UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2018

OR	
TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE S	ECURITIES EXCHANGE ACT OF 1934
For the Transition Period from	to
Commission File Numb	per 001-33650
CALADRIUS BIOSCI (Exact name of registrant as sp	·
DELAWARE	22-2343568
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
110 Allen Road, 2nd Floor, Basking Ridge, New Jersey	07920
(Address of principal executive offices)	(zip code)
Registrant's telephone number, includ	ing area code: 908-842-0100
ndicate by check mark whether the registrant (1) has filed all reports required to during the preceding 12 months (or for such shorter period that the registrant was equirements for the past 90 days. Yes x No o ndicate by check mark whether the registrant has submitted electronically every Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for stiles). Wes x No o	as required to file such reports), and (2) has been subject to such filing as required to file such subject to such filing as Interactive Data File required to be submitted pursuant to Rule 405 of uch shorter period that the registrant was required to submit and post such
ndicate by check mark whether the registrant is a large accelerated filer, an accelerating growth company. See the definitions of "large accelerated filer," "accelerated filerated filer," "accelerated filerated fi	
Large accelerated filer o	Accelerated filer o
Non-accelerated filer x	Smaller reporting company x
	Emerging growth o
f an emerging growth company, indicate by a check mark if the registrant has elected evised financial accounting standards provided pursuant to Section 13(a) of the Exc	
ndicate by check mark whether the registrant is a shell company (as defined in Rule $^\prime$ es o No x	e 12b-2 of the Exchange Act).
ndicate the number of shares outstanding of each of the issuer's classes of common	stock, as of the latest practicable date.
9,841,983 Shares, \$0.001 Par Val	lue, as of November 7, 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 to comply with healthcare laws and regulations or any other adverse effect or limitations caused by government regulation of our business;
- whether any of our current or future patent applications result in issued patents, the scope of those patents and our ability to obtain and maintain other rights to technology required or desirable for the conduct of our business; and our ability to commercialize products without infringing upon the claims of third party patents;
- whether any potential strategic or financial benefits of various licensing agreements will be realized;
- · the results of our development activities;
- our ability to complete our other planned clinical trials (or initiate other trials) in accordance with our estimated timelines due to delays associated with enrolling patients due to the novelty of the treatment, the size of the patient population and the need of patients to meet the inclusion criteria of the trial or otherwise; and
- other factors discussed in "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 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*, 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

	5	September 30, 2018	December 31, 2017		
ASSETS		(Unaudited)			
Cash and cash equivalents	\$	14,374,344	\$	29,163,200	
Restricted cash		_		5,004,789	
Marketable securities		31,775,525		25,916,681	
Prepaid and other current assets		1,102,979		1,312,503	
Total current assets		47,252,848		61,397,173	
Property and equipment, net		182,603		256,905	
Other assets		418,150		1,721,604	
Total assets	\$	47,853,601	\$	63,375,682	
LIABILITIES AND STOCKHOLDERS' EQUITY					
Liabilities					
Accounts payable	\$	447,219	\$	1,343,089	
Accrued liabilities		4,444,844		7,810,948	
Notes payable, current		_		159,180	
Total current liabilities		4,892,063		9,313,217	
Other long-term liabilities		2,152,258		3,872,679	
Total liabilities	\$	7,044,321	\$	13,185,896	
Commitments and Contingencies					
STOCKHOLDERS' EQUITY					
Stockholders' Equity					
Preferred stock, authorized, 20,000,000 shares Series B convertible redeemable preferred stock liquidation value, 1 share of common stock, \$0.01 par value; 825,000 shares designated; issued and outstanding, 10,000 shares at September 30, 2018 and December 31, 2017, respectively		100		100	
Common stock, \$0.001 par value, authorized 500,000,000 shares; issued and outstanding, 9,853,063 and 9,483,911 shares at September 30, 2 and December 31, 2017, respectively	018	9,853		9,484	
Additional paid-in capital		436,227,287		433,044,209	
Treasury stock, at cost; 11,080 shares at September 30, 2018 and December 31, 2017		(707,637)		(707,637	
Accumulated deficit		(394,419,255)		(381,810,109	
Accumulated other comprehensive loss		(28,621)		(27,978	
Total Caladrius Biosciences, Inc. stockholders' equity		41,081,727		50,508,069	
Noncontrolling interests		(272,447)		(318,283	
Total stockholders' equity		40,809,280		50,189,786	
	\$	47,853,601	\$	63,375,682	

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

	T	hree Months En	ded Se	ptember 30,	N	line Months En	ded S	September 30,
		2018		2017		2018		2017
Operating Expenses:								
Research and development	\$	1,701,253	\$	3,187,024	\$	6,086,103	\$	11,190,939
General and administrative		2,061,553		2,942,877		7,104,567		9,081,806
Total operating expenses		3,762,806		6,129,901		13,190,670		20,272,745
Operating loss		(3,762,806)		(6,129,901)		(13,190,670)		(20,272,745)
Other income (expense):								
Other income (expense), net		213,769		176,855		584,961		137,288
Interest expense		(187)		(8,687)		(5,148)		(372,099)
Total other income (expense), net		213,582		168,168		579,813		(234,811)
Loss from continuing operations before benefit from income taxes and noncontrolling interests		(3,549,224)		(5,961,733)		(12,610,857)		(20,507,556)
Benefit from income taxes		_		(2,413,951)		_		(8,301,494)
Net loss from continuing operations		(3,549,224)		(3,547,782)		(12,610,857)		(12,206,062)
Discontinued operations - net of taxes		_		_		_		37,329,963
Net (loss) income	\$	(3,549,224)	\$	(3,547,782)	\$	(12,610,857)	\$	25,123,901
Less - net income (loss) from continuing operations attributable to noncontrolling interests		972		(119,342)		(1,711)		(149,509)
Less - net loss from discontinued operations attributable to noncontrolling interests		_		_		_		(568,156)
Net (loss) income attributable to Caladrius Biosciences, Inc. common stockholders	\$	(3,550,196)	\$	(3,428,440)	\$	(12,609,146)	\$	25,841,566
Amounts attributable to Caladrius Biosciences, Inc. common stockholders:								
Loss from continuing operations		(3,550,196)		(3,428,440)		(12,609,146)		(12,056,553)
Discontinued operations - net of taxes		_		_		_		37,898,119
Net (loss) income attributable to Caladrius Biosciences, Inc. common stockholders	\$	(3,550,196)	\$	(3,428,440)	\$	(12,609,146)	\$	25,841,566
Basic and diluted (loss) income per share								
Continuing operations	\$	(0.36)	\$	(0.38)	\$	(1.31)	\$	(1.37)
Discontinued operations	\$	_	\$	_	\$	_	\$	4.30
Caladrius Biosciences, Inc. common stockholders	\$	(0.36)	\$	(0.38)	\$	(1.31)	\$	2.94
Weighted average common shares outstanding:								
Basic and diluted shares		9,744,680		9,093,880		9,633,603		8,803,784

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

	 Three Months En	ded	September 30,		Nine Months End	ded September 30,			
	2018		2017		2018		2017		
Net (loss) income	\$ (3,549,224)	\$	(3,547,782)	\$	(12,610,857)	\$	25,123,901		
Other comprehensive income (loss):									
Available for sale securities - net unrealized income (loss)	 30,103		(28,717)		(643)		(28,717)		
Total other comprehensive income (loss)	30,103		(28,717)		(643)		(28,717)		
Comprehensive (loss) income	(3,519,121)		(3,576,499)		(12,611,500)		25,095,184		
Comprehensive income (loss) attributable to noncontrolling interests	 972		(119,342)		(1,711)		(717,665)		
Comprehensive (loss) income attributable to Caladrius Biosciences, Inc. common stockholders	\$ (3,520,093)	\$	(3,457,157)	\$	(12,609,789)	\$	25,812,849		

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

		Convertible red Stock	Common	Stock	Additional		cumulated Other			Total Caladrius Biosciences, Inc.	Non- Controlling	
	Shares	Amount	Shares	Amount	Paid in Capital	Con	nprehensive Loss	Accumulated Deficit	Treasury Stock	Stockholders' Equity	Interest in Subsidiary	Total Equity
Balance at December 31, 2016	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 income	_	_	_	_	_		_	25,841,566	_	25,841,566	(717,665)	25,123,901
Unrealized loss on marketable securities	_	_	_	_	_		(28,717)	_	_	(28,717)	_	(28,717)
Share-based compensation	_	_	54,545	55	2,412,926		_	_	_	2,412,981	_	2,412,981
Net proceeds from issuance of common stock	_	_	1,162,831	1,162	5,677,470		_	_	_	5,678,632	_	5,678,632
Proceeds from option exercises	_	_	3,835	4	13,572		_	_	_	13,576	_	13,576
Elimination of equity associated with PCT sale	_	_	_	_	_		_	_	_	_	(3,686,526)	(3,686,526)
Conversion of redeemable securities	_	_	_	_	14,733,908		_	_	_	14,733,908	4,666,092	19,400,000
Change in ownership in subsidiary					(203,145)					(203,145)	203,145	
Balance at September 30, 2017	10,000	\$ 100	9,427,001	\$9,427	\$433,006,780	\$	(28,717)	\$(378,947,243)	\$(707,637)	\$53,332,710	\$ (352,383)	\$52,980,327
		Convertible red Stock	Common	Stock	Additional		cumulated Other			Total Caladrius Biosciences, Inc.	Non- Controlling	
	Shares	Amount	Shares	Amount	Paid in Capital	Con	nprehensive Loss	Accumulated Deficit	Treasury Stock	Stockholders' Equity	Interest in Subsidiary	Total Equity
Balance at December 31, 2017	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	_	_	_	_	_		_	(12,609,146)	_	(12,609,146)	(1,711)	(12,610,857)
Unrealized loss on marketable securities	_	_	_	_	_		(643)	_	_	(643)	_	(643)
Share-based compensation	_	_	126,759	127	1,878,418		_	_	_	1,878,545	_	1,878,545
Net proceeds from issuance of common stock	_	_	164,896	165	997,544		_	_	_	997,709	_	997,709
Proceeds from option exercises	_	_	77,497	77	354,663		_	_	_	354,740	_	354,740
Change in ownership in subsidiary					(47,547)					(47,547)	47,547	
Balance at September 30, 2018	10,000	\$ 100	9,853,063	\$9,853	\$436,227,287	\$	(28,621)	\$(394,419,255)	\$(707,637)	\$41,081,727	\$ (272,447)	\$40,809,280

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

	 Nine Months End	ed Sept	tember 30,
	2018		2017
Cash flows from operating activities:			
Net (loss) income	\$ (12,610,857)	\$	25,123,901
Income from discontinued operations	_		(37,329,963)
Adjustments to reconcile net (loss) income to net cash used in operating activities:			
Share-based compensation	2,281,077		1,881,712
Depreciation and amortization	207,981		284,005
(Gain) loss on disposal of assets	(1,428,762)		175,793
Accretion on marketable securities	197,485		218,755
Changes in operating assets and liabilities:			
Prepaid and other current assets	209,522		717,711
Other assets	182,218		164,788
Due to/from PCT	_		(1,681,593)
Accounts payable, accrued liabilities and other liabilities	 (5,982,395)		(5,823,272)
Net cash used in operating activities - continuing operations	(16,943,731)		(16,268,163)
Net cash used in operating activities - discontinued operations	 <u> </u>		(638,069)
Net cash used in operating activities	 (16,943,731)		(16,906,232)
Cash flows from investing activities:			
Purchase of marketable securities	(60,190,972)		(51,724,691)
Sale of marketable securities	54,134,000		7,105,603
Proceeds from CFC device sale	2,550,000		_
Net proceeds from PCT sale	_		74,689,814
Net cash sold in PCT sale	_		(6,727,263)
Acquisition of property and equipment	 (133,679)		(118,478)
Net cash (used in) provided by investing activities - continuing operations	(3,640,651)		23,224,985
Net cash used in investing activities - discontinued operations	 <u> </u>		(188,794)
Net cash (used in) provided by investing activities	 (3,640,651)		23,036,191
Cash flows from financing activities:			
Proceeds from exercise of options	354,740		13,576
Tax withholding payments on net share settlement equity awards	(402,532)		(357,665)
Net proceeds from issuance of common stock	997,709		5,678,632
Repayment of long-term debt	_		(5,651,354)
Proceeds from notes payable	_		400,998
Repayment of notes payable	 (159,180)		(764,402)
Net cash provided by (used in) financing activities - continuing operations	790,737		(680,215)
Net cash used in financing activities - discontinued operations	 <u> </u>		(74,231)
Net cash provided by (used in) financing activities	 790,737		(754,446)
Net (decrease) increase in cash, cash equivalents and restricted cash	(19,793,645)		5,375,513
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	\$ 14,374,344	\$	20,080,521
Supplemental Disclosure of Cash Flow Information:			
Cash paid during the period for:			
Interest	\$ 5,148	\$	706,231
Taxes	\$ _	\$	_

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 late-stage therapeutics development biopharmaceutical company committed to the development of innovative products that have the potential to restore the health of people with chronic illnesses. Our leadership team collectively has decades of biopharmaceutical development experience and world-recognized scientific achievement in the fields of cardiovascular and autoimmune disease, among other areas. The Company's goal is to build a broad portfolio of novel and versatile products that address important unmet medical needs. Our current product candidates include three developmental treatments for cardiovascular diseases based on our CD34 cell therapy platform: CLBS12, recipient of SAKIGAKE designation, in Phase 2 testing in Japan and eligible for early conditional approval for the treatment of critical limb ischemia; CLBS14-CMD, in Phase 2 testing for the treatment of coronary microvascular dysfunction and CLBS14-RfA in late-stage development for refractory angina for which it has received RMAT designation. Caladrius' autoimmune product candidate in Phase 2 testing, CLBS03, is an *ex vivo* expanded polyclonal T regulatory cell therapy for the treatment of recent-onset type 1 diabetes. CLBS03 has been awarded Fast Track and Orphan designations by the FDA.

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 CLBS12, our product candidate in CLI, 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") assigned CLBS12 "SAKIGAKE" designation (a Japanese regulatory status similar to "breakthrough" designation awarded by the U.S. Food and Drug Administration ("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 FDA. On June 19, 2018, the Company announced that it received regenerative medicine advanced therapy ("RMAT") designation from the FDA for CLBS14-RfA for the treatment of refractory angina. This designation affords the Company an opportunity to work with the FDA to more rapidly and efficiently advance the development of this therapeutic candidate in an indication that has no effective treatment options and high morbidity. On October 30, 2018, we met with FDA in response to our request for a Type B meeting to discuss the final development requirements for CLBS14-RfA. While multiple development paths to registration for CLBS-14RfA remain possibilities at this time, we believe that the meeting was both collaborative and positive and our assessment of the conversation is that FDA is demonstrating maximum flexibility afforded under the RMAT designation as we work together to establish the development steps necessary to bring this product to registration. We will be working with FDA to finalize the next development steps and to formalize the minutes of the October 30, 2018 meeting.

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, which study is enrolling patients at the Mayo Clinic in Rochester, MN and Cedars-Sinai Medical Center in Los Angeles, CA.

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 TID, only lifelong insulin therapy, which often does not prevent serious co-morbidities. Two independent 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 TID. 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 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. 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 September 30, 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 September 30, 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 nine months ended September 30, 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 amount of revenues and expenses during the reporting period. The Company bases its estimates on historical experience and other assumptions believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. The Company makes critical estimates and assumptions in determining stock-based awards values and income taxes. Accordingly, actual results could differ from those estimates and assumptions.

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

Principles of Consolidation

The Consolidated Financial Statements include the accounts of Caladrius Biosciences, Inc. and its wholly-owned and partially-owned subsidiaries and affiliates, 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 and nine months ended September 30, 2018.

Concentration of Risks

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

Share-Based Compensation

The Company expenses all share-based payment awards to employees, directors, and consultants, including grants of stock options, warrants, and restricted stock, over the requisite service period based on the grant date fair value of the awards. Consultant awards are remeasured each reporting period through vesting. For awards with performance-based vesting criteria, the Company estimates the probability of achievement of the performance criteria and recognizes compensation expense related to those awards

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expected to vest. The Company determines the fair value of option awards using the Black-Scholes option-pricing model, which uses both historical and current market data to estimate the fair value. This method incorporates various assumptions such as the risk-free interest rate, expected volatility, expected dividend yield and expected life of the options or warrants. The fair value of the Company's restricted stock and restricted stock units is based on the closing market price of the Company's common stock on the date of grant.

Income Taxes

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

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

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

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

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). This ASU requires that a lessee recognize lease assets and lease liabilities for those leases classified as operating leases. The guidance 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 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.

In June 2018 the FASB issued ASU No. 2018-07, "Improvements to Nonemployee Share-Based Payment Accounting", which supersedes ASC 505-50 and expands the scope of ASC 718 to include all share-based payments arrangements related to the acquisition of goods and services from both employees and nonemployees. For public companies, the amendments are effective for annual reporting periods beginning after December 15, 2018, including interim periods within those annual periods. Early adoption is permitted, but no earlier than a company's adoption date of ASC 606. The Company is currently assessing the impact that adopting this new accounting guidance will have on its financial statements and footnote disclosures.

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 was classified as restricted cash on the consolidated balance sheets as of December 31, 2017. In June 2018, the escrow agent disbursed to the Company the Escrow Amount in full. 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% was paid in May 2018 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 co-founder and 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:

• Simultaneous with the closing of the 2017 Hitachi Transaction, Caladrius would pay to Dr. Preti \$1.9 million (the "First Retention Payment").

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- 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 would 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"). In May 2018, the Second Retention Payment was paid to Dr. Preti.
- 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):

			Septemb	er 30,	2018			December 31, 2017									
	Cost	Un	Gross realized Gains	U	Gross nrealized Losses	Estimated Fair Value			Cost		Gross realized Gains	Gross Unrealized Losses			stimated air Value		
Corporate debt securities	\$ 32,409	\$	_	\$	(29)	\$	32,380	\$	42,701	\$	_	\$	(28)	\$	42,673		
Money market funds	8,316		_		_		8,316		9,212		_		_		9,212		
Total	\$ 40,725	\$	_	\$	(29)	\$	40,696	\$	51,913	\$	_	\$	(28)	\$	51,885		

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

	Septembe	er 30, 2018	Deceml	oer 31, 2017
Cash and cash equivalents	\$	8,920	\$	25,968
Marketable securities		31,776		25,917
Total	\$	40,696	\$	51,885

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

		Septembe	r 30, 2	018
	Amor	Estimated Fair Value		
Less than one year	\$	40,725	\$	40,696
Greater than one year		_		_
Total	\$	40,725	\$	40,696

Note 5 - Loss Per Share

For the three and nine months ended September 30, 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 September 30, 2018 and 2017, the Company excluded the following potentially dilutive securities:

	Septemb	ier 30,
	2018	2017
Stock Options	1,036,271	1,105,790
Warrants	48,654	218,978
Restricted Stock Units	45,248	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 September 30, 2018, and December 31, 2017 (in thousands).

				Septembe	r 30,	, 2018		December 31, 2017										
	Lev	el 1]	Level 2	1	Level 3		Total	Level 1		Level 2		Level 3			Total		
Assets:																		
Marketable securities - available for sale	\$	_	\$	31,776	\$	_	\$	31,776	\$	_	\$	25,917	\$	_	\$	25,917		
	\$		\$	31,776	\$	_	\$	31,776	\$	_	\$	25,917	\$	_	\$	25,917		

Note 7 - Accrued Liabilities

Accrued liabilities as of September 30, 2018 and December 31, 2017 were as follows (in thousands):

	S	September 30, 2018	December 31, 2017
Salaries, employee benefits and related taxes	\$	1,379	\$ 1,389
Retention payments		_	2,233
CIRM upfront funding - current		2,583	2,446
Other		483	1,743
Total	\$	4,445	\$ 7,811

Note 8 - Debt

Notes Payable

The Company's notes payable relate to certain equipment financings, require monthly payments, and mature within one year.

Note 9 – Stockholders' 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, preexisting 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 Agreement

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 provided 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 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 (limited to a maximum of 2,790,697 shares). Subject to the terms and conditions of the Sales Agreement, HCW will use its commercially reasonable efforts consistent with its normal trading and sales practices to sell the shares from time to time, based upon the Company's instructions, including any price, time or size limits specified by the Company. The Company has provided HCW with customary indemnification rights, and HCW will be entitled to a commission at a fixed commission rate equal to 3.0% of the gross proceeds per share sold. The Company has no obligation to sell any of the shares and may at any time suspend sales under the Sales Agreement or terminate the Sales Agreement. The Sales Agreement will terminate upon the sale of all of the shares under the Sales Agreement unless terminated earlier by either party as permitted under the Sales Agreement.

In August 2018, the Company entered into an amendment to the Sales Agreement to reflect that the shares will be issued pursuant to a Registration Statement on Form S-3 (Registration No. 333-226319) that was declared effective in August 2018 and that replaced the Company's previously effective shelf registration statement. In connection with the amendment, the number of shares of common stock that may be sold pursuant to the Sales Agreement was increased from an aggregate offering amount of \$12 million to \$25 million (limited to a maximum of 4,921,260 shares). All other provisions of the Sales Agreement remained unchanged. During the nine months ended September 30, 2018, the Company issued 149,041 shares of common stock under the Sales Agreement for net proceeds of \$1.0 million.

Stock Options and Warrants

The following table summarizes the activity for stock options and warrants for the nine months ended September 30, 2018:

	Stock Options						Wa	rrants			
	Shares		hted Average ercise Price	Weighted Average Remaining Contractual Term (Years)		Aggregate rinsic Value (In Thousands)	Shares	ghted Average xercise Price	Weighted Average Remaining Contractual Term (Years)	Intr	Aggregate insic Value (In l'housands)
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	156,760		4.00				_	_			
Exercised	(77,498)		4.60				_	_			
Forfeited	(3,030)		3.80				_	_			
Expired	(112,460)		33.20				(160,164)	50.30			
Outstanding at September 30, 2018	1,036,271	\$	30.50	5.46	\$	903.2	49,654	\$ 62.70	2.70	\$	0.3
Vested at September 30, 2018 or expected to vest in the future	1,021,775	\$	30.90	5.41	\$	876.4	49,654	\$ 62.70	2.70	\$	0.3
Vested at September 30, 2018	914,102	\$	34.00	4.94	\$	678.8	49,654	\$ 62.70	2.70	\$	0.3

Restricted Stock

During the nine months ended September 30, 2018 and 2017, the Company issued restricted stock for services as follows (\$ in thousands):

	Nine Months En	ided September 30,
	2018	2017
Number of restricted stock issued	91,740	132,726
Value of restricted stock issued (\$ in thousands)	\$ 348	\$ 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 and nine months ended September 30, 2018 and 2017 (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,				
		2018		2017		2018		2017
Research and development	\$	32	\$	_	\$	413	\$	208
General and administrative		135		62		1,869		1,674
Discontinued operations		_		_		_		889
Total share-based compensation expense	\$	167	\$	62	\$	2,282	\$	2,771

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 were expected to be recognized at September 30, 2018 were as follows (in thousands):

	Stock	COptions	Restrict	ed Stock
Unrecognized compensation cost	\$	685	\$	_
Expected weighted-average period in years of compensation cost to be recognized		2.57		0.00

Total fair value of shares vested and the weighted average estimated fair values of shares granted for the nine months ended September 30, 2018 and 2017 were as follows (in thousands):

		Stock Options			
	Ni	ne Months En	led Sep	tember 30,	
		2018		2017	
Total fair value of shares vested	\$	218	\$	5,002	
Weighted average estimated fair value of shares granted	\$	2.61	\$	1.72	

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.

The Company received \$5.7 million in initial funding in May 2017, a \$1.9 million milestone payment in December 2017, and \$0.3 million progress payment in March 2018, of which the total will be amortized over the estimated award period through July 2020 as a reduction to the related research and development expenses. As of September 30, 2018, \$2.6 million of the funding received was recorded in accrued liabilities, representing the amount expected to be recognized over the next 12 months, and \$2.2 million of the funding received was recorded in other long-term liabilities. During the three and nine months ended September 30, 2018, the Company amortized and recognized \$0.6 million and \$1.9 million in credits, respectively to research and development related to CIRM funds received. During the three and nine months ended September 30, 2017, the Company amortized and recognized \$0.4 million and \$0.7 million in credits, respectively 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 is available through 2036.

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

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

As of September 30, 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. In June 2018, the escrow agent disbursed to the Company the Escrow Amount in full. 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% was paid in May 2018 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):

Enimarylus of consideration received	¢	70.425
Fair value of consideration received	\$	79,425
Transaction and retention costs		(6,919)
Carrying value of segment non-controlling interest		3,687
	\$	76,193
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)
	\$	24,449
	φ.	E4 744
Gain on sale of PCT Segment	<u>\$</u>	51,744

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 nine months ended September 30, 2017 were as follows (in thousands):

	 lonths Ended aber 30, 2017
Revenue	\$ 16,039
Cost of revenues	(15,321)
Research and development	(257)
Selling, general, and administrative	(3,251)
Other expense	(16)
Provision for income taxes	(11,608)
Gain on sale of PCT Segment	51,744
Income from discontinued operations	\$ 37,330

Note 14 - Commitments and Contingencies

Lease Commitments

We lease facilities under various operating lease agreements in Basking Ridge, New Jersey, and Rye Brook, New York, each of which certain have escalation clauses and renewal options. 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 September 30, 2018 are as follows (in thousands):

Years ended	Operating Leases	
2018	\$	224
2019		906
2020		829
2021		476
2022 and thereafter		130
Total minimum lease payments	\$	2,565

Expense incurred under operating leases was approximately \$0.2 million and \$0.7 million for the three and nine months ended September 30, 2018, respectively, and \$0.3 million and \$1.1 million for the three and nine months ended September 30, 2017.

Contingencies

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

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

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Cautionary Note Regarding Forward-Looking Statements" herein and under "Risk Factors" in our 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 late-stage therapeutics development biopharmaceutical company committed to the development of innovative products that have the potential to restore the health of people with chronic illnesses. Our leadership team collectively has decades of biopharmaceutical development experience and world-recognized scientific achievement in the fields of cardiovascular and autoimmune disease, among other areas. The Company's goal is to build a broad portfolio of novel and versatile products that address important unmet medical needs. Our current product candidates include three developmental treatments for cardiovascular diseases based on our CD34 cell therapy platform: CLBS12, recipient of SAKIGAKE designation, in Phase 2 testing in Japan and eligible for early conditional approval for the treatment of critical limb ischemia; CLBS14-CMD, in Phase 2 testing for the treatment of coronary microvascular dysfunction and CLBS14-RfA in late-stage development for refractory angina for which it has received RMAT designation. Caladrius' autoimmune product candidate in Phase 2 testing, CLBS03, is an ex vivo expanded polyclonal T regulatory cell therapy for the treatment of recent-onset type 1 diabetes. CLBS03 has been awarded Fast Track and Orphan designations by the FDA.

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 CLBS12, our product candidate in CLI, 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") assigned CLBS12 "SAKIGAKE" designation (a Japanese regulatory status similar to "breakthrough" designation awarded by the U.S. Food and Drug Administration ("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 FDA. On June 19, 2018, the Company announced that it received regenerative medicine advanced therapy ("RMAT") designation from the FDA for CLBS14-RfA for the treatment of refractory angina. This designation affords the Company an opportunity to work with the FDA to more rapidly and efficiently advance the development of this therapeutic candidate in an indication that has no effective treatment options and high morbidity. On October 30, 2018, we met with FDA in response to our request for a Type B meeting to discuss the final development requirements for CLBS14-RfA. While multiple development paths to registration for CLBS-14RfA remain possibilities at this time, we believe that the meeting was collaborative and positive and our assessment of the conversation is that FDA is demonstrating maximum flexibility afforded under the RMAT designation as we work together to establish the development steps necessary to bring this product to registration. We will be working with FDA to finalize the next development steps and to formalize the minutes of the October 30, 2018 meeting.

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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, which study is enrolling patients at the Mayo Clinic in Rochester, MN and Cedars-Sinai Medical Center in Los Angeles, CA.

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 TID, only lifelong insulin therapy, which often does not prevent serious co-morbidities. Two independent 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 TID. 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 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 September 30, 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 and Nine Months Ended September 30, 2018 Compared to Three and Nine Months Ended September 30, 2017

Net losses from continuing operations were \$3.5 million and \$12.6 million for the three and nine months ended September 30, 2018, compared to net losses from continuing operations of \$3.5 million and \$12.2 million for the three and nine months ended September 30, 2017.

On May 18, 2017, the Company sold its remaining 80.1% membership interest in PCT to Hitachi, and as a result, all operations of the PCT Segment, including the gain on sale of \$51.7 million, was reported as discontinued operations. For the nine months ended September 30, 2017, income from discontinued operations was \$37.3 million.

Overall, net losses were \$3.5 million and \$12.6 million for the three and nine months ended September 30, 2018, compared to net loss of \$3.5 million for the three months ended September 30, 2017, and net income of \$25.1 million for the nine months ended September 30, 2017.

Operating Expenses

For the three months ended September 30, 2018, operating expenses totaled \$3.8 million compared to \$6.1 million for the three months ended September 30, 2017, representing a decrease of \$2.4 million, or 39%. Operating expenses were comprised of the following:

- Research and development expenses were approximately \$1.7 million for the three months ended September 30, 2018, compared to \$3.2 million for the three months ended September 30, 2017, representing a decrease of approximately \$1.5 million, or 47%.
 - Immune Modulation Immune modulation expenses primarily related to expenses associated with our Phase 2 study of CLBS03 in T1D. During the three months ended September 30, 2018, we had a net benefit of \$0.1 million, primarily due to the recognition of approximately \$0.6 million of amortization of grants received from the California Institute of Regenerative Medicine (CIRM), compared with \$2.5 million of net expense for the three months ended September 30, 2017, which included \$0.4 million of CIRM grant recognition. In December 2017, we completed enrollment in the Phase 2 study, along with all manufacturing-related costs. Our 2018 expenses reflect significantly lower expenses, along with higher CIRM grant recognition as we transition our activities into the follow-up phase of the Phase 2 study.
 - Ischemic Repair Ischemic repair expenses were \$1.8 million for the three months ended September 30, 2018, compared to \$0.7 million for the three months ended September 30, 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, (ii) the initiation of our Phase 1b/2a study for CLBS14-CMD in coronary microvascular dysfunction, and (iii) expenses associated with the planning of our CLBS14-RfA program in refractory angina.
- General and administrative expenses were approximately \$2.1 million for the three months ended September 30, 2018, compared to \$2.9 million for the three months ended September 30, 2017, representing a decrease of approximately \$0.9 million, or 30%. The decrease was due to lower G&A headcount and corporate-related activities compared with the prior year period.

For the nine months ended September 30, 2018, operating expenses totaled \$13.2 million compared to \$20.3 million for the nine months ended September 30, 2017, representing a decrease of \$7.1 million, or 35%. Operating expenses were comprised of the following:

• Research and development expenses were approximately \$6.1 million for the nine months ended September 30, 2018, compared to \$11.2 million for the nine months ended September 30, 2017, representing a decrease of approximately \$5.1 million, or 46%.

- 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 nine months ended September 30, 2018, which included \$1.9 million of CIRM grant recognition, compared to \$10.4 million for the nine months ended September 30, 2017, which included \$0.7 million of CIRM grant recognition. In December 2017, we completed enrollment in the Phase 2 study, along with all manufacturing-related costs. Our 2018 expenses reflect significantly lower expenses, along with higher CIRM grant recognition as we transition our activities into the follow-up phase of the Phase 2 study.
- *Ischemic Repair* Ischemic repair expenses were \$5.9 million for the nine months ended September 30, 2018, compared to \$1.0 million for the nine months ended September 30, 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, (ii) the initiation of our Phase 1b/2a study for CLBS14-CMD in coronary microvascular dysfunction, and (iii) expenses associated with the planning of our CLBS14-RfA program in refractory angina.
- General and administrative expenses were approximately \$7.1 million for the nine months ended September 30, 2018, compared to \$9.1 million for the nine months ended September 30, 2017, representing a decrease of approximately \$2.0 million, or 22%. The decrease was due to the sale of our CFC device in the second quarter of 2018, resulting in a gain on sale of \$1.4 million. Excluding the gain on sale of the CFC device, overall G&A expenses were lower compared with the prior year period due to general corporate-related activities.

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

Other Income (Expense)

Total other income (expense) is primarily comprised of investment income on cash and marketable securities, offset by interest expense on notes and loans payables. In May 2017, we repaid all outstanding debt to Oxford Finance LLC, resulting in significantly lower interest expense subsequent to the repayment date.

Benefit from Income Taxes

The benefit from income taxes was \$2.4 million and \$8.3 million for the three and nine months ended September 30, 2017, respectively. The Company reported both continuing and discontinued operations in 2017. ASC 740-20-45-7 addresses the income tax accounting treatment when there is a loss from continuing operations and income from discontinuing operations, whereby the Company considered the gain from discontinued operations for purposes of allocating a tax benefit to the current year loss from continuing operations. There are three acceptable methods on how a company can record its tax provision in interim periods. The Company adopted a method in which the income from discontinued operations was recognized as a discrete item in the period in which it occurred and applied the concepts of the annual effective tax rate during each period in computing the income tax provision from continuing operations. This method resulted in tax expense for discontinued operations and an income tax benefit for the loss generated from continuing operations. The Company forecasted losses from continuing operations for the remainder of 2017 against which an income tax benefit was recorded.

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 disbursed to the Company the Escrow Amount in full. 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% was paid in May 2018 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
	\$ 76,193
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)
	\$ 24,449
Gain on sale of PCT Segment	\$ 51,744

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 nine months ended September 30, 2017 were as follows (in thousands):

	Nine Months Ende September 30, 201	
Revenue	\$	16,039
Cost of revenues		(15,321)
Research and development		(257)
Selling, general, and administrative		(3,251)
Other expense		(16)
Provision for income taxes		(11,608)
Gain on sale of PCT Segment		51,744
Loss from discontinued operations	\$	37,330

Analysis of Liquidity and Capital Resources

At September 30, 2018, we had cash, cash equivalents, and marketable securities of approximately \$46.1 million, working capital of approximately \$42.4 million, and stockholders' equity of approximately \$41.1 million.

During the nine months ended September 30, 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):

	Nine Months Ended September 30,					
	2018			2017		
Net cash used in operating activities - continuing operations	\$	(16,944)	\$	(16,268)		
Net cash (used in) provided by investing activities - continuing operations		(3,641)		23,225		
Net cash provided by (used in) financing activities - continuing operations		791		(680)		

Operating Activities - Continuing Operations

Our cash used in operating activities from continuing operations during the nine months ended September 30, 2018 was \$16.9 million, which is comprised of (i) our net loss from continuing operations of \$12.6 million, adjusted for non-cash expenses totaling \$1.3 million (which includes adjustments for equity-based compensation, depreciation and amortization, gain on disposal of assets, and amortization/accretion of marketable securities), and (ii) changes in operating assets and liabilities using approximately \$5.6 million.

Our cash used in operating activities from continuing operations during the nine months ended September 30, 2017 was \$16.3 million, which is comprised of (i) our net loss from continuing operations of \$12.2 million, adjusted for non-cash expenses totaling \$2.6 million (which includes adjustments for equity-based compensation, depreciation and amortization, loss on disposal of assets and amortization/accretion of marketable securities), and (ii) changes in operating assets and liabilities providing approximately \$6.6 million.

Investing Activities - Continuing Operations

Our cash used in investing activities during the nine months ended September 30, 2018 totaled \$3.6 million, and was primarily due to \$6.1 million net purchases of net investments in marketable securities, approximately \$0.1 million for equipment purchases, and partially offset by \$2.6 million in proceeds from the sale of our CFC device.

Our cash provided by investing activities in the nine months ended September 30, 2017 totaled approximately \$23.2 million. On May 18, 2017, Hitachi paid us \$74.7 million in connection with the sale of our 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. We also invested net \$44.6 million in marketable securities, and approximately \$0.1 million for equipment purchases.

Financing Activities - Continuing Operations

Our cash used in financing activities during the nine months ended September 30, 2018 consisted of the following:

- We raised net proceeds of approximately \$1.0 million through the issuance of 149,041 shares of our common stock under the provisions of our Common Stock Sales Agreement with H.C. Wainwright.
- We raised \$0.4 million option exercise proceeds.
- We paid \$0.2 million for obligations under equipment finance leases.
- We made tax withholding-related payments on net share settlement equity awards to employees of \$0.4 million.

Our cash provided by financing activities during the nine months ended September 30, 2017 consisted of the following:

- We raised gross proceeds of \$4.4 million through the issuance of 932,204 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 \$5.7 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. Any future development of CLBS14-RfA will be the subject of the use of proceeds of a future capital raise. Similarly, any future development of CLBS12 in the USA will also be the subject of the use of proceeds of a future capital raise.

In February 2018, we entered into a common stock sales agreement (the "Sales Agreement") with H.C. Wainwright & Co., LLC ("HCW"), as sales agent, in connection with an "at the market offering" under which we from time to time may offer and sell shares of our common stock, which was further amended in August 2018, having an aggregate offering price of up to \$25 million. Subject to the terms and conditions of the Sales Agreement, HCW will use its commercially reasonable efforts consistent with its normal trading and sales practices to sell the shares from time to time, based upon our instructions, including any price, time or size limits specified by us. We have provided HCW with customary indemnification rights, and HCW will be entitled to a commission at a fixed commission rate equal to 3.0% of the gross proceeds per share sold. We have no obligation to sell any of the shares, and may at any time suspend sales under the Sales Agreement or terminate the Sales Agreement. The Sales Agreement will terminate upon the sale of all of the shares under the Sales Agreement unless terminated earlier by either party as permitted under the Sales Agreement. As of September 30, 2018, we issued 149,041 shares of common stock under the Sales Agreement for net proceeds of \$1.0 million.

In February 2017, the California Institute for Regenerative Medicine ("CIRM") awarded us funds of up to \$12.2 million to support the T-Rex Study. The funding was based upon the achievement of certain milestones related to the proportion of subjects enrolled in California, as well as manufacturing and development costs incurred in California. In March 2018, CIRM calculated the precise amount of the funding award as \$8.6 million, based on the actual number of subjects enrolled in California. We have received total funding of \$7.9 million through September 30, 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 and nine months ended September 30, 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 the controls and other procedures we have designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act") is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports that we file under the Exchange Act is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Due to the inherent limitations of control systems, not all misstatements may be detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Controls and procedures can only provide reasonable, not absolute, assurance that the above objectives have been met.

As of September 30, 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

Other than as set forth below, 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."

Because our development activities are expected to rely heavily on sensitive and personal information, an area which is highly regulated by privacy laws, we may not be able to generate, maintain or access essential patient samples or data to continue our research and development efforts in the future on reasonable terms and conditions, which may adversely affect our business.

Although we are not subject to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as we are neither a Covered Entity nor Business Associate (as defined in HIPAA and the Health Information Technology and Clinical Health Act (the "HITECH Act")), we may have access to very sensitive data regarding patients whose tissue samples are used in our studies. This data will contain information that is personal in nature. The maintenance of this data is subject to certain privacy-related laws, which impose upon us administrative and financial burdens, and litigation risks. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws govern the collection, use, disclosure and protection of health-related and other personal information. For instance, the rules promulgated by the Department of Health and Human Services under HIPAA create national standards to protect patients' medical records and other personal information in the U.S. These rules require that healthcare providers and other covered entities obtain written authorizations from patients prior to disclosing protected health care information of the patient to companies. If the patient fails to execute an authorization or the authorization fails to contain all required provisions, then we will not be allowed access to the patient's information and our research efforts can be substantially delayed. Furthermore, use of protected health information that is provided to us pursuant to a valid patient authorization is subject to the limits set forth in the authorization (i.e., for use in research and in submissions to regulatory authorities for product approvals). As such, we are required to implement policies, procedures and reasonable and appropriate security measures to protect individually identifiable health information we receive from covered entities, and to ensure such information is used only as authorized by the patient. Any violations of these rules by us could subject us to civil and criminal penalties and adverse publicity, and could harm our ability to initiate and complete clinical trials required to support regulatory applications for our product candidates. In addition, HIPAA does not replace federal, state, or other laws that may grant individuals even greater privacy protections.

International data protection laws and regulations may also apply to some or all of our clinical data obtained outside of the U.S. For example, in April 2016, the EU approved a new data protection regulation, known as the General Data Protection Regulation (the "GDPR"), which become effective in May 2018. The GDPR includes new operational requirements for companies that receive or process personal data of EU residents, as well as significant penalties for non-compliance. Complying with the GDPR may cause us to incur substantial operational costs or require us to change our business practices.

Failure to comply with data protection laws and regulations could result in government enforcement actions, which may involve civil and criminal penalties, private litigation and/or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

We can provide no assurance that future legislation will not prevent us from generating or maintaining personal data or that patients will consent to the use of their personal information, either of which may prevent us from undertaking or publishing essential research. These burdens or risks may prove too great for us to reasonably bear, and may adversely affect our ability to achieve profitability or maintain profitably in the future.

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.

By: /s/ David J. Mazzo, PhD Name: David J. Mazzo, PhD

November 8, 2018 Title: President and Chief Executive Officer

(Principal Executive Officer)

By: <u>/s/ Joseph Talamo</u> Name: Joseph Talamo

November 8, 2018

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

and Accounting Officer)

CALADRIUS BIOSCIENCES, INC. FORM 10-Q

Exhibit Index

<u>31.1</u>	*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
<u>31.2</u>	*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
<u>32.1</u>	**	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
<u>32.2</u>	**	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

^{*} 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: November 8, 2018

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

Title: President and 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: November 8, 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 September 30, 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: November 8, 2018

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

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

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

In connection with the Quarterly Report on Form 10-Q of Caladrius Biosciences, Inc. (the "Company") for the quarter ended September 30, 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: November 8, 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.