UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2019

OR

o 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

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 x No o

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 x No o

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 the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer o	Accelerated filer o
Non-accelerated filer x	Smaller reporting company x
	Emerging growth company o

If an emerging growth company, indicate by a 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.o

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

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

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

Indicate 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 8, 2019
Common stock, $0.001 par value per share	10,382,232 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; 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 March 14, 2019, as subsequently amended on March 19, 2019 (our "2018 Form 10-K").

The factors discussed herein, including those risks described in "Item 1A. Risk Factors" and elsewhere in our 2018 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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Item 1. Consolidated Financial Statements

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

	March 31, 2019	December 31, 2018
ASSETS	**(Unaudited)**	
Cash and cash equivalents	$ 14,424	$ 10,299
Marketable securities	23,946	32,754
Prepaid and other current assets	1,276	1,053
Total current assets	39,646	44,106
Property and equipment, net	148	165
Other assets	1,494	309
Total assets	$ 41,288	$ 44,580
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities		
Accounts payable	$ 553	$ 762
Accrued liabilities	4,548	4,857
Total current liabilities	5,101	5,619
Other long-term liabilities	1,729	1,507
Total liabilities	$ 6,830	$ 7,126
Commitments and Contingencies		
STOCKHOLDERS' EQUITY		
Stockholders' Equity		
Preferred stock, authorized, 20,000,000 shares Series B convertible redeemable preferred stock liquidation value, 1 share of common stock, $0.01 par value; 825,000 shares designated; issued and outstanding, 10,000 shares at March 31, 2019 and December 31, 2018, respectively	—	—
Common stock, $0.001 par value, authorized 500,000,000 shares; issued and outstanding, 10,393,312 and 9,865,735 shares at March 31, 2019 and December 31, 2018, respectively	10	10
Additional paid-in capital	437,850	436,433
Treasury stock, at cost; 11,080 shares at March 31, 2019 and December 31, 2018	(708)	(708)
Accumulated deficit	(402,406)	(397,977)
Accumulated other comprehensive loss	(18)	(32)
Total Caladrius Biosciences, Inc. stockholders' equity	34,728	37,726
Noncontrolling interests	(270)	(272)
Total stockholders' equity	34,458	37,454
Total liabilities and stockholders' equity	$ 41,288	$ 44,580

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,	
	2019	**2018**
Operating Expenses:		
Research and development	$ 2,038	$ 2,262
General and administrative	2,554	2,897
Total operating expenses	4,592	5,159
Operating loss	(4,592)	(5,159)
Other income (expense):		
Investment income, net	227	178
Interest expense	—	(3)
Total other income (expense), net	227	175
Net loss	$ (4,365)	$ (4,984)
Less - net income (loss) attributable to noncontrolling interests	2	(2)
Net loss attributable to Caladrius Biosciences, Inc. common stockholders	$ (4,367)	$ (4,982)
Basic and diluted loss per share		
Caladrius Biosciences, Inc. common stockholders	$ (0.44)	$ (0.52)
Weighted average common shares outstanding		
Basic and diluted shares	10,027	9,557

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,	
	2019	**2018**
Net loss	$ (4,365)	$ (4,984)
Other comprehensive income (loss):		
Available for sale securities - net unrealized income (loss)	14	(1)
Total other comprehensive income (loss)	14	(1)
Comprehensive loss	(4,351)	(4,985)
Comprehensive income (loss) attributable to noncontrolling interests	2	(2)
Comprehensive loss attributable to Caladrius Biosciences, Inc. common stockholders	$ (4,353)	$ (4,983)

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								
	Shares	Amount	Shares	Amount	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
Balance at December 31, 2017	10	$ —	9,484	$ 9	$ 433,044	$ (28)	$ (381,810)	$ (708)	$ 50,507	$ (318)	$ 50,189
Net loss	—	—	—	—	—	—	(4,982)	—	(4,982)	(2)	(4,984)
Unrealized loss on marketable securities	—	—	—	—	—	(31)	—	—	(31)	—	(31)
Share-based compensation	—	—	79	1	102	—	—	—	103	—	103
Proceeds from option exercises	—	—	12	—	40	—	—	—	40	—	40
Change in ownership in subsidiary	—	—	—	—	(48)	—	—	—	(48)	48	—
Balance at March 31, 2018	10	$ —	9,575	$ 10	$ 433,138	$ (59)	$ (386,792)	$ (708)	$ 45,589	$ (272)	$ 45,317

	Series B Convertible Preferred Stock		Common Stock								
	Shares	Amount	Shares	Amount	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
Balance at December 31, 2018	10	$ —	9,866	$ 10	$ 436,433	$ (32)	$ (397,977)	$ (708)	$ 37,726	$ (272)	$ 37,454
Adoption of accounting standard	—	—	—	—	—	—	(62)	—	(62)	—	(62)
Net loss	—	—	—	—	—	—	(4,367)	—	(4,367)	2	(4,365)
Unrealized loss on marketable securities	—	—	—	—	—	14	—	—	14	—	14
Share-based compensation	—	—	96	—	417	—	—	—	417	—	417
Net proceeds from issuance of common stock	—	—	431	—	1,000	—	—	—	1,000	—	1,000
Balance at March 31, 2019	10	$ —	10,393	$ 10	$ 437,850	$ (18)	$ (402,406)	$ (708)	$ 34,728	$ (270)	$ 34,458

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,	
	2019	2018
Cash flows from operating activities:		
Net loss	$ (4,365)	$ (4,984)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	547	147
Depreciation and amortization	17	87
Accretion on marketable securities	82	82
Changes in operating assets and liabilities:		
Prepaid and other current assets	(223)	(3)
Other assets	91	90
Accounts payable, accrued liabilities and other liabilities	(1,635)	(1,718)
Net cash used in operating activities	(5,486)	(6,299)
Cash flows from investing activities:		
Purchase of marketable securities	(16,264)	(24,144)
Sale of marketable securities	25,005	22,964
Acquisition of property and equipment	—	(9)
Net cash provided by (used in) investing activities	8,741	(1,189)
Cash flows from financing activities:		
Proceeds from exercise of options	—	40
Tax withholding payments on net share settlement equity awards	(130)	(45)
Net proceeds from issuance of common stock	1,000	—
Repayment of notes payable	—	(67)
Net cash provided by (used in) financing activities	870	(72)
Net increase (decrease) in cash, cash equivalents and restricted cash	4,125	(7,560)
Cash, cash equivalents and restricted cash at beginning of period	10,299	34,168
Cash, cash equivalents and restricted cash at end of period	$ 14,424	$ 26,608
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the period for:		
Interest	$ —	$ 3

See accompanying notes to consolidated financial statements.

CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

Note 1 – The Business

Caladrius Biosciences, Inc. (“we,” “us,” "our," “Caladrius” or the “Company”) is a late-stage therapeutics development biopharmaceutical company committed to the development of innovative products that have the potential to restore the health of people with chronic illnesses. The Company's leadership team collectively has decades of biopharmaceutical development experience and world-recognized scientific achievement in the fields of cardiovascular and autoimmune disease, among other areas. The Company's goal is to build a broad portfolio of novel and versatile products that address important unmet medical needs. The Company's current product candidates include three developmental treatments for cardiovascular diseases based on its CD34+ cell therapy platform: CLBS12, recipient of SAKIGAKE designation, in Phase 2 testing in Japan and eligible for early conditional approval in Japan for the treatment of critical limb ischemia ("CLI"); CLBS14-CMD, in Phase 2 in the U.S. for the treatment of coronary microvascular dysfunction ("CMD"); and CLBS14-NORDA, for which the Company is in discussions with the U.S. Food and Drug Administration (the "FDA") to finalize the Phase 3 trial protocol for no-option refractory disabling angina ("NORDA") for which it has received RMAT designation.

Ischemic Repair (CD34 Cell Technology)

The Company's CD34+ cell technology 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 its CD34+ cell technology, including but not limited to CLI, CMD and NORDA.

Regarding CLBS12, the Company's product candidate for CLI, after detailed discussion and agreement with the Japanese Pharmaceutical and Medical Device Agency ("PMDA"), the Company opened a Phase 2 trial for enrollment in December 2017 and announced in March 2018 treatment of the first patient. Based on discussions with the PMDA, the Company expects that a successful outcome of this trial will make CLBS12 eligible for early conditional approval in Japan, thereby effectively making the Phase 2 trial a potential registration trial in that strategic market. The initial responses observed in the small number of 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 and the U.S. While these early signs are encouraging, it is clear that the final outcome of the trial will be dependent on all data from all subjects.

In October 2017, the Company announced the award of a $1.9 million grant from the National Institutes of Health to support a clinical study of CD34+ cells in patients with CMD. This led to the initiation of development of CLBS14-CMD and enrollment of patients in the Company's ESCaPE-CMD Phase 2 proof-of-concept study at the Mayo Clinic in Rochester, MN and Cedars-Sinai Medical Center, Los Angeles, CA. The early results observed in this open label trial from the small number of subjects who have reached the 6-month (primary endpoint) follow-up visit support our expectations for CLBS14-CMD and a positive therapeutic effect and acceptable safety profile in this indication. While the final outcome of the trial will be dependent on the 6-month data from all subjects, these early observations of increased coronary flow reserve and decreased angina symptoms in treated patients are encouraging.

To support a development program of CD34+ cells in the indication of NORDA, 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 under the previous investigational new drug application (“IND”) holder. The Company has designated this program CLBS14-NORDA and reactivated the IND with the FDA with Caladrius as the sponsor. The Company is presently working with the FDA to finalize the design of a single registration trial for the registration of CLBS14-NORDA and is targeting the initiation of that trial in fall of 2019.

Immunomodulation (Treg Technology)

The Company has been developing for the last several years an innovative therapy for T1D (identified as CLBS03) that is based on a proprietary T regulatory cell platform technology for immunomodulation. CLBS03 was granted Fast Track and Orphan drug designations from the FDA for this proposed indication and was granted Advanced Therapeutic Medicinal Product ("ATMP") classification from the European Medicines Agency ("EMA"). This program is based on the use of Tregs (T-regulatory cells) to treat diseases caused by imbalances in an individual's immune system. This novel approach seeks to restore immune balance by enhancing Treg number and function. Tregs are a natural part of the human immune system and regulate the activity of effector T cells, the cells that are responsible for protecting the body from pathogens and foreign antigens. When Tregs function properly, only harmful foreign materials are attacked by effector T cells. In autoimmune disease, however, it is thought that deficient Treg activity and numbers permit the effector T cells to attack the body's own beneficial cells. In the case of T1D, the beta cells in the pancreas are attacked, thereby reducing and/or eliminating over time the patient's ability to produce insulin.

In 2016, the Company commenced patient enrollment in the first of two cohorts in The Sanford Project: T-Rex Study, a Phase 2a prospective, randomized, placebo-controlled, double-blind clinical trial to evaluate the safety and efficacy of CLBS03 in adolescents with recent onset T1D (the "T-Rex Study"). On February 13, 2019, the Company announced top line results indicating that the therapy was well-tolerated but that the study's primary endpoint of preservation of C-peptide had not been achieved. The Company further indicated that it and its collaborators are conducting a comprehensive analysis of all data from the trial (including any 2-year follow-up data to come) and will make decisions regarding further development of CLBS03 based on the results of those analyses.

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. These include additional indications for both its Treg product and its CD34+ cell technology.

The Company's current long-term strategy focuses on advancing its therapies through development with the aim eventually to obtain market authorizations and enter commercialization, either alone or with partners, to provide treatment options to patients suffering from life-threatening medical conditions. The Company believes that it is 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.

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, 2019, 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, 2018 and 2017 included in our 2018 Form 10-K. Operating results for the three months ended March 31, 2019 are not necessarily indicative of the results that may be expected for the year ending December 31, 2019.

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 revenues and 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 and income taxes. Accordingly, actual results could differ from those estimates and assumptions.

An accounting policy is considered to be critical if it is important to the Company’s financial condition and results of operations and if it requires management’s most difficult, subjective and complex judgments in its application.

Principles of Consolidation

The Consolidated Financial Statements include the accounts of Caladrius Biosciences, Inc. and its wholly-owned and partially-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, our significant accounting policies are described in Note 2 of the Notes to Consolidated Financial Statements included in our 2018 Form 10-K. There were no changes to these policies during the three months ended March 31, 2019.

Concentration of Risks

We are subject to credit risk from our portfolio of cash, cash equivalents and marketable securities. Under our investment policy, we limit 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 our 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.

Income Taxes

The Company recognizes (a) the amount of taxes payable or refundable for the current year and (b) deferred tax liabilities and assets for the future tax consequences of events that have been recognized in the Company's financial statements or tax returns.

The Tax Cuts and Jobs Act ("the Tax Act") was enacted on December 22, 2017. The income tax effects of changes in tax laws are recognized in the period when enacted. The Tax Act provides for significant tax law changes and modifications with varying effective dates, which include reducing the U.S. federal corporate income tax rate from 35% to 21%, creating a territorial tax system (with a one-time mandatory repatriation tax on previously deferred foreign earnings), and allowing for immediate capital expensing of certain qualified property acquired and placed in service after September 27, 2017 and before January 1, 2023.

In response to the enactment of the Tax Act in late 2017, the SEC issued Staff Accounting Bulletin No. 118 ("SAB 118") to address situations where the accounting is incomplete for certain income tax effects of the Tax Act upon issuance of an entity's financial statements for the reporting period in which the Tax Act was enacted. Under SAB 118, a company may record provisional amounts during a measurement period for specific income tax effects of the Tax Act for which the accounting is incomplete, but a reasonable estimate can be determined, and when unable to determine a reasonable estimate for any income tax effects, report provisional amounts in the first reporting period in which a reasonable estimate can be determined.

The Company continues to evaluate the accounting for uncertainty in tax positions at the end of each reporting period. The guidance requires companies to recognize in their financial statements the impact of a tax position if the position is more likely than not of being sustained if the position were to be challenged by a taxing authority. The position ascertained inherently requires judgment and estimates by management. The Company recognizes interest and penalties as a component of income tax expense.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). This ASU requires that a lessee recognize lease assets and lease liabilities for those leases classified as operating leases. The guidance was effective for interim and annual periods beginning after December 15, 2018 and was adopted as of January 1, 2019. The Company adopted the standard using the optional transition method, with an immaterial adjustment to accumulated deficit upon adoption. The comparative information has not been restated and continues to be reported under the accounting standards that were in effect for those periods. The Company concluded that the adoption of ASU 2016-02 was non-cash in nature, did not affect the Company's cash position, and did not have a material impact on the Company's financial statements.

In June 2018, the FASB issued ASU No. 2018-07, "Improvements to Nonemployee Share-Based Payment Accounting", which supersedes ASC 505-50 and expands the scope of ASC 718 to include all share-based payments arrangements related to the acquisition of goods and services from both employees and nonemployees. For public companies, the amendments are effective for annual reporting periods beginning after December 15, 2018, including interim periods within those annual periods. Early adoption is permitted, but no earlier than a company's adoption date of ASC 606. The Company determined that the adoption of this new accounting guidance did not have a material impact on its 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, 2019				December 31, 2018			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities	$ 25,532	$ —	$ (18)	$ 25,514	$ 33,536	$ —	$ (32)	$ 33,504
Money market funds	10,607	—	—	10,607	4,314	—	—	4,314
Total	$ 36,139	$ —	$ (18)	$ 36,121	$ 37,850	$ —	$ (32)	$ 37,818

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, 2019	December 31, 2018
Cash and cash equivalents	$ 12,175	$ 5,064
Marketable securities	23,946	32,754
Total	$ 36,121	$ 37,818

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

	March 31, 2019	
	Amortized Cost	Estimated Fair Value
Less than one year	$ 36,139	$ 36,121
Greater than one year	—	—
Total	$ 36,139	$ 36,121

Note 4 – Loss Per Share

For the three months ended March 31, 2019 and 2018, the Company incurred net losses from continuing operations and therefore no common stock equivalents were utilized in the calculation of diluted loss per share as they are anti-dilutive. At March 31, 2019 and 2018, the Company excluded the following potentially dilutive securities (in thousands):

	March 31,	
	2019	2018
Stock Options	1,214	1,073
Warrants	30	210
Restricted Shares	155	182
Restricted Stock Units	118	10

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, 2019, and December 31, 2018 (in thousands).

	March 31, 2019				December 31, 2018			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Marketable securities - available for sale	$ —	$ 23,946	$ —	$ 23,946	$ —	$ 32,754	$ —	$ 32,754
	$ —	$ 23,946	$ —	$ 23,946	$ —	$ 32,754	$ —	$ 32,754

Note 6 – Accrued Liabilities

Accrued liabilities as of March 31, 2019 and December 31, 2018 were as follows (in thousands):

	March 31, 2019	December 31, 2018
Salaries, employee benefits and related taxes	$ 908	$ 1,758
Operating lease liabilities - current	396	—
CIRM upfront funding - current	2,583	2,583
Other	661	516
Total	$ 4,548	$ 4,857

Note 7 – Operating Leases

The Company has operating leases for two offices with terms that expire in 2022 and 2023. In addition, the Company pays for facility space through a third-party manufacturing contract that contains an embedded operating lease, with an estimated expiration in 2020. 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. Upon adoption of Topic 842 on January 1, 2019, we recognized $1.4 million of operating lease liabilities and $1.3 million of operating lease right-of-use assets for our existing operating leases in our balance sheet. As of March 31, 2019, our operating lease liabilities and right-of-use assets were $1.3 million and $1.2 million, respectively. Each of our leases include options for us to extend the lease term.

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, 2019
Right-of Use Assets:		
Other assets	$	1,184
Total Right-of-Use Asset	$	1,184
Operating Lease Liabilities:		
Accrued liabilities	$	396
Other long-term liabilities		868
Total Operating Lease Liabilities	$	1,264

As of March 31, 2019, the weighted average remaining lease term for our operating leases was 2.7 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, 2019 were as follows (in thousands):

Years ended		Operating Leases
2019	$	428
2020		403
2021		411
2022		236
2023		27
Total lease payments		1,505
Less: Amounts representing interest		(241)
Present value of lease liabilities	$	1,264

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.

Common Stock Sales Agreement

In February 2018, the Company entered into a common stock sales agreement (the "Sales Agreement") with H.C. Wainwright & Co., LLC ("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 $12 million (limited to a maximum of 2,790,697 shares). Subject to the terms and conditions of the Sales Agreement, HCW will use its 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.

In August 2018, the Company entered into an amendment to the Sales Agreement to reflect that the shares will be issued pursuant to a Registration Statement on Form S-3 (Registration No. 333-226319) that was declared effective in August 2018 and that replaced the Company’s previously effective shelf registration statement. In connection with the amendment, the number of shares of common stock that may be sold pursuant to the Sales Agreement was increased from an aggregate offering amount of $12 million to $25 million (limited to a maximum of 4,921,260 shares). All other provisions of the Sales Agreement remained unchanged. During the three months ended March 31, 2019, the Company did not issue shares of common stock under the Sales Agreement. As of March 31, 2019, the Company has issued 149,041 shares of common stock under the Sales Agreement for net proceeds of $1.0 million since inception.

Stock Options and Warrants

The following table summarizes the activity for stock options and warrants for the three months ended March 31, 2019:

	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, 2018	1,018,530	$ 30.50	5.30	$ 3.3	30,000	$ 5.89	4.19	$ —
Changes during the period:								
Granted	199,346	4.90			—	—		
Exercised	(240)	3.50			—	—		
Forfeited	—	—			—	—		
Expired	(4,002)	8.30			—	—		
Outstanding at March 31, 2019	1,213,634	$ 26.40	5.85	$ 12.9	30,000	$ 5.89	3.95	$ —
Vested at March 31, 2019 or expected to vest in the future	1,185,882	$ 26.90	5.76	$ 12.9	30,000	$ 5.89	3.95	$ —
Vested at March 31, 2019	974,249	$ 31.80	4.96	$ 12.9	30,000	$ 5.89	3.95	$ —

Restricted Stock

During the three months ended March 31, 2019 and 2018, the Company issued restricted stock for services as follows ($ in thousands):

	Three Months Ended March 31,	
	2019	2018
Number of restricted stock issued	123,564	127,688
Value of restricted stock issued ($ in thousands)	$ 612	$ 351

Restricted Stock Units

During the three months ended March 31, 2019 and 2018, the Company issued restricted stock units for services as follows ($ in thousands, except share data):

	Three Months Ended March 31,	
	2019	2018
Number of restricted stock units issued	184,454	34,988
Value of restricted stock units issued	$ 909	$ 133

The weighted average estimated fair value of restricted stock issued for services in the three months ended March 31, 2019 and 2018 was $4.93 and $3.79 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.

<u>Note 9 – Share-Based Compensation</u>

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, 2019 and 2018 (in thousands):

	Three Months Ended March 31,	
	2019	2018
Research and development	$ 124	$ 41
General and administrative	423	106
Total share-based compensation expense	$ 547	$ 147

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, 2019 were as follows (in thousands):

	Stock Options	Restricted Stock
Unrecognized compensation cost	$ 934	$ 427
Expected weighted-average period in years of compensation cost to be recognized	2.25	0.72

Total fair value of shares vested and the weighted average estimated fair values of shares granted for the three months ended March 31, 2019 and 2018 were as follows (in thousands):

	Stock Options	
	Three Months Ended March 31,	
	2019	2018
Total fair value of shares vested	$ 372	$ 82
Weighted average estimated fair value of shares granted	$ 3.24	$ 2.41

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, CIRM awarded us 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. In March 2018, CIRM calculated the precise amount of the funding award as $8.6 million, based on the actual number of subjects enrolled in California.

The Company received $5.7 million in initial funding in May 2017, a $1.9 million milestone payment in December 2017, and $0.3 million progress payment in March 2018, of which the total will be amortized over the estimated award period through July 2020 as a reduction to the related research and development expenses. As of March 31, 2019, $2.6 million of the funding received was recorded in accrued liabilities, representing the amount expected to be recognized over the next 12 months, and $0.9 million of the funding received was recorded in other long-term liabilities. During the three months ended March 31, 2019 and March 31, 2018, the Company amortized and recognized $0.6 million and $0.6 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, 2018, the Company had approximately $225 million of Federal NOLs available to offset future taxable income expiring from 2030 through 2036. 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. If a change of ownership did occur, there would be an annual limitation on the usage of the Company’s losses, which is available through 2036.

The Company performed an analysis and determined that it has had ownership changes of greater than 50% over a 3 year testing period. The last ownership change was determined to be in 2015. Based on a market capitalization of $124.5 million and using an applicable federal rate of 2.5%, the annual limitation would be approximately $3.0 million. Post change losses from June 3, 2015 through December 31, 2016 would not be subject to 382 limitations. Additionally, the Company would be able to further increase NOL limitations by the realized built in gain on the sale of PCT in May of 2017.

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 certain tax positions as a component of income tax expense.

As of March 31, 2019, 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.

The Company completed the audit of its federal tax returns for the years 2012 and 2013 during the fourth quarter of 2016. The audit resulted in an adjustment to the Company's NOL carryforward. For years prior to 2014, 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. The Company ceased doing business in China in 2012. After 2012, the Company had no foreign tax filing obligations. The foreign returns filed for 2012 and prior are subject to examination for five years.

Note 12 – Contingencies

Contingencies

Under license agreements with third parties the Company is typically required to pay maintenance fees, make milestone payments and/or pay other fees and expenses and pay royalties upon commercialization of products. The Company also sponsors research at various academic institutions, which research agreements generally provide us with an option to license new technology discovered during the course of the sponsored research.

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 2018 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 2018 Form 10-K.

Overview

Caladrius Biosciences, Inc. ("we," "us," "our," "Caladrius" or the "Company") is a late-stage therapeutics development biopharmaceutical company committed to the development of innovative products that have the potential to restore the health of people with chronic illnesses. Our leadership team collectively has decades of biopharmaceutical development experience and world-recognized scientific achievement in the fields of cardiovascular and autoimmune disease, among other areas. Our goal is to build a broad portfolio of novel and versatile products that address important unmet medical needs. Our current product candidates include three developmental treatments for cardiovascular diseases based on its CD34+ cell therapy platform: CLBS12, recipient of SAKIGAKE designation, in Phase 2 testing in Japan and eligible for early conditional approval in Japan for the treatment of critical limb ischemia ("CLI"); CLBS14-CMD, in Phase 2 in the U.S. for the treatment of coronary microvascular dysfunction ("CMD"); and CLBS14-NORDA, for which we are in discussions with the U.S. Food and Drug Administration (the "FDA") to finalize the Phase 3 trial protocol for no-option refractory disabling angina ("NORDA") for which it has received RMAT designation.

Ischemic Repair (CD34 Cell Technology)

Our CD34+ cell technology 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 its CD34+ cell technology, including but not limited to CLI, CMD and NORDA.

Regarding CLBS12, our product candidate for CLI, after detailed discussion and agreement with the Japanese Pharmaceutical and Medical Device Agency ("PMDA"), we opened a Phase 2 trial for enrollment in December 2017 and announced in March 2018 treatment of the first patient. Based on discussions with the PMDA, we expect that a successful outcome of this trial will make CLBS12 eligible for early conditional approval in Japan, thereby effectively making the Phase 2 trial a potential registration trial in that strategic market. The initial responses observed in the small number of 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 and the U.S. While these early signs are encouraging, it is clear that the final outcome of the trial will be dependent on all data from all subjects.

In October 2017, we announced the award of a $1.9 million grant from the National Institutes of Health to support a clinical study of CD34+ cells in patients with CMD. This led to the initiation of development of CLBS14-CMD and enrollment of patients in the Company's ESCaPE-CMD Phase 2 proof-of-concept study at the Mayo Clinic in Rochester, MN and Cedars-Sinai Medical

Center, Los Angeles, CA. The early results observed in this open label trial from the small number of subjects who have reached the 6-month (primary endpoint) follow-up visit support our expectations for CLBS14-CMD and a positive therapeutic effect and acceptable safety profile in this indication. While the final outcome of the trial will be dependent on the 6-month data from all subjects, these early observations of increased coronary flow reserve and decreased angina symptoms in treated patients are encouraging.

To support a development program of CD34+ cells in the indication of NORDA, 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 under the previous investigational new drug application (“IND”) holder. We have designated this program CLBS14-NORDA and reactivated the IND with the FDA with Caladrius as the sponsor. We are presently working with the FDA to finalize the design of a single registration trial for the registration of CLBS14-NORDA and are targeting the initiation of that trial in fall if 2019.

Immunomodulation (Treg Technology)

We have been developing for the last several years an innovative therapy for T1D (identified as CLBS03) that is based on a proprietary T regulatory cell platform technology for immunomodulation. CLBS03 was granted Fast Track and Orphan drug designations from the FDA for this proposed indication and was granted Advanced Therapeutic Medicinal Product ("ATMP") classification from the European Medicines Agency ("EMA"). This program is based on the use of Tregs (T-regulatory cells) to treat diseases caused by imbalances in an individual's immune system. This novel approach seeks to restore immune balance by enhancing Treg number and function. Tregs are a natural part of the human immune system and regulate the activity of effector T cells, the cells that are responsible for protecting the body from pathogens and foreign antigens. When Tregs function properly, only harmful foreign materials are attacked by effector T cells. In autoimmune disease, however, it is thought that deficient Treg activity and numbers permit the effector T cells to attack the body's own beneficial cells. In the case of T1D, the beta cells in the pancreas are attacked, thereby reducing and/or eliminating over time the patient's ability to produce insulin.

In 2016, we commenced patient enrollment in the first of two cohorts in The Sanford Project: T-Rex Study, a Phase 2a prospective, randomized, placebo-controlled, double-blind clinical trial to evaluate the safety and efficacy of CLBS03 in adolescents with recent onset T1D (the "T-Rex Study"). On February 13, 2019, we announced top line results indicating that the therapy was well-tolerated but that the study's primary endpoint of preservation of C-peptide had not been achieved. We and our collaborators are conducting a comprehensive analysis of all data from the trial (including any 2-year follow-up data to come) and will make decisions regarding further development of CLBS03 based on the results of those analyses.

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. These include additional indications for both our Treg product and our CD34+ cell technology.

Our current long-term strategy focuses on advancing our therapies through development with the aim of eventually 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 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.

Results of Operations

Three Months Ended March 31, 2019 Compared to Three Months Ended March 31, 2018

Overall, net loss was $4.4 million for the three months ended March 31, 2019, compared to $5.0 million for the three months ended March 31, 2018.

Operating Expenses

For the three months ended March 31, 2019, operating expenses totaled $4.6 million compared to $5.2 million for the three months ended March 31, 2018, representing a decrease of $0.6 million, or 11%. Operating expenses were comprised of the following:

- Research and development expenses were approximately $2.0 million for the three months ended March 31, 2019, compared to $2.3 million for the three months ended March 31, 2018, representing a decrease of approximately $0.2 million, or 10%. Research and development in both periods focused on the advancement of our ischemic repair platform, and related to (i) expenses associated with our ongoing Phase 2 study of CLBS12 in critical limb ischemia development program in Japan, (ii) expense associated with our ongoing Phase 1b/2a study for CLBS14-CMD in coronary microvascular dysfunction, and (iii) expenses associated with the planning of our CLBS14-NORDA program in refractory angina.

- General and administrative expenses were approximately $2.6 million for the three months ended March 31, 2019, compared to $2.9 million for the three months ended March 31, 2018, representing a decrease of approximately $0.3 million, or 12%. 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 primarily comprised of investment income on cash and marketable securities, offset by interest expense on notes and loans payables.

Analysis of Liquidity and Capital Resources

At March 31, 2019, we had cash, cash equivalents, and marketable securities of approximately $38.4 million, working capital of approximately $34.5 million, and stockholders' equity of approximately $34.7 million.

During the three months ended March 31, 2019, 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 provided by or used in operating, investing and financing activities from continuing operations were as follows (in thousands):

	Three Months Ended March 31,	
	2019	2018
Net cash used in operating activities	$ (5,486)	$ (6,299)
Net cash provided by (used in) investing activities	8,741	(1,189)
Net cash provided by (used in) financing activities	870	(72)

Operating Activities

Our cash used in operating activities during the three months ended March 31, 2019 was $5.5 million, which is comprised of (i) our net loss of $4.4 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 $1.8 million.

Our cash used in operating activities during the three months ended March 31, 2018 was $6.3 million, which is comprised of (i) our net loss of $5.0 million, adjusted for non-cash expenses totaling $0.3 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 providing approximately $1.6 million.

Investing Activities

Our cash provided by investing activities during the three months ended March 31, 2019 totaled $8.7 million, and was entirely due to net proceeds from the sale of marketable securities (net of proceeds on purchases of marketable securities).

Our cash used in investing activities in the three months ended March 31, 2018 totaled approximately $1.2 million, and was primarily due to net payments on the purchase of marketable securities (net of proceeds from the sale of marketable securities).

Financing Activities

Our cash provided by financing activities during the three months ended March 31, 2019 consisted of proceeds of $1.0 million through the issuance of 250,000 shares of our common stock under the provisions of our common stock purchase agreement with Lincoln Park Capital, which were 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, 2018 consisted of payment obligations under equipment finance leases and tax withholding-related payments on net share settlement equity awards to employees, which were partially offset by minor option exercise proceeds.

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. 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. Any future development of CLBS14-NORDA will be the subject of the use of proceeds of a future capital raise. Similarly, any future development of CLBS12 in the USA will also be the subject of the use of proceeds of a future capital raise.

On March 13, 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 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.

In February 2018, we entered into a common stock sales agreement (the "Sales 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, which was further amended in August 2018, having an aggregate offering price of up to $25 million. Subject to the terms and conditions of the Sales Agreement, HCW will use its commercially reasonable efforts consistent with its normal trading and sales practices to sell the shares from time to time, based upon our instructions, including any price, time or size limits specified by us. We have 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. We have 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. As of March 31, 2019, we issued 149,041 shares of common stock under the Sales Agreement for net proceeds of $1.0 million.

In February 2017, the California Institute for Regenerative Medicine ("CIRM") awarded us funds of up to $12.2 million to support the T-Rex Study. The funding was 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. In March 2018, CIRM calculated the precise amount of the funding award as $8.6 million, based on the actual number of subjects enrolled in California. We have received total funding of $7.9 million through March 31, 2019.

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, 2019, compared to those reported in our 2018 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 the Chief Executive Officer and Chief 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 March 31, 2019, we carried out an evaluation, with the participation of our management, including our Chief Executive Officer and Chief 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 Chief Executive Officer and Chief 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 Chief Executive Officer and Chief 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.

PART II

OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

There are no material changes to the disclosures previously reported in our 2018 Form 10-K.

ITEM 1A. RISK FACTORS

There have been no material changes to the risk factors previously reported in our 2018 Form 10-K. See the risk factors set forth in our 2018 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 9, 2019	By: /s/ David J. Mazzo, PhD Name: David J. Mazzo, PhD Title: President and Chief Executive Officer (Principal Executive Officer)
May 9, 2019	By: /s/ Joseph Talamo Name: Joseph Talamo Title: Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)

CALADRIUS BIOSCIENCES, INC.
FORM 10-Q

Exhibit Index

31.1	*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	**	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	**	Certification of Chief Financial 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

CERTIFICATION

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 9, 2019

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

Exhibit 31.2

CERTIFICATION

I, Joseph Talamo, 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 9, 2019

/s/ Joseph Talamo
Name: Joseph Talamo
Title: Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)

Exhibit 32.1

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, 2019 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 9, 2019

/s/ David J. Mazzo, PhD
David J. Mazzo, PhD
President and Chief Executive Officer (Principal Executive 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.

Exhibit 32.2

**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, 2019 filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph Talamo, Senior Vice President and Chief Financial 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 9, 2019

/s/ Joseph Talamo

Joseph Talamo

Senior Vice President and Chief Financial Officer (Principal Financial and 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.