

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED September 30, 2016

OR

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

For the Transition Period from _____ to _____

Commission File Number 001-33650

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

DELAWARE
(State or other jurisdiction of
incorporation or organization)

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

106 ALLEN ROAD, FOURTH FLOOR BASKING RIDGE, NJ
(Address of principal executive offices)

07920
(zip code)

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

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

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

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

8,169,407 Shares, \$.001 Par Value, as of November 1, 2016

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

EXPLANATORY NOTE

Unless stated otherwise, the information contained in these consolidated financial statements gives retroactive effect to a one-for-ten reverse stock split of the Company's common shares effected on July 28, 2016. See Note 1 of the consolidated financial statements for further information.

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;
- our ability to integrate our acquired businesses successfully and grow such acquired businesses as anticipated, including expanding our PCT 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 and medical developments beyond our control;
- our ability to obtain and maintain, as applicable, appropriate governmental licenses, accreditations or certifications or comply with healthcare laws and regulations or any other adverse effect or limitations caused by government regulation of our business;
- whether any of our current or future patent applications result in issued patents, the scope of those patents and our ability to obtain and maintain other rights to technology required or desirable for the conduct of our business; and our ability to commercialize products without infringing the claims of third party patents;
- whether any potential strategic or financial benefits of various licensing agreements will be realized;
- the results of our development activities;
- 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;
- our ability to satisfy our obligations under our loan agreement; 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 15, 2016 (our "2015 Form 10-K").

The factors discussed herein, including those risks described in "Item 1A. Risk Factors" and elsewhere in our 2015 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.

TABLE OF CONTENTS

	Page No.
PART I- FINANCIAL INFORMATION	
Item 1. Financial Statements:	4
Consolidated Balance Sheets at September 30, 2016 and December 31, 2015	4
Consolidated Statements of Operations for the three and nine months ended September 30, 2016 and 2015	5
Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2016 and 2015	6
Consolidated Statements of Equity for the nine months ended September 30, 2016 and 2015	7
Consolidated Statements of Cash Flows for the nine months ended September 30, 2016 and 2015	8
Notes to Unaudited Consolidated Financial Statements	9
Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations	23
Item 3. Quantitative and Qualitative Disclosures About Market Risk	31
Item 4. Controls and Procedures	31
PART II- OTHER INFORMATION	
Item 1. Legal Proceedings	32
Item 1A. Risk Factors	32
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	32
Item 3. Defaults Upon Senior Securities	32
Item 4. Mine Safety Disclosures	32
Item 5. Other Information	32
Item 6. Exhibits	33
Signatures	34

PART I. FINANCIAL INFORMATION

ITEM I. FINANCIAL STATEMENTS

Item 1. Consolidated Financial Statements

CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	September 30, 2016	December 31, 2015
	(Unaudited)	(Unaudited)
ASSETS		
Current Assets		
Cash and cash equivalents	\$ 18,606,743	\$ 20,318,411
Accounts receivable, net of allowances of \$572,500 at September 30, 2016 and \$0 at December 31, 2015	4,274,800	2,566,101
Deferred costs	4,315,977	2,911,743
Prepaid expenses and other current assets	2,767,243	3,476,177
Total current assets	29,964,763	29,272,432
Property, plant and equipment, net	17,123,693	17,064,900
Goodwill	7,013,315	7,013,315
Intangible assets, net	2,450,380	2,877,880
Other assets	726,787	976,768
Total assets	\$ 57,278,938	\$ 57,205,295
LIABILITIES AND EQUITY		
Current Liabilities		
Accounts payable	\$ 3,245,779	\$ 4,107,388
Accrued liabilities	6,372,789	6,198,488
Long-term debt, current	2,319,844	4,171,456
Notes payable, current	745,234	1,192,666
Unearned revenues	5,869,586	5,345,225
Total current liabilities	18,553,232	21,015,223
Long-term Liabilities		
Deferred income taxes	1,079,948	932,662
Notes payable	224,722	583,041
Unearned revenues - long-term	4,329,950	—
Long-term debt	3,331,510	10,828,544
Other long-term liabilities	370,081	562,001
Total liabilities	\$ 27,889,443	\$ 33,921,471
Commitments and Contingencies (see Note 15)		
Redeemable Securities	19,400,000	—
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, 2016 and December 31, 2015	100	100
Common stock, \$0.001 par value, authorized 500,000,000 shares; issued and outstanding, 8,181,921 and 5,673,302 shares, at September 30, 2016 and December 31, 2015, respectively	8,182	5,673
Additional paid-in capital	410,276,001	396,547,401
Treasury stock, at cost; 10,999 shares at September 30, 2016 and December 31, 2015, respectively	(707,637)	(707,637)
Accumulated deficit	(398,830,656)	(372,132,490)
Accumulated other comprehensive income	—	486
Total Caladrius Biosciences, Inc. stockholders' equity	10,745,990	23,713,533
Noncontrolling interests	(756,495)	(429,709)
Total equity	9,989,495	23,283,824
Total liabilities and equity	\$ 57,278,938	\$ 57,205,295

*Adjusted to reflect the impact of the 1:10 reverse stock split that became effective on July 28, 2016

See accompanying notes to consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues	\$ 9,317,473	\$ 5,888,450	\$ 25,107,391	\$ 14,927,691
Costs and expenses:				
Cost of revenues	8,611,208	4,808,679	21,891,010	13,976,087
Research and development	2,630,632	6,315,613	12,534,775	20,719,989
Impairment of intangible assets	—	—	—	9,400,000
Selling, general, and administrative	4,936,486	5,147,166	16,100,696	24,971,438
Total operating costs and expenses	16,178,326	16,271,458	50,526,481	69,067,514
Operating loss	(6,860,853)	(10,383,008)	(25,419,090)	(54,139,823)
Other income (expense):				
Other income (expense), net	5,117	(410,233)	17,662	4,398,585
Interest expense	(384,915)	(552,983)	(1,671,457)	(1,651,222)
	(379,798)	(963,216)	(1,653,795)	2,747,363
Loss before provision for income taxes and noncontrolling interests	(7,240,651)	(11,346,224)	(27,072,885)	(51,392,460)
Provision (benefit) for income taxes	46,954	46,633	147,286	(3,610,097)
Net loss	(7,287,605)	(11,392,857)	(27,220,171)	(47,782,363)
Less - loss attributable to noncontrolling interests	(405,072)	(16,907)	(522,005)	(93,257)
Net loss attributable to Caladrius Biosciences, Inc. common stockholders	\$ (6,882,533)	\$ (11,375,950)	\$ (26,698,166)	\$ (47,689,106)
Basic and diluted loss per share attributable to Caladrius Biosciences, Inc. common stockholders	\$ (1.09)	\$ (2.06)	\$ (4.45)	\$ (10.40)
Weighted average common shares outstanding*	6,323,427	5,523,912	6,001,572	4,586,757

*Adjusted to reflect the impact of the 1:10 reverse stock split that became effective on July 28, 2016

See accompanying notes to consolidated financial statements.

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Net loss	\$ (7,287,605)	\$ (11,392,857)	\$ (27,220,171)	\$ (47,782,363)
Other comprehensive loss:				
Available for sale securities - net unrealized (loss) gain	—	(988)	(486)	(451)
Total other comprehensive loss	—	(988)	(486)	(451)
Comprehensive loss	(7,287,605)	(11,393,845)	(27,220,657)	(47,782,814)
Comprehensive loss attributable to noncontrolling interests	(405,072)	(16,908)	(522,005)	(93,257)
Comprehensive loss attributable to Caladrius Biosciences, Inc. common stockholders	<u>\$ (6,882,533)</u>	<u>\$ (11,376,937)</u>	<u>\$ (26,698,652)</u>	<u>\$ (47,689,557)</u>

See accompanying notes to consolidated financial statements.

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

	Series B Convertible Preferred Stock		Common Stock*		Additional Paid in Capital*	Accumulated Other Comprehensive Income	Accumulated Deficit	Treasury Stock	Total Caladrius Biosciences, Inc. Stockholders' Equity	Non-Controlling Interest in Subsidiary	Total Equity
	Shares	Amount	Shares	Amount							
Balance at December 31, 2014	10,000	\$ 100	3,678,386	\$ 3,678	\$ 350,462,009	\$ 1,329	\$(291,246,538)	\$(705,742)	\$58,514,836	\$(441,047)	\$58,073,789
Net loss	—	—	—	—	—	—	(47,689,106)	—	(47,689,106)	(93,257)	(47,782,363)
Unrealized gain/loss on marketable securities	—	—	—	—	—	(451)	—	—	(451)	—	(451)
Equity-based compensation expense	—	—	81,184	81	8,568,524	—	—	—	8,568,605	—	8,568,605
Proceeds from issuance of common stock	—	—	1,790,155	1,790	36,135,049	—	—	—	36,136,839	—	36,136,839
Change in Ownership in Subsidiary	—	—	—	—	(101,367)	—	—	—	(101,367)	101,367	—
Balance at September 30, 2015	10,000	\$ 100	5,549,725	\$ 5,549	\$ 395,064,215	\$ 878	\$(338,935,644)	\$(705,742)	\$55,429,356	\$(432,937)	\$54,996,419

	Series B Convertible Preferred Stock		Common Stock*		Additional Paid in Capital*	Accumulated Other Comprehensive Income	Accumulated Deficit	Treasury Stock	Total Caladrius Biosciences, Inc. Stockholders' Equity	Non-Controlling Interest in Subsidiary	Total Equity
	Shares	Amount	Shares	Amount							
Balance at December 31, 2015	10,000	\$ 100	5,673,302	\$ 5,673	\$ 396,547,401	\$ 486	\$(372,132,490)	\$(707,637)	\$23,713,533	\$(429,709)	\$23,283,824
Net loss	—	—	—	—	—	—	(26,698,166)	—	(26,698,166)	(522,005)	(27,220,171)
Unrealized gain/loss on marketable securities	—	—	—	—	—	(486)	—	—	(486)	—	(486)
Equity-based compensation expense	—	—	104,754	105	2,275,511	—	—	—	2,275,616	—	2,275,616
Proceeds from issuance of common stock	—	—	2,403,865	2,404	11,648,308	—	—	—	11,650,712	—	11,650,712
Change in Ownership in Subsidiary	—	—	—	—	(195,219)	—	—	—	(195,219)	195,219	—
Balance at September 30, 2016	10,000	\$ 100	8,181,921	\$ 8,182	\$ 410,276,001	\$ —	\$(398,830,656)	\$(707,637)	\$10,745,990	\$(756,495)	\$ 9,989,495

*Adjusted to reflect the impact of the 1:10 reverse stock split that became effective on July 28, 2016

See accompanying notes to consolidated financial statements.

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

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	\$ (27,220,171)	\$ (47,782,363)
Adjustments to reconcile net loss to net cash used in operating activities:		
Equity-based compensation expense	2,275,616	8,568,605
Depreciation and amortization	2,093,153	1,893,028
Change in acquisition-related contingent consideration	—	(4,380,000)
Impairment of intangible assets	—	9,400,000
Loss on disposal of assets	591,307	—
Bad debt recovery	—	(3,774)
Deferred income taxes	147,286	(3,610,097)
Accretion on marketable securities	—	77,577
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	708,935	908,011
Accounts receivable	(1,708,699)	815,231
Deferred costs	(1,404,234)	(781,629)
Unearned revenues	4,854,312	1,163,954
Other assets	249,493	53,743
Accounts payable, accrued liabilities and other liabilities	(879,228)	3,147,091
Net cash used in operating activities	<u>(20,292,230)</u>	<u>(30,530,623)</u>
Cash flows from investing activities:		
Purchase of marketable securities	—	(6,081,900)
Sale of marketable securities	—	7,734,528
Acquisition of property, plant and equipment	(2,315,753)	(2,573,784)
Net cash used in investing activities	<u>(2,315,753)</u>	<u>(921,156)</u>
Cash flows from financing activities:		
Net proceeds from issuance of common stock	11,650,712	36,136,839
Repayment of long-term debt	(9,348,646)	—
Proceeds from notes payable	368,615	1,087,361
Repayment of notes payable	(1,174,366)	(903,783)
Sale of ownership interest in subsidiary	19,400,000	—
Net cash provided by financing activities	<u>20,896,315</u>	<u>36,320,417</u>
Net (decrease) increase in cash and cash equivalents	(1,711,668)	4,868,638
Cash and cash equivalents at beginning of period	20,318,411	19,174,061
Cash and cash equivalents at end of period	<u>\$ 18,606,743</u>	<u>\$ 24,042,699</u>
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the period for:		
Interest	\$ 1,679,880	\$ 1,122,479

See accompanying notes to consolidated financial statements.

CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS****Note 1 – The Business*****Overview***

Caladrius Biosciences, Inc. (“we,” “us,” “our,” “Caladrius” or the “Company”), through its subsidiary, PCT, LLC, a Caladrius Company™ (“PCT”), is a leading provider of development and manufacturing services to the cell and cell-based gene therapy industry. PCT has significant cell therapy-specific experience and expertise, an expansive list of noteworthy clients and significant revenue growth over the past two years. Notably, PCT and Hitachi Chemical Co. America, Ltd. and Hitachi Chemical Co., Ltd. (each independently or collectively referred to herein as “Hitachi Chemical”) are engaged in a strategic collaboration to accelerate the creation of a global commercial cell therapy development and manufacturing enterprise with deep engineering expertise. Caladrius leverages both its internal specialized cell therapy clinical development expertise and PCT’s prowess to select and develop early-stage cell therapy candidates with the intention of partnering these candidates post proof-of-concept in man to both generate value for our shareholders and to expand PCT’s client base. Our current lead product candidate, CLBS03, is a T regulatory cell (“Treg”) clinical Phase 2 therapy targeting adolescents with recent-onset type 1 diabetes.

Cell Therapy Development and Manufacturing

PCT is a leading cell therapy development and manufacturing provider (often called a contract development and manufacturing organization, or “CDMO”), specializing in cell and cell-based gene therapies. PCT offers high-quality development and manufacturing capabilities (e.g., current Good Manufacturing Practice (“cGMP”) manufacturing systems and facilities), quality systems, cell and tissue processing, logistics, storage and distribution and engineering solutions (e.g., process and assay development, optimization and automation) to clients with therapeutic candidates at all stages of development. PCT produces clinical supplies and ultimately, intends also to produce commercial product for its clients. PCT has worked with over 100 clients and produced over 20,000 cell therapy products since it was founded 17 years ago. PCT’s manufacturing services are designed to reduce the capital investment and time required by clients to advance their development programs compared to conducting the process development and manufacturing in-house. PCT has demonstrated regulatory expertise, including the support of over 50 U.S. and European Union (“EU”) regulatory filings for clients and expertise across multiple cell types and therapeutic applications, including immunotherapy (e.g. CAR-T therapies), neuro/endocrine therapies, hematopoietic replacement and tissue repair/regeneration. PCT offers a complete development pathway for its clients, with services supporting preclinical through commercial phase, all underpinned by timely process optimization and automation support. We currently operate facilities qualified under cGMPs in each of Allendale, New Jersey and Mountain View, California, including EU-grade production suites. On March 11, 2016, PCT entered into a strategic collaboration and license agreement with Hitachi Chemical to accelerate the creation of a global commercial cell therapy development and manufacturing enterprise with deep engineering expertise. PCT is positioned to expand its capacity both in the United States and internationally, as needed. As the industry continues to mature and a growing number of cell therapy companies approach commercialization, we believe that PCT is well positioned to serve as an external manufacturing partner of choice for commercial-stage cell therapy companies.

CLBS03

We are developing, through the utilization of our core development and manufacturing expertise, a product candidate that is an innovative therapy for type 1 diabetes mellitus (“T1D”). This therapy is based on a proprietary platform technology for immunomodulation. We have selected as an initial target the unmet medical need of pediatric patients who are newly diagnosed with T1D. 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 T effector cells; the cells that are responsible for protecting the body from viruses and other foreign antigens. When Tregs function properly, only harmful foreign materials are attacked by T effector cells. In autoimmune disease, however, it is thought that deficient Treg activity and numbers permit the T effector cells to attack the body's own beneficial cells. In the case of T1D, there are currently no curative treatments, only lifelong insulin therapy, which often does not prevent serious co-morbidities. Two Phase 1 clinical trials of this technology in T1D patients demonstrated safety and tolerance, feasibility of manufacturing, an implied durability of effect and an early indication of efficacy 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 to evaluate the safety and efficacy of our Treg product candidate, CLBS03, in adolescents with recent onset T1D. In August 2016, we completed enrollment of the first 19 patients, and after a satisfactory evaluation of the safety of this initial cohort by our independent Data Safety Monitoring Board, we resumed the enrollment of the remaining 92 patients. A subsequent interim analysis of early therapeutic effect is planned after approximately 50% of patients reach the six-month follow-up milestone. 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 classification from the European Medicines Agency.

Additional Technology Platforms

Our broad intellectual property portfolio of cell therapy assets includes notable programs available for out-licensing and partnering in order to continue our clinical development. These include platforms using CD34 technology for ischemic repair and tumor cell/dendritic cell technology for immuno-oncology. Both have the benefit of promising Phase 2 clinical data and are applicable to multiple indications. With respect to our ischemic repair platform, the Company's Clinical Trial Notification for a pivotal Phase 2 trial investigating CLBS12 (a candidate for critical limb ischemia, or "CLI") was submitted to the Japanese Pharmaceuticals and Medical Devices Agency ("PMDA") and was cleared to proceed. The protocol design was agreed with PMDA and if successful, could provide the basis for a conditional approval under Japan's favorable regenerative medicine law. We are seeking to collaborate on CLBS12 with development and/or manufacturing partners. In January 2016, we out-licensed our CD34 technology to SPS Cardio, LLC for chronic heart failure and acute myocardial infarction (candidate CLBS10) in India and other designated territories and non-major world markets outside the United States. The immuno-oncology platform is based on our extensive intellectual property portfolio and includes CLBS20, a candidate for metastatic melanoma which was investigated in two Phase 2 trials and recently in a discontinued Phase 3 clinical trial. In February 2016, we out-licensed a cell-derived dermatological product technology for topical skin application to AiVita Biomedical, Inc. ("AiVita"), which product is distributed through ALPHAEON Corporation. Furthermore, in May 2016, we out-licensed our tumor cell/dendritic cell technology to AiVita for ovarian cancer (candidate CLBS23) for worldwide use. Finally, our Treg immune modulation platform has potential applications across multiple autoimmune and allergic diseases beyond T1D for which we are exploring partnering opportunities, including steroid-resistant asthma, multiple sclerosis, chronic obstructive pulmonary disease, inflammatory bowel disease, graft versus host disease, lupus and rheumatoid arthritis.

Our long-term strategy focuses on advancing cell-based therapies to the market and assisting patients suffering from life-threatening medical conditions. Coupling our clinical development expertise with our process development and manufacturing capabilities, we believe we are positioned to realize potentially meaningful value increases within our own proprietary pipeline based on demonstration of proof-of-concept in man as well as process and manufacturing advancements.

Financial Information & Liquidity

On March 11, 2016, PCT and Caladrius entered into a global licensing, development and equity collaboration with Hitachi Chemical, a Japanese-based global conglomerate with a growing franchise in life sciences including regenerative medicine ("Hitachi Transaction"), including a commitment to receive an aggregate of \$25.0 million in cash, of which \$22.5 million was received in March 2016, \$1.25 million was received in June 2016, and the remainder is expected to be received before the end of 2016. PCT will retain \$10.0 million of the \$25.0 million proceeds, and Caladrius received \$15.0 million of the proceeds. Concurrent with the Hitachi Transaction, Caladrius used \$7.0 million of the proceeds to repay a portion of its outstanding loan with Oxford Finance.

On September 14, 2016, the Company entered into a securities purchase agreement with a single institutional investor (the "Purchaser"), pursuant to which the Company issued and sold to the Purchaser, in a registered direct offering, an aggregate of 0.8 million shares of the Company's common stock at a purchase price of \$4.72 per share. The gross proceeds to the Company from the registered direct offering of the shares of common stock were \$4.0 million.

In concurrent private placements, on September 14, 2016, the Company entered into Securities Purchase Agreements (each a "Private Placement Purchase Agreement" and, collectively, the "Private Placement Purchase Agreements") with certain accredited investors (the "Investors") with whom it had a substantive, pre-existing relationship, including certain existing stockholders, for the sale by the Company of an aggregate of 4.4 million shares of its common stock, at a purchase price of \$4.72 per share. The investments will be placed in two tranches: (i) \$12.6 million upon an initial closing (the "Initial Closing"), and (ii) \$8.4 million, subject to certain conditions, including the enrollment of 70 subjects in the Company's Phase 2 CLBS03 clinical trial, in a second closing (the "Second Closing"). As of September 30, 2016, \$6.6 million of the Initial Closing tranche was received, and 1.4 million shares of common stock had been issued. Based on management's expectations, the remaining \$6.0 million of the Initial Closing tranche is expected to be received in the fourth quarter of 2016, and 1.3 million shares of common stock will then be issued.

In September 2016, the Company used \$3.0 million of the proceeds to repay a portion of its outstanding loan from Oxford Finance.

The Company anticipates requiring additional capital in order to grow the PCT business, to fund the development of CLBS03, to fund other operating expenses and to make principal and interest payments on the loan with Oxford Finance. To meet its short and long term liquidity needs, the Company currently expects to use existing cash and cash equivalents balances, additional cash to be raised through the Private Placement Purchase Agreements, revenue generating activities and a variety of other means, including its common stock purchase agreements with Aspire Capital. 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. In addition, the Company will continue to seek appropriate grants for scientific and clinical studies from various governmental agencies and foundations. While the Company continues 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. If the Company is unable to access capital necessary to meet its long-term liquidity needs, it may have to delay or discontinue the development of CLBS03 and/or the expansion of its business or raise funds on terms that the Company currently consider unfavorable. The Company's inability to raise additional capital would also raise substantial doubt about the Company's ability to continue as a going concern for a reasonable period of time. These unaudited consolidated financial statements have been prepared on a going concern basis and, as such, do not include any adjustments that might result from the outcome of this uncertainty that might be necessary should the Company be unable to continue as a going concern.

On July 28, 2016, the Company implemented a one-for-ten reverse split of its issued and outstanding shares of common stock (the "Reverse Stock Split"), as authorized at the annual meeting of stockholders on June 22, 2016. The Reverse Stock Split became effective on July 27, 2016 at 5:00 pm and the common stock of the Company began trading on The NASDAQ Capital Market on a post-split basis at the open of business on July 28, 2016. As of July 28, 2016, every ten shares of the Company's issued and outstanding common stock were combined into one share of its common stock, except to the extent that the Reverse Stock Split resulted in any of the Company's stockholders owning a fractional share, which was rounded up to the next highest whole share. In connection with the Reverse Stock Split, there was no change in the nominal par value per share of \$0.001. The Reverse Stock Split was effectuated in order to increase the per share trading price of the Company's common stock to satisfy the \$1.00 minimum bid price requirement for continued listing on The NASDAQ Capital Market. By letter dated August 11, 2016, The NASDAQ Capital Market, Listing Qualification Department, confirmed that the Company's common stock was in compliance with listing requirements.

All share and per share amounts of common stock, options and warrants in the accompanying financial statements have been restated for all periods to give retroactive effect to the Reverse Stock Split. Accordingly, the consolidated statements of equity reflect the impact of the Reverse Stock Split by reclassifying from "common stock" to "Additional paid-in capital" in an amount equal to the par value of the decreased shares resulting from the Reverse Stock Split.

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, 2016 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, 2015, 2014 and 2013 included in our 2015 Form 10-K. Operating results for the nine months ended September 30, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements. Estimates also affect the reported amounts of revenues and expenses during the reporting period. The Company bases its estimates on historical experience and other assumptions believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. The Company makes critical estimates and assumptions in determining the fair values of goodwill for potential goodwill impairments, useful lives of our tangible long lived assets, allowances for doubtful accounts, and stock-based awards values. 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 listed below. All intercompany activities have been eliminated in consolidation.

Entity	Percentage of Ownership	Location
Caladrius Biosciences, Inc.	100%	United States of America
Amorcyte, LLC	100%	United States of America
PCT, LLC, a Caladrius Company (1)	80.1%	United States of America
NeoStem Family Storage, LLC (1)	80.1%	United States of America
Athelos Corporation (2)	98.2%	United States of America
PCT Allendale, LLC (1)	80.1%	United States of America
NeoStem Oncology, LLC	100%	United States of America

(1) As of September 30, 2016, Hitachi's ownership interest was 19.9% (see Note 3).

(2) As of September 30, 2016, Becton Dickinson's ownership interest was 1.8%.

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 2015 Form 10-K. There were no changes to these policies during the nine months ended September 30, 2016.

Concentration of Risks

We are subject to credit risk from our portfolio of cash and 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.

We are also subject to credit risk from our accounts receivable related to our services. The majority of our trade accounts receivable arises from services in the United States.

For the nine months ended September 30, 2016, the 3 largest customers represented 43% of total revenues recognized, the largest of which was 18%. As of September 30, 2016, 3 customers represented 37% of our accounts receivable, the largest of which was 15%.

Share-Based Compensation

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

Goodwill

Goodwill is the excess of purchase price over the fair value of identified net assets of businesses acquired. The Company reviews goodwill at least annually, or at the time a triggering event is identified for possible impairment. Goodwill is reviewed for possible impairment between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of the reporting unit below its carrying value. The Company tests its goodwill each year on December 31. The Company reviews the carrying value of goodwill utilizing an income approach model, and, where appropriate, a market value approach is also utilized to supplement the discounted cash flow model. The Company makes assumptions regarding estimated future cash flows, discount rates, long-term growth rates and market values to determine each reporting unit's estimated fair value. If these estimates or related assumptions change in the future, the Company may be required to record impairment charges. In accordance with its accounting policy, the Company tested goodwill for impairment as of December 31, 2015 and June 30, 2015 and determined as of December 31, 2015 goodwill valued at \$18.2 million related to the Company's Research and Development reporting unit was impaired.

Definite-Lived Intangible Assets

Definite-lived intangible assets consist of customer lists, manufacturing technology, tradenames, patents and rights. These intangible assets are amortized on a straight line basis over their respective useful lives. The Company reviews definite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset exceeds the fair value of the asset. If other events or changes in circumstances indicate that the carrying amount of an asset that the Company expects to hold and use may not be recoverable, the Company will estimate the undiscounted future cash flows expected to result from the use of the asset and/or its eventual disposition, and recognize an impairment loss, if any. The impairment loss, if determined to be necessary, would be measured as the amount by which the carrying amount of the assets exceeds the fair value of the assets. No triggering events were noted in the quarter ended September 30, 2016 that would require interim impairment assessment.

Revenue Recognition

Clinical Services: The Company recognizes revenue for its (i) process development and (ii) clinical manufacturing services based on the terms of individual contracts.

We recognize revenues when all of the following conditions are met:

- persuasive evidence of an arrangement exists;
- delivery has occurred or the services have been rendered;
- the fee is fixed or determinable; and
- collection is probable.

The Company considers signed contracts as evidence of an arrangement. The Company assesses whether the fee is fixed or determinable based on the payment terms associated with the transaction and whether the payment terms are subject to refund or adjustment. The Company assesses cash collectability based on a number of factors, including past collection history with the client and the client's creditworthiness. If the Company determines that collectability is not reasonably assured, it defers revenue recognition until collectability becomes reasonably assured, which is generally upon receipt of the cash. The Company's arrangements are generally non-cancellable, though clients typically have the right to terminate their agreement for cause if the Company materially fails to perform.

Revenues associated with process development services generally contain multiple stages that do not have stand-alone values and are dependent upon one another, and are recognized as revenue on a completed contract basis. Progress billings collected prior to contract completion are recorded as unearned revenue until such time the contract is completed, which usually requires formal client acceptance.

Clinical manufacturing services are generally distinct arrangements whereby the Company is paid for time and materials or for fixed monthly amounts. Revenue is recognized when contractual terms have been met.

Some client agreements include multiple elements, comprised of cell process development and cell manufacturing services. The Company believes that process development and clinical manufacturing services each have stand-alone value because these services can be provided separately by other companies. In accordance with ASC Update No. 2009-13, "Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements," the Company (1) separates deliverables into separate units of accounting when deliverables are sold in a bundled arrangement and (2) allocates the arrangement's consideration to each unit in the arrangement based on its relative selling price.

Clinical Services Reimbursements: The Company separately charges the customers for the expenses associated with certain consumable resources (reimbursable expenses) that are specified in each clinical services contract. On a monthly basis, the Company bills customers for reimbursable expenses and immediately recognizes these billings as revenue, as the revenue is deemed earned as reimbursable expenses are incurred. For the three months ended September 30, 2016 and 2015, clinical services reimbursements were \$1.6 million and \$0.9 million, respectively. For the nine months ended September 30, 2016 and 2015, clinical services reimbursements were \$5.0 million and \$2.3 million, respectively.

Processing and Storage Services: The Company recognizes revenue related to the collection and cryopreservation of autologous adult stem cells when the cryopreservation process is completed which is approximately twenty-four hours after cells have been collected. Revenue related to advance payments of storage fees is recognized ratably over the period covered by the advance payments.

License Fees: PCT and Hitachi Chemical also entered into an exclusive license agreement for Asia pursuant to which PCT will receive \$5.6 million from Hitachi Chemical in three fee driven payments throughout 2016. PCT licensed to Hitachi Chemical certain cell therapy technology and know-how (including an exclusive license to use the PCT brand in Asia) and agreed to provide Hitachi Chemical with certain training and support. As additional consideration, Hitachi Chemical will pay PCT royalties on contract revenue generated in Asia for a minimum of ten years. The initial term of the License Agreement is ten years and may be automatically extended for successive additional two year terms. The Company recognizes the payments as revenue on a straight-line basis over the initial ten-year term. PCT has received \$4.4 million under the Technology License Agreement through September 30, 2016. For the three and nine months ended September 30, 2016, the Company recognized \$0.11 million and \$0.2 million of license fee revenue, respectively. As of September 30, 2016, \$0.4 million of Hitachi license fees were included in unearned revenue, and \$4.3 million was included in unearned revenue - long-term.

Recently Issued Accounting Pronouncement

In May 2014, the FASB issued Accounting Standards Update ("ASU") 2014-09, "Revenue from Contracts with Customers (Topic 606)." The new revenue recognition standard provides a five-step analysis to determine when and how revenue is recognized. The standard requires that a company recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. This ASU is effective for annual periods beginning after December 15, 2017 and will be applied retrospectively to each period presented or as a cumulative-effect adjustment as of the date of adoption. The Company is currently evaluating the impact of the pending adoption of ASU 2014-09 on its consolidated financial statements.

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 is effective for interim and annual periods beginning after December 15, 2016, with early adoption permitted. The guidance will be applied prospectively, retrospectively, or by means of a cumulative-effect adjustment to equity as of the beginning of the period in which the guidance is adopted, dependent upon the specific amendment that is adopted within the ASU. The Company is currently evaluating the effect that adopting this new guidance will have 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 is effective in first quarter of fiscal 2018 and earlier adoption is permitted. The Company is currently evaluating the effect that the updated standard will have on the consolidated financial statements and related disclosures.

In October 2016, the FASB issued ASU 2016-16, Intra-Entity Transfers of Assets Other Than Inventory. ASU 2016-16 requires the income tax consequences of intra-entity transfers of assets other than inventory to be recognized as current period income tax expense or benefit at the transaction date and removes the option to defer and amortize the consolidated tax consequences of intra-

entity transfers. The new standard will be effective on January 1, 2018 and will be adopted using a modified retrospective approach which requires a cumulative effect adjustment to retained earnings as of the beginning of the period of adoption. Early adoption is permitted at the beginning of a fiscal year. The Company is currently evaluating the effect that the updated standard will have on the consolidated financial statements and related disclosures.

Note 3 – Collaboration and License Agreement

Hitachi

On March 11, 2016, PCT entered into a global collaboration that includes licensing, development and equity components with Hitachi Chemical to develop our PCT business outside of the United States. This collaboration consists of an equity investment in and a license agreement with PCT.

Under the equity investment agreement, Hitachi Chemical 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. Caladrius remains the majority shareholder retaining an 80.1% ownership interest.

PCT and Hitachi Chemical 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 will receive \$5.6 million from Hitachi Chemical in three fee-driven payments throughout 2016, \$4.4 million of which has been received as of September 30, 2016 and the remainder of which is expected to be received before the end of 2016. PCT licensed certain cell therapy technology and know-how (including an exclusive license in Asia) and agreed to provide Hitachi Chemical with certain training and support. As additional consideration, Hitachi Chemical will pay PCT royalties on contract revenue generated in Asia for a minimum of ten years.

Lastly, as part of the transaction, PCT and Hitachi Chemical agreed to explore the possibility of pursuing a collaboration in cell therapy contract development and manufacturing in Europe.

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):

	September 30, 2016				December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Certificate of deposits	\$ —	\$ —	\$ —	\$ —	\$ 249.0	\$ —	\$ —	\$ 249.0
Corporate debt securities	—	—	—	—	1,047.2	—	—	1,047.2
Money market funds	2,562.9	—	—	2,562.9	837.7	—	—	837.7
Municipal debt securities	1,829.0	—	(0.5)	1,828.5	4,740.9	0.8	—	4,741.7
Total	\$ 4,391.9	\$ —	\$ (0.5)	\$ 4,391.4	\$ 6,874.8	\$ 0.8	\$ —	\$ 6,875.6

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

	September 30, 2016	December 31, 2015
Cash and cash equivalents	\$ 4,391.4	\$ 6,875.6
Marketable securities	—	—
Total	\$ 4,391.4	\$ 6,875.6

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

	September 30, 2016	
	Amortized Cost	Estimated Fair Value
Less than one year	\$ 4,391.9	\$ 4,391.4
Greater than one year	—	—
Total	\$ 4,391.9	\$ 4,391.4

Note 5 – Deferred Costs

Deferred costs, representing work in process for costs incurred on process development contracts that have not been completed, were \$4.3 million and \$2.9 million as of September 30, 2016 and December 31, 2015, respectively. The Company also has deferred revenue of approximately \$4.9 million and \$4.9 million of advance billings received as of September 30, 2016 and December 31, 2015, respectively, related to these contracts.

Note 6 – Loss Per Share

For the three and nine months ended September 30, 2016 and 2015, the Company incurred net losses and therefore no common stock equivalents were utilized in the calculation of loss per share as they are anti-dilutive. At September 30, 2016 and 2015, the Company excluded the following potentially dilutive securities:

	September 30	
	2016	2015
Stock Options	942,129	661,148
Warrants	362,650	351,645
Restricted Shares	61,456	11,358

Note 7 – 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 Company had no financial assets and liabilities that were accounted for at fair value on a recurring basis as of September 30, 2016, and December 31, 2015.

Note 8 – Goodwill and Other Intangible Assets

The Company's goodwill was \$7.0 million as of September 30, 2016 and December 31, 2015. All goodwill resides in the PCT reporting unit.

The Company's intangible assets and related accumulated amortization as of September 30, 2016 and December 31, 2015 consisted of the following (in thousands):

	Useful Life	September 30, 2016			December 31, 2015		
		Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Customer list	10 years	\$ 1,000.0	\$ (570.1)	\$ 429.9	\$ 1,000.0	\$ (495.1)	\$ 504.9
Manufacturing technology	10 years	3,900.0	(2,223.4)	1,676.6	3,900.0	(1,930.9)	1,969.1
Tradenname	10 years	800.0	(456.1)	343.9	800.0	(396.1)	403.9
Total Intangible Assets		\$ 5,700.0	\$ (3,249.6)	\$ 2,450.4	\$ 5,700.0	\$ (2,822.1)	\$ 2,877.9

Total intangible amortization expense was classified in the operating expense categories for the periods included below as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Cost of revenue	\$ 78.5	\$ 79.2	\$ 235.8	\$ 229.7
Research and development	19.0	27.1	56.7	89.2
Selling, general and administrative	45.0	45.0	135.0	135.0
Total	\$ 142.5	\$ 151.3	\$ 427.5	\$ 453.9

Estimated intangible amortization expense for the succeeding five years is as follows (in thousands):

2016	\$ 142.5
2017	570.0
2018	570.0
2019	570.0
2020	570.0
Thereafter	27.9
Total	\$ 2,450.4

Note 9 – Accrued Liabilities

Accrued liabilities as of September 30, 2016 and December 31, 2015 were as follows (in thousands):

	September 30, 2016	December 31, 2015
Salaries, employee benefits and related taxes	\$ 4,093.0	\$ 2,771.2
Professional fees	376.7	480.7
Other	1,903.1	2,946.5
Total	\$ 6,372.8	\$ 6,198.4

Note 10 – Debt

Notes Payable

As of September 30, 2016 and December 31, 2015, the Company had notes payable of approximately \$1.0 million and \$1.8 million, respectively. The notes relate to certain insurance policies and equipment financings, require monthly payments, and mature within one to three years.

Long-Term Debt

On September 26, 2014, the Company entered into a loan and security agreement (the “Loan and Security Agreement”)

with Oxford Finance LLC (together with its successors and assigns, the "Lender") pursuant to which the Lender disbursed \$15.0 million (the "Loan"). The debt offering/issuance costs have been recorded as debt issuance costs in other assets in the consolidated balance sheet, and will be amortized to interest expense throughout the life of the Loan using the effective interest rate method.

On March 11, 2016, upon execution of the Hitachi Transaction, the Company and the Lender entered into an amendment to the Loan and Security Agreement whereby (i) the Company paid \$7.0 million to Lender, comprising principal, interest and early termination fees, (ii) the Company's subsidiaries PCT, PCT Allendale, LLC, and NeoStem Family Storage, LLC (collectively the "Removed Borrowers") were removed as borrowers under the Loan, (iii) Lender's security interests in any and all assets of the Removed Borrowers were released, (iv) the interest only period on the remaining outstanding Loan balance was extended until January 1, 2017, and (v) in the event the Company received gross proceeds from the sale or issuance of any equity securities or subordinated debt, or any partnership, licenses, collaboration, dividend, grant or asset sale through March 31, 2017, 20% of such proceeds will be paid to Lender, up to a \$3.0 million maximum as additional partial repayment of Loan. On September 14, 2016, concurrent with the Company's September 2016 Registered Direct Offering and Concurrent Private Placement, the Company repaid \$3.0 million of such proceeds to the Lender. The outstanding balance was approximately \$5.7 million and \$15.0 million at September 30, 2016 and December 31, 2015, respectively, of which \$2.3 million is payable within twelve months as of September 30, 2016.

The Company is making interest-only payments on the outstanding amount of the Loan on a monthly basis at a rate of 8.50% per annum. Commencing on January 1, 2017, the Company will make 21 consecutive monthly payments of principal and interest. The Loan matures on September 1, 2018. At its option, the Company may prepay all amounts owed under the Loan and Security Agreement (including all accrued and unpaid interest), subject to a prepayment fee that is determined based on the date the loan is prepaid. The Company is also required to pay Lender a final payment fee equal to 8% of the Loan. The final payment fee will be amortized to interest expense throughout the life of the Loan using the effective interest rate method. The Company paid a facility fee in the amount of \$100,000 in connection with the Loan.

Under the Loan and Security Agreement, the Lender holds a security interest ("Lenders' Security Interest") in all of the Company's property, excluding the security interests in any and all assets of the Removed Borrowers, and excluding intellectual property and certain other assets and exemptions. The Lender also holds a security interest in the shares owned by the Company in the Company's subsidiaries. The Loan and Security Agreement restricts the ability of the Company to: (a) convey, lease, sell, transfer or otherwise dispose of any part of Lenders' Security Interest and (b) incur any additional indebtedness. The Loan and Security Agreement provides for standard indemnification of Lender and contains representations, warranties and certain covenants of the Company. Upon the occurrence of an event of default by the Company under the Loan and Security Agreement, Lender will have customary acceleration, collection and foreclosure remedies. There are no financial covenants associated to the Loan and Security Agreement. As of September 30, 2016, the Company was in compliance with all covenants under the Loan and Security Agreement.

Estimated future principal payments, interest, and fees due under the Loan and Security Agreement are as follows:

Years Ending December 31,	(in millions)
2016	\$ 0.1
2017	3.5
2018	3.1
Total	<u>\$ 6.7</u>

During the three and nine months ended September 30, 2016, the Company recognized \$0.2 million and \$0.7 million of interest expense, respectively, related to the Loan and Security Agreement. During the three and nine months ended September 30, 2015, the Company recognized \$0.3 million and \$1.0 million of interest expense, respectively, related to the Loan and Security Agreement.

Note 11 – Redeemable Securities

Under the Hitachi Transaction (see Note 3), Hitachi may, at any time following the 10th anniversary of the Hitachi Transaction closing date on March 11, 2016, have the right on one occasion to require Caladrius or PCT to purchase all or some of the equity securities in PCT then held by Hitachi ("Hitachi Put Right") for an amount equal to the lower of (i) the fair market value of the Hitachi equity holdings and (ii) the original purchase price paid of \$19.4 million on March 11, 2016 for its 19.9% ownership interest, plus interest at a rate of 2.0% per annum compounded annually; *provided, however*, that if Hitachi ownership interests increases subsequent to its initial ownership interest, and it offers to sell its equity holdings in excess of 21% of PCT's outstanding

equity securities, then the Company shall be required to purchase all such equity holdings of Hitachi but in no event shall the aggregate purchase price of such Hitachi equity holdings exceed \$20.5 million plus interest at the rate of 2.0% per annum compounded annually.

Since Hitachi has the right to deliver the equity interests in PCT it holds in exchange for cash from Caladrius or PCT, the initial \$19.4 million value of the non-controlling interest is considered redeemable equity, requiring it to be treated as mezzanine equity. Redeemable non-controlling interest is required to be initially measured at the initial carrying amount. If the non-controlling interest is not currently redeemable and also not probable of becoming redeemable (e.g., it is not probable a contingency that triggers redemption will be met), the non-controlling interest should be classified in mezzanine equity.

Note 12 – Shareholders' Equity

Reverse Stock Split

On July 28, 2016, the Company implemented the Reverse Stock Split, as authorized at the annual meeting of stockholders on June 22, 2016 and unanimously approved by the Company's board of directors on July 22, 2016. The Reverse Stock Split became effective on July 27, 2016 at 5:00pm and the common stock of the Company began trading on The NASDAQ Capital Market on a post-split basis at the open of business on July 28, 2016. As of July 28, 2016, every ten shares of the Company's issued and outstanding common stock were combined into one share of its common stock, except to the extent that the Reverse Stock Split resulted in any of the Company's stockholders owning a fractional share, which was rounded up to the next highest whole share. In connection with the Reverse Stock Split, there was no change in the nominal par value per share of \$0.001.

All share and per share amounts of common stock, options and warrants in the accompanying financial statements have been restated for all periods to give retroactive effect to the Reverse Stock Split. Accordingly, the consolidated statements of equity reflect the impact of the Reverse Stock Split by reclassifying from "common stock" to "Additional paid-in capital" in an amount equal to the par value of the decreased shares resulting from the Reverse Stock Split.

Equity Issuances

March 2016 Private Placement

On March 10, 2016, the Company entered into a securities purchase agreement with certain investors, pursuant to which the Company issued and sold in a private placement an aggregate of 141,844 shares of common stock and two-year warrants to purchase up to an aggregate of 141,844 shares of the Company's common stock, at an exercise price of \$10.00 per share. The unit purchase price for a share of the Company's common stock and warrant to purchase one share of the Company's common stock was \$7.05 per unit, with \$1.0 million of gross proceeds received by the Company. On April 8, 2016, the Company filed a registration statement on Form S-3 to register the shares of common stock and the shares of common stock issuable upon exercise of the warrants acquired in the private placement, which registration statement became effective on June 7, 2016.

September 2016 Registered Direct Offering and Concurrent Private Placement

On September 14, 2016, the Company entered into a securities purchase agreement (the "RD Purchase Agreement") with a single institutional investor (the "Purchaser"), pursuant to which the Company issued and sold to the Purchaser, in a registered direct offering, an aggregate of 847,458 shares of the Company's common stock at a purchase price of \$4.72 per share. The gross proceeds to the Company from the registered direct offering of the shares of common stock were \$4.0 million.

In concurrent private placements, on September 14, 2016, the Company entered into Securities Purchase Agreements (each a "Private Placement Purchase Agreement" and, collectively, the "Private Placement Purchase Agreements") with certain accredited investors (the "Investors") with whom it had a substantive, pre-existing relationship, including certain existing stockholders, for the sale by the Company of an aggregate of 4,449,153 shares of Common Stock, at a purchase price of \$4.72 per share. The investments will be placed in two tranches: (i) \$12.6 million upon an initial closing (the "Initial Closing"), and (ii) \$8.4 million, subject to certain conditions, including the enrollment of 70 subjects in the Company's Phase 2 CLBS03 clinical trial, in a second closing (the "Second Closing"). As of September 30, 2016, \$6.6 million of the Initial Closing tranche was received, and 1,398,305 shares of common stock had been issued. Based on management's expectations, the remaining \$6.0 million of the Initial Closing tranche is expected to be received in the fourth quarter of 2016, and 1,271,186 shares of common stock will then be issued.

Aspire Purchase Agreements

In November 2015, the Company entered into a common stock purchase agreement (the "Purchase Agreement") with Aspire Capital Fund, LLC, an Illinois limited liability company ("Aspire Capital"), which provides that, subject to certain terms and conditions, Aspire Capital is 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 is obtained or certain minimum sale price levels are reached) of the Company's common stock over a 24-month term. As consideration for entering into the Purchase Agreement, the Company issued 84,270 shares of its common stock to Aspire Capital. During the nine months ended September 30, 2016, the Company issued 5,000 shares of common stock under the Purchase Agreement for gross proceeds of \$0.03 million. Overall, as of September 30, 2016, the Company has issued 109,270 shares under the Purchase Agreement for gross proceeds of \$0.3 million.

Under the Purchase Agreement, at the Company's discretion, it may present Aspire Capital with purchase notices from time to time to purchase the Company's common stock, provided certain price, trading volume and conditions, including NASDAQ's trading requirements, are met. The purchase price for the shares of common stock is based upon one of two formulas set forth in the Purchase Agreement depending on the type of purchase notice the Company submits to Aspire Capital, and is based on market prices of the Company's common stock (in the case of regular purchases) or a discount of 5% applied to volume weighted average prices (in the case of VWAP purchases), in each case as determined by parameters defined in the Purchase Agreements. We have filed a registration statement with the SEC and a related prospectus supplement that covers the offering of shares of our common stock subject to the Purchase Agreement, and therefore can initiate sales to Aspire Capital at any time, subject to the limitation discussed above.

We are party to one other existing agreement with Aspire Capital (the "May 2015 Purchase Agreement"). The registration statement we previously filed with the SEC to cover offerings of shares of our common stock subject to the May 2015 Purchase Agreement has expired, and we have not, and currently have no intention to include such shares in a registration statement filed with the SEC. Unless and until we include such shares in a registration statement filed with the SEC, we are unable to initiate sales to Aspire under the May 2015 Purchase Agreement. Under the May 2015 Purchase Agreement, Aspire Capital is committed to purchase up to an aggregate of \$30 million of shares. As consideration for entering into the May 2015 Purchase Agreement, the Company issued 36,484 shares of its common stock to Aspire Capital. The Company has not issued any additional shares under the May 2015 Purchase Agreement.

Stock Options and Warrants

The following table summarizes the activity for stock options and warrants for the nine months ended September 30, 2016, as adjusted for the Reverse Stock Split:

	Stock Options				Warrants			
	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (In Thousands)	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (In Thousands)
Outstanding at December 31, 2015	666,348	\$ 64.60	6.88	\$ 0.1	321,404	\$ 137.20	1.26	\$ —
Changes during the period:								
Granted	448,365	5.30			141,845	10.00		
Exercised	—	—			—	—		
Forfeited	(61,983)	34.20			—	—		
Expired	(110,601)	45.90			(100,850)	145.10		
Outstanding at September 30, 2016	942,129	\$ 40.90	7.95	\$ 0.2	362,399	\$ 85.40	1.08	\$ —
Vested at September 30, 2016 or expected to vest in the future	938,964	\$ 41.10	7.93	\$ 0.2	362,399	\$ 85.40	1.08	\$ —
Vested at September 30, 2016	761,371	\$ 47.30	7.65	\$ —	362,650	\$ 85.40	1.08	\$ —

Restricted Stock

During the nine months ended September 30, 2016 and 2015, the Company issued restricted stock for services as follows (in thousands, except share data):

	<u>Nine Months Ended September 30,</u>	
	<u>2016</u>	<u>2015</u>
Number of Restricted Stock Issued	107,719	81,184
Value of Restricted Stock Issued	\$ 651.7	\$ 2,367.5

The weighted average estimated fair value of restricted stock issued for services in the nine months ended September 30, 2016 and 2015 was \$6.05 and \$29.16 per share, respectively. The fair value of the restricted stock was determined using the Company's closing stock price on the date of issuance, as adjusted for the Reverse Stock Split.

Note 13 – Share-Based Compensation

Share-based Compensation

We utilize share-based compensation in the form of stock options, warrants and restricted stock. The following table summarizes the components of share-based compensation expense for the three and nine months ended September 30, 2016 and 2015 (in thousands):

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Cost of goods sold	\$ 11.7	\$ 14.4	\$ 306.3	\$ 509.5
Research and development	6.0	115.9	298.3	1,642.8
Selling, general and administrative	317.8	306.2	1,671.0	6,416.2
Total share-based compensation expense	\$ 335.5	\$ 436.5	\$ 2,275.6	\$ 8,568.5

Total compensation cost related to nonvested awards not yet recognized and the weighted-average periods over which the awards are expected to be recognized at September 30, 2016 were as follows (in thousands):

	<u>Stock Options</u>	<u>Restricted Stock</u>
Unrecognized compensation cost	\$ 2,178.3	\$ 454.0
Expected weighted-average period in years of compensation cost to be recognized	1.29	1.87

Total fair value of shares vested and the weighted average estimated fair values of shares granted for the nine months ended September 30, 2016 and 2015 were as follows, as adjusted for the Reverse Stock Split (in thousands):

	<u>Stock Options</u>	
	<u>Nine Months Ended September 30,</u>	
	<u>2016</u>	<u>2015</u>
Total fair value of shares vested	\$ 2,189.4	\$ 5,303.9
Weighted average estimated fair value of shares granted	\$ 3.25	\$ 21.03

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 14 – Income Taxes

As of December 31, 2015, the Company had approximately \$221.5 million of Federal net operating loss carryforwards ("NOLs") available to offset future taxable income expiring from 2025 through 2035. In accordance with Section 382 of the Internal Revenue code, the usage of the Company's NOLs could be limited in the event of a change in ownership. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period when those temporary

differences become deductible. If a change of ownership did occur there would be an annual limitation on the usage of the Company's losses which are available through 2035.

In assessing the ability to realize deferred tax assets, including the 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 the Company's ability to generate taxable income remains uncertain at this time.

Deferred tax liabilities were \$1.1 million and \$0.9 million as of September 30, 2016 and December 31, 2015, respectively, and relate to the taxable temporary differences on the goodwill recognized in the PCT acquisition in 2011. The taxable temporary differences, which are tax deductible and will be amortized over 15 years, will continue to increase the deferred tax liability balance over the amortization period, with an associated charge to the deferred tax provision in each period. The deferred tax liability will only reverse when the indefinite-lived asset is sold, impaired, or reclassified from an indefinite-lived asset to a finite-lived asset.

As of September 30, 2016, 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's federal tax returns are currently being audited for the years 2012 and 2013. For years prior to 2011 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 15 – Commitments and Contingencies

Lease Commitments

We entered into an assignment agreement with an unaffiliated third party, effective February 19, 2015, for general office space located in Basking Ridge, NJ. This property is used as the Company's corporate headquarters. The space is approximately 18,000 rentable square feet. The base monthly rent is currently \$31,875 and the lease term ends July 31, 2020. In addition, there are two five-year renewal options. In connection with the assumption of the lease, the third party (a) conveyed its rights in various scheduled furniture and equipment and (b) paid the Company approximately \$580,000. The amount paid to the Company included a security deposit of approximately \$115,000. The Company also leases facilities in New York, NY, Irvine, CA, and Mountain View, CA, of which certain have escalation clauses and renewal options, and also leases equipment under certain noncancelable operating leases that 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, 2016 are as follows (in thousands):

Years ended	Operating Leases	
2016	\$	520.3
2017		1,876.5
2018		1,046.7
2019		994.9
2020 and thereafter		960.2
Total minimum lease payments	\$	5,398.6

Expense incurred under operating leases was approximately \$1.5 million and \$1.2 million for the nine months ended September 30, 2016 and 2015, respectively.

Contingencies

We have entered into a strategic collaboration with Sanford Research with the goal of developing a therapy for the treatment of T1D. The initial focus of the collaboration will be the execution of a prospective, randomized, placebo-controlled, double-

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

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

Under the Hitachi Transaction, Hitachi may require the Company to purchase all of its ownership in PCT if a Change of Control has occurred (as defined in the Amended and Restated Operating Agreement of PCT), and if such Change of Control can reasonably be expected to have a material adverse effect on PCT's ability to conduct its business in the ordinary course consistent with its past practice and its then current annual budget, at a price to be agreed upon by mutual agreement, provided, however, if mutual agreement is not obtained, the price will be determined by independent valuation firms.

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 2015 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 2015 Form 10-K.

Overview

Caladrius Biosciences, Inc. ("we," "us," "our," "Caladrius" or the "Company"), through its subsidiary, PCT, LLC, a Caladrius Company™ ("PCT"), is a leading provider of development and manufacturing services to the cell and cell-based gene therapy industry. PCT has significant cell therapy-specific experience and expertise, an expansive list of noteworthy clients and significant revenue growth over the past two years. Notably, PCT and Hitachi Chemical Co. America, Ltd. and Hitachi Chemical Co., Ltd. (each independently or collectively referred to herein as "Hitachi Chemical") are engaged in a strategic collaboration to accelerate the creation of a global commercial cell therapy development and manufacturing enterprise with deep engineering expertise. Caladrius leverages both its internal specialized cell therapy clinical development expertise and PCT's prowess to select and develop early-stage cell therapy candidates with the intention of partnering these candidates post proof-of-concept in man to both generate value for our shareholders and to expand PCT's client base. Our current product candidate, CLBS03, is a T regulatory cell ("Treg") clinical Phase 2 therapy targeting adolescents with recent-onset type 1 diabetes.

Cell Therapy Development and Manufacturing

PCT is a leading cell therapy development and manufacturing provider (often called a contract development and manufacturing organization, or "CDMO"), specializing in cell and cell-based gene therapies. PCT offers high-quality development and manufacturing capabilities (e.g., current Good Manufacturing Practice ("cGMP") manufacturing systems and facilities), quality systems, cell and tissue processing, logistics, storage and distribution and engineering solutions (e.g., process and assay development, optimization and automation) to clients with therapeutic candidates at all stages of development. PCT produces clinical supplies and ultimately, intends also to produce commercial product for its clients. PCT has worked with over 100 clients and produced over 20,000 cell therapy products since it was founded 17 years ago. PCT's manufacturing services are designed to reduce the capital investment and time required by clients to advance their development programs compared to conducting the process development and manufacturing in-house. PCT has demonstrated regulatory expertise, including the support of over 50 U.S. and European Union ("EU") regulatory filings for clients and expertise across multiple cell types and therapeutic applications, including immunotherapy (e.g. CAR-T therapies), neuro/endocrine therapies, hematopoietic replacement and tissue repair/

regeneration. PCT offers a complete development pathway for its clients, with services supporting preclinical through commercial phase, all underpinned by timely process optimization and automation support. We currently operate facilities qualified under cGMPs in each of Allendale, New Jersey and Mountain View, California, including EU-grade production suites. On March 11, 2016, PCT entered into a strategic collaboration and license agreement with Hitachi Chemical to accelerate the creation of a global commercial cell therapy development and manufacturing enterprise with deep engineering expertise. PCT is positioned to expand its capacity both in the United States and internationally, as needed. As the industry continues to mature and a growing number of cell therapy companies approach commercialization, we believe that PCT is well positioned to serve as an external manufacturing partner of choice for commercial-stage cell therapy companies.

CLBS03

We are developing, through the utilization of our core development and manufacturing expertise, a product candidate that is an innovative therapy for type 1 diabetes mellitus ("T1D"). This therapy is based on a proprietary platform technology for immunomodulation. We have selected as an initial target the unmet medical need of pediatric patients who are newly diagnosed with T1D. 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 T effector cells; the cells that are responsible for protecting the body from viruses and other foreign antigens. When Tregs function properly, only harmful foreign materials are attacked by T effector cells. In autoimmune disease, however, it is thought that deficient Treg activity and numbers permit the T effector cells to attack the body's own beneficial cells. In the case of T1D, there are currently no curative treatments, only lifelong insulin therapy, which often does not prevent serious co-morbidities. Two Phase 1 clinical trials of this technology in T1D patients demonstrated safety and tolerance, feasibility of manufacturing, an implied durability of effect and an early indication of efficacy 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 to evaluate the safety and efficacy of our Treg product candidate, CLBS03, in adolescents with recent onset T1D. In August 2016, we completed enrollment of the first 19 patients, and after a satisfactory evaluation of the safety of this initial cohort by our independent Data Safety Monitoring Board, we resumed the enrollment of the remaining 92 patients. A subsequent interim analysis of early therapeutic effect is planned after approximately 50% of patients reach the six-month follow-up milestone. 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 classification from the European Medicines Agency.

Additional Technology Platforms

Our broad intellectual property portfolio of cell therapy assets includes notable programs available for out-licensing and partnering in order to continue their clinical development. These include platforms using CD34 technology for ischemic repair and tumor cell/dendritic cell technology for immuno-oncology. Both have the benefit of promising Phase 2 clinical data and are applicable to multiple indications. With respect to our ischemic repair platform, the Company's Clinical Trial Notification for pivotal Phase 2 trial investigating CLBS12 (a candidate for critical limb ischemia, or "CLI") was submitted to the Japanese Pharmaceutical and Medical Devices Agency ("PMDA") and was cleared to proceed. The protocol design was agreed with PMDA and if successful, could provide the basis for a conditional approval under Japan's favorable regenerative medicine law. We are seeking to collaborate on CLBS 12 with development and/or manufacturing partners. In January 2016, we out-licensed our CD34 technology to SPS Cardio, LLC for chronic heart failure and acute myocardial infarction (candidate CLBS10) in India and other designated territories and non-major world markets outside the United States. The immuno-oncology platform is based on our extensive intellectual property portfolio and includes CLBS20, a candidate for metastatic melanoma which was investigated in two Phase 2 trials and recently in a discontinued Phase 3 clinical trial. In February 2016, we out-licensed a cell-derived dermatological product technology for topical skin application to AiVita Biomedical, Inc. ("AiVita"), which product is distributed through ALPHAEON Corporation. Furthermore, in May 2016, we out-licensed our tumor cell/dendritic cell technology to AiVita for ovarian cancer (candidate CLBS23) for worldwide use. Finally, our Treg immune modulation platform has potential applications across multiple autoimmune and allergic diseases beyond T1D for which we are exploring partnering opportunities, including steroid-resistant asthma, multiple sclerosis, chronic obstructive pulmonary disease, inflammatory bowel disease, graft versus host disease, lupus and rheumatoid arthritis.

Our long-term strategy focuses on advancing cell-based therapies to the market and assisting patients suffering from life-threatening medical conditions. Coupling our clinical development expertise with our process development and manufacturing capabilities, we believe we are positioned to realize potentially meaningful value increases within our own proprietary pipeline based on demonstration of proof-of-concept in man as well as process and manufacturing advancements.

Reverse Stock Split

On July 28, 2016, we implemented a one-for-ten reverse split of our issued and outstanding shares of common stock (the "Reverse Stock Split"), as authorized at the annual meeting of stockholders on June 22, 2016. The Reverse Stock Split became effective on July 27, 2016 and our common stock began trading on The NASDAQ Capital Market on a post-split basis at the open of business on July 28, 2016. As of July 28, 2016, every ten shares of our issued and outstanding common stock were combined into one share of our common stock, except to the extent that the Reverse Stock Split resulted in any of our stockholders owning a fractional share, which was rounded up to the next highest whole share. In connection with the Reverse Stock Split, there was no change in the nominal par value per share of \$0.001. The Reverse Stock Split was effectuated in order to increase the per share trading price of our common stock to satisfy the \$1.00 minimum bid price requirement for continued listing on The NASDAQ Capital Market. By letter dated August 11, 2016, the NASDAQ Capital Market, Listing Qualification Department, confirmed that the Company's common stock was in compliance with listing requirements.

Unless otherwise noted, all references in this Quarterly Report on Form 10-Q to number of shares of common stock, price per share and weighted average shares of common stock have been adjusted to reflect the Reverse Stock Split on a retroactive basis for all periods presented.

Results of Operations

Three and Nine Months Ended September 30, 2016 Compared to Three and Nine Months Ended September 30, 2015

Net loss for the three months ended September 30, 2016 was approximately \$7.3 million compared to \$11.4 million for the three months ended September 30, 2015. Net loss for the nine months ended September 30, 2016 was approximately \$27.2 million compared to \$47.8 million for the nine months ended September 30, 2015.

Net loss for the nine months ended September 30, 2015 included the impact of the Company's decision to no longer pursue further development of CLBS10 upon completion of the ongoing PreSERVE-AMI Phase 2 clinical study. Based on this decision, the Company determined that in process research and development ("IPR&D") valued at \$9.4 million was fully impaired (recorded in impairment of intangible assets in our consolidated statement of operations), and the associated deferred tax liability of \$3.7 million was reversed (recorded in benefit from income taxes in our consolidated statement of operations). In addition, the fair value of contingent consideration associated with earn out payments on CLBS10 future revenues was reduced from \$5.6 million to \$0 as of September 30, 2015 (recorded in other income in our consolidated statement of operations). The overall net impact for these changes was a \$20,000 increase in net loss.

Revenues

For the three months ended September 30, 2016, total revenues were approximately \$9.3 million compared to \$5.9 million for the three months ended September 30, 2015, representing an increase of \$3.4 million, or 58%. Revenues were comprised of the following (in thousands):

	Three Months Ended September 30,	
	2016	2015
Clinical Services	\$ 6,549.6	\$ 4,099.7
Clinical Services Reimbursables	1,585.4	878.4
Processing and Storage Services	1,074.4	910.4
Other	108.0	—
Total Revenues	\$ 9,317.5	\$ 5,888.5

- Clinical Services were approximately \$6.5 million for the three months ended September 30, 2016 compared to \$4.1 million for the three months ended September 30, 2015, representing an increase of approximately \$2.4 million or 60%, and was comprised of the following:
 - *Process Development Revenue* - Process development revenues were approximately \$2.7 million for the three months ended September 30, 2016 compared to \$0.6 million for the three months ended September 30, 2015. In accordance with our revenue recognition policy, process development revenue is recognized upon contract completion (*i.e.*, when the services under a particular contract are completed). Process development revenue will

continue to fluctuate from period to period as a result of our process development revenue recognition policy, and the timing upon when services for a contract are completed. Accordingly, unearned revenue relating to process development contracts decreased from \$5.4 million as of June 30, 2016 to \$4.1 million as of September 30, 2016, representing billings on contracts that have not been completed.

- *Clinical Manufacturing Revenue* - Clinical manufacturing revenues were approximately \$3.8 million for the three months ended September 30, 2016 compared to \$3.5 million for the three months ended September 30, 2015. Clinical manufacturing revenues are driven by the increased number of patients our customers have enrolled and treated in clinical trials, which number varies depending on the stage of the clinical trial. As of September 30, 2016, however, we determined that approximately \$0.6 million of clinical manufacturing billings during the three months ended September 30, 2016 had not met our revenue recognition criteria, since collectability was not reasonably assured due to the financial condition of one customer. We have deferred revenue recognition on this customer's billings until collectability becomes reasonably assured, which is generally upon receipt of cash.
- Clinical Services Reimbursables were approximately \$1.6 million for the three months ended September 30, 2016 compared to \$0.9 million for the three months ended September 30, 2015, representing an increase of approximately \$0.7 million, or 80%. Generally, clinical services reimbursables correlate with clinical services revenues. However, differences in the cost of supplies to be reimbursed can vary greatly from contract to contract based on the cost of supplies needed for each client's manufacturing and development process and may impact this correlation. In addition, our terms for billing reimbursable expenses do not include a significant mark-up in the acquisition cost of such consumables, and as a result, changes in this revenue category have little impact on our gross margin and net loss.
- Processing and Storage Services were approximately \$1.1 million for the three months ended September 30, 2016 compared to \$0.9 million for the three months ended September 30, 2015, representing an increase of approximately \$0.2 million or 18%. The increase was primarily due to higher volume for our oncology stem cell processing services.

For the nine months ended September 30, 2016, total revenues were approximately \$25.1 million compared to \$14.9 million for the nine months ended September 30, 2015, representing an increase of \$10.2 million, or 68%. Revenues were comprised of the following (in thousands):

	Nine Months Ended September 30,	
	2016	2015
Clinical Services	\$ 16,618.4	\$ 9,580.3
Clinical Services Reimbursables	4,958.5	2,263.0
Processing and Storage Services	3,317.7	2,964.4
Other	212.9	120.0
	\$ 25,107.4	\$ 14,927.7

- Clinical Services were approximately \$16.6 million for the nine months ended September 30, 2016 compared to \$9.6 million for the nine months ended September 30, 2015, representing an increase of approximately \$7.0 million, or 73%, and was comprised of the following:
 - *Process Development Revenue* - Process development revenues were approximately \$4.4 million for the nine months ended September 30, 2016 compared to \$2.6 million for the nine months ended September 30, 2015. In accordance with our revenue recognition policy, process development revenue is recognized upon contract completion (*i.e.*, when the services under a particular contract are completed). Process development revenue will continue to fluctuate from period to period as a result of our process development revenue recognition policy, and the timing upon when services for a contract are completed. Accordingly, unearned revenue relating to process development contracts decreased from \$4.2 million as of December 31, 2015 to \$4.1 million as of September 30, 2016, representing billings on contracts that have not been completed.
 - *Clinical Manufacturing Revenue* - Clinical manufacturing revenues were approximately \$12.2 million for the nine months ended September 30, 2016 compared to \$6.9 million for the nine months ended September 30, 2015. The increase is primarily due to an increase in the number of patients our customers have enrolled and treated in clinical trials, which number varies depending on the stage of the clinical trial. The increase was partially offset by approximately \$0.6 million of clinical manufacturing billings during the three months ended September 30, 2016 that had not met our revenue recognition criteria, since collectability was not reasonably assured due to the

financial condition of one customer. We have deferred revenue recognition on this customer's billings until collectability becomes reasonably assured, which is generally upon receipt of cash.

- Clinical Services Reimbursables were approximately \$5.0 million for the nine months ended September 30, 2016 compared to \$2.3 million for the nine months ended September 30, 2015, representing an increase of approximately \$2.7 million, or 119%. Generally, clinical services reimbursables correlate with clinical services revenues. However, differences in the cost of supplies to be reimbursed can vary greatly from contract to contract based on the cost of supplies needed for each client's manufacturing and development process and may impact this correlation. In addition, our terms for billing reimbursable expenses do not include a significant mark-up in the acquisition cost of such consumables, and as a result, changes in this revenue category have little impact on our gross margin and net loss.
- Processing and Storage Services were approximately \$3.3 million for the nine months ended September 30, 2016 compared to \$3.0 million for the nine months ended September 30, 2015, representing an increase of approximately \$0.4 million, or 12%. The increase was primarily due to higher volume for our oncology stem cell processing services.

Operating Costs and Expenses

For the three months ended September 30, 2016, operating costs and expenses totaled \$16.2 million compared to \$16.3 million for the three months ended September 30, 2015, representing a decrease of \$0.1 million, or 1%. Operating costs and expenses were comprised of the following:

- Cost of revenues were approximately \$8.6 million for the three months ended September 30, 2016 compared to \$4.8 million for the three months ended September 30, 2015, representing an increase of \$3.8 million, or 79%. Overall, gross margin for the three months ended September 30, 2016 was \$0.7 million, or 8%, compared to \$1.1 million, or 18% for the three months ended September 30, 2015. The decrease in gross margin during the three months ended September 30, 2016 was directly impacted by approximately \$0.6 million of clinical manufacturing billings for services provided that had not met our revenue recognition criteria, since collectability was not reasonably assured due to the financial condition of one customer. Gross margin percentages generally will increase/decrease as Clinical Services revenue increases/decreases. However, gross margin percentages will also fluctuate from period to period due to the mix of service and reimbursable revenues and costs.
- Research and development expenses were approximately \$2.6 million for the three months ended September 30, 2016 compared to \$6.3 million for the three months ended September 30, 2015, representing a decrease of approximately \$3.7 million, or 58%.
 - *Immune Modulation* - Immune modulation expenses, including expenses associated with our Phase 2 study of CLBS03 in T1D, were \$2.2 million for the three months ended September 30, 2016, representing an increase of \$1.7 million compared to the three months ended September 30, 2015.
 - *Immuno-oncology* - Immuno-oncology expenses, which are primarily associated with the close-out activities for the Intus Phase 3 clinical trial for the immunotherapy product candidate CLBS20, were \$0.1 million for the three months ended September 30, 2016, representing a decrease of \$3.6 million compared to the three months ended September 30, 2015. In January 2016, we discontinued the clinical development of CLBS20. Accordingly, we expect expenses to decrease to zero as close-out activities are completed.
 - *Ischemic Repair* - Ischemic repair expenses were \$0.1 million for the three months ended September 30, 2016, representing a decrease of approximately \$1.5 million compared to the three months ended September 30, 2015. The decrease is primarily due to lower program expenses associated with the decision to only conduct clinical study activity for a critical limb ischemia development program in Japan with a partner, and lower expenses associated with the close-out activities of the PreSERVE-AMI Phase 2 study for CLBS10. Expenses associated with CLBS10 are expected to decrease to zero as close-out activities are completed.
 - *Other* - Other research and development expenses were \$0.3 million for the three months ended September 30, 2016, representing a decrease of approximately \$0.3 million compared to the three months ended September 30, 2015. The decrease included approximately \$0.1 million of lower equity-based compensation expenses during the three months ended September 30, 2016 compared to the prior year.
- Selling, general and administrative expenses were approximately \$4.9 million for the three months ended September 30, 2016 compared to \$5.1 million for the three months ended September 30, 2015, representing a decrease of approximately

\$0.2 million, or 4%. Equity-based compensation included in selling, general and administrative expenses for the three months ended September 30, 2016 was approximately \$0.9 million, compared to approximately \$0.3 million for the three months ended September 30, 2015, representing an increase of \$0.6 million. Non-equity-based general and administrative expenses for the three months ended September 30, 2016 were approximately \$4.1 million, compared to approximately \$4.8 million for the three months ended September 30, 2015, representing a decrease of \$0.8 million. The decrease was primarily related to operational and compensation-related cost reductions compared to the prior year period.

For the nine months ended September 30, 2016, operating costs and expenses totaled \$50.5 million compared to \$69.1 million for the nine months ended September 30, 2015, representing a decrease of \$18.5 million or 27%. Operating costs and expenses were comprised of the following:

- Cost of revenues were approximately \$21.9 million for the nine months ended September 30, 2016 compared to \$14.0 million for the nine months ended September 30, 2015, representing an increase of \$7.9 million, or 57%. Overall, gross margin for the nine months ended September 30, 2016 was \$3.2 million, or 13%, compared to gross margin for the nine months ended September 30, 2015 of \$1.0 million, or 6%. The gross margin during the three months ended September 30, 2016 was negatively impacted by approximately \$0.6 million of clinical manufacturing billings for services provided that had not met our revenue recognition criteria, since collectability was not reasonably assured due to the financial condition of one customer. Gross margin percentages generally will increase/decrease as Clinical Service revenue increases/decreases. However, gross margin percentages will also fluctuate from period to period due to the mix of service and reimbursable revenues and costs.
- Research and development expenses were approximately \$12.5 million for the nine months ended September 30, 2016 compared to \$20.7 million for the nine months ended September 30, 2015, representing a decrease of approximately \$8.2 million, or 40%.
 - *Immune Modulation* - Immune modulation expenses, including expenses associated with on our Phase 2 study of CLBS03 in T1D, were \$6.0 million for the nine months ended September 30, 2016, representing an increase of \$3.1 million compared to the nine months ended September 30, 2015.
 - *Immuno-oncology* - Immuno-oncology expenses, which are primarily associated with the Intus Phase 3 clinical trial for our lead immunotherapy product candidate CLBS20, were \$2.6 million for the nine months ended September 30, 2016, representing a decrease of \$6.3 million compared to the nine months ended September 30, 2015. In January 2016, we discontinued the clinical development of CLBS20. Accordingly, we expect expenses to decrease to zero as close-out activities are completed.
 - *Ischemic Repair* - Ischemic repair expenses were \$2.0 million for the nine months ended September 30, 2016, representing a decrease of approximately \$4.0 million compared to the nine months ended September 30, 2015. The decrease is primarily due to lower program expenses associated with the decision to only conduct clinical study activity for a critical limb ischemia development program in Japan with a partner, and lower expenses associated with the close-out activities of the PreSERVE-AMI Phase 2 study for CLBS10. Expenses associated with CLBS10 are expected to decrease to zero as close-out activities are completed.
 - *Other* - Other research and development expenses were \$2.0 million for the nine months ended September 30, 2016, representing a decrease of approximately \$1.0 million compared to the nine months ended September 30, 2015. The decrease was primarily due to approximately \$1.3 million of lower equity-based compensation expenses and \$0.8 million lower non-core research and development expenses, which was partially offset by \$1.2 million in one-time restructuring costs for severance and loss on disposal of assets during the nine months ended September 30, 2016 compared to the prior year.
- Impairment of intangible assets for the nine months ended September 30, 2015 relates to the full impairment of IPR&D associated with CLBS10 valued at \$9.4 million, based on the Company's decision that it will not pursue further development of CLBS10 upon completion of the ongoing PreSERVE-AMI Phase 2 clinical study.
- Selling, general and administrative expenses were approximately \$16.1 million for the nine months ended September 30, 2016 compared to \$25.0 million for the nine months ended September 30, 2015, representing a decrease of approximately \$8.9 million, or 36%. Equity-based compensation included in selling, general and administrative expenses for the nine months ended September 30, 2016 was approximately \$1.6 million, compared to approximately \$6.4 million for the nine months ended September 30, 2015, representing a decrease of \$4.8 million. Non-equity-based general and administrative expenses for the nine months ended September 30, 2016 were approximately \$14.5 million, compared to approximately

\$18.6 million for the nine months ended September 30, 2015, representing a decrease of \$4.1 million. The decrease was primarily related to operational and compensation-related cost reductions compared to the prior year period.

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)

Other income (expense), net, for the three and nine months ended September 30, 2015 was \$0.4 million expense and \$4.4 million income, respectively, and primarily relates to changes in the estimated fair value of contingent consideration liabilities. As of December 31, 2015, all estimated fair values of the contingent consideration liabilities were \$0, and there were no changes in the estimated fair values for the three and nine months ended September 30, 2016.

Interest expense was \$0.4 million and \$1.7 million for the three and nine months ended September 30, 2016, respectively, compared with \$0.6 million and \$1.7 million for the three and nine months ended September 30, 2015, respectively, and is primarily related to interest expense on the loan from Oxford Finance LLC.

Provision for Income Taxes

The provision from income taxes for the three and nine months ended September 30, 2016 and the three months ended September 30, 2015 relates to the taxable temporary differences on the goodwill recognized in the PCT acquisition in 2011, which is being amortized over 15 years for tax purposes.

The benefit from income taxes for the nine months ended September 30, 2015 includes the taxable temporary differences on the goodwill recognized in the PCT acquisition in 2011, which is being amortized over 15 years for tax purposes, as well as the reversal of the deferred tax liability of \$3.7 million associated with the impairment of the in process research and development intangible asset valued at \$9.4 million.

A tax provision will continue to be recognized each period over the amortization period, and will only reverse when the goodwill is eliminated through a sale, impairment, or reclassification from an indefinite-lived asset to a finite-lived asset.

Analysis of Liquidity and Capital Resources

At September 30, 2016, we had cash and cash equivalents and marketable securities of approximately \$18.6 million, working capital of approximately \$11.4 million, and stockholders' equity of approximately \$10.7 million.

During the nine months ended September 30, 2016, we met our immediate cash requirements through revenue generated from our PCT operations, cash received from the transaction with Hitachi (net of repayments on our long-term debt to Oxford Finance LLC), proceeds from the issuances of our common stock, and 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,	
	2016	2015
Net cash used in operating activities	\$ (20,292.2)	\$ (30,530.6)
Net cash used in investing activities	(2,315.8)	(921.2)
Net cash provided by financing activities	20,896.3	36,320.4

Operating Activities

Our cash used in operating activities in the nine months ended September 30, 2016 totaled approximately \$20.3 million, which is the sum of (i) our net loss of \$27.2 million, adjusted for non-cash expenses totaling \$5.1 million (which includes adjustments

for equity-based compensation, depreciation and amortization, loss on disposal of assets, and deferred tax liabilities), and (ii) changes in operating assets and liabilities providing approximately \$1.8 million.

Our cash used in operating activities in the nine months ended September 30, 2015 totaled approximately \$30.5 million, which is the sum of (i) our net loss of \$47.8 million, adjusted for non-cash expenses totaling \$11.9 million (which includes adjustments for equity-based compensation, depreciation and amortization, impairments of intangible assets, and changes in acquisition-related contingent consideration liabilities and deferred tax liabilities), and (ii) changes in operating assets and liabilities providing approximately \$5.3 million.

Investing Activities

- During the nine months ended September 30, 2016, we spent approximately \$2.3 million for property and equipment.
- During the nine months ended September 30, 2015, we spent approximately \$2.6 million for property and equipment, and sold (net of purchases) approximately \$1.7 million in marketable securities available for sale.

Financing Activities

During the nine months ended September 30, 2016, our financing activities consisted of the following:

- We raised \$4.0 million in a registered direct offering through the issuance of 0.8 million shares of common stock, and \$6.6 million in concurrent private placement offerings through the issuance of 1.4 million shares of common stock.
- Hitachi Chemical purchased a 19.9% membership interest in PCT for \$19.4 million.
- In March 2016, we paid \$6.3 million in principal payments on our long term debt to Oxford Finance LLC upon execution of the Hitachi Transaction, and in September 2016, we paid an additional \$3.0 million in principal payments on our long term debt to Oxford Finance LLC.
- We raised \$1.0 million in a private placement through the issuance of 141,844 shares of common stock and two-year warrants to purchase up to an aggregate of 141,844 shares our common stock, at an exercise price of \$10.00 per share.

During the nine months ended September 30, 2015, our financing activities consisted of the following:

- We raised \$28.8 million (or \$26.5 million in net proceeds after deducting underwriting discounts and commissions and offering expenses) through an underwritten offering of 1.4 million shares of common stock at a public offering price of \$20.00 per share.
- We raised gross proceeds of approximately \$9.4 million through the issuance of approximately 0.3 million shares of common stock under the provisions of our equity line of credit with Aspire Capital.

Liquidity and Capital Requirements Outlook

Liquidity

We anticipate requiring additional capital to grow the PCT business, to fund the development of CLBS03 and other operating expenses, and to make principal and interest payments on our loan with Oxford Finance. To meet our short and long term liquidity needs, we currently expect to use existing cash balances, additional cash to be raised pursuant to the Private Placement Purchase Agreements, our revenue generating activities, and a variety of other means, including our common stock purchase agreements with Aspire Capital. 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. In addition, we will continue to seek as appropriate grants for scientific and clinical studies from various governmental agencies and foundations.

In September 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 the Company's common stock, at a purchase price of \$4.72 per share. The gross proceeds to the Company from the registered direct offering of the shares of common stock were \$4.0 million. In concurrent private placements, in September 2016, we entered into Private Placement Purchase Agreements with certain accredited investors for the sale of an aggregate of 4.4 million shares of common stock, at a purchase price of \$4.72 per

share. The investments will be placed in two tranches: (i) \$12.6 million upon an initial closing (the "Initial Closing"), and (ii) \$8.4 million, subject to certain conditions, including the enrollment of 70 subjects in the Company's Phase 2 CLBS03 clinical trial, in a second closing (the "Second Closing"). As of September 30, 2016, \$6.6 million of the Initial Closing tranche was received, and 1.4 million shares of common stock had been issued. Based on management's expectations, the remaining \$6.0 million of the Initial Closing tranche is expected to be received in the fourth quarter of 2016, and 1,271,186 shares of common stock will then be issued.

In March 2016, PCT and Caladrius entered into a global collaboration that includes licensing, development and equity, with Hitachi Chemical, a Japanese-based global conglomerate with a growing franchise in life sciences including regenerative medicine ("Hitachi Transaction"), and will receive an aggregate of \$25.0 million in cash, of which \$22.5 million was received in March 2016, \$1.25 million was received in June 2016, and the remainder is expected to be received before the end of 2016. PCT will retain \$10.0 million of the \$25.0 million proceeds, and Caladrius received \$15.0 million of the proceeds.

In March 2016, we entered into a securities purchase agreement with certain investors, pursuant to which we issued and sold in a private placement an aggregate of 141,844 shares of common stock and two-year warrants to purchase up to an aggregate of 141,844 shares of our common stock, at an exercise price of \$10.00 per share. The unit purchase price for a share of our common stock and warrant to purchase one share of our common stock was \$7.05 per unit, with \$1.0 million of gross proceeds received by us. On April 8, 2016, we filed a registration statement on Form S-3 to register the shares of common stock and the shares of common stock issuable upon exercise of the warrants acquired in the private placement, which registration statement became effective on June 7, 2016.

In November 2015, we entered into a common stock purchase agreement with Aspire Capital (the "Aspire Agreement"), whereby we can sell to Aspire Capital, subject to terms and conditions under the Aspire Agreement as well as NASDAQ rules, the lesser of (i) \$30 million of Common Stock or (ii) the dollar value of approximately 1.1 million shares of Common Stock based on the market price of the Common Stock at the time of such sale as determined under the Purchase Agreement. The Company has issued 109,270 shares under the Aspire Agreement for gross proceeds of \$0.3 million.

In September 2014, we entered into a Loan and Security Agreement with Oxford Finance LLC and received \$15.0 million in gross proceeds. We have been making interest-only payments on the outstanding amount of the loan on a monthly basis at a rate of 8.50% per annum. On March 11, 2016, upon execution of the Hitachi Transaction, the Company and Oxford Finance LLC entered into an amendment to the Loan and Security Agreement whereby (i) the Company paid \$7.0 million to Oxford Finance LLC, comprised of principal, interest and early termination fees, (ii) the Company's subsidiaries PCT, PCT Allendale, LLC, and NeoStem Family Storage, LLC (collectively the "Removed Borrowers") were removed as borrowers under the Loan, (iii) Oxford Finance LLC's security interests in any and all assets of the Removed Borrowers were released, (iv) the interest only period on the remaining outstanding Loan balance was extended until January 1, 2017. In September 2016, the Company paid \$3.0 million to repay a portion of the outstanding loan with Oxford Finance. The loan matures on September 1, 2018. As of September 30, 2016, the outstanding principal amount under the Loan was \$5.7 million.

Other sources of liquidity could include additional potential issuances of debt or equity securities in public or private financings, additional warrant exercises, option exercises, 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.

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 or discontinue the development of CLBS03, and/or the expansion of our business or raise funds on terms that we currently consider unfavorable. The Company's inability to raise additional capital would also raise substantial doubt about the Company's ability to continue as a going concern for a reasonable period of time.

Seasonality

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

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

There have been no material changes in our critical accounting policies and estimates during the three months ended September 30, 2016, compared to those reported in our 2015 Form 10-K.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES.

(a) Disclosure Controls and Procedures

Disclosure controls and procedures are our controls and other procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act") is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports that we file under the Exchange Act is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In

designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Due to the inherent limitations of control systems, not all misstatements may be detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Controls and procedures can only provide reasonable, not absolute, assurance that the above objectives have been met.

As of September 30, 2016, 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 the Company's 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 2015 Form 10-K.

ITEM 1A. RISK FACTORS

There have been no material changes to the risk factors previously reported in our 2015 Form 10-K. See the risk factors set forth in our Annual Report on our 2015 Form 10-K under the caption "Item 1 A - Risk Factors."

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

On September 14, 2016, the Company entered into Securities Purchase Agreements (each a "Private Placement Purchase Agreement" and, collectively, the "Private Placement Purchase Agreements") with certain accredited investors (the "Investors") with whom it had a substantive, pre-existing relationship, including certain existing stockholders, for the sale by the Company of an aggregate of 4.4 million shares of its common stock, at a purchase price of \$4.72 per share. The investments will be placed in two tranches: (i) \$12.6 million upon an initial closing (the "Initial Closing"), and (ii) \$8.4 million, subject to certain conditions, including the enrollment of 70 subjects in the Company's Phase 2 CLBS03 clinical trial, in a second closing (the "Second Closing"). As of September 30, 2016, \$6.6 million of the Initial Closing tranche was received, and 1.4 million shares of common stock had been issued. Based on management's expectations, the remaining \$6.0 million of the Initial Closing tranche is expected to be received in the fourth quarter of 2016, and 1,271,186 shares of common stock will then be issued. The issuance of the shares of common stock by the Company in the private placement under the Private Placement Purchase Agreements is exempt from registration pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

In September 2016, the Company used \$3.0 million of the proceeds to repay a portion of its outstanding loan from Oxford Finance.

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.

November 7, 2016

CALADRIUS BIOSCIENCES, INC.

By: /s/ David J. Mazzo, PhD

Name: David J. Mazzo, PhD

Title: Chief Executive Officer
(Principal Executive Officer)

November 7, 2016

By: /s/ Joseph Talamo

Name: Joseph Talamo

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

CALADRIUS BIOSCIENCES, INC.
FORM 10Q

Exhibit Index

31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2**	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

* 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 7, 2016

/s/ David J. Mazzo, PhD

Name: David J. Mazzo, PhD

Title: Chief Executive Officer (Principal Executive Officer)

CERTIFICATION

I, Joseph Talamo, certify that:

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

Date: November 7, 2016

/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, 2016 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 7, 2016

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

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

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

In connection with the Quarterly Report on Form 10-Q of Caladrius Biosciences, Inc. (the "Company") for the quarter ended September 30, 2016 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 7, 2016

/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.