

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, 2018

OR

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

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

Commission File Number 001-33650

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

DELAWARE  
(State or other jurisdiction of incorporation or organization)

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

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

07920  
(zip code)

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

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 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

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

Emerging growth

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.

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.

9,569,853 Shares, \$0.001 Par Value, as of May 6, 2018

## 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. Without limiting the foregoing, the words "plan," "intend," "may," "will," "expect," "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 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 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; and
- 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 22, 2018, as subsequently amended on April 2, 2018 (our "2017 Form 10-K").

The factors discussed herein, including those risks described in "Item 1A. Risk Factors" and elsewhere in our 2017 Form 10-K and in our other periodic filings with the SEC, which are available for review at [www.sec.gov](http://www.sec.gov), could cause actual results and developments to be materially different from those expressed or implied by such statements. All forward-looking statements attributable to us are expressly qualified in their entirety by these and other factors. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date they were made. Except as required by law, we undertake no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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## PART I. FINANCIAL INFORMATION

## ITEM I. FINANCIAL STATEMENTS

## Item 1. Consolidated Financial Statements

CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS

	March 31, 2018	December 31, 2017
<b>ASSETS</b>	<b>(Unaudited)</b>	
<b>Current Assets</b>		
Cash and cash equivalents	\$ 21,600,899	\$ 29,163,200
Restricted cash	5,007,531	5,004,789
Marketable securities	26,983,626	25,916,681
Accounts receivable, net of allowances of \$0 at March 31, 2018 and December 31, 2017, respectively	144,256	234,461
Prepaid and other current assets	792,961	790,514
Total current assets	54,529,273	61,109,645
Property and equipment, net	178,109	256,905
Deferred tax assets	575,055	575,055
Other assets	1,434,077	1,434,077
Total assets	\$ 56,716,514	\$ 63,375,682
<b>LIABILITIES AND EQUITY</b>		
<b>Current Liabilities</b>		
Accounts payable	\$ 866,840	\$ 1,343,089
Accrued liabilities	6,998,396	7,810,948
Notes payable, current	92,048	159,180
Total current liabilities	7,957,284	9,313,217
Other long-term liabilities	3,443,609	3,872,679
Total liabilities	\$ 11,400,893	\$ 13,185,896
<b>Commitments and Contingencies</b>		
<b>EQUITY</b>		
<b>Stockholders' Equity</b>		
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, 2018 and December 31, 2017, respectively	100	100
Common stock, \$.001 par value, authorized 500,000,000 shares; issued and outstanding, 9,574,685 and 9,483,911 shares at March 31, 2018 and December 31, 2017, respectively	9,575	9,484
Additional paid-in capital	433,137,593	433,044,209
Treasury stock, at cost; 11,080 shares at March 31, 2018 and December 31, 2017, respectively	(707,637)	(707,637)
Accumulated deficit	(386,792,688)	(381,810,109)
Accumulated other comprehensive loss	(58,724)	(27,978)
Total Caladrius Biosciences, Inc. stockholders' equity	45,588,219	50,508,069
<b>Noncontrolling interests</b>	(272,598)	(318,283)
Total equity	45,315,621	50,189,786
Total liabilities and equity	\$ 56,716,514	\$ 63,375,682

See accompanying notes to consolidated financial statements.

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

	<b>Three Months Ended March 31,</b>	
	<b>2018</b>	<b>2017</b>
<b>Operating Expenses:</b>		
Research and development	\$ 2,262,240	\$ 3,726,132
General and administrative	2,896,444	2,706,394
Total operating expenses	5,158,684	6,432,526
Operating loss	(5,158,684)	(6,432,526)
<b>Other income (expense):</b>		
Other income (expense), net	177,538	(44,395)
Interest expense	(3,295)	(158,928)
Total other income (expense), net	174,243	(203,323)
Loss from continuing operations before benefit from income taxes and noncontrolling interests	(4,984,441)	(6,635,849)
Benefit from income taxes	—	—
Net loss from continuing operations	(4,984,441)	(6,635,849)
Discontinued operations - net of taxes	—	(3,157,475)
Net loss	<u>\$ (4,984,441)</u>	<u>\$ (9,793,324)</u>
Less - net loss from continuing operations attributable to noncontrolling interests	(1,862)	(64,666)
Less - net loss from discontinued operations attributable to noncontrolling interests	—	(368,831)
Net loss attributable to Caladrius Biosciences, Inc. common stockholders	<u>\$ (4,982,579)</u>	<u>\$ (9,359,827)</u>
<b>Amounts attributable to Caladrius Biosciences, Inc. common stockholders:</b>		
Loss from continuing operations	(4,982,579)	(6,571,183)
Loss from discontinued operations - net of taxes	—	(2,788,644)
Net loss attributable to Caladrius Biosciences, Inc. common stockholders	<u>\$ (4,982,579)</u>	<u>\$ (9,359,827)</u>
<b>Basic and diluted loss per share</b>		
Continuing operations	\$ (0.52)	\$ (0.78)
Discontinued operations	\$ —	\$ (0.33)
Caladrius Biosciences, Inc. common stockholders	\$ (0.52)	\$ (1.12)
<b>Weighted average common shares outstanding:</b>		
Basic and diluted shares	9,557,347	8,386,903

See accompanying notes to consolidated financial statements.

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

	<u>Three Months Ended March 31,</u>	
	<u>2018</u>	<u>2017</u>
Net loss	\$ (4,984,441)	\$ (9,793,324)
Other comprehensive loss:		
Available for sale securities - net unrealized loss	(30,746)	—
Total other comprehensive loss	(30,746)	—
Comprehensive loss	(5,015,187)	(9,793,324)
Comprehensive loss attributable to noncontrolling interests	(1,862)	(433,497)
Comprehensive loss attributable to Caladrius Biosciences, Inc. common stockholders	<u>\$ (5,013,325)</u>	<u>\$ (9,359,827)</u>

See accompanying notes to consolidated financial statements.

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

	Series B Convertible Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Treasury Stock	Total Caladrius Biosciences, Inc. Stockholders' Equity	Non-Controlling Interest in Subsidiary	Total Equity
	Shares	Amount	Shares	Amount							
<b>Balance at December 31, 2016</b>	10,000	\$ 100	8,205,790	\$ 8,206	\$ 410,372,049	\$ —	\$(404,788,809)	\$(707,637)	\$ 4,883,909	\$ (817,429)	\$ 4,066,480
Net loss	—	—	—	—	—	—	(9,359,827)	—	(9,359,827)	(433,497)	(9,793,324)
Share-based compensation	—	—	113,287	113	509,437	—	—	—	509,550	—	509,550
Net proceeds from issuance of common stock	—	—	634,235	634	3,240,826	—	—	—	3,241,460	—	3,241,460
Change in ownership in subsidiary	—	—	—	—	(66,066)	—	—	—	(66,066)	66,066	—
<b>Balance at March 31, 2017</b>	10,000	\$ 100	8,953,312	\$ 8,953	\$ 414,056,246	\$ —	\$(414,148,636)	\$(707,637)	\$ (790,974)	\$ (1,184,860)	\$ (1,975,834)

	Series B Convertible Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Treasury Stock	Total Caladrius Biosciences, Inc. Stockholders' Equity	Non-Controlling Interest in Subsidiary	Total Equity
	Shares	Amount	Shares	Amount							
<b>Balance at December 31, 2017</b>	10,000	\$ 100	9,483,911	\$ 9,484	\$ 433,044,209	\$ (27,978)	\$(381,810,109)	\$(707,637)	\$ 50,508,069	\$ (318,283)	\$ 50,189,786
Net loss	—	—	—	—	—	—	(4,982,579)	—	(4,982,579)	(1,862)	(4,984,441)
Unrealized loss on marketable securities	—	—	—	—	—	(30,746)	—	—	(30,746)	—	(30,746)
Share-based compensation	—	—	79,102	79	101,284	—	—	—	101,363	—	101,363
Proceeds from option exercises	—	—	11,672	12	39,647	—	—	—	39,659	—	39,659
Change in ownership in subsidiary	—	—	—	—	(47,547)	—	—	—	(47,547)	47,547	—
<b>Balance at March 31, 2018</b>	10,000	\$ 100	9,574,685	\$ 9,575	\$ 433,137,593	\$ (58,724)	\$(386,792,688)	\$(707,637)	\$ 45,588,219	\$ (272,598)	\$ 45,315,621

See accompanying notes to consolidated financial statements.

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

	<b>Three Months Ended March 31,</b>	
	<b>2018</b>	<b>2017</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (4,984,441)	\$ (9,793,324)
Loss from discontinued operations	—	3,157,475
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	146,533	395,698
Depreciation and amortization	87,324	98,924
Loss on disposal of assets	—	47,301
Accretion on marketable securities	82,221	—
Changes in operating assets and liabilities:		
Prepaid and other current assets	(2,447)	86,263
Accounts receivable	90,204	10,510
Other assets	—	20,141
Due to/from PCT	—	1,943,774
Accounts payable, accrued liabilities and other liabilities	(1,717,871)	(560,032)
Net cash used in operating activities - continuing operations	(6,298,477)	(4,593,270)
Net cash used in operating activities - discontinued operations	—	(5,494,638)
Net cash used in operating activities	(6,298,477)	(10,087,908)
<b>Cash flows from investing activities:</b>		
Purchase of marketable securities	(24,143,913)	—
Sale of marketable securities	22,964,000	—
Acquisition of property and equipment	(8,528)	(69,650)
Net cash used in investing activities - continuing operations	(1,188,441)	(69,650)
Net cash used in investing activities - discontinued operations	—	(101,626)
Net cash used in investing activities	(1,188,441)	(171,276)
<b>Cash flows from financing activities:</b>		
Proceeds from exercise of options	39,659	—
Tax withholding payments on net share settlement equity awards	(45,169)	(23,647)
Net proceeds from issuance of common stock	—	3,241,460
Repayment of long-term debt	—	(756,966)
Proceeds from notes payable	—	400,998
Repayment of notes payable	(67,131)	(193,518)
Advance payment received from potential PCT sale	—	5,000,000
Net cash (used in) provided by financing activities - continuing operations	(72,641)	7,668,327
Net cash used in financing activities - discontinued operations	—	(116,545)
Net cash (used in) provided by financing activities	(72,641)	7,551,782
Net decrease in cash, cash equivalents and restricted cash	(7,559,559)	(2,707,402)
Cash, cash equivalents and restricted cash at beginning of period - continuing operations	34,167,989	7,076,651
Cash and cash equivalents at beginning of period - discontinued operations	—	7,628,357
Cash, cash equivalents and restricted cash at end of period	\$ 26,608,430	\$ 11,997,606
Less cash and cash equivalents of discontinued operations at end of period	—	3,082,099
Cash, cash equivalents and restricted cash of continuing operations at end of period	26,608,430	8,915,507
<b>Supplemental Disclosure of Cash Flow Information:</b>		
Cash paid during the period for:		
Interest	\$ 3,295	\$ 130,204
Taxes	\$ —	\$ —

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 company developing cellular therapeutics to treat select cardiovascular and autoimmune diseases. We leverage specialized development expertise to advance our therapies through development with the aim of eventually obtaining market authorization and commercializing, either alone or with partners, and providing treatment options to patients suffering from life-threatening medical conditions. Our product candidates include autologous CD34 cell-based therapies for ischemic repair that are in phase 2 of clinical development as well as an autologous, ex vivo expanded and activated, polyclonal regulatory T cell (“Treg”) therapy completing a phase 2 study targeting recent-onset type 1 diabetes mellitus (“T1D”) in children aged 8-17. We also have acquired the rights to data and regulatory filings for a CD34-based cell therapy program for refractory angina, which had advanced to phase 3 under the previous owner. We have designated this program CLBS14-RfA.

***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 blood vessels 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 critical limb ischemia (“CLI”), coronary microvascular dysfunction (“CMD”) and refractory angina (“RfA”). Published reports in *Circulation Cardiovascular Interventions*, *Atherosclerosis*, *Stem Cells and Circulation Journal*, provide preliminary evidence that CD34 cell therapy is safe and can exert significant therapeutic effects in patients with CLI, a condition in which blood flow to the legs is severely impaired, causing pain and non-healing ulcers and, ultimately, potentially resulting in the need for amputation. Our Clinical Trial Notification for a pivotal Phase 2 trial investigating our product candidate in CLI, CLBS12, was submitted to the Japanese Pharmaceutical and Medical Device Agency (“PMDA”) and was cleared to proceed. The protocol design was agreed to with PMDA, the study was opened for enrollment in December 2017 and treatment of the first patient was announced in March 2018. Based on our discussions with the PMDA, we expect that a successful outcome of this trial will qualify CLBS12 for consideration of early conditional approval in Japan, thereby effectively making our phase 2 trial a registration trial. In addition, Japan’s Ministry of Health, Labour and Welfare (“MHLW”) recently assigned CLBS12 “SAKIGAKE” designation (a Japanese regulatory status similar to “breakthrough” designation awarded by FDA in the USA) reflecting its expectation of “prominent effectiveness” based on data of mechanism of action from non-clinical and early phase clinical trials. The SAKIGAKE Designation System promotes research and development in Japan, driving early practical application for innovative pharmaceutical products, medical devices and regenerative medicines. As a designated therapy under the system, CLBS12 should have the benefits of prioritized consultation, a dedicated review system to support the development and review process, as well as reduced review time from the normal 12 months down to 6 months. In anticipation of a successful trial outcome and the possibility of conditional approval, we continue to seek a local partner for CLBS12 in Japan. We also have acquired the rights to data and regulatory filings for a CD34-based cell therapy program for refractory angina, which had advanced to phase 3 under the previous investigational new drug application (“IND”) holder. We have designated this program CLBS14-RfA and recently reactivated the IND with the U.S. Food and Drug Administration (“FDA”). Furthermore, we submitted grant applications in an effort to seek non-dilutive financing to investigate the CD34 technology for additional clinical indications in the United States. 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 coronary microvascular dysfunction. The first patient has been enrolled in this study of CLBS14-CMD.

***Immunomodulation (Treg Technology)***

We are developing strategically, through the utilization of our core development expertise, a product candidate (CLBS03) that has the potential to be an innovative therapy for T1D. This therapy is based on a proprietary platform technology for immunomodulation. We have selected, as an initial target, the unmet medical need of patients who are newly diagnosed with T1D, most of whom will be under the age of 18. This program is based on the use of Tregs 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. Insulin is necessary to regulate sugar metabolism and maintain proper sugar levels in the blood. Inconsistent or unnatural insulin levels can lead to many complications, including blindness, vascular disease and, if no insulin supplement is provided, even death. There are currently no curative treatments for T1D, only lifelong insulin therapy, which often does not prevent serious co-morbidities. Two Phase 1 clinical trials of Treg technology in T1D, taken together demonstrated safety and tolerance, feasibility of manufacturing, an implied durability of effect as well as an early indication of potential therapeutic effect through the preservation of beta cell function. In the first quarter of 2016, we commenced patient enrollment in the first of two cohorts in The Sanford Project: T-Rex Study, a Phase 2 prospective, randomized, placebo-controlled, double-blind clinical trial (the "TRex Study") to evaluate the safety and efficacy of CLBS03 in adolescents with recent onset T1D. We entered into a strategic collaboration with Sanford Research to support the execution of this trial. Sanford Research is a U.S.-based non-profit research organization that supports an emerging translational research center focused on finding a cure for T1D.

CLBS03 has been granted Fast Track and orphan drug designations from the U.S. Food and Drug Administration ("FDA") as well as Advanced Therapeutic Medicinal Product ("ATMP") classification from the European Medicines Agency ("EMA"). In October 2016, we received a satisfactory safety evaluation by our independent Data Safety Monitoring Board based on safety data then available from the first 19 patients enrolled in the trial. A subsequent interim analysis was conducted after approximately 50% of patients reached the six-month follow-up milestone, the results of which were publicly released in March 2018 that the therapy continued to be well tolerated and was deemed non-futile for therapeutic effect. In January 2018, we announced completion of enrollment (110 patients) of the TRex Study.

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 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. We have received total funding of \$7.9 million through March 31, 2018.

### ***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 our Treg product and additional indications for our CD34 cell technology.

Our current long-term strategy focuses on advancing our therapies through development with the aim of eventually obtaining market authorization and commercializing, 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.

### ***Discontinued Operations***

On May 18, 2017, we completed the previously announced sale of our remaining 80.1% membership interest in PCT, LLC, a Caladrius company ("PCT") to Hitachi Chemical Co. America, Ltd. ("Hitachi"), pursuant to the Interest Purchase Agreement (the "Purchase Agreement") dated as of March 16, 2017, by and among us, PCT and Hitachi (the "2017 Hitachi Transaction"), for \$75.0 million in cash plus an additional cash adjustment of \$4.4 million based on PCT's cash and outstanding indebtedness as of the closing date and a potential future milestone payment (see Note 3). The sale of PCT represented a strategic shift that has had a major effect on our operations, and therefore, all periods presented were adjusted to reflect PCT as discontinued operations. PCT is now known as Hitachi Chemical Advanced Therapeutic Systems ("HCATS").

### ***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, 2018, 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, 2017 and 2016 included in our 2017 Form 10-K. Operating results for the three months ended March 31, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018.

### ***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 amounts 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, as well as the operations of our former subsidiaries PCT, LLC, a Caladrius company, NeoStem Family Storage, LLC, and PCT Allendale, LLC entities (collectively the "PCT Segment") through May 18, 2017, representing the date which these entities were sold to Hitachi (see Note 3). The PCT Segment is reported in discontinued operations. All intercompany activities have been eliminated in consolidation, except for intercompany activities between Caladrius and the PCT Segment, which are reported without intercompany eliminations in continuing operations and discontinued operations, respectively.

### **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 2017 Form 10-K. There were no changes to these policies during the three months ended March 31, 2018.

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

We are subject to credit risk from our portfolio of cash, cash equivalents, restricted cash, 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 Act") was enacted on December 22, 2017. The income tax effects of changes in tax laws are recognized in the period when enacted. The 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 Act in late 2017, the U.S. Securities and Exchange Commission 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 is effective for interim and annual periods beginning after December 15, 2018, and will be applied at the beginning of the earliest period presented using a modified retrospective approach. This ASU may have a material impact on the Company’s financial statements. The impact on the Company’s results of operations is currently being evaluated. The impact of the ASU is non-cash in nature and will not affect the Company’s cash position.

In March 2016, the FASB issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting. This ASU simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, accounting for forfeitures, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The guidance was effective for interim and annual periods beginning after December 15, 2016. The adoption of this new guidance did not have a material effect on the consolidated results of operations, cash flows, and financial position.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. ASU 2016-15 clarifies how companies present and classify certain cash receipts and cash payments in the statement of cash flows where diversity in practice exists. ASU 2016-15 was effective in first quarter of fiscal 2018. The adoption of this new guidance did not have a material effect on the consolidated results of operations, cash flows, and financial position.

In October 2016, the FASB issued ASU 2016-16, Intra-Entity Transfers of Assets Other Than Inventory. ASU 2016-16 requires the income tax consequences of intra-entity transfers of assets other than inventory to be recognized as current period income tax expense or benefit at the transaction date and removes the option to defer and amortize the consolidated tax consequences of intra-entity transfers. The new standard was effective on January 1, 2018. The adoption of this new guidance did not have a material effect on the consolidated results of operations, cash flows, and financial position.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash. ASU 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. The new standard was effective on January 1, 2018 and the Company early adopted the standard in 2017, with all adjustments reflected as of the beginning of the fiscal years reported.

In May 2017, the FASB issued ASU 2017-09, "Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting," to provide clarity and reduce both diversity in practice and cost complexity when applying the guidance in Topic 718 to a change to the terms and conditions of a stock-based payment award. ASU 2017-09 also provides guidance about the types of changes to the terms or conditions of a share-based payment award that require an entity to apply modification accounting in accordance with Topic 718. For all entities, including emerging growth companies, the standard is effective for annual periods beginning after December 15, 2017, and for interim periods therein. Early adoption is permitted. The adoption of this new guidance did not have a material effect on the consolidated results of operations, cash flows, and financial position.

### **Note 3 – Collaboration and License Agreement**

#### ***2016 Hitachi Transaction***

On March 11, 2016, PCT entered into a global collaboration with Hitachi (the "2016 Hitachi Transaction"). This collaboration consisted of an equity investment in and a license agreement with PCT.

Under the equity investment agreement, Hitachi purchased a 19.9% membership interest in PCT for \$19.4 million of which \$15.0 million of proceeds was distributed to Caladrius from PCT and \$4.4 million remained at PCT to be used for the continued expansion and improvements at PCT in support of commercial product launch readiness as well as for general corporate purposes.

PCT and Hitachi also entered into an exclusive license agreement for the acceleration of the creation of a global commercial cell therapy development and manufacturing expertise in Asia pursuant to which PCT received \$5.6 million from Hitachi in 2016. PCT licensed certain cell therapy technology and know-how (including an exclusive license in Asia) and agreed to provide Hitachi with certain training and support. As additional consideration, Hitachi agreed to pay PCT royalties on contract revenue generated in Asia for a minimum of ten years. In connection with the 2017 Hitachi Transaction described below, this exclusive license agreement was terminated.

### **2017 Hitachi Transaction**

On May 18, 2017, the Company sold its remaining 80.1% membership interest in PCT to Hitachi pursuant to the Purchase Agreement, dated as of March 16, 2017, by and among Caladrius PCT and Hitachi (the "2017 Hitachi Transaction"). The aggregate purchase price to the Company consisted of (i) \$75.0 million in cash, (ii) \$4.4 million, representing additional consideration based on PCT's cash and outstanding indebtedness as of the closing date, and (iii) a potential future milestone payment of \$5.0 million if PCT achieves \$125 million in cumulative revenue (excluding clinical service reimbursables) (the "Milestone") for the period from January 1, 2017 through December 31, 2018 (the "Milestone Period").

Hitachi paid the Company \$5.0 million in March 2017 as an advance payment pending shareholder approval of the transaction and other closing conditions. On the closing date, the Company received \$65.0 million, with an additional \$5.0 million of the purchase consideration (the "Escrow Amount") deposited into an escrow account to cover potential indemnification claims against Caladrius. The Escrow Amount is classified as restricted cash on the consolidated balance sheets as of March 31, 2018 and December 31, 2017. In June 2018, the escrow agent will disburse to the Company the Escrow Amount less (i) that portion of the Escrow Amount previously paid in satisfaction of claims for indemnification pursuant to the terms of the Purchase Agreement and (ii) that portion of the Escrow Amount that is determined, in the reasonable judgment of Hitachi, to be necessary to satisfy all unsatisfied or disputed claims for indemnification specified in any claim notice delivered to the Company. The Company also received the \$4.4 million additional consideration payment in July 2017. The Company incurred approximately \$6.9 million in transaction costs related to the 2017 Hitachi Transaction, including \$4.3 million in retention payments to PCT employees, of which 50% was paid in June 2017, and the other 50% payable on the one-year anniversary of the closing date.

Concurrent with the signing of the Purchase Agreement, on March 16, 2017, Caladrius entered into a Retention and Incentive Agreement with Robert A. Preti, a former Caladrius director and a co-founder and the President of PCT, (the "Retention Agreement"). The Retention Agreement superseded all prior agreements and understandings between Dr. Preti and Caladrius regarding the subject matter of the Retention Agreement. Among other things, the Retention Agreement provided:

- Simultaneously with the closing of the 2017 Hitachi Transaction, Caladrius pay to Dr. Preti \$1.9 million (the "First Retention Payment").
- As an incentive to remain employed with PCT and to use commercially reasonable efforts to cause PCT to maximize its overall performance and in particular to achieve the Milestone (but not contingent upon achieving the Milestone), Dr. Preti receive a lump-sum cash retention and incentive payment equal to \$1.9 million for the period from the closing date of the 2017 Hitachi Transaction until the date one year after the date of the closing (the "Anniversary Date"), subject to Dr. Preti's continued employment with PCT through the Anniversary Date (the "Second Retention Payment").
- Dr. Preti is entitled to 5% of the Milestone if it is successfully earned.

### **Note 4 – 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, 2018				December 31, 2017			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities	\$ 35,330	\$ —	\$ (55)	\$ 35,275	\$ 42,701	\$ —	\$ (28)	\$ 42,673
Money market funds	6,996	—	—	6,996	9,212	—	—	9,212
<b>Total</b>	<b>\$ 42,326</b>	<b>\$ —</b>	<b>\$ (55)</b>	<b>\$ 42,271</b>	<b>\$ 51,913</b>	<b>\$ —</b>	<b>\$ (28)</b>	<b>\$ 51,885</b>

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

	March 31, 2018	December 31, 2017
Cash and cash equivalents	\$ 15,287	\$ 25,968
Marketable securities	26,984	25,917
<b>Total</b>	<b>\$ 42,271</b>	<b>\$ 51,885</b>

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

	March 31, 2018	
	Amortized Cost	Estimated Fair Value
Less than one year	\$ 42,326	\$ 42,271
Greater than one year	—	—
<b>Total</b>	<b>\$ 42,326</b>	<b>\$ 42,271</b>

#### **Note 5 – Loss Per Share**

For the three months ended March 31, 2018 and 2017, 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, 2018 and 2017, the Company excluded the following potentially dilutive securities:

	March 31,	
	2018	2017
Stock Options	1,072,499	1,133,459
Warrants	209,818	336,062
Restricted Shares	181,908	132,726
Restricted Stock Units	10,260	—

#### **Note 6 – 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, 2018, and December 31, 2017 (in thousands).

	March 31, 2018				December 31, 2017			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
<b>Assets:</b>								
Marketable securities - available for sale	\$ —	\$ 26,984	\$ —	\$ 26,984	\$ —	\$ 25,917	\$ —	\$ 25,917
	\$ —	\$ 26,984	\$ —	\$ 26,984	\$ —	\$ 25,917	\$ —	\$ 25,917

### **Note 7 – Accrued Liabilities**

Accrued liabilities as of March 31, 2018 and December 31, 2017 were as follows (in thousands):

	March 31, 2018	December 31, 2017
Salaries, employee benefits and related taxes	\$ 666	\$ 1,389
Retention payments	2,233	2,233
Professional fees	161	287
CIRM upfront funding - current	2,583	2,446
Other	1,355	1,456
Total	\$ 6,998	\$ 7,811

### **Note 8 – Debt**

#### ***Notes Payable***

As of March 31, 2018 and December 31, 2017, the Company had notes payable of approximately \$0.1 million and \$0.2 million, respectively. The notes relate to certain equipment financings, require monthly payments, and mature within one year.

### **Note 9 – Shareholders' Equity**

#### ***Equity Issuances***

##### **September 2016 Private Placement**

In September 2016, the Company entered into Securities Purchase Agreements with certain accredited investors with whom it had a substantive, pre-existing relationship, including certain existing stockholders, for the sale by the Company of its common stock, at a purchase price of \$4.72 per share. The investments were placed in two tranches whereby (i) \$6.6 million was received and 1.4 million shares of common stock were issued in 2016 upon an initial closing, and (ii) \$4.4 million was received and 0.9 million shares of common stock were issued in 2017, which was subject to certain closing conditions, including the enrollment of 70 subjects in the Company's Phase 2 CLBS03 clinical trial, in a second closing.

##### **Aspire Purchase Agreements**

In November 2015, the Company entered into a common stock purchase agreement (the "Purchase Agreement") with Aspire Capital Fund, LLC, an Illinois limited liability company ("Aspire Capital"), which provides that, subject to certain terms and conditions and Nasdaq rules, Aspire Capital was committed to purchase up to an aggregate of \$30 million of shares (limited to a maximum of approximately 1.1 million shares, unless stockholder approval was obtained or certain minimum sale price levels were reached) of the Company's common stock over a 24-month term. The Company has issued 319,776 shares under the Purchase Agreement for gross proceeds of \$1.5 million, which Purchase Agreement expired in November 2017.

### 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. 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. In addition, pursuant to the terms of the Sales Agreement, the Company agreed to reimburse HCW \$50,000 for legal fees incurred in connection with entering into the Sales Agreement, plus up to \$2,500 per calendar quarter in fees for other filing requirements arising from the transactions contemplated by the Sales Agreement. Sales of the shares, if any, under the sales agreement may be made in transactions that are deemed to be "at the market offerings" as defined in Rule 415 under the Securities Act of 1933, as amended. 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. As of March 31, 2018, the Company has not issued any shares under the Sales Agreement.

### Stock Options and Warrants

The following table summarizes the activity for stock options and warrants for the three months ended March 31, 2018:

	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, 2017	1,072,499	\$ 33.50	4.76	\$ 0.1	209,818	\$ 53.20	0.95	\$ —
Changes during the period:								
Granted	140,410	3.80			—	—		
Exercised	(11,673)	4.60			—	—		
Forfeited	(1,080)	3.80			—	—		
Expired	(57,197)	22.60			(158,664)	50.20		
Outstanding at March 31, 2018	1,142,959	\$ 29.90	5.37	\$ 975.2	51,154	\$ 62.70	3.10	\$ —
Vested at March 31, 2018 or expected to vest in the future	1,129,369	\$ 30.30	5.32	\$ 947.8	51,154	\$ 62.70	3.10	\$ —
Vested at March 31, 2018	1,034,190	\$ 32.70	4.91	\$ 759.0	51,154	\$ 62.70	3.10	\$ —

### Restricted Stock

During the three months ended March 31, 2018 and 2017, the Company issued restricted stock for services as follows (in thousands, except share data):

	Three Months Ended March 31,	
	2018	2017
Number of restricted stock issued	127,688	132,726
Value of restricted stock issued	\$ 351	\$ 470

### Note 10 – 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, 2018 and 2017 (in thousands):

	Three Months Ended March 31,	
	2018	2017
Research and development	\$ 40	\$ 46
General and administrative	106	350
Discontinued operations	—	137
Total share-based compensation expense	\$ 146	\$ 533

The approval of the 2017 Hitachi Transaction (see Note 3) by our stockholders resulted in a change in control under our equity compensation plans (as defined in the 2009 Plan and the 2015 Equity Plan). Accordingly, all outstanding unvested equity awards were accelerated upon the closing date of the 2017 Hitachi Transaction, resulting in an acceleration of \$1.9 million of equity compensation in the second quarter of 2017. In addition, in connection with the 2017 Hitachi Transaction, the Company agreed to extend the post-termination option exercise period for all PCT employees transitioning to Hitachi from 90 days to the earlier of (i) two years (May 18, 2019) or (ii) the date of the employees' termination from PCT. The post-termination option exercise period modification resulted in an additional expense of \$0.3 million, which was recorded entirely during the three months ended June 30, 2017 and recorded in discontinued operations, since there were no future service requirements to receive the extended benefit.

Total compensation cost related to nonvested awards not yet recognized and the weighted-average periods over which the awards are expected to be recognized at March 31, 2018 were as follows (in thousands):

	Stock Options	Restricted Stock
Unrecognized compensation cost	\$ 275.1	\$ —
Expected weighted-average period in years of compensation cost to be recognized	2.41	0.00

Total fair value of shares vested and the weighted average estimated fair values of shares granted for the three months ended March 31, 2018 and 2017 were as follows (in thousands):

	Stock Options	
	Three Months Ended March 31,	
	2018	2017
Total fair value of shares vested	\$ 82.4	\$ 507.1
Weighted average estimated fair value of shares granted	\$ 2.41	\$ 2.34

### 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 11 – 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.

We 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, 2018, \$2.6 million of the funding received is

recorded in accrued liabilities, representing the amount expected to be recognized over the next 12 months, and \$3.4 million of the funding received is recorded in other long-term liabilities. During the three months ended March 31, 2018, the Company amortized and recognized a \$0.6 million credit to research and development related to CIRM funds received.

## **Note 12 – 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, 2017, the Company had approximately \$210.3 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 are 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, 2018, 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 13 – Discontinued Operations**

### **PCT Segment**

On May 18, 2017, the Company sold its remaining 80.1% membership interest in PCT to Hitachi pursuant to the 2017 Hitachi Transaction (see Note 3). The aggregate purchase price to the Company consisted of (i) \$75.0 million in cash, (ii) \$4.4 million, representing additional consideration based on PCT's cash and outstanding indebtedness as of the closing date, and (iii) a potential future milestone payment of \$5.0 million if PCT achieves \$125 million in cumulative revenue (excluding clinical service reimbursables) for the period from January 1, 2017 through December 31, 2018. The Company has determined that the fair value of the milestone payment as of the closing date was valued at zero.

Hitachi paid the Company \$5.0 million in March 2017 as an advance payment pending shareholder approval of the transaction and other closing conditions. On the closing date, the Company received \$65.0 million, with an additional \$5.0 million of the purchase consideration (the "Escrow Amount") deposited into an escrow account to cover potential indemnification claims against Caladrius. The Escrow Amount is classified as restricted cash on the balance sheet as of March 31, 2018. In June 2018, the escrow agent will disburse to the Company the Escrow Amount less (i) that portion of the Escrow Amount previously paid in satisfaction of claims for indemnification pursuant to the terms of the Purchase Agreement and (ii) that portion of the Escrow Amount that is determined, in the reasonable judgment of Hitachi, to be necessary to satisfy all unsatisfied or disputed claims for indemnification.

specified in any claim notice delivered to the Company. The Company also received the \$4.4 million additional consideration payment in July 2017. The Company incurred approximately \$6.9 million in transaction costs related to the 2017 Hitachi Transaction, including \$4.3 million in retention payments to PCT employees, of which 50% was paid in June 2017, and the other 50% payable on the one year anniversary of the closing date.

The Company recognized the following gain on the date of sale of its 80.1% interest in PCT (in thousands):

Fair value of consideration received	\$	79,425
Transaction and retention costs		(6,919)
Carrying value of segment non-controlling interest		3,687
	\$	<u>76,193</u>
Less carrying amount of assets and liabilities sold:		
Cash	\$	6,727
Accounts receivable		3,702
Deferred costs		4,685
Prepaid expenses and other current assets		743
Property, plant and equipment, net		14,900
Goodwill		7,013
Intangibles, net		2,090
Other assets		215
Accounts payable		(2,278)
Accrued liabilities		(2,927)
Due from Caladrius		450
Unearned revenues		(10,529)
Notes payable		(342)
	\$	<u>24,449</u>
Gain on sale of PCT	\$	<u>51,744</u>

The operations and cash flows of the PCT Segment were eliminated from ongoing operations with the sale of the Company's PCT Interest. The operating results of the PCT Segment for the three months ended March 31, 2017 were as follows (in thousands):

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2017</b>	
Revenue	\$	10,310
Cost of revenues		(10,053)
Research and development		(113)
Selling, general, and administrative		(3,243)
Other expense		(9)
Provision for income taxes		(50)
Loss from discontinued operations	\$	<u>(3,157)</u>

#### **Note 14 – Commitments and Contingencies**

##### ***Lease Commitments***

We lease facilities under various operating lease agreements in Basking Ridge, NJ, Rye Brook, NY, and Irvine, CA, of which certain have escalation clauses and renewal options. We also lease equipment under certain noncancelable operating leases. Our leases expire from time to time through 2021.

A summary of future minimum rental payments required under operating leases that have initial or remaining terms in excess of one year as of March 31, 2018 are as follows (in thousands):

<b>Years ended</b>	<b>Operating Leases</b>	
2018	\$	669
2019		905
2020		827
2021		474
2022 and thereafter		129
Total minimum lease payments	\$	3,004

Expense incurred under operating leases was approximately \$0.3 million and \$0.4 million for the three months ended March 31, 2018 and 2017, respectively.

### **Contingencies**

We have entered into a strategic collaboration with Sanford Research with the goal of developing a therapy for the treatment of T1D. The initial focus of the collaboration will be the execution of a prospective, randomized, placebo-controlled, double-blind clinical trial (The Sanford Project: T-Rex Study) to evaluate the safety and efficacy of the Company's T regulatory cell product candidate, CLBS03, in adolescents with recent onset T1D. The Phase 2 study has an open and active IND in place and subject enrollment commenced in the first quarter of 2016. We were initially responsible for the supply of all study drug to the first 19 enrolled patients while Sanford assumed all patient and clinical site costs for subjects enrolled in their two centers as well as the expense associated with general clinical monitoring services. For the remaining 92 patients in the study, we will continue to be responsible for the supply of all study drug and the costs of study enrollment for sites outside of the Sanford centers.

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 2017 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 2017 Form 10-K.

### **Overview**

Caladrius Biosciences, Inc. ("we," "us," "our," "Caladrius" or the "Company") is a company developing cellular therapeutics to treat select cardiovascular and autoimmune diseases. We leverage specialized development expertise to advance our therapies through development with the aim of eventually obtaining market authorization and commercializing, either alone or with partners, and providing treatment options to patients suffering from life-threatening medical conditions. Our product candidates include autologous CD34 cell-based therapies for ischemic repair that are in phase 2 of clinical development as well as an autologous, ex vivo expanded and activated, polyclonal regulatory T cell ("Treg") therapy completing a phase 2 study targeting recent-onset type 1 diabetes mellitus ("T1D") in children aged 8-17. We also have acquired the rights to data and regulatory filings for a CD34-based cell therapy program for refractory angina, which had advanced to phase 3 under the previous owner. We have designated this program CLBS14-RfA.

### ***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 blood vessels 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 critical limb ischemia ("CLI"), coronary microvascular dysfunction ("CMD") and refractory angina ("RfA"). Published reports in *Circulation Cardiovascular Interventions*, *Atherosclerosis*, *Stem Cells* and *Circulation Journal*, provide preliminary evidence that CD34 cell therapy is safe and can exert significant therapeutic effects in patients with CLI, a condition in which blood flow to the legs is severely impaired, causing pain and non-healing ulcers and, ultimately, potentially resulting in the need for amputation. Our Clinical Trial Notification for a pivotal Phase 2 trial investigating our product candidate in CLI, CLBS12, was submitted to the Japanese Pharmaceutical and Medical Device Agency ("PMDA") and was cleared to proceed. The protocol design was agreed to with PMDA, the study was opened for enrollment in December 2017 and treatment of the first patient was announced in March 2018. Based on our discussions with the PMDA, we expect that a successful outcome of this trial will qualify CLBS12 for consideration of early conditional approval in Japan, thereby effectively making our phase 2 trial a registration trial. In addition, Japan's Ministry of Health, Labour and Welfare ("MHLW") recently assigned CLBS12 "SAKIGAKE" designation (a Japanese regulatory status similar to "breakthrough" designation awarded by FDA in the USA) reflecting its expectation of "prominent effectiveness" based on data of mechanism of action from non-clinical and early phase clinical trials. The SAKIGAKE Designation System promotes research and development in Japan, driving early practical application for innovative pharmaceutical products, medical devices and regenerative medicines. As a designated therapy under the system, CLBS12 should have the benefits of prioritized consultation, a dedicated review system to support the development and review process, as well as reduced review time from the normal 12 months down to 6 months. In anticipation of a successful trial outcome and the possibility of conditional approval, we continue to seek a local partner for CLBS12 in Japan. We also have acquired the rights to data and regulatory filings for a CD34-based cell therapy program for refractory angina, which had advanced to phase 3 under the previous investigational new drug application ("IND") holder. We have designated this program CLBS14-RfA and recently reactivated the IND with the U.S. Food and Drug Administration ("FDA"). Furthermore, we submitted grant applications in an effort to seek non-dilutive financing to investigate the CD34 technology for additional clinical indications in the United States. 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 coronary microvascular dysfunction. The first patient has been enrolled in this study of CLBS14-CMD.

### ***Immunomodulation (Treg Technology)***

We are developing strategically, through the utilization of our core development expertise, a product candidate (CLBS03) that has the potential to be an innovative therapy for T1D. This therapy is based on a proprietary platform technology for immunomodulation. We have selected, as an initial target, the unmet medical need of patients who are newly diagnosed with T1D, most of whom will be under the age of 18. This program is based on the use of Tregs 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. Insulin is necessary to regulate sugar metabolism and maintain proper sugar levels in the blood. Inconsistent or unnatural insulin levels can lead to many complications, including blindness, vascular disease and, if no insulin supplement is provided, even death. There are currently no curative treatments for T1D, only lifelong insulin therapy, which often does not prevent serious comorbidities. Two Phase 1 clinical trials of Treg technology in T1D, taken together demonstrated safety and tolerance, feasibility of manufacturing, an implied durability of effect as well as an early indication of potential therapeutic effect through the preservation of beta cell function. In the first quarter of 2016, we commenced patient enrollment in the first of two cohorts in The Sanford Project: T-Rex Study, a Phase 2 prospective, randomized, placebo-controlled, double-blind clinical trial (the "TRex Study") to evaluate the safety and efficacy of CLBS03 in adolescents with recent onset T1D. We entered into a strategic collaboration with Sanford Research to support the execution of this trial. Sanford Research is a U.S.-based non-profit research organization that supports an emerging translational research center focused on finding a cure for T1D.

CLBS03 has been granted Fast Track and orphan drug designations from the U.S. Food and Drug Administration ("FDA") as well as Advanced Therapeutic Medicinal Product ("ATMP") classification from the European Medicines Agency ("EMA"). In October 2016, we received a satisfactory safety evaluation by our independent Data Safety Monitoring Board based on safety data then available from the first 19 patients enrolled in the trial. A subsequent interim analysis was conducted after approximately 50% of patients reached the six-month follow-up milestone, the results of which were publicly released in March 2018 that the therapy continued to be well tolerated and was deemed non-futile for therapeutic effect. In January 2018, we announced completion of enrollment (110 patients) of the TRex Study.

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 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. We have received total funding of \$7.9 million through March 31, 2018.

### ***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 our Treg product and additional indications for our CD34 cell technology.

Our current long-term strategy focuses on advancing our therapies through development with the aim of eventually obtaining market authorization and commercializing, 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.

### ***Discontinued Operations***

On May 18, 2017, we completed the previously announced sale of our remaining 80.1% membership interest in PCT, LLC, a Caladrius company ("PCT") to Hitachi Chemical Co. America, Ltd. ("Hitachi"), pursuant to the Interest Purchase Agreement (the "Purchase Agreement") dated as of March 16, 2017, by and among us, PCT and Hitachi (the "2017 Hitachi Transaction"), for \$75.0 million in cash plus an additional cash adjustment of \$4.4 million based on PCT's cash and outstanding indebtedness as of the closing date and a potential future milestone payment (see Note 3). The sale of PCT represented a strategic shift that has had a major effect on our operations, and therefore, all periods presented were adjusted to reflect PCT as discontinued operations. PCT is now known as Hitachi Chemical Advanced Therapeutic Systems ("HCATS").

## **Results of Operations**

### ***Three Months Ended March 31, 2018 Compared to Three Months Ended March 31, 2017***

Net loss from continuing operations was \$5.0 million for the three months ended March 31, 2018, compared to net loss from continuing operations of \$6.6 million for the three months ended March 31, 2017. Overall net loss for the three months ended

March 31, 2018 was approximately \$5.0 million, compared to overall net loss of \$9.8 million for the three months ended March 31, 2017. The overall net loss during the three months ended March 31, 2017 included losses from discontinued operations of \$3.2 million.

## Operating Expenses

For the three months ended March 31, 2018, operating expenses totaled \$5.2 million compared to \$6.4 million for the three months ended March 31, 2017, representing a decrease of \$1.3 million, or 20%. Operating expenses were comprised of the following:

- Research and development expenses were approximately \$2.3 million for the three months ended March 31, 2018, compared to \$3.7 million for the three months ended March 31, 2017, representing a decrease of approximately \$1.5 million, or 39%.
  - *Immune Modulation* - Immune modulation expenses, primarily related to expenses associated with our Phase 2 study of CLBS03 in T1D, were \$0.2 million for the three months ended March 31, 2018, compared to \$4.0 million for the three months ended March 31, 2017. In December 2017, we completed enrollment in the Phase 2 study, along with all manufacturing-related costs. Our 2018 expenses reflect significantly lower expenses as we transition our activities into the follow-up phase of the Phase 2 study.
  - *Ischemic Repair* - Ischemic repair expenses were \$2.1 million for the three months ended March 31, 2018, compared to \$0.1 million for the three months ended March 31, 2017. The increase is primarily related to (i) expenses associated with our Phase 2 study of CLBS12 in critical limb ischemia development program in Japan, and (ii) initiation-related program expenses associated with our Phase 1 study for CLBS14-CMD in coronary microvascular dysfunction.
- General and administrative expenses were approximately \$2.9 million for the three months ended March 31, 2018, compared to \$2.7 million for the three months ended March 31, 2017, representing an increase of approximately \$0.2 million, or 7%. The minor increase was due to higher overall corporate development activity expenses, which were partially offset by lower overall equity-based compensation expenses.

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. Total other income, net for the three months ended March 31, 2018 was \$0.2 million, compared with total other expense, net of \$0.2 million for the three months ended March 31, 2017. The investment income increase in the current year period as a result of higher cash and cash equivalents, and marketable securities balances compared with the prior year period. Interest expense in 2017 primarily related to interest expense on the loan from Oxford Finance LLC, which was paid in full concurrent with the PCT sale in May 2017.

## Discontinued Operations

On May 18, 2017, we completed the sale of our remaining 80.1% membership interest in PCT to Hitachi. Pursuant to the Purchase Agreement, the aggregate purchase price to us consisted of (i) \$75.0 million in cash, (ii) a \$4.4 million cash adjustment, based on PCT's cash and outstanding indebtedness as of the closing date, and (iii) a potential future milestone payment of \$5.0 million, if PCT achieves \$125 million in cumulative revenue (excluding clinical service reimbursables) (the "Milestone") for the period from January 1, 2017 through December 31, 2018 (the "Milestone Period"). We have determined that the fair value of the milestone payment as of the closing date was valued at zero.

Pursuant to the terms of the Purchase Agreement, Hitachi paid us \$5.0 million in March 2017, as an advance payment pending shareholder approval of the transaction and other closing conditions included in the Purchase Agreement. On the closing date, we received \$65.0 million, with an additional \$5.0 million of the purchase consideration (the "Escrow Amount") deposited into an escrow account to cover potential indemnification claims against us. In June 2018, the escrow agent will disburse to the Company the Escrow Amount less (i) that portion of the Escrow Amount previously paid in satisfaction of claims for indemnification pursuant

to the terms of the Purchase Agreement and (ii) that portion of the Escrow Amount that is determined, in the reasonable judgment of Hitachi, to be necessary to satisfy all unsatisfied or disputed claims for indemnification specified in any claim notice delivered to us. We also received the additional \$4.4 million cash adjustment payment in July 2017. We incurred approximately \$6.9 million in transaction costs related to the sale, including \$4.3 million in retention payments to PCT employees, of which 50% was paid in June 2017, and the other 50% payable on the one year anniversary of the closing date.

We recognized the following gain on the date of sale of our 80.1% interest in PCT (in thousands):

Fair value of consideration received	\$	79,425
Transaction and retention costs		(6,919)
Carrying value of segment non-controlling interest		3,687
	\$	<u>76,193</u>
Less carrying amount of assets and liabilities sold:		
Cash	\$	6,727
Accounts receivable		3,702
Deferred costs		4,685
Prepaid expenses and other current assets		743
Property, plant and equipment, net		14,900
Goodwill		7,013
Intangibles, net		2,090
Other assets		215
Accounts payable		(2,278)
Accrued liabilities		(2,927)
Due from Caladrius		450
Unearned revenues		(10,529)
Notes payable		(342)
	\$	<u>24,449</u>
Gain on sale of PCT	\$	<u>51,744</u>

The operations and cash flows of the PCT segment were eliminated from ongoing operations with the sale of our PCT interest. The operating results of the PCT segment for the three months ended March 31, 2017 were as follows (in thousands):

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2017</b>	
Revenue	\$	10,310
Cost of revenues		(10,053)
Research and development		(113)
Selling, general, and administrative		(3,243)
Other expense		(9)
Provision for income taxes		(50)
Loss from discontinued operations	\$	<u>(3,157)</u>



## Analysis of Liquidity and Capital Resources

At March 31, 2018, we had cash, cash equivalents, restricted cash, and marketable securities of approximately \$53.6 million, working capital of approximately \$46.6 million, and stockholders' equity of approximately \$45.6 million.

During the three months ended March 31, 2018, 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,	
	2018	2017
Net cash used in operating activities - continuing operations	\$ (6,298.5)	\$ (4,593.3)
Net cash used in investing activities - continuing operations	(1,188.4)	(69.7)
Net cash (used in) provided by financing activities - continuing operations	(72.6)	7,668.3

### Operating Activities - Continuing Operations

Our cash used in operating activities from continuing operations during the three months ended March 31, 2018 was \$6.3 million, which is comprised of (i) our net loss from continuing operations 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 using approximately \$1.6 million.

Our cash used in operating activities from continuing operations during the three months ended March 31, 2017 was \$4.6 million, which is comprised of (i) our net loss from continuing operations of \$6.6 million, adjusted for non-cash expenses totaling \$0.5 million (which includes adjustments for equity-based compensation, depreciation and amortization, and loss on disposal of assets), and (ii) changes in operating assets and liabilities providing approximately \$1.5 million.

### Investing Activities - Continuing Operations

Our cash used in investing activities during the three months ended March 31, 2018 totaled \$1.2 million, and primarily consisted of net investments in marketable securities.

Our cash used in investing activities during the three months ended March 31, 2017 totaled \$0.1 million, and consisted of property and equipment purchases.

### Financing Activities - Continuing Operations

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.

Our cash provided by financing activities during the three months ended March 31, 2017 consisted of the following:

- We received \$5.0 million from Hitachi as an advance payment in connection with the sale of our remaining 80.1% membership interest in PCT.
- We raised gross proceeds of \$2.0 million through the issuance of 423,729 shares of our common stock under the conditions of the Second Closing (achievement of the enrollment of 70 subjects in our Phase 2 CLBS03 clinical trial), relating to the September 2016 private placement offering.
- We raised gross proceeds of approximately \$1.2 million through the issuance of 210,506 shares of our common stock under the provisions of our Common Stock Purchase Agreement with Aspire.
- We paid \$0.8 million in principal payments on our long-term debt to Oxford Finance.

## 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 the development of CLBS03 and other operating expenses for at least the next 12 months following the issuance of our financial statements.

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, having an aggregate offering price of up to \$12 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. In addition, pursuant to the terms of the Sales Agreement, we agreed to reimburse HCW \$50,000 for legal fees incurred in connection with entering into the Sales Agreement, plus up to \$2,500 per calendar quarter in fees for other filing requirements arising from the transactions contemplated by the Sales Agreement. Sales of the shares, if any, under the sales agreement may be made in transactions that are deemed to be "at the market offerings" as defined in Rule 415 under the Securities Act of 1933, as amended. 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, 2018, we have not issued any shares under the Sales Agreement.

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, 2018.

In 2016, Hitachi purchased a 19.9% membership interest in PCT for \$19.4 million, of which \$15.0 million of proceeds was distributed to us from PCT and \$4.4 million remained at PCT. In 2017, we received \$74.6 million (net) in connection with the sale of our remaining 80.1% ownership interest in PCT to Hitachi, less \$6.7 million of cash held by our PCT subsidiary on the date of the acquisition.

In 2016, we entered into a securities purchase agreement with a single institutional investor pursuant to which we issued in a registered direct offering, an aggregate of 0.8 million shares of our common stock at a purchase price of \$4.72 per share. The gross proceeds to us from the registered direct offering of the shares of common stock were \$4.0 million. In concurrent private placements, in 2016, we entered into securities purchase agreements with certain accredited investors with whom we had a substantive, pre-existing relationship, including certain existing stockholders, for the sale by us of common stock, at a purchase price of \$4.72 per share. The investments were placed in two tranches whereby (i) \$6.6 million was received and 1.4 million shares of common stock were issued in 2016 upon an initial closing, and (ii) \$4.4 million was received and 0.9 million shares of common stock were issued in 2017, which was subject to certain closing conditions, including the enrollment of 70 subjects in our Phase 2 CLBS03 clinical trial, in a second closing.

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, 2018, compared to those reported in our 2017 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 our controls and other procedures that are 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, 2018, 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 2017 Form 10-K.

**ITEM 1A. RISK FACTORS**

There have been no material changes to the risk factors previously reported in our 2017 Form 10-K. See the risk factors set forth in our 2017 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 10, 2018

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

May 10, 2018

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

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

**Exhibit Index**

<a href="#">31.1</a>	*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
<a href="#">31.2</a>	*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
<a href="#">32.1</a>	**	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
<a href="#">32.2</a>	**	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.

## 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 10, 2018

/s/ David J. Mazzo, PhD

Name: David J. Mazzo, PhD

Title: Chief Executive Officer (Principal Executive Officer)

## 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 10, 2018

/s/ Joseph Talamo

Name: Joseph Talamo

Title: Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)



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

In connection with the Quarterly Report on Form 10-Q of Caladrius Biosciences, Inc. (the "Company") for the quarter ended March 31, 2018 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 10, 2018

/s/ David J. Mazzo, PhD  
David J. Mazzo, PhD  
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.

**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, 2018 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 10, 2018

/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.