the deliberate search for a stem 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 a stem 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 CLI, CMD, DKD and NORDA.

HONEDRA® for Treatment of Critical Limb Ischemia

Our randomized and open-label, registration-eligible study of HONEDRA® in Japan for the treatment of CLI has shown strong results to date. The initial responses observed in the subjects who have reached an endpoint in this open label study are consistent with a positive therapeutic effect and safety profile as reported by previously published clinical trials in Japan. The study's enrollment continues to be been slowed by the COVID-19 pandemic's impact in Japan, however, we are encouraged by the patient pre-screening pipeline and continue to make progress towards study completion, the exact date of which is impossible to predict given the continuing impact of COVID-19 on clinical trials like ours in Japan. While the final outcome of the trial will depend on all data from all subjects, data, to date, are very encouraging.

CLBS16 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 CLBS16 for the treatment of CMD, a disease that afflicts millions of patients with no current targeted treatment options. That study, the ESCaPE-CMD trial, was a Phase 2a proof-of-concept study that enrolled patients at the Mayo Clinic in Rochester, MN and Cedars-Sinai Medical Center in Los Angeles, CA. That data set showed a positive therapeutic effect with a statistically significant improvement in angina frequency, coronary flow reserve, Canadian Cardiovascular Society Angina Class and Seattle Questionnaire score, as well as an acceptable safety profile. The 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 CLBS16 as a therapy for CMD. The first patient in the study was subsequently treated in January 2021 at The Christ Hospital Health Network in Cincinnati, Ohio. This 105-patient double-blind randomized and placebo-controlled clinical trial (FREEDOM Trial) is 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. To our knowledge, this is the first controlled regenerative medicine trial in CMD.

CLBS201 for Treatment of Diabetic Kidney Disease

We have prepared an initial development plan for the clinical study of CLBS201, a CD34+ investigational product for administration into the renal arteries to slow the deterioration or reverse the decline of renal function in patients with diabetic kidney disease ("DKD") who, although at a pre-dialysis stage, exhibit rapidly progressive disease. Progressive kidney failure is associated with attrition of the microcirculation of the kidney. Pre-clinical studies in kidney disease and injury models have demonstrated that protection or replenishment of the microcirculation results in improved kidney function. A Phase 2 proof of concept, randomized, placebo-controlled study is planned for initiation in the second half of 2021.

OLOGO™ for Treatment of No Option Refractory Disabling Angina

We acquired the rights to data and regulatory filings for a CD34+ cell therapy program for refractory angina that had been advanced to Phase 3 by a previous sponsor.

Based on the clinical evidence from the completed studies that a single administration of OLOGO™ reduces mortality, improves angina and increases exercise capacity in patients with otherwise untreatable angina, this product received Regenerative Medicine Advanced Therapy (“RMAT”) designation from the FDA. We continue to seek an agreement with the FDA on the design of a Phase 3 study of appropriate and practical size and scope which, in combination with previously filed Phase 1, 2 and 3 data, will be considered for the registration of OLOGO™. Notably, the RMAT designation affords the product a 6-month review time for a biologics license application ("BLA"), once submitted.

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 be reasonably estimated at this time. In response to the 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 re-implemented in Japan on January 7, 2021 through March 21, 2021 covering Tokyo and other regions in response to increased number of COVID-19 patients. Due to recently reported large increases in COVID-19 cases in Japan, a renewed “State of Emergency” has been implemented again on April 25, 2021 through May 11, 2021. This newly reinstated “State of Emergency” continues negatively to impact enrollment of the on-going clinical trial.

Results of Operations

Three Months Ended March 31, 2021 Compared to Three Months Ended March 31, 2020

Overall, net losses were $8.1 million for the three months ended March 31, 2021, compared to net loss of $4.0 million for the three months ended March 31, 2020.

Operating Expenses

For the three months ended March 31, 2021, operating expenses totaled $8.1 million compared to $4.1 million for the three months ended March 31, 2020, representing an increase of 99%. Operating expenses comprised the following:

- Research and development expenses were approximately $5.1 million for the three months ended March 31, 2021, compared to $1.5 million for the three months ended March 31, 2020, representing an increase of $3.6 million or 239%. Research and development in both periods focused on the advancement of our ischemic repair platform and related to:

    - ongoing registration-eligible study expenses for HONEDRA® in critical limb ischemia in Japan, whereby we continue to focus spending on our patient enrollment. We have experienced significant delays in enrollment in that study due to the "State of Emergency" in effect in Japan for most of 2020 and re-implemented in Japan on January 7, 2021 through March 21, 2021 covering Tokyo and other regions in response to increased number of COVID-19 patients as well as a severe shortage of beds in intensive care units (and other hospital beds) affecting all of our clinical sites. We continue to make progress towards study completion;

    - expenses associated with the proof-of-concept study for CLBS16 in coronary microvascular dysfunction, whereby study enrollment was completed in the second quarter of 2019 and full results reported in May 2020 and continuing efforts to advance our CLBS16 Phase 2b study (the FREEDOM study) which commenced in the fourth quarter of 2020 with the first patient in the study treated in January 2021; and

    - 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 2 proof of concept, randomized, placebo-controlled study is planned for initiation in the second half of 2021.

- General and administrative expenses were approximately $3.0 million for the three months ended March 31, 2021, compared to $2.6 million for the three months ended March 31, 2020, representing an increase of 18%. 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

Total other income is primarily comprised of investment income on cash, cash equivalents and marketable securities.

Analysis of Liquidity and Capital Resources

March 31, 2021, we had cash, cash equivalents and marketable securities of approximately $111.5 million, working capital of approximately $109.6 million, and stockholders' equity of approximately $110.3 million.

During the three months ended March 31, 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):

	Three Months Ended March 31,	
	2021	2020
Net cash used in operating activities	$ (7,975)	$ (4,241)
Net cash (used in) provided by investing activities	(65,090)	11,102
Net cash provided by (used in) financing activities	85,297	(148)

Operating Activities

Our cash used in operating activities during the three months ended March 31, 2021 was $8.0 million, which is comprised of (i) our net loss of $8.1 million, adjusted for non-cash expenses totaling $0.9 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 $0.8 million.

Our cash used in operating activities during the three months ended March 31, 2020 was $4.2 million, which is comprised of (i) our net loss of $4.0 million, adjusted for non-cash expenses totaling $0.6 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 $0.9 million.

Investing Activities

Our cash used in investing activities during the three months ended March 31, 2021 totaled $65.1 million and was primarily due to net purchases of marketable securities (net of sales of marketable securities).

Our cash provided by investing activities during the three months ended March 31, 2020 totaled $11.1 million and was primarily due to net proceeds from sales of marketable securities (net of purchases of marketable securities).

Financing Activities

Our cash provided by financing activities during the three months ended March 31, 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 used in financing activities during the three months ended March 31, 2020 consisted of 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 considering the assumption that any initiation of an OLOGO™ Phase 3 study is contingent on reaching agreement with the FDA on a study design of appropriate and practical size and scope.

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 H.C. Wainwright & Co., LLC (“HCW”). As 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. We will no longer make any sales of our common stock pursuant to the Sales Agreement unless and until a new prospectus supplement is filed with the Securities and Exchange Commission.

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 March 31, 2021, we had not made any sales of common stock to Lincoln Park under the Purchase Agreement other than the Initial Purchase.

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 months ended March 31, 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 Chief Executive Officer and Chief Compliance 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 March 31, 2021, we carried out an evaluation, with the participation of our management, including our Chief Executive Officer and Chief Compliance 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 Chief Executive Officer and Chief Compliance 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 Chief Executive Officer and Chief Compliance 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.

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.

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.

	CALADRIUS BIOSCIENCES, INC.
May 6, 2021	By: /s/ David J. Mazzo, PhD Name: David J. Mazzo, PhD Title: President and Chief Executive Officer (Principal Executive Officer and Principal Financial Officer)

CALADRIUS BIOSCIENCES, INC.
FORM 10-Q

Exhibit Index

10.1		Form of Securities Purchase Agreement, dated as of January 21, 2021, by and between Caladrius Biosciences, Inc. and each purchaser identified on the signature pages thereto (incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed on January 25, 2021).
10.2		Form of Registration Rights Agreement, dated as of January 21, 2021, by and between Caladrius Biosciences, Inc. and each purchaser identified on the signature pages thereto (incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed on January 25, 2021).
10.3		Form of Institutional Securities Purchase Agreement, by and between Caladrius Biosciences, Inc. and each purchaser identified on the signature pages thereto (incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed on February 16, 2021).
10.4		Form of Institutional Additional Securities Purchase Agreement, by and between Caladrius Biosciences, Inc. and each purchaser identified on the signature pages thereto (incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed on February 16, 2021).
31.1	*	Certification of Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32	**	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.

Exhibit 31.1

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: May 6, 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)

Exhibit 32

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 March 31, 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: May 6, 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.