UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2017

OR

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

For the Transition Period from _____ to _____

Commission File Number 001-33650

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

DELAWARE	22-2343568
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
110 Allen Road, 2nd Floor, Basking Ridge, New Jersey	07920
(Address of principal executive offices)	(zip code)

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

Securities Registered Pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange On Which Registered
Common Stock, par value $0.001 per share	The Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes o No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes o No x

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

Indicate by check mark whether the registrant has submitted electronically 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 x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this Chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.Yes x No o

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 definition of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company x
	Emerging growth company o

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

Yes o No x

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2017 (the last business day of the most recently completed second fiscal quarter) was approximately $39.6 million, computed by reference to the last sale price of $4.65 for the common stock on the Nasdaq Capital Market reported for such date. Shares held by executive officers, directors and persons owning directly or indirectly more than

10% of the outstanding common stock have been excluded from the preceding number because such persons may be deemed to be affiliates of the registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

On March 22, 2018, 9,552,653 shares of the registrant's common stock, par value 0.001 per share, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K: Certain information required in Part III of this Annual Report on Form 10-K is incorporated from the Registrant's Proxy Statement for the Annual Meeting of Stockholders.

All references in this Annual Report on Form 10-K to “we,” “us,” the “Company” and “CALADRIUS” mean CALADRIUS, Inc., including subsidiaries and predecessors, except where it is clear that the term refers only to CALADRIUS, Inc. This Annual Report on Form 10-K contains forward-looking statements, which involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those set forth under “Cautionary Note Regarding Forward-Looking Statements” and under “Risk Factors” and elsewhere in this Annual Report on Form 10-K.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report (this "Annual 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 Annual Report, statements that are not statements of current or historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words “plan,” “intend,” “may,” “will,” “expect,” “believe,” “could,” “anticipate,” “estimate,” “continue” or similar expressions or other variations or comparable terminology are intended to identify such forward-looking statements, although some forward-looking statements are expressed differently. We remind readers that forward-looking statements are merely predictions and therefore inherently subject to uncertainties and other factors and involve known and unknown risks that could cause the actual results, performance, levels of activity or our achievements or industry results, to be materially different from any future results, performance, levels of activity or our achievements or industry results expressed or implied by such forward-looking statements. Factors that could cause our actual results to differ materially from anticipated results expressed or implied by forward-looking statements include, among others:

- our ability to obtain sufficient capital or strategic business arrangements to fund our operations and expansion plans, including meeting our financial obligations under various licensing and other strategic arrangements, the funding of our clinical trials for product candidates, and the commercialization of the relevant technology;
- our ability to build and maintain the management and human resources infrastructure necessary to support the growth of our business;
- whether a market is established for our cell-based products and services and our ability to capture a meaningful share of this market;
- scientific, regulatory and medical developments beyond our control;
- our ability to obtain and maintain, as applicable, appropriate governmental licenses, accreditations or certifications or comply with healthcare laws and regulations or any other adverse effect or limitations caused by government regulation of our business;
- whether any of our current or future patent applications result in issued patents, the scope of those patents and our ability to obtain and maintain other rights to technology required or desirable for the conduct of our business; and our ability to commercialize products without infringing the claims of third party patents;
- whether any potential strategic or financial benefits of various licensing agreements will be realized;
- the results of our development activities; and
- our ability to complete our other planned clinical trials (or initiate other trials) in accordance with our estimated timelines due to delays associated with enrolling patients due to the novelty of the treatment, the size of the patient population and the need of patients to meet the inclusion criteria of the trial or otherwise.

The factors discussed herein, including those risks described in "Item 1A. Risk Factors" and in the Company's other periodic filings with the SEC, which are available for review at *www.sec.gov* under “Search for Company Filings,” 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, the Company undertakes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

PART I

ITEM 1. BUSINESS.

OVERVIEW

Caladrius Biosciences, Inc. (“we,” “us,” "our," “Caladrius” or the “Company”) is a company developing cellular therapeutics to treat certain diseases. We leverage specialized development expertise to selectively advance therapeutic product candidates to their next significant development milestone and, if appropriate, partner such candidates. Our most advanced product candidate, CLBS03, is an autologous polyclonal regulatory T cell ("Treg") clinical phase 2 therapy targeting children aged 8-17 with recent-onset type 1 diabetes mellitus ("T1D"). We also have phase 2 studies either underway or due to commence shortly involving our CD34 cell therapy for ischemic repair.

Immunomodulation (Treg Technology)

We are developing strategically, through the utilization of our core development expertise, a product candidate (CLBS03) that has the potential to be an innovative therapy for T1D. This therapy is based on a proprietary platform technology for immunomodulation. We have selected as an initial target the unmet medical need of patients who are newly diagnosed with T1D, most of whom will be under the age of 18. This program is based on the use of Tregs to treat diseases caused by imbalances in an individual's immune system. This novel approach seeks to restore immune balance by enhancing Treg number and function. Tregs are a natural part of the human immune system and regulate the activity of effector T cells, the cells that are responsible for protecting the body from pathogens and foreign antigens. When Tregs function properly, only harmful foreign materials are attacked by effector T cells. In autoimmune disease, however, it is thought that deficient Treg activity and numbers permit the effector T cells to attack the body's own beneficial cells. In the case of T1D, the beta cells in the pancreas are attacked, thereby reducing and/or eliminating over time the patient's ability to produce insulin. Insulin is necessary to regulate sugar metabolism and maintain proper sugar levels in the blood. Inconsistent or unnatural insulin levels can lead to many complications, including blindness, vascular disease and, if no insulin supplement is provided, even death. There are currently no curative treatments for TID, only lifelong insulin therapy, which often does not prevent serious co-morbidities. Two Phase 1 clinical trials of Treg technology in T1D, taken together, demonstrated safety and tolerance, feasibility of manufacturing, an implied durability of effect as well as an early indication of potential therapeutic effect through the preservation of beta cell function. In the first quarter of 2016, we commenced patient enrollment in the first of two cohorts in The Sanford Project: T-Rex Study, a Phase 2 prospective, randomized, placebo-controlled, double-blind clinical trial (the "TRex Study") to evaluate the safety and efficacy of CLBS03 in adolescents with recent onset TID. We entered into a strategic collaboration with Sanford Research to support the execution of this trial. Sanford Research is a U.S.-based non-profit research organization that supports an emerging translational research center focused on finding a cure for T1D. On February 23, 2017, the California Institute for Regenerative Medicine ("CIRM") awarded us funds of up to $12.2 million to support the T-Rex Study. The funding will be based upon the achievement of certain milestones related to the proportion of subjects enrolled in California, as well as manufacturing and development costs incurred in California. We received $5.7 million in initial funding on May 4, 2017. CLBS03 has been granted Fast Track and orphan drug designations from the U.S. Food and Drug Administration ("FDA") as well as Advanced Therapeutic Medicinal Product ("ATMP") classification from the European Medicines Agency ("EMA"). In October 2016, we received a satisfactory safety evaluation by our independent Data Safety Monitoring Board based on safety data then available from the first 19 patients enrolled in the trial. A subsequent interim analysis was conducted after approximately 50% of patients reached the six-month follow-up milestone, the results of which were publicly released on March 8, 2018, that the therapy continued to be well tolerated and was and deemed non-futile for therapeutic effect. On January 18, 2018, we announced completion of enrollment (110 patients) in the TRex Study.

Ischemic Repair (CD34 Cell Technology)

Our CD34 cell technology has led to the development of therapeutic product candidates designed to address diseases and conditions caused by ischemia. Ischemia occurs when the supply of oxygenated blood to healthy tissue is restricted. Through the administration of CD34 cells, we seek to promote the development and formation of new blood vessels and thereby increase blood flow to the impacted area. We believe that conditions caused by underlying ischemic injury can be improved through our CD34 cell technology, including critical limb ischemia ("CLI"), coronary microvascular disfunction ("CMD") and refractory angina ("RfA"). Published reports in Circulation Cardiovascular Interventions, Atherosclerosis, Stem Cells and Circulation Journal, provide preliminary evidence that CD34 cell therapy is safe and can exert significant therapeutic effects in patients with CLI, a condition in which blood flow to the legs is severely impaired, causing pain and non-healing ulcers and, ultimately, potentially resulting in the need for amputation. Our Clinical Trial Notification for a pivotal Phase 2 trial investigating our product candidate (CLBS12) in CLI was submitted to the Japanese Pharmaceutical and Medical Device Agency ("PMDA") and was cleared to proceed. The protocol design was agreed to with PMDA, the study was opened for enrollment in December 2017 and treatment

of the first patient was announced in March 2018. Based on our discussions with the PMDA, we expect that a successful outcome of this trial will qualify CLBS12 for consideration of early conditional approval in Japan. In anticipation of a successful trial outcome and the possibility of conditional approval, we continue to seek a local partner for CLBS12 in Japan. Furthermore, we submitted grant applications in an effort to seek non-dilutive financing to investigate the CD34 technology for additional clinical indications in the United States. On October 2, 2017, we announced the award of a $1.9 million grant from the National Institutes of Health to support a clinical study of CD34 cells in patients with coronary microvascular dysfunction and we are targeting the initiation of the study by early second quarter 2018.

Additional Out-licensing Opportunities

Our broad intellectual property portfolio of cell therapy assets includes notable programs available for out-licensing in order to continue their clinical development. These include additional indications for our Treg product and additional indications for our CD34 cell technology.

Our current long-term strategy focuses on advancing our therapies through development with the aim of eventually obtaining market authorization, either alone or with partners, to provide treatment options to patients suffering from life-threatening medical conditions. We believe that we are positioned to realize potentially meaningful value increases within our own proprietary pipeline if we are successful in advancing our product candidates to their next significant development milestones.

Discontinued Operations

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

Corporate Information

We incorporated in 1980 as a Delaware corporation and our principal executive offices are located at 110 Allen Road, Second Floor, Basking Ridge, NJ 07920. Our telephone number is (908) 842-0100 and our corporate website address is *www.caladrius.com*. We include our website address in this Annual Report on Form 10-K only as an inactive textual reference and do not intend it to be an active link to our website. The information on our website is not incorporated by reference into this Annual Report on Form 10-K.

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports, as well as other documents we file with the U.S. Securities and Exchange Commission ("SEC"), are available free of charge through the Investors section of our website as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. The public can obtain documents that we file with the SEC at *www.sec.gov*.

This Annual Report on Form 10-K includes the following trademarks, service marks and trade names owned by us: Caladrius®, Amorcyte®, and Athelos™. These trademarks, service marks and trade names are the property of Caladrius and its affiliates. This Annual Report on Form 10-K also includes other trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and traded names included herein are the property of their respective owners.

OVERVIEW OF THE CELL THERAPY FIELD

Regenerative medicine is defined as the process of replacing or regenerating human cells, tissues or organs to restore normal function. Among the categories of therapeutic technology platforms within this field are cell therapy, tissue engineering, tools, device diagnostics and aesthetic medicine. In 2017, the Alliance for Regenerative Medicine recognized over 759 regenerative medicine companies worldwide, including gene and cell therapy developers and over 802 clinical trials.

All living complex organisms start as a single cell that replicates and differentiates (matures), thereby yielding the vast array of organs and organ systems in an adult organism. Cell therapy is the process that uses cells to prevent, treat or cure disease, or regenerate damaged or aged tissue. To date, the most common type of cell therapy has been the replacement of mature, functioning cells through blood and platelet transfusions. Since the 1970s, marrow and blood and umbilical cord-derived stem cells have been used to restore bone marrow, as well as blood and immune system cells damaged by the chemotherapy and radiation used to treat many cancers. These types of cell therapies are standard practice world-wide and are often reimbursed by insurance.

There are two general classes of cell therapies: autologous and allogeneic. When cells are collected from a person (donor) and are ultimately transplanted into, or used to develop a treatment solely for that patient (recipient) with or without modification, the treatment paradigm is known as “autologous” cell therapy. In cases in which the donor and the recipient are not the same individual, the procedures are referred to as “allogeneic” cell therapy. Patient-Specific Cell Therapy ("PSCT") includes all autologous cell therapies as well as allogeneic cell therapies in which a specific donor's cells are used for a specific matched recipient's treatment. Our immune modulation program focuses on PSCTs. Autologous cells offer a low likelihood of rejection by the patient. In the case of some allogeneic cell therapies, also known as Off-The-Shelf Cell Therapy ("OSCT"), donor cells are expanded many fold in tissue culture and large banks of cells are frozen in individual portions that may result in treatments for many different people.

Various cell therapies are in clinical development for an array of human diseases, including autoimmune, oncologic, cardiovascular, neurologic and orthopedic diseases, among other indications. While no assurances can be given regarding future medical developments, we believe that the field of cell therapy holds the promise to better the human experience and minimize or ameliorate the pain and suffering from many common and often life-threatening diseases.

CELL THERAPY PRODUCT DEVELOPMENT

Immune Modulation (T Regulatory Cell Program)

Our T Regulatory Cell program is based on a technology platform derived in part from intellectual property created from research performed at the University of California, San Francisco ("UCSF") and we are pursuing the development of cell therapies designed to use autologous immune cells as a therapeutic product to treat disorders of the immune system. Many immune-mediated diseases are a result of an imbalance between immune effector and regulatory mechanisms whereby pro-inflammatory cells and cytokines eventually go unchecked and mistakenly attack beneficial cells in the body. Our T regulatory cell therapy represents a novel approach to restoring immune balance by enhancing Treg number and function to control pathologic immune responses.

Clinical Development

Through world-wide patent licenses, we have secured the rights to a broad patent estate within the Treg field, including IP related to TID. T1D, also known as insulin dependent diabetes or juvenile diabetes, is caused by the autoimmune destruction of insulin-producing beta cells of the pancreas. We have established a collaboration with UCSF and the laboratories of Drs. Jeffrey Bluestone and Qizhi Tang, experts in the field of Tregs and immune tolerance, to develop CLBS03, autologous *ex vivo* expanded polyclonal Tregs, for the treatment of T1D. This collaboration has advanced our Treg Program to a Phase 2 trial, initiated in the first quarter of 2016, to evaluate the safety and efficacy of autologous Tregs in patients recently diagnosed with T1D.

A Phase 1 open-label uncontrolled dose escalation study of autologous Treg immunotherapy for T1D was funded by the Juvenile Diabetes Research Foundation and conducted by Dr. Stephen Gitelman at UCSF and Dr. Kevan Harold at Yale University, in collaboration with Dr. Bluestone. Results were published by Dr. Gitelman in *Science Translational Medicine* in November 2015. This clinical trial provided preliminary safety and feasibility data supporting the development of a novel therapy for the treatment of T1D with the goal of inducing immune tolerance and preserving pancreatic beta cell function. The investigators in that study reported that 14 patients between 18 and 45 years of age with a mean duration of disease of 10 months received a single infusion of one of four doses of autologous expanded Tregs. The majority of adverse events reported were mild. There were three serious adverse events, or SAEs, two of which were deemed unrelated to treatment by the investigator and a third SAE of grade 3 pre-syncope was deemed unlikely related. Common side effects included mild infections. Infused Tregs peaked in circulation three to seven days after infusion and were detectable at up to twelve months. The average levels of stimulated C-peptide, an indicator of pancreatic islets beta cell function that was measured in the clinical trial as a safety biomarker, for some patients remained stable from baseline for as long as two years post treatment. These data suggest that the treatment was manageable and did not adversely affect residual beta cell function. The Tregs were observed to be highly functional and relatively long lived in treated individuals.

While the U.S. Phase 1 clinical trial was designed to evaluate safety and tolerability in adults who suffered T1D for various durations, supportive evidence of the utility of Tregs for T1D in humans was provided by a study of pediatric patients 5 to 18 years of age with new onset T1D, as published in the July 2014 issue of *Clinical Immunology*. In that open label non-randomized study conducted in Poland, Marek-Trzonkowska, *et al.* reported that treatment with expanded autologous Tregs preserved function of pancreatic beta cells and reduced the need for exogenous insulin in the majority of patients treated. Through 12 months of follow-up, about 66% of the 12 children treated were in remission, according to study specified criteria, compared to only 20% of 10 concurrent controls. In addition, two (or about 17%) of Treg treated children achieved complete insulin independence, while none of the children in the control group achieved this endpoint. Importantly, the study utilized a Treg -ased product similar to CLBS03 and provided additional information on the safety and feasibility of this approach in new onset children with T1D.

In the first quarter of 2016, we commenced patient enrollment in the first of two cohorts in The Sanford Project: T-Rex Study, a Phase 2 prospective, randomized, placebo-controlled, double-blind clinical trial (the "T-Rex Study") to evaluate the safety and efficacy of CLBS03 in adolescents with recent onset TID. We entered into a strategic collaboration with Sanford Research to

support the execution of this trial. Sanford Research is a U.S. based non-profit research organization that supports an emerging translational research center focused on finding a cure for T1D. On February 23, 2017, the California Institute for Regenerative Medicine ("CIRM") awarded us funds of up to $12.2 million to support the T-Rex Study. The funding will be based upon the achievement of certain milestones related to the proportion of subjects enrolled in California, as well as manufacturing and development costs incurred in California. We received $5.7 million in initial funding on May 4, 2017. CLBS03 has been granted Fast Track and orphan drug designations from the U.S. Food and Drug Administration ("FDA") as well as Advanced Therapeutic Medicinal Product ("ATMP") classification from the European Medicines Agency ("EMA"). In October 2016, we received satisfactory safety evaluation by our independent Data Safety Monitoring Board based on safety data then available from the first 19 patients enrolled in the trial. A subsequent interim analysis was conducted after approximately 50% of patients reached the six-month follow-up milestone, the results of which were publicly released on March 8, 2018, that the therapy drug continued to be well tolerated and was deemed non-futile for therapeutic effect. On January 18, 2018, we announced completion of enrollment (110) patients in the TRex Study.

Market Opportunity and Competition

In 2015, *The International Diabetes Foundation Atlas*, 7th Ed. reported that, worldwide, an estimated 86,000 children younger than 15 develop T1D annually, with annual increases in incidence of about 3%. In the United States, a SEARCH for National Diabetes Statistic Report, 2014 cites an annual incidence of 18,436 in newly diagnosed individuals less than 20 years of age. T1D inflicts a significant economic cost on the U.S. healthcare system, estimated at $14.4 billion annually, and it is expected that a therapy that can modify the course of T1D could potentially achieve significant cost savings, and thus command high market penetration and premium pricing. In the near future, the market for T1D is expected to continue to be dominated by insulin replacement therapies. Other novel approaches, however, including immune modulatory agents such as CLBS03, are expected progressively to penetrate the market as the magnitude and durability of their therapeutic effect becomes well characterized.

Currently, there are no approved therapies for new onset T1D with potential curative effect but only regimens such as insulin or adjuvants to insulin that address the disease when the pancreas can no longer produce insulin. While not a direct competitor, in a more advanced population of T1D, sotagliflozin, an oral adjunctive therapy to insulin, is expected to receive FDA approval following positive results from a pivotal Phase 3 trial conducted by Lexicon Pharmaceuticals in collaboration with Sanofi SA and JDRF. There are multiple agents in development targeting the modification of the course of the disease. Current approaches in development can be broadly divided into immune modulatory agents that attempt to improve metabolic function by rescuing insulin producing beta cells, or regenerative agents that attempt to replace beta cells. From a broad review of these agents and approaches, no other therapy for new-onset T1D is expected to be in advanced clinical trials or provide direct competition to our polyclonal regulatory T cell platform in the near future.

Ischemic Repair (CD34 Cell Technology)

Our CD34 cell technology has led to the development of therapeutic candidates designed to address diseases and conditions caused by ischemia. Ischemia occurs when the supply of oxygenated blood to healthy tissue is restricted. Through the administration of CD34 cells, we seek to promote the development and formation of new blood vessels and thereby eliminate the ischemic condition. We believe that conditions caused by underlying ischemic injury can be improved by the administration of our CD34 cell technology. Published reports provide preliminary evidence that CD34 cell therapy is safe and can exert significant therapeutic effects in patients with CLI, a condition in which blood flow to the legs is severely impaired, causing pain and non-healing ulcers and, ultimately, potentially resulting in the need for amputation. Prior studies have shown benefits of CD34 cell therapy that included pain relief, ulcer healing and reduced amputation rates. Conditions such as CLI are often difficult to study in large randomized controlled programs and Japan’s recent Regenerative Medicine Law is designed to advance regenerative medicine therapies such as these. The new regulations support conditional approval when there is data to show sufficient safety and some preliminary evidence of therapeutic effect. We explored how best to work within the Japanese Regenerative Medicine Law framework to advance this and potentially other programs through extensive consultations with the Japanese Pharmaceuticals and Medical Devices Agency (PMDA). We then submitted to the PMDA a Clinical Trial Notification for a pivotal Phase 2 trial to investigate our product candidate (CLB12) in CLI, for which the PMDA provided clearance for us to proceed. The protocol design, as well as the CMC and quality plans, were agreed to with PMDA and we opened the study for enrollment in December 2017. Based on our discussion with the PMDA, a successful outcome of this trial is expected to qualify CLBS12 for consideration of early conditional approval in Japan. In anticipation of a successful trial result and the possibility of conditional approval in Japan, we continue to seek a local partner for CLBS12 in Japan. Furthermore, we submitted grant applications in an effort to seek non-dilutive financing to investigate the CD34 technology for additional clinical indications in the United States.

The goal of CLBS12 is to prevent the serious adverse consequences of no-option CLI (cases where there is no longer the potential for other treatment beyond amputation) by extending the time of continuous CLI free status through improved blood flow in the affected limb. We also believe a CD34 product could have potential in treating other cardiovascular and/or peripheral arterial diseases such as claudication, refractory angina and Syndrome X, also known as coronary microvascular disfunction. On October 2, 2017, we announced the award of a $1.9 million grant from the National Institutes of Health to support a clinical study of CD34 cells (CLBS14-CMD) in patients with coronary microvascular dysfunction ("CMD" or "Syndrome X") and target the

initiation of the study by early second quarter 2018. In addition, on March 7, 2018, we announced that we acquired from Shire plc (Nasdaq: SHPG) an exclusive worldwide license to data from a late stage CD34 cell therapy program for the treatment of chronic myocardial ischemia targeting refractory angina. Under the terms of the agreement Caladrius received the exclusive worldwide rights to the data set and regulatory filings for the CD34 cell therapy program for the treatment of refractory angina in exchange for an upfront consideration, milestones and a royalty on product sales. The comprehensive data set that Caladrius licensed includes preclinical (in vivo and in vitro) and Phase 1, Phase 2 and Phase 3 clinical study data of CD34 cell therapy as a treatment for no-option refractory angina, along with the corresponding regulatory filings. Upon reactivation of the Baxalta IND under the sponsorship of Caladrius, the Company will proceed with discussions with FDA to determine the most expeditious path to potential approval for this product candidate, now known as CLBS14-RfA.

TECHNOLOGY OUT-LICENSING OPPORTUNITIES

Immune Modulation (T Regulatory Cell Technology)

Our Treg technology platform is potentially applicable to multiple autoimmune and allergic diseases beyond our current target indication of TID. For example, certain evidence suggests that a failure of Tregs may be important in the development systemic lupus erythematosus ("SLE") and that Treg therapy may therefore be helpful in treatment of SLE. Additionally, Tregs have been evaluated in early phase human clinical trials and have indicated clinical benefit, for graft-versus-host disease ("GVHD"). Allogeneic hematopoietic cell transplantation, multiple sclerosis, rheumatoid arthritis, chronic obstructive pulmonary disease and inflammatory bowel disease are other indications for which we believe Tregs may have a meaningful therapeutic effect. Trials sponsored by the University of California, San Francisco are currently underway for active cutaneous lupus and immune tolerance following kidney transplantation.

Immune Modulation Intellectual Property Platform

We have assembled a patent portfolio through licenses to IP from leaders in the field of Tregs (UCSF/Jeffrey Bluestone et al, Centenary Institute) comprising:

- Eight patents and eight pending patent applications;
- Claims covering many facets of Tregs, including:
  - Methods of Treg isolation, expansion and activation/stimulation as sourced from peripheral blood and cord blood; and
  - Methods of treating or preventing Type 1 diabetes using Tregs.
- Patents and applications cover international geographies (United States, EU, Japan, China, Australia and Canada).
- An option on patent licenses to critical reagents employed in Treg therapeutic development.

Ischemic Repair (CD34 Cell Technology

As is the case with our T Regulatory Cell Technology, our CD 34 Cell Technology is a platform technology with potential application to a broad array of ischemic conditions and we will seek to out-license our technology in geographies or indications that we do not intend directly to pursue.

Ischemic Repair (CD34 Cell) Intellectual Property Platform

Our developed and owned ischemic repair patent portfolio comprises the following:

- Nine U.S. patents, two EU patents (each filed in 11 individual countries) and 15 other patents outside the U.S (Japan, South Africa, Malaysia, Philippines, Canada, Russia, Israel, Hong Kong)
- Claims cover, *inter alia*, a pharmaceutical composition that contains a therapeutic concentration of non-expanded CD34 stem cells that move in response to SDF-1 or VEGF, together with a stabilizing amount of serum, and that can be delivered to repair an injury caused by vascular insufficiency.
- Issued and pending claims can be applied to a broad range of conditions caused by underlying ischemia, including: AMI, chronic myocardial ischemia post-AMI; chronic heart failure; critical limb ischemia; and ischemic brain injury
- 12 patent applications outside the United States are pending.

Market Opportunity and Competition for CLI

In Japan there are roughly 24,000 patients with CLI, of whom roughly 11,000 are not candidates for revascularization, making them the addressable population for CLBS12. The addressable population is roughly 1.4 million in the EU and 1.3 million in the U.S.

The field of cardiovascular cell therapy development is competitive. There are a number of companies that are developing stem cell-based therapies for cardiovascular diseases, including, but not limited to, Celyad, Capricor, Inc., Mesoblast Limited, Athersys, Inc., Pluristem Therapeutics Inc. and Vericel Corporation. These companies are utilizing a number of different therapeutic approaches in their development efforts. There are both autologous and allogeneic based competitive therapies that derive cells principally from four sources: fat, peripheral blood, cord blood, and bone marrow. CLBS12 is an autologous therapy that derives its cells from peripheral blood via apheresis. Stempeutics Research Pvt. Ltd. and the joint venture between Pluristem Therapeutics Inc. and Sosei CVC, are examples of companies also seeking to launch clinical trials in Japan for allogeneic cell therapy product candidates for CLI.

Neurological Regeneration

Our intellectual property portfolio provides the opportunity for research collaboration for a variety of neurological disorders. StemRemedium Hedge Fund, LLC ("StemRemedium") has out-licensed the exclusive rights in the field of use for spinal cord injury to our neuronal progenitor cell product technology, which technology StemRemedium intends to develop and make commercially available. We will receive payments based on achieving certain milestones throughout its clinical development as well as royalties on gross sales.

Neurological Regeneration Intellectual Property Platform

We own the following intellectual property:

- Portfolio of three granted patents applications for a neurological regeneration product, including:
  - Methods of Derivation of Neuronal Progenitor Cells from Embryonic Stem Cells;
  - Human Neuronal Progenitor Cells Co-Expressing Nestin and PAX6, and Co-Expressing NEUN or TUJ1; and
  - Cellular Therapeutic Approaches to Traumatic Brain and Spinal Cord Injury.
- The portfolio is international, including filings in the United States and the EU.

GOVERNMENT REGULATION

The health care industry is one of the most highly regulated industries in the United States and abroad. Various governmental regulatory authorities, as well as private accreditation organizations, oversee and monitor the activities of individuals and businesses engaged in the development, manufacture and delivery of health care products and services. The following is a general description of certain current laws and regulations that are relevant to our business.

Pharmaceutical and Biologic Product and Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries, extensively regulate, among other things, the research, development, testing, manufacture, including any manufacturing changes, packaging, storage, recordkeeping, labeling, advertising and promotion, distribution, marketing, import and export of pharmaceutical and biological products, such as CLBS03, CLBS12 or CLBS14. The process of obtaining required regulatory approvals and the subsequent compliance with appropriate statutes and regulations requires the expenditure of substantial time and money, and there is no guarantee that we will successfully complete the steps needed to obtain regulatory approval of CLBS03, CLBS12, CLBS14-CMD or CLBS14-RfA or any future product candidates. In addition, these regulations may change and our product candidates may be subject to new laws or regulations.

In the United States, pharmaceutical and biologic products, including cellular therapies, are subject to extensive pre- and post- market regulation by the FDA. The Federal Food, Drug, and Cosmetic Act (“FD&C Act”) and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Biological products are approved for marketing under provisions of the Public Health Service Act ("PHS Act"). However, because most biological products also meet the definition of “drugs” under the FD&C Act, they are also subject to regulation under FD&C Act provisions. The PHS Act requires the submission of a biologics license application ("BLA"), rather than a New Drug Application ("NDA"), for market authorization. However, the application process and requirements for approval of BLAs are similar to those for NDAs, and the review process for biologics is associated with similar approval risks and costs as the process for drugs.

Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial

sanctions, such as FDA refusal to approve pending NDAs or BLAs, untitled or warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution. Under certain circumstances, individual members of company management may also be subject to civil or criminal penalties related to company violations of applicable legal requirements.

Pharmaceutical and biologic product development in the United States typically involves preclinical laboratory and animal tests; submission to the FDA of an investigational new drug application (“IND”), which must become effective before clinical trials can commence and the performance of adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug or biologic for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical and other nonclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long term nonclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

Submission of an IND may not result in FDA authorization to initiate a clinical trial if FDA raises concerns or questions about the design of the clinical trial or the preclinical or manufacturing information supporting it, including concerns that human research subjects will be exposed to unreasonable health risks. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations; good clinical practices ("GCPs"), as set forth in FDA guidance, which is meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; and under FDA-approved protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND. Sponsors of most clinical trials involving FDA regulated products, including drugs and biologics, are required to register and disclose certain clinical trial information on a public registry and results database. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public on the database as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial is not being conducted in accordance with FDA requirements, or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board ("IRB") at each institution at which the trial will be performed. It will review the proposed research to ensure compliance with applicable research and ethical guidelines. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements.

Clinical trials to support NDAs or BLAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. Under certain circumstances, a fourth post-approval phase may be required.

- *Phase 1*: Trials in this phase are initially conducted in a limited population of healthy volunteers to test the product candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients, such as cancer patients, when the drug or biologic is too toxic to be ethically given to healthy individuals.
- *Phase 2*: These clinical trials are generally conducted in a limited patient population to identify appropriate therapeutic dose and dose frequency as well as any corresponding additional possible adverse effects and safety risks and to determine the presence and approximate magnitude of therapeutic effect of the product for specific targeted indications. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- *Phase 3*: These are commonly referred to as pivotal or registration studies. When Phase 2 evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase 3 clinical trials are typically undertaken in a larger patient population to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple and geographically-dispersed clinical trial sites. In most cases, FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug as a requirement for registration.

- *Phase 4*: In some cases, FDA may condition approval of an NDA or BLA for a product candidate on the sponsor's agreement to conduct additional clinical trials after NDA or BLA approval. In other cases, a sponsor may voluntarily carry out additional trials post approval to gain more information about the drug or biologic.

Expedited Review and Approval

FDA is required to facilitate the development and expedite the review of drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the Fast Track Program, the sponsor of an IND for a drug candidate may request that FDA designate the drug candidate for a specific indication as a Fast Track drug concurrent with, or after, the submission of the IND for the drug candidate. FDA must determine if the drug candidate qualifies for Fast Track designation within 60 days of receipt of the sponsor’s request.

Under the FDA’s accelerated approval regulations, FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients beyond existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post- approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow FDA to withdraw the drug from the market on an expedited basis. Unless otherwise informed by the FDA, for an accelerated approval product an applicant must submit to the FDA for consideration during the preapproval review period copies of all promotional materials, including promotional labeling as well as advertisements, intended for dissemination or publication within 120 days following marketing approval. After 120 days following marketing approval, unless otherwise informed by the FDA, the applicant must submit promotional materials at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement

In addition to other benefits such as the ability to use surrogate endpoints and engage in more frequent interactions with FDA, FDA may initiate review of sections of a Fast Track drug’s NDA before the application is complete. This "rolling review' is available if the applicant provides, and FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. FDA’s time period goal for reviewing an application, however, does not begin until the last section of the NDA is submitted. Additionally, the Fast Track designation may be withdrawn by FDA if FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

During Phase 1, Phase 2, or Phase 3 clinical development, FDA may designate an investigational product as a Breakthrough Therapy or as a Regenerative Medicine Advanced Therapy. Breakthrough Therapy ("RMAT") designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). RMAT designation may be granted if: (a) the product candidate is a regenerative medicine therapy, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, except for those regulated solely under Section 361 of the Public Health Service Act and part 1271 of Title 21, Code of Federal Regulations; (b) the product candidate is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (c) preliminary clinical evidence indicates that the product candidate has the potential to address unmet medical needs for such disease or condition. Either a breakthrough or RMAT designation may help accelerate product development by allowing more frequent interactions with FDA and receiving intensive FDA guidance on efficient drug development.

After completion and analysis of the results of the required clinical testing, an NDA or BLA is prepared and submitted to the FDA. FDA approval of the NDA or BLA is required before marketing of the product may begin in the United States. The NDA or BLA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA or BLA is substantial. Under federal law, most NDA or BLA submissions are additionally subject to a substantial application user fee. The current fee for FY2018 is $2,421,495 and an annual program fee, currently $304,162, must also be paid for approved drugs or biologics. These fees are typically adjusted annually.

The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be accepted for filing

based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. Under certain NDA and BLA review performance goals to which FDA has agreed, most applications for standard review of drug or biologic products are reviewed within ten to twelve months, and most applications for priority review drugs or biologics are reviewed within six to eight months. If a sponsor submits a major amendment to a filed NDA or BLA at any time during the review cycle, FDA may extend these reviews by three months. Priority review can be applied to drugs or biologics that, in the FDA's determination, offer major advances in treatment or provide a treatment for a disease or condition for which no adequate therapy exists. For biologics, priority review is further limited to products intended to treat a serious or life-threatening disease relative to currently approved products.

The FDA may refer applications for novel drug or biologic products, or drug or biologic products which present difficult questions of safety or efficacy, to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but the FDA will carefully consider them.

Before approving an NDA or BLA, the FDA will typically inspect one or more clinical trial sites to ensure compliance with GCPs. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMPs, including the establishment of a quality system to regulate manufacturing operations, is satisfactory and the NDA or BLA contains data that provide substantial evidence that the drug or biologic is safe and effective for the proposed indication.

After the FDA evaluates the NDA or BLA and the manufacturing facilities, the FDA issues an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmitted NDA or BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions within two or six months, depending on the type of information included.

Pediatric Information

Under the Pediatric Research Equity Act ("PREA") NDAs or BLAs or supplements to NDAs or BLAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers or deferrals for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

The Best Pharmaceuticals for Children Act ("BPCA") provides approved NDA and BLA holders a six-month extension of any exclusivity that attaches to the end of all existing marketing exclusivities and patents for the drug. Conditions for exclusivity include the FDA’s determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product but limited to the specific, approved indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same indication, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation, the sponsor receives tax credits for certain research and a waiver of the NDA or BLA application user fee.

Other Health Care Regulations

Other federal and state laws and regulations that could directly or indirectly affect our ability to operate the business and/or financial performance include:

- state and local licensure, registration and regulation of laboratories, the processing and storage of human cells and tissue, and the development and manufacture of pharmaceuticals and biologics;
- other laws and regulations administered by the United States FDA, including the FD&C Act and related laws and

regulations and the PHS Act and related laws and regulations;

- laws and regulations administered by the United States Department of Health and Human Services, including the Office for Human Research Protections;
- state laws and regulations governing human subject research;
- federal and state coverage and reimbursement laws and regulations, including laws and regulations administered by the Centers for Medicare & Medicaid Services and state Medicaid agencies;
- the federal Medicare and Medicaid Anti-Kickback Law and similar state laws and regulations;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act and similar state laws and regulations;
- the federal physician self-referral prohibition commonly known as the Stark Law, and state equivalents of the Stark Law;
- Occupational Safety and Health Administration requirements;
- state and local laws and regulations dealing with the handling and disposal of medical waste; and
- the Intermediate Sanctions rules of the IRS providing for potential financial sanctions with respect to “Excess Benefit Transactions” with tax-exempt organizations.

Japan’s Pharmaceutical and Medical Device Authority Regulation of Regenerative Medicine

Prior to 2014 there was no specific regulatory oversight of regenerative medicine products in Japan. However, in November 2013, the Japanese Diet revised the Pharmaceutical Affairs Law and renamed it the Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act (the "PMD Act"). The new legislation became effective on November 25, 2014 and provides for a timely introduction of innovative regenerative medicine products. The new legislation formalizes a legal basis for development of regenerative medicine therapies. The new legislation defines regenerative medicine products as processed human cells that are intended to be used for either (1) the reconstructive repair, or formation of structures or functions of the human body; (2) the treatment or prevention of human diseases; or (3) gene therapy.

The legislation allows the PMDA/Ministry of Health, Labor and Welfare ("MHLW") to award conditional approval to a regenerative medicine therapy if there is evidence of adequate safety and results which predict likely efficacy. The evidence for efficacy may be based on surrogate endpoints and may come from an exploratory study. This conditional approval is time-limited, and there must be an agreement with PMDA/MHLW as to follow-up collection of information which confirms efficacy and safety, similar to a post-marketing commitment in the United States.

Under the PMD Act, products under consideration may also be given a sakigake designation (similar to a fast track designation) or may be granted a priority review status. Additionally, there is a commitment that the PMDA will facilitate research and development by giving scientific and regulatory advice to sponsors from the early stage of development.

According to the new legislation, the sponsor prepares a marketing authorization application which is submitted for review to the PMDA. The PMDA reviews the application and prepares a review report and recommendation which is submitted to the MHLW. The MHLW reviews the recommendation and makes a decision regarding approval of the product. This procedure is followed for both a conditional approval and subsequently for a full approval after the post-marketing commitments have been fulfilled.

EMPLOYEES

As of December 31, 2017, we had 22 full-time employees. Most of our senior management and professional employees have had prior experience in pharmaceutical or biotechnology companies. None of our employees is covered by collective bargaining agreements. We believe that our relations with our employees are good.

ITEM 1A. RISK FACTORS.

Our business, financial condition, operating results and cash flows can be affected by a number of factors, including, but not limited to, those set forth below, any one of which could cause our actual results to vary materially from recent results or from our anticipated future results. The risks described below are not the only ones we face, but those we currently consider to be material. There may be other risks which we now consider immaterial, or which are unknown or unpredictable, with respect to our business, our competition, the regulatory environment or otherwise that could have a material adverse effect on our business, financial condition and results of operations.

RISKS RELATED TO OUR FINANCIAL CONDITION AND CAPITAL REQUIREMENTS

We have incurred substantial losses and negative cash flow from operations in the past, and expect to continue to incur losses and negative cash flow for the foreseeable future.

We have a limited operating history, limited capital, and limited sources of revenue. Since our inception in 1980 through December 31, 2017, we have incurred aggregate net losses of approximately $381.8 million. Our net losses from continuing operations attributable to common stockholders for the years ended December 31, 2017 and December 31, 2016 were approximately $16.0 million and $31.0 million, respectively. As of December 31, 2017, our cash and cash equivalents, restricted cash, and marketable securities were $60.1 million. Our current business has not generated revenues in the past and for the foreseeable future we do not expect it to generate revenue to be sufficient to cover costs attributable to that business or to our operations as a whole, including our development activities associated with our product candidates. Ultimately, we may never generate sufficient revenue from our business to reach profitability, generate positive cash flow or sustain, on an ongoing basis, our current or projected levels of product development and other operations.

We anticipate that we will need substantial additional financing to continue our operations; if we are unable to raise additional capital, we may be forced to delay, reduce or eliminate one or more of our product development programs, and our business will be harmed.

Our current operating plan will require significant levels of additional capital to fund the continued development of our cell therapy product candidates and our clinical development activities.

We initiated a Phase 2 clinical trial of CLBS03 for TID in early 2016, and have other costs relating to that program, particularly due to the licensing of patents, data and collaboration with third parties. Our clinical activities are expected to continue to grow as these programs are advanced and they will require significant investment over a period of several years before they could be approved by FDA and commercialized by us, if ever. Even if we were to achieve encouraging results from the Phase 2 trial for CLBS03 and other product candidates, we are required to conduct additional clinical trials of the product candidates, including larger and more expensive pivotal Phase 3 trials to pursue commercialization of the candidates. To do so, we will need to raise additional capital, enter into collaboration agreements with third parties or undertake any combination thereof. If we are unsuccessful in our efforts to raise capital or find collaborative partners, we will likely need to otherwise delay or abandon the trials.

The amount and timing of our future capital requirements also will likely depend on many other factors, including:

- the scope, progress, results, costs, timing and outcomes of our cell therapy research and development programs and product candidates;
- our ability to enter into any collaboration agreements with third parties for our product candidates and the timing and terms of any such agreements;
- the costs associated with the consummation of one or more strategic transactions;
- the timing of and the costs involved in obtaining regulatory approvals for our product candidates, a process which could be particularly lengthy or complex given the FDA's limited experience with marketing approval for cell therapy products;
- the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities; and
- the cost of expansion of our development operations and personnel.

To both fund our clinical trials and support our future operations, we would likely seek to raise capital through a variety of different public and/or private financings vehicles. This could include, but not be limited to, implementation of our at-the-market ("ATM") sales agreement with H.C. Wainwright & Co., potential warrant exercises, option exercises, issuances of other debt or equity securities in public or private financings, and/or sale of assets. If we raise capital through the sale of equity, or securities convertible into equity, it would result in dilution to our then existing stockholders. Servicing the interest and principal repayment obligations under debt we incur, or whether we call it, diverts funds that would otherwise be available to support research and development, clinical or commercialization activities. In addition, debt financing involves covenants that restrict our ability to

operate our business. In certain cases, we also may seek funding through collaborative arrangements that would likely require us to relinquish certain rights to our technology or product candidates and share in the future revenues associated with the partnered product.

Ultimately, we may be unable to raise capital or enter into collaborative relationships on terms that are acceptable to us, if at all. Our inability to obtain necessary capital or financing to fund our future operating needs could adversely affect our business, results of operations and financial condition.

We have never generated any revenue from product sales and our ability to generate revenue from product sales and become profitable depends significantly on our success in a number of factors.

We have no products approved for commercial sale, have not generated any revenue from product sales, and do not anticipate generating any revenue from product sales until sometime after we have received regulatory approval for the commercial sale of a product candidate, which may never occur. Our ability to generate revenue from product sales and achieve profitability depends significantly on our success in many factors, including:

- completing research regarding, and nonclinical and clinical development of, our product candidates;
- obtaining regulatory approvals and marketing authorizations for product candidates for which we complete clinical trials;
- developing a sustainable and scalable manufacturing process for our product candidates;
- identifying and contracting with contract manufacturers that have the ability and capacity to manufacture our development products and make them at an acceptable cost;
- launching and commercializing product candidates for which we obtain regulatory approvals and marketing authorizations, either directly or with a collaborator or distributor;
- obtaining market acceptance of our product candidates as viable treatment options;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and/or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and
- attracting, hiring, and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA, or other regulatory agencies, domestic or foreign, to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those that we currently anticipate. If we are successful in obtaining regulatory approvals to market one or more of our product candidates, our revenue will depend, in part, upon the size of the markets in the territories for which we obtain regulatory approval, the accepted price for the product, the ability to receive reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable disease patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved products, we may never become profitable.

If our status as a smaller reporting company changes, Section 404(b) of the Sarbanes-Oxley Act of 2002 may require an independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Any delays or difficulty in satisfying these requirements could adversely affect our future results of operations and our stock price.

Section 404(b) of the Sarbanes-Oxley Act of 2002 requires an independent registered public accounting firm to test the internal control over financial reporting of public companies, and to report on the effectiveness of such controls, for each fiscal year ending after June 15, 2010. Under the Dodd Frank Wall Street Reform and Consumer Protection Act of 2010, we are exempt from Section 404(b) as long as we remain a smaller reporting company or a non-accelerated filer. If our status as a smaller reporting company changes, we may be required to comply with this auditor attestation requirement.

In addition, we may in the future discover areas of our internal controls that need improvement, particularly with respect to businesses that we may acquire. If so, we cannot be certain that any remedial measure we take will ensure that we have adequate internal controls over our financial processes and reporting in the future. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could harm our operating results or cause us to fail to meet our reporting

obligations. If we are unable to conclude that we have effective internal controls over financial reporting, or if it becomes necessary for our independent registered public accounting firm to provide us with an unqualified report regarding the effectiveness of our internal control over financial reporting and it is unable to do so, investors could lose confidence in the reliability of our financial statements. This could result in a decrease in the value of our common stock.

RISKS RELATED TO OUR CELL THERAPY PRODUCT DEVELOPMENT EFFORTS

Our future success may be dependent on the timely and successful development and commercialization of CLBS03, our TID product candidate, and if we encounter delays or difficulties in the development of this product candidate, as well as CLBS12, our experimental product for CLI that is in clinical development in Japan, or CLBS14 for CMD, our business prospects would be significantly harmed.

We are dependent upon the successful development, approval and commercialization of our product candidates. Before we are able to seek regulatory approval of our product candidates, we must conduct and complete extensive clinical trials to demonstrate their safety and efficacy in humans. All of our product candidates are in early stages of development.

In early 2016 we initiated a Phase 2 clinical trial for CLBS03, a Treg based therapeutic being developed for T1D. In late 2017 we initiated a clinical trial in Japan of CLBS12 taking advantage of the paradigm of potential conditional approval for regenerative medicine products established by new regulations in Japan for products that show sufficient safety evidence and some evidence of efficacy with CLI. We also expect to commence a clinical trial using CD34 cells to treat CMD later is year (CLBS14). Additionally, we are exploring the possibility of reactivating an IND originally filed by Baxalta for treating refractory angina with CD34 cells and engaging in discussions with the FDA about further development of a product under that IND, of which we are now the sponsor. Clinical testing is expensive, difficult to design and implement, and can take many years to complete. Importantly, a failure of one or more of these or any other clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to complete our clinical trials, receive regulatory approval or commercialize our cell therapy product candidates, including the following:

- suspensions, delays or changes in the design, initiation, enrollment, implementation or completion of required clinical trials;
- adverse changes in our financial position or significant and unexpected increases in the cost of our clinical development program;
- changes or uncertainties in, or additions to, the regulatory approval process that require us to alter our current development strategy;
- clinical trial results that are negative, inconclusive or even less than desired as to safety and/or efficacy, which could result in the need for additional clinical trials or the termination of the product's development;
- delays in our ability to manufacture the product in quantities or in a form that is suitable for any required clinical trials;
- intellectual property constraints that prevent us from making, using, or commercializing any of our cell therapy product candidates;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of these product candidates may be insufficient or inadequate:
- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation of clinical trials;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, contract manufacturing organizations or CMOs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, CMOs and clinical trial sites;
- delays in obtaining required IRB approval at each clinical trial site;
- inability to file IND's for our development candidates;
- imposition of a temporary or permanent clinical hold by the FDA or similar restrictions by other regulatory agencies for a number of reasons, including after review of an IND or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical trial operations or clinical trial sites; developments on trials conducted by competitors or approved products post-market for related technology that raises FDA concerns about risk to patients of the technology broadly; or if FDA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- difficulty collaborating with patient groups and investigators;

- failure by our CROs, CMOs other third parties, or us to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA or international GCP requirements;
- failure to reach agreement with the FDA on a satisfactory development path of our development candidates;
- delays in having patients qualify for or complete participation in a trial or return for post-treatment follow-up;
- patients dropping out of a clinical trial;
- occurrence of adverse events associated with the product candidate;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials or abandoning existing trials;
- transfer of manufacturing processes from our academic collaborators to larger-scale facilities operated by either a contract manufacturing organization, or CMO, or by us, and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process;
- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing; and
- FDA may not accept clinical data from trials that are conducted in countries where the standard of care is potentially different from the United States.

Any inability to successfully complete nonclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct bridging studies to demonstrate the equivalence of our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Even if we are able to successfully complete our clinical development program for our product candidates, and ultimately receive regulatory approval to market one or more of the products, we may, among other things:

- obtain approval for indications that are not as broad as the indications we sought;
- have the product removed from the market after obtaining marketing approval;
- encounter problems with respect to the manufacturing of commercial supplies
- be subject to additional post-marketing testing requirements; and/or
- be subject to restrictions on how the product is distributed or used.

We may experience delays in enrolling patients in our clinical trials, which could delay or prevent the receipt of necessary regulatory approvals.

We may not be able to initiate or complete as planned any clinical trials if we are unable to identify and enroll a sufficient number of eligible patients to participate in the clinical trials required by the FDA or other regulatory authorities. We also may be unable to engage a sufficient number of clinical trial sites to conduct our trials. Moreover, because PCT does not currently have manufacturing facilities operating outside of the United States, our ability to conduct trials outside of the United States may be constrained by our ability to transport trial materials to foreign destinations within the expiry period of such materials unless and until we commence operation outside of the United States or find another source of supply.

We may face challenges in enrolling patients to participate in our clinical trials due to the novelty of our cell-based therapies, the size of the patient populations and the eligibility criteria for enrollment in the trial. In addition, some patients may have concerns regarding cell therapy that may negatively affect their perception of therapies under development and their decision to enroll in the trials. Furthermore, patients suffering from diseases within target indications may enroll in competing clinical trials, which could negatively affect our ability to complete enrollment of our trials. Enrollment challenges in clinical trials often result in increased development costs for a product candidate, significant delays and potentially the abandonment of the clinical trial.

We may have other delays in completing our clinical trials and we may not complete them at all.

We have not completed the clinical trials necessary to obtain FDA approval to market CLBS03, CLBS12 CLBS14 or any of our other product candidates in development. We have not initiated Phase 3 clinical trials for any of our product candidates now in development. Our management lacks significant experience in completing Phase 3 trials and bringing a drug through commercialization. Clinical trials for other products in development may be delayed or terminated as a result of many factors, including the following:

- patients failing to complete clinical trials due to dissatisfaction with the treatment, side effects or other reasons;
- failure by regulators to authorize us to commence a clinical trial;
- suspension or termination by regulators of clinical research for many reasons, including concerns about patient safety or failure of our contract manufacturers to comply with cGMP requirements;
- delays or failure to obtain clinical supply for our products necessary to conduct clinical trials from contract manufacturers, including commercial grade clinical supply for our trials;
- treatment candidates demonstrating a lack of efficacy during clinical trials;
- inability to continue to fund clinical trials or to find a partner to fund the clinical trials;
- competition with ongoing clinical trials and scheduling conflicts with participating clinicians; and
- delays in completing data collection and analysis for clinical trials.

Any delay or failure to complete clinical trials and obtain FDA approval for our product candidates could have a material adverse effect on our cost to develop and commercialize, and our ability to generate revenue from, a particular product candidate.

We may be unable to manage multiple late stage clinical trials for a variety of product candidates simultaneously.

As our current clinical trials progress, we may need to manage multiple late stage clinical trials simultaneously in order to continue developing all of our current products. Our management team does not have significant experience in completing late stage clinical trials and the management of late stage clinical trials is more complex and time consuming than early stage trials. Typically, early stage trials involve several hundred patients in no more than 30 clinical sites. Late stage (Phase 3) trials may involve up to several thousand patients in up to several hundred clinical sites and may require facilities in several countries. Therefore, the project management required to supervise and control such an extensive program is substantially larger than early stage programs. As the need for these resources is not known until some months before the trials begin, it is necessary to recruit large numbers of experienced and talented individuals very quickly. If the labor market does not allow this team to be recruited quickly, the sponsor is faced with a decision to delay the program or to initiate it with inadequate management resources. This may result in recruitment of inappropriate patients, inadequate monitoring of clinical investigators and inappropriate handling of data or data analysis. Consequently, it is possible that conclusions of efficacy or safety may not be acceptable to permit submission of a BLA for any one of the above reasons or a combination of several.

The development of our cell therapy product candidates are subject to uncertainty because autologous cell therapy is inherently variable.

When manufacturing an autologous cell therapy, the number and the composition of the cell population varies from patient to patient. Such variability in the number and composition of these cells could adversely affect our ability to manufacture autologous cell therapies in a cost-effective or profitable manner and meet acceptable product release specifications for use in a clinical trial or, if approved, for commercial sale. As a consequence, the development and regulatory approval process for autologous cell therapy products could be delayed or may never be completed.

Any disruption to our access to the reagents we are using in the clinical development of our cell therapy product candidates could adversely affect our ability to perform clinical trials and seek future regulatory submissions.

Reagents, including CD3 and CD28 antibody conjugated magnetic beads manufactured by Life Technologies Corporation, as well as, devices, materials and systems that we are using in our clinical trials, that we intend to use in our planned clinical trials and that we may need or use in commercial production, are provided by unaffiliated third parties. Any lack of continued availability of these reagents, devices, materials and systems for any reason would have a material adverse effect on our ability to complete these studies and could adversely impact our ability to achieve commercial manufacture of our planned therapeutic products. Although other available sources for these reagents, devices, materials and systems may exist in the marketplace, we have not evaluated their cost, effectiveness, or intellectual property foundation and therefore cannot guarantee the suitability or availability of such other potential sources.

The initiation of pivotal Phase 3 clinical trials for cell therapy product candidates requires the validation and establishment of manufacturing controls that may delay the products' development timeline.

To conduct pivotal Phase 3 clinical trials, we are required to have certain validated and established manufacturing controls with respect to the safety, purity and potency of our product when administered to patients. If we determine that the results of our planned Phase 2 clinical trial in T1D, or the results of any other Phase 2 clinical trial we may conduct support Phase 3 development, we expect to initiate and complete one or more pivotal Phase 3 clinical trials for such programs and would need to address any outstanding chemistry, manufacturing and controls, or CMC, issues raised by the FDA prior to initiating such trials. We may not be successful in our efforts to address any CMC issues raised by the FDA. If we cannot initiate, or if we are delayed in initiating, a pivotal Phase 3 clinical program as a result of our failure to satisfy the FDA's CMC concerns or otherwise, the timing of regulatory

submission for commercialization of our product candidates would be delayed, or we may be unable to seek regulatory approval to commercialize our products at all.

Product candidates that appear promising in research and development may be delayed or may fail to reach later stages of clinical development.

The successful development of pharmaceutical product candidates is highly uncertain. Product candidates that appear promising in research and development and early clinical trials may be delayed or fail to reach later stages of development. Decisions regarding the further development of product candidates must be made with limited and incomplete data, which makes it difficult to ensure or even accurately predict whether the allocation of limited resources and the expenditure of additional capital on specific product candidates will result in desired outcomes. Preclinical and clinical data can be interpreted in different ways, and negative or inconclusive results or adverse events during a clinical trial could delay, limit or prevent the development of a product candidate.

A Fast Track designation by the FDA may not lead to a faster development, regulatory review or approval process.

If a product is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet needs for this condition, the treatment sponsor may apply for FDA Fast Track designation. We were granted Fast Track designation for CLBS03 from the FDA in July 2016. However, Fast Track designation does not ensure that we will experience a faster development, regulatory review or approval process compared to conventional FDA procedures. Additionally, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from the clinical development program.

Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which would prevent or delay regulatory approval and commercialization.

The clinical trials of our product candidates are, and the manufacturing and marketing of our products will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. In particular, because our product candidates are subject to regulation as biological drug products, we will need to demonstrate that they are safe, pure, and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. The risk/benefit profile required for product licensure will vary depending on these factors and may include adequate duration of response, a delay in the progression of the disease, and/or an improvement in survival. For example, response rates from the use of our product candidates may not be sufficient to obtain regulatory approval unless we can also show an adequate duration of response.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Exploratory trends and results observed in earlier stage clinical trials, particularly trends and results observed for small subsets that were not prespecified, may not be replicated in later stage clinical trials. Product candidates in Phase 3 clinical trials may fail to demonstrate sufficient efficacy despite having progressed through initial clinical trials, even if certain exploratory subset analyses of primary or secondary endpoints in those early trials showed trends toward efficacy or, in some analyses, nominal statistical significance. The results of clinical trials in one set of patients or line of treatment may not be predictive of those obtained in another.

We expect there may be greater variability in results for products processed and administered on a patient-by-patient basis, as anticipated for our product candidates, than for “off-the-shelf” products, like many other drugs. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

Data from earlier studies conducted by the third-party research institutions such as UCSF/Yale for CLBS03 should not be relied upon as evidence that later or larger-scale clinical trials will succeed. Some future trials may have different patient populations than current studies and will test our product candidates in different indications, among other differences. In addition, our proposed manufacturing processes for our product candidates include what we believe will be process improvements that are not part of the production processes that were previously used in the earlier conducted clinical trials being conducted by the research institutions. Accordingly, our results with our product candidates may not be consistent with the results of the clinical trials.

In addition, even if such trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as do we, and more trials could be required before we submit our product candidates for approval. To the

extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

We presently lack sufficient manufacturing capabilities to produce our product candidates at commercial scale quantities and do not have an alternate manufacturing supply, which could negatively impact our ability to meet any future demand for the products.

We expect that HCATS will provide exclusively the cell processing services necessary for clinical production for our CLBS03 Phase 2 T1D trial and for our CLBS14 study. The Foundation for Biomedical Research and Innovation, a Japanese Corporation with its principal place of business in Kobe, Japan ("FBRI") will provide all cell processing services for the CLBS12 CLI trial. HCATS and FBRI also provide services and produce materials for clinical trials on behalf of unaffiliated third parties. To date, neither has produced any products at commercial scale quantities. We expect that HCATS and FBRI would need to expand significantly their manufacturing capabilities to meet potential commercial demand for CLBS03, CLBS12 and any other of our product candidates, if approved, as well as any of our other product candidates that might attain regulatory approval. Such expansion would require additional regulatory approvals. Even if they increase their manufacturing capabilities, it is possible that they may still lack sufficient capacity to meet demand. Ultimately, if we are unable to supply our products to meet commercial demand, whether because of processing constraints or other disruptions, delays or difficulties that we experience, sales of the products and their long term commercial prospects could be significantly damaged.

We do not presently have redundant suppliers for CLBS03, CLBS12 or any of our other product candidates. If our facilities where these product candidates are being manufactured or equipment were significantly damaged or destroyed, or if there were other disruptions, delays or difficulties affecting manufacturing capacity, our planned and future clinical trials and commercial production for these product candidates would likely be significantly disrupted and delayed. It would be both time consuming and expensive to replace this capacity with third parties, particularly since any new facility would need to comply with regulatory requirements.

Ultimately, if we are unable to supply our cell therapy product candidates to meet commercial demand, were commercial approval obtained, whether because of processing constraints or other disruptions, delays or difficulties that we experience, our production costs could dramatically increase and sales of the product and its long-term commercial prospects could be significantly damaged.

The commercial potential and profitability of our products are unknown and subject to significant risk and uncertainty.

Even if we successfully develop and obtain regulatory approval for our cell therapy product candidates, the market may not understand or accept the products, which could adversely affect both the timing and level of future sales. Ultimately, the degree of market acceptance of our product candidates (or any of our future product candidates) will depend on a number of factors, including:

- be subject to restrictions on how the product is distributed or used;
- our ability to distinguish our products (which involve adult cells) from any ethical and political controversies associated with stem cell products derived from human embryonic or fetal tissue; and
- the cost of the product, the reimbursement policies of government and third-party payors and our ability to obtain sufficient third-party coverage or reimbursement.

Even if we are successful in achieving sales of our product candidates, it is not clear to what extent, if any, the products will be profitable. The costs of goods associated with production of cell therapy products are significant. While we are working to improve the speed and efficiency and lower the cost of our manufacturing processes, there can be no assurance that we will be successful in these efforts. In addition, some changes in manufacturing processes or procedures generally require FDA or foreign regulatory authority review and approval prior to implementation. We may need to conduct additional nonclinical studies and clinical trials to support approval of any such changes. Furthermore, this review process could be costly and time-consuming and could delay or prevent the commercialization of product candidates.

We may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe are essential to product commercialization or will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute the shares of our existing stockholders, or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates

because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy.

Further, collaborations involving our product candidates, such as our collaborations with third-party research institutions, are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into collaboration agreements and strategic partnerships or license our products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition, and results of operations.

We have limited experience in the development and marketing of cell therapies and may be unsuccessful in our efforts to establish a profitable business.

We have limited experience in the areas of cell therapy product development and marketing, and in the related regulatory issues and processes. Although we have recruited a team that has experience with designing and conducting clinical trials, as a company we have limited experience in conducting clinical trials and no experience in conducting clinical trials through to regulatory approval of any product candidate. In part because of this lack of experience, we cannot be certain that ongoing or planned clinical trials will begin or be completed on time, if at all.

Our cell therapy business is based on novel technologies that are inherently expensive, risky and may not be understood by or accepted in the marketplace, which could adversely affect our future value.

The clinical development, commercialization and marketing of cell and tissue-based therapies are at an early-stage, substantially research-oriented and financially speculative. To date, very few companies have been successful in their efforts to develop and commercialize a cell therapy product. In general, cell-based or tissue-based products may be susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy, or other characteristics that may prevent or limit their approval or commercial use. Regulatory approval of novel product candidates such as CLBS03, CLBS2 and CLBS14, which is manufactured using novel and proprietary manufacturing processes can be more complex and expensive and take longer than other, more well-known or extensively studied pharmaceutical or biopharmaceutical products, due to the FDA's lack of experience with them. To our knowledge, the FDA has only approved one personalized immunotherapy product to date. This lack of experience may lengthen the regulatory review process, require us to conduct additional

studies or clinical trials, which would increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these product candidates or lead to significant post-approval limitations or restrictions. Furthermore, the number of people who may use cell or tissue-based therapies is difficult to forecast with accuracy. Our future success is dependent on the establishment of a large global market for cell- and tissue-based therapies and our ability to capture a share of this market with our product candidates.

If competitors develop and market products that are more effective, safer, or less expensive than our product candidates or offer other advantages, our commercial prospects will be limited.

Our cell therapy development programs now face, and will continue to face, intense competition from pharmaceutical, biopharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies engaged in drug discovery activities or funding, both in the United States and abroad. Some of these competitors are pursuing the development of drugs and other therapies that target the same diseases and conditions that we are targeting with our product candidates.

Our T regulatory cell therapy product candidate for TID, CLBS03 faces competition from other immunomodulatory drugs being developed for other autoimmune diseases as well from other cellular therapies that fall outside of the coverage of our intellectual property. Currently, there are no approved therapies for newly onset T1D, but only regimens such as insulin or adjuvants to insulin that address the disease when the pancreas can no longer produce insulin. While not a direct competitor, in a more advanced population of T1D, sotagliflozin, an oral adjunctive therapy to insulin, is expected to receive FDA approval following positive results from a pivotal phase 3 trial conducted by Lexicom Pharmaceuticals in collaboration with Sanofi and JDRF. There are multiple agents in development targeting the modification of the course of the disease. Current approaches in development can be broadly divided into immune modulatory agents aiming to improve metabolic function by rescuing insulin producing beta cells, or regenerative agents that are aiming to replace beta cells. From a broad review of these agents and approaches, no other therapy for new-onset T1D is expected to be in advanced clinical trials or provide direct competition to our polyclonal regulatory T cell platform in the near future. If these therapies are easier to manufacture and have similar or better safety and efficacy profiles to CLBS03, the commercial prospects of our T regulatory cell therapy may be limited.

As a general matter, we also face competition from many other companies that are researching and developing cell therapies. Many of these companies have financial and other resources substantially greater than ours. In addition, many of these competitors have significantly greater experience in testing pharmaceutical and other therapeutic products, obtaining FDA and other regulatory approvals, and marketing and selling. If we ultimately obtain regulatory approval for any of our product candidates, we also will be competing with respect to manufacturing efficiency and marketing capabilities, areas in which we have limited or no commercial-scale experience. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in resources being even more concentrated by our competitors. Competition may increase further as a result of advances made in the commercial applicability of our technologies and greater availability of capital for investment in these fields.

Our cell therapy product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an existing reference product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product is approved under a biologics license application, or BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

There is a risk that the FDA will not consider any of our therapeutic candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Additionally, this period of regulatory exclusivity does not apply to companies pursuing regulatory approval via their own traditional BLA, rather than via the abbreviated pathway. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

We may be subject to significant product liability claims and litigation, including potential exposure from the use of our product candidates in human subjects, and our insurance may be inadequate to cover claims that may arise.

Our business exposes us to potential product liability risks inherent in the testing, processing and marketing of cell therapy products. Such liability claims may be expensive to defend and result in large judgments against us. We face an inherent risk of product liability exposure related to the testing of our current and any future product candidates in human clinical trials and will

face an even greater risk with respect to any commercial sales of our products should they be approved. No product candidate has been widely used over an extended period of time, and therefore safety data is limited. Cell therapy companies derive the raw materials for manufacturing of product candidates from human cell sources, and therefore the manufacturing process and handling requirements are extensive, which increases the risk of quality failures and subsequent product liability claims. We presently have product liability insurance limited to $10 million per incident and $10 million in annual aggregate.

We will need to increase our insurance coverage when we begin commercializing product candidates, if ever. At that time, we may not be able to obtain or maintain product liability insurance on acceptable terms with adequate coverage or at all, or if claims against us substantially exceed our coverage, then our financial position could be significantly impaired.

Whether or not we are ultimately successful in any product liability litigation that may arise, such litigation could consume substantial amounts of our financial and managerial resources, decreased demand for our products and injure our reputation.

We seek to maintain errors and omissions, directors and officers, workers' compensation and other insurance at levels we believe to be appropriate to our business activities. If, however, we were subject to a claim in excess of this coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim from our own limited resources, which could have a material adverse effect on our financial condition, results of operations and business. Additionally, liability or alleged liability could harm our business by diverting the attention and resources of our management and damaging our reputation.

We may be unable to retain key officers or employees or hire new key officers or employees needed to implement our business strategy and develop our products and businesses.

Given the specialized nature of cell therapy and that it is a relatively new field, there is an inherent scarcity of experienced personnel in the field. We are substantially dependent on the skills and efforts of current senior management for their management and operations, as well as for the implementation of our business strategy. In addition, our future success depends upon our ability to attract and retain additional qualified personnel (including medical, scientific, technical, commercial, business and administrative personnel) necessary to support our anticipated growth, develop our business, perform our contractual obligations to third parties and maintain appropriate licensure. There can be no assurance that we will be successful in attracting or retaining personnel required by us to continue to grow our operations. The loss of a key employee, the failure of a key employee to perform in his or her current position or our inability to attract and/or retain skilled employees, as needed, could result in our inability to continue to grow our business or to implement our business strategy, or may have a material adverse effect on our business, financial condition and operating results.

Our internal computer systems, or those used by our clinical investigators, clinical research organizations or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of development programs for our product candidates.

We rely on information technology systems to keep financial records, maintain laboratory and corporate records, communicate with staff and external parties and operate other critical functions. Any significant insufficiency degradation or failure of these computer systems could cause us to inaccurately calculate or lose our data. Despite the implementation of security measures, these internal computer systems and those used by our clinical investigators, clinical research organizations, and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. The techniques that could be used by criminal elements or foreign governments to attack these computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. While we have not experienced any such system failure, theft of information, accident or security breach to date, if such an event were to occur and cause interruptions in its operations, it could result in a material disruption of our clinical development activities. For example, the loss of clinical trial data from historical or future clinical trials could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. To the extent that any disruption, theft of information, or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the clinical development and the future development of our product candidates could be delayed.

RISKS RELATED TO MANUFACTURING OUR DEVELOPMENT PRODUCT CANDIDATES

On March 16, 2017, we entered the Purchase Agreement to sell our remaining membership interest in PCT to Hitachi. As a result of that Sale we will no longer have any ownership interest in PCT. See "Item 1. Business-Overview- Discontinued Operations". Consequently, we have no internal capacity to manufacture our development product candidates and have no assurance that we will continue to have access to manufacturers in our industry that can effectively make our development products or make them at an affordable, saleable or otherwise commercially reasonable price or quantity.

Cell manufacturer's have a finite manufacturing capacity, which could inhibit the long-term growth prospects of our business.

We currently have manufacturing contracts to produce materials for our clinical trials with HCATS at its existing manufacturing facilities in Allendale, New Jersey and Mountain View, California as well as with FBRI at its manufacturing facility in Kobe, Japan. These facilities are intended and have been designed to be compliant with FDA cGMP, and cGTP requirements. While we believe these facilities provide us with sufficient capacity to meet our expected near-term needs, it is possible that the demand for our products could exceed their existing manufacturing capacity. We expect that as our own cell therapy development programs progress and demand for cell therapy services in the industry expand, it may become necessary or desirable for us to expand our manufacturing vendors for cell therapy services and products in the future, which may require us to invest significant amounts of capital and to obtain regulatory approvals. If HCATS or FBRI is unable to meet our rising demand for products and services on a timely basis or unable to maintain cGMP compliance standards, then it is likely that we will seek to obtain the products and services from competitors, the availability of which we cannot guarantee, and the progress of our own programs will be impaired which could materially and adversely affect the overall success of our development programs.

Components of therapeutic products approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMPs. Manufacturers of cell-based product candidates such as CLBS03 also must comply with cGTPs. In addition, manufacturers of therapeutic products may be required to modify their manufacturing processes from time to time in response to FDA requests. The manufacture of live cellular-based products is complex and imposes significant regulatory burdens that may change over time. We may encounter difficulties in the production of our product candidates due to our limited manufacturing experience.

We will need to improve manufacturing efficiency at our contract manufacturers in order to establish cost of goods levels that will permit approved products to succeed commercially.

HCAT is working to improve the efficiency of cell therapy product development through the development of engineering and innovation solutions that go beyond current practices to develop long-term solutions to the unique challenges of cell therapy manufacturing with the ultimate goal of improving scale up, cost of goods quality control and robustness of the manufacturing process. They cannot provide assurances that they will be able to develop process enhancements that are acceptable to the FDA, on a timely basis, on commercially reasonable terms, or at all, or that any expected improvement in profitability will be realized. If they are unsuccessful in their efforts to develop these improvements, we may be unable to develop commercially viable products, which would impair our ability to continue our operations.

Lack of access to safe, reliable and effective transportation options could adversely affect our ability to meet our needs.

To effectively and efficiently deliver our cell therapy product, we also need to establish and maintain cost-effective relationships with reliable and experienced transportation carriers. Most existing transportation carriers are not optimally designed for the transportation of cell therapy products. For example, these carriers generally lack a true point-to-point chain of control, may have non-controlled X-ray and inspection, do not guarantee package orientation, handling or storage conditions and, in many cases, lack a standard, documented and tracked operating procedures. While reliable ground carriers with experience in the transport of blood products exist in major U.S. metropolitan areas, air carriers meeting such needs are limited. If carriers we currently use should cease medical shipping operations or otherwise become unable to properly meet our transportation needs, the lack of access to safe, reliable and effective transportation options could adversely affect our ability to meet our needs.

RISKS RELATED TO THE SALE

We are subject to five-year non-competition and non-solicitation covenants under the Purchase Agreement, which may limit our ability to operate our business in certain respects or sell the Retained Business to a third party.

During the period from March 16, 2017 (the “Effective Date”), the date of the Purchase Agreement by and among us, PCT, LLC and Hitachi until the fifth anniversary of the Effective Date (the “Non-Competition Period”), we are subject to non-competition and non-solicitation covenants made in the Purchase Agreement. During the Non-Competition Period, we will be restricted from (i) engaging in the provision of service solutions for the contract research, development, manufacture, testing, storage, distribution and commercialization of cell based therapies (the “Business”) and (ii) establishing any joint venture or other arrangement with a third party other than Hitachi America if such joint venture or other arrangement would compete with PCT or Hitachi America in any aspect of the Business, subject to certain exceptions, and from soliciting for employment persons who are employees or consultants of PCT or Hitachi America and their affiliates that are controlled by Hitachi America.

These limitations may negatively impact the scope and/or volume of our business, which may adversely affect our financial condition and results of operations. In addition, certain third party acquirers of our current business would be subject to these limitations during the Non-Competition Period, which may limit our opportunities with respect to a future sale transaction of our current business during the Non-Competition Period that may otherwise be favorable to our stockholders.

PCT may not achieve the milestone under the Purchase Agreement, which would result in us not receiving the milestone payment.

Pursuant to the terms of the Purchase Agreement, Hitachi will pay us a $5.0 million milestone payment if PCT achieves $125 million in cumulative revenue (excluding clinical service reimbursables) for the period from January 1, 2017 through December 31, 2018. PCT's revenue would have to increase significantly to achieve the milestone. Accordingly, there can be no assurance that we will receive the $5.0 million milestone payment contemplated by the Purchase Agreement.

We are obligated to indemnify Hitachi America for certain losses resulting from breaches of the representation and warranties and covenants in the Purchase Agreement as well as for certain litigation relating to the Sale.

Under the terms of the Purchase Agreement, we are obligated to indemnify Hitachi America for certain losses resulting from breaches of the representations and warranties and covenants in the Purchase Agreement as well as certain litigation relating to the Sale. Upon closing of the Sale, $5.0 million of the purchase price was paid into an escrow fund to be used as partial security to cover any liabilities that may result from indemnification claims that Hitachi America may have pursuant to the Purchase Agreement. Moreover, in certain instances, our liability to Hitachi America for indemnification claims could be higher than the $5 million set aside in the escrow fund. Any and all such liability would reduce the net proceeds from the Sale that are available for our use.

We may be exposed to litigation related to the Sale from the holders of our stock.

Transactions such as the Sale are often subject to lawsuits by stockholders. Because the holders of our stock did not receive any consideration from the Sale, it is possible that they may sue us or our board of directors. Such lawsuits could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

RISKS RELATED TO GOVERNMENT REGULATION

The development and commercialization of our product candidates is subject to extensive regulation by the FDA and other regulatory agencies in the United States and abroad, and the failure to receive regulatory approvals for our cell therapy product candidates would likely have a material and adverse effect on our business and prospect

To date, we have not received regulatory approval to market any of our product candidates in any jurisdiction. If we seek approval of any of our cell therapy product candidates, we will be required to submit to FDA and European and potentially other regulatory authorities extensive preclinical and clinical data supporting the safety and efficacy of such products, as well as information about the manufacturing process and to undergo inspection of manufacturing facilities, among other things. The process of obtaining FDA and other regulatory approvals is expensive, typically takes many years and is subject to numerous risks and uncertainties, particularly with complex and/or novel product candidates such as our cell-based product candidates. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application or may make it easier for our competitors to gain regulatory approval to enter the marketplace. Ultimately, the FDA and other regulatory agencies have substantial discretion in the approval process and may refuse to accept any application or may decide that our product candidate data are insufficient for approval without the submission of additional preclinical, clinical or other time-consuming studies. In addition, varying agency interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable

Any of the following factors, among others, could cause regulatory approval for our product candidates to be delayed, limited or denied:

- the product candidates require significant clinical testing to demonstrate safety and effectiveness before applications for marketing approval can be submitted to the FDA and other regulatory authorities;
- data obtained from animal testing and other nonclinical testing and clinical trials can be interpreted in different ways, and regulatory authorities may not agree with our respective interpretations or may require us to conduct additional testing
- negative or inconclusive results or the occurrence of serious or unexpected adverse events during a clinical trial could cause us to delay or terminate development efforts for a product candidate; and/or
- the FDA and other regulatory authorities may require expansion of the size and scope of the clinical trials.

Any difficulties or failures that we encounter in securing regulatory approval for our product candidates would likely have a substantial adverse impact on our ability to generate product sales and could make any search for a collaborative partner more difficult.

We may be unsuccessful in our efforts to comply with applicable federal, state and international laws and regulations, which could result in loss of licensure, certification or accreditation or other government enforcement actions or impact our ability to secure regulatory approval of our product candidates.

Although we seek to conduct our business in compliance with applicable laws and regulations, these laws and regulations are exceedingly complex and often subject to varying interpretations. The cell therapy industry is the topic of significant government interest, and thus the laws and regulations applicable to our business are subject to frequent change and/or reinterpretation. As such, there can be no assurance that we will be able, or will have the resources, to maintain compliance with all such healthcare laws and regulations. Failure to comply with such healthcare laws and regulations could result in significant enforcement actions, civil or criminal penalties, which along with the costs associated with such compliance or with enforcement of such healthcare laws and regulations, may have a material adverse effect on our operations or may require restructuring of our operations or impair our ability to operate profitably.

Facilities engaged in the recovery, processing, storage, labeling, packaging or distribution of any HCT/Ps, or the screening or testing of a donor, are required to register with the FDA. Any third party retained by us to process our samples must be similarly registered with the FDA and comply with HCT/P regulations as well as with FDA's cGTP regulations. If they fail to comply with cGTP requirements they will be out of compliance with FDA regulations which could adversely affect our business.

FDA's cGMP regulations govern the manufacture, processing, packaging and holding of cell therapy products regulated as drugs. FDA's Quality System Regulation, ("QSR"), similarly governs the manufacture, processing, packaging and holding of cell therapy products regulated as medical devices. Any third-party manufacturers that prepare our products must comply with cGMP or QSR requirements including quality control, quality assurance and the maintenance of records and documentation for certain products. They may be unable to comply with these cGMP or QSR requirements and with other FDA, state and foreign regulatory requirements. These requirements may change over time and we or third-party manufacturers may be unable to comply with the revised requirements.

If we are unable to conduct clinical trials in accordance with regulations and accepted standards, we may be delayed in receiving, or may never receive, regulatory approvals of our product candidates from the FDA and other regulatory authorities.

To obtain marketing approvals for our product candidates in the United States and abroad, we must, among other requirements, complete adequate and well-controlled clinical trials sufficient to demonstrate to the FDA and other regulatory bodies that the product candidate is safe and effective for each indication for which approval is sought. If the FDA finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury, due to, among other things, occurrence of one or more serious adverse events in an ongoing clinical trial, the FDA can place one or more of our clinical trials on partial or full clinical hold. If safety concerns develop, we may, or the FDA, a foreign regulatory authority, or an IRB may require us to, stop the affected trials before completion.

The completion of our clinical trials also may be delayed or terminated for a number of other reasons, including if:

- third-party clinical investigators do not perform the clinical trials on the anticipated schedule or consistent with the clinical trial protocol, good clinical practices required by the FDA and other regulatory requirements, or other third parties do not perform data collection and analysis in a timely or accurate manner;
- inspections of clinical trial sites by the FDA or by IRBs of research institutions participating in the clinical trials, reveal regulatory violations that require the sponsor of the trial to undertake corrective action, suspend or terminate one or more sites, or prohibit use of some or all of the data in support of marketing applications; or
- the FDA or one or more IRBs suspends or terminates the trial at an investigational site, or precludes enrollment of additional subjects.

Our development costs will increase if there are material delays in our clinical trials, or if we are required to modify, suspend, terminate or repeat a clinical trial. If we are unable to conduct our clinical trials properly, we may never receive regulatory approval to market our product candidates.

We will continue to be subject to extensive FDA regulation following any product approvals, and if we fail to comply with these regulations, we may suffer a significant setback in our business.

Even if we are successful in obtaining regulatory approval of our product candidates, we will continue to be subject to the requirements of and review by, the FDA and comparable regulatory authorities in the areas of manufacturing processes, quality assurance, post-approval clinical data, adverse event reporting, labeling, advertising and promotional activities, among other things. In addition, any marketing approval we receive may be limited in terms of the approved product indication or require costly post-marketing testing and surveillance. Discovery after approval of previously unknown problems with a product, manufacturer or manufacturing process, or a failure to comply with regulatory requirements, may result in actions such as:

- warning letters or untitled letters or other actions requiring changes in product manufacturing processes or restrictions on product marketing or distribution;
- product recalls or seizures or the temporary or permanent withdrawal of a product from the market; and
- fines, restitution or disgorgement of profits or revenue, the imposition of civil penalties or criminal prosecution.

The occurrence of any of these actions would likely cause a material adverse effect on our business, financial condition and results of operations.

Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by our product candidates after obtaining U.S. or foreign regulatory approval or other products with the same or related active ingredients, a number of potentially consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may require a recall of the product or we may voluntarily recall a product;
- regulatory authorities may require the addition of warnings or contradictions in the product labeling, narrowing of the indication in the product label or issuance of field alerts to physicians and pharmacies;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients or institute a REMS;
- we may be subject to limitation as to how we promote the product;
- we may be required to change the way the product is administered or modify the product in some other way;
- the FDA or applicable foreign regulatory authority may require additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;
- sales of the product may decrease significantly;
- we could be sued and held liable for harm caused to patients; and
- our brand and reputation may suffer

Health care companies have been the subject of federal and state investigations, and we could become subject to investigations in the future.

Both federal and state government agencies have heightened civil and criminal enforcement efforts. There are numerous ongoing investigations of health care companies, including drug, biologic an medical device companies, as well as their executives and managers. In addition, amendments to the Federal False Claims Act, including under healthcare reform, have made it easier for private parties to bring "*qui tam*" (whistleblower) lawsuits against companies under which the whistleblower may be entitled to receive a percentage of any money paid to the government. The Federal False Claims Act provides, in part, that an action can be brought against any person or entity that has knowingly presented, or caused to be presented, a false or fraudulent request for payment from the federal government, or who has made a false statement or used a false record to get a claim approved. The government has taken the position that claims presented in violation of the federal anti-kickback law, Stark Law or other healthcare-related laws, including laws enforced by the FDA, may be considered a violation of the Federal False Claims Act. Penalties include substantial fines for each false claim, plus three times the amount of damages that the federal government sustained because of the act of that person or entity and/or exclusion from the Medicare program. In addition, a majority of states have adopted similar state whistleblower and false claims provisions.

We are not aware of any government investigations involving any of our facilities or management. While we believe that we are in material compliance with applicable governmental healthcare laws and regulations, any future investigations of our business or executives could cause us to incur substantial costs, and result in significant liabilities or penalties, as well as damage to our reputation.

It is uncertain to what extent the government, private health insurers and third-party payors will approve coverage or provide reimbursement for the therapies and products to which our services relate. Availability for such reimbursement may be further limited by an increasing uninsured population and reductions in Medicare and Medicaid funding in the United States.

To the extent that health care providers cannot obtain coverage or reimbursement for our therapies and products, they may elect not to provide such therapies and products to their patients and, thus, may not need our services. Further, as cost containment pressures are increasing in the health care industry, government and private payors may adopt strategies designed to limit the amount of reimbursement paid to health care providers.

Similarly, the trend toward managed health care and bundled pricing for health care services in the United States, could significantly influence the purchase of healthcare services and products, resulting in lower prices and reduced demand for our therapeutic products under development.

We may receive a portion of our revenues from services rendered to patients enrolled in federal health care programs, such as Medicare, and we may also directly or indirectly receive revenues from federal health care programs. Federal health care programs are subject to changes in coverage and reimbursement rules and procedures, including retroactive rate adjustments. These contingencies could materially decrease the range of services covered by such programs or the reimbursement rates paid

directly or indirectly for our products and services. To the extent that any health care reform favors the reimbursement of other therapies over our therapeutic products under development, such reform could affect our ability to sell our services, which may have a material adverse effect on our revenues.

The limitation on reimbursement available from private and government payors may reduce the demand for, or the price of, our services, which could have a material adverse effect on our revenues. Additional legislation or regulation relating to the health care industry or third-party coverage and reimbursement may be enacted in the future which could adversely affect the revenues generated from the sale of our products and services.

Furthermore, there has been a trend in recent years towards reductions in overall funding for Medicare and Medicaid. There has also been an increase in the number of people who do not have any form of health care coverage in recent years and who are not eligible for or enrolled in Medicare, Medicaid or other governmental programs. The extent to which the reforms brought about under healthcare reform may be successful in reducing the number of such uninsured is unclear, and the reduced funding of governmental programs and increase in uninsured populations could have a negative impact on the demand for our services to the extent they relate to products and services which are reimbursed by government and private payors.

Unintended consequences of healthcare reform legislation in the U.S. may adversely affect our business.

The healthcare industry is undergoing fundamental changes resulting from political, economic and regulatory influences. In the U.S., comprehensive programs are under consideration that seek to, among other things, increase access to healthcare for the uninsured and control the escalation of healthcare expenditures within the economy. In March 2010, the Patient Protection and Affordable Care Act (“PPACA”), as amended by the Health Care and Education Reconciliation Act, or the Affordable Care Act, was passed, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. While we do not believe this legislation will have a direct impact on our business, the legislation requires the adoption of implementing regulations, which may have unintended consequences or indirectly impact our business. For instance, the scope and implications of the amendments pursuant to the Fraud Enforcement and Recovery Act of 2009 (“FERA”), have yet to be fully determined or adjudicated and as a result it is difficult to predict how future enforcement initiatives may impact our business. Also, in some instances our clients may be health insurers that will be subject to limitations on their administrative expenses and federal review of “unreasonable” rate increases that could impact the prices they pay for our services. If the legislation causes such unintended consequences or indirect impact, it could have a material adverse effect on our business, financial condition and results of operations.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation’s automatic reduction to several government programs. This included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Strong, partisan disagreement in Congress has prevented implementation of various PPACA provisions, and the Trump Administration has made repeal of the PPACA a priority. One of the first executive orders of the Trump administration granted federal agencies broad powers to unwind regulations under the PPACA. On January 11, 2017, the Senate voted to approve a “budget blueprint” allowing Republicans to repeal parts of the law while avoiding Democrat filibuster. The “Obamacare Repeal Resolution” passed 51-48. Certain legislators are continuing their efforts to repeal the PPACA, although there is little clarity on how such a repeal would be implemented and what a PPACA replacement might look like. For the immediate future, there is significant uncertainty regarding the health care, health care coverage and health care insurance markets.

The U.S. government has in the past considered, is currently considering and may in the future consider healthcare policies and proposals intended to curb rising healthcare costs, including those that could significantly affect both private and public reimbursement for healthcare services. State and local governments, as well as a number of foreign governments, are also considering or have adopted similar types of policies. Future significant changes in the healthcare systems in the United States or elsewhere, and current uncertainty about whether and how changes may be implemented, could have a negative impact on the demand for our products. We are unable to predict whether other healthcare policies, including policies stemming from legislation or regulations affecting our business, may be proposed or enacted in the future; what effect such policies would have on our business; or the effect ongoing uncertainty about these matters will have on the purchasing decisions of our customers.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressures.

Competitor companies or hospitals may be able to take advantage of EU rules permitting sales of unlicensed medicines for individual patients to sell competing products without a marketing authorization.

The EU medicines rules allow individual member states to permit the supply of a medicinal product without a marketing authorization to fulfill special needs, where the product is supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of a healthcare professional and for use by an individual patient under his direct personal responsibility. This may in certain countries also apply to products manufactured in a country outside the EU and imported to treat specific patients or small groups of patients. In addition, advanced therapy medicinal products do not need a marketing authorization if they are prepared on a non-routine basis and are used within the same EU member state in a hospital in accordance with a medical prescription for an individual patient.

These exemptions could allow our competitors to make sales in the EU without having obtained a marketing authorization and without undergoing the expense of clinical trials, especially if those competitors have cell processing facilities in the relevant EU member state. Similarly, certain hospitals may be able to compete with us on the basis of these rules. Because any such sales would be made without a marketing authorization, there would be no need for the competitor company or hospital to refer to the clinical data in our marketing authorization dossiers, and so any data exclusivity protection that we may obtain for our products would not prevent such competing sales.

A variety of risks associated with operating our business internationally could materially adversely affect our business.

We plan to seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we, and any potential collaborators in those jurisdictions, will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls, and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign laws;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our planned international operations may materially adversely affect our ability to attain or maintain profitable operations.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

We may be unable to obtain or maintain patent protection for our products and product candidates, which could have a material adverse effect on our business.

Our commercial success will depend, in part, on obtaining and maintaining patent protection for new technologies, product candidates, products and processes and successfully defending such patents against third party challenges. To that end, we file patent applications, and have been issued patents, that are intended to cover certain methods and uses of stem cells as well as compositions and methods relating to T regulatory cells and hematopoietic stem cells. These patent applications may never result in the issuance of patents.

The patent positions of biotechnology companies can be highly uncertain and involve complex legal, scientific and factual questions and recent court decisions have introduced significant uncertainty regarding the strength of patents in the industry. Moreover, the legal systems of some foreign countries do not favor the aggressive enforcement of patents and may not protect our

intellectual property rights to the same extent as the laws of the United States. Any of the issued patents we own or license may be challenged by third parties and held to be invalid, unenforceable or with a narrower or different scope of coverage that what we currently believe, effectively reducing or eliminating protection we believed we had against competitors with similar products or technologies. If we ultimately engage in and lose any such patent disputes, we could be subject to competition and/or significant liabilities, we could be required to enter into third-party licenses or we could be required to cease using the disputed technology or product. In addition, even if such licenses are available, the terms of any license requested by a third party could be unacceptable or unaffordable to us.

Product development and approval timelines in the biotechnology industry are very lengthy. As such, it is possible that any patents that may cover an approved product may have expired at the time of commercialization or only have a short remaining period of exclusivity, thereby reducing the commercial advantages of the patent. In such case, we would then rely solely on other forms of exclusivity, such as regulatory exclusivity provided by the FDC Act, which may provide less protection to our competitive position.

Litigation relating to intellectual property is expensive, time consuming and uncertain, and we may be unsuccessful in our efforts to protect against infringement by third parties or defend ourselves against claims of infringement.

To protect our intellectual property, we may initiate litigation or other proceedings. In general, intellectual property litigation is costly, time-consuming, diverts the attention of management and technical personnel and could result in substantial uncertainty regarding our future viability, even if we ultimately prevail. Some of our competitors may be able to sustain the costs of such litigation or other proceedings more effectively than can we because of their substantially greater financial resources. The loss or narrowing of our intellectual property protection, the inability to secure or enforce our intellectual property rights or a finding that we have infringed the intellectual property rights of a third party could limit our ability to develop or market our products and services in the future or adversely affect our revenues. Furthermore, any public announcements related to such litigation or regulatory proceedings could adversely affect the price of our common stock.

Third parties may allege that the research, development and commercialization activities we conduct infringe patents or other proprietary rights owned by such parties. While we do not believe any of our current activities infringe the rights of others, we have not conducted an exhaustive search or analysis of third-party patent rights to determine whether our pre-clinical or clinical research and development or activities may infringe or be alleged to infringe any third-party patent rights. If we are found to have infringed the patents of a third party, we may be required to pay substantial damages; we also may be required to seek from such party a license, which may not be available on acceptable terms, if at all, to continue our activities. A judicial finding or infringement or the failure to obtain necessary licenses could prevent us from commercializing our products, which would have a material adverse effect on our business, operating results and financial condition.

If we are unable to maintain our licenses, patents or other intellectual property we could lose important protections that are material to continuing our operations and our future prospects.

To obtain and maintain patent protection and licensing rights under certain of our license agreement, we must, among other things, ensure the timely payment of all applicable filing and maintenance fees. Any failure to do so could result in the loss of some or all of our rights to proprietary technology or the inability to secure or enforce intellectual property protection.

Additionally, our license agreements require us to meet certain diligence obligations in the development of the licensed products. Our failure to meet these diligence obligations could result in the loss of some or all of our rights, which could materially and adversely affect our business and future prospects.

If we are unable to protect the confidentiality of trade secrets, our competitive position could be impaired.

A significant amount of our technology, especially regarding manufacturing processes, is unpatented and is maintained as trade secrets and /or know-how. We expend significant energy, resources and know-how in an effort to protect these trade secrets and know-how, including through the use of confidentiality agreement. Even so, improper use or disclosure of our confidential information could occur and in such case adequate remedies may not exist. The disclosure of trade secrets and know-how could impair our competitive position.

In certain countries, patent holders may be required to grant compulsory licenses, which would likely have a significant and detrimental effect on any future revenues in such country.

Many countries, including some countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, most countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may be limited to monetary relief and may be unable to enjoin infringement, which could materially diminish the value of the patent. Compulsory licensing of life-saving products is also becoming increasingly common in developing countries, either through direct legislation or international initiatives. Such compulsory licenses could be extended to our product candidates, which may limit our potential revenue opportunities, including with respect to any future revenues that may result from our product candidates.

Changes to U.S. patent law may have a material adverse effect on our intellectual property rights.

The Leahy-Smith America Invents Act (AIA), which was signed into law on September 16, 2011, significantly changed United States patent law. It may take some time to establish what the law means, since it is just being interpreted by the lower courts, and any lower court decisions have not been reviewed by either the Federal Circuit Court of Appeals or the Supreme Court, a process that will take years. The first major change is that AIA switches the U.S. patent system from a "first to invent" system to a "first to file" system. Now that the first to file system is in effect, there is a risk that another company may independently develop identical or similar patents at approximately the same time, and be awarded the patents instead of us. Further, for the second major change, AIA abolished interference proceedings, and establishes derivation proceedings to replace interference proceedings in all cases in which the time period for instituting an interference proceeding has not lapsed where an inventor named in an earlier application derived the claimed invention from a named inventor. Now that the derivation proceedings are in effect, there is a risk that the inventorship of any pending patent application can be challenged for reasons of derivation. The third major change is that AIA established post-grant opposition proceedings that will apply only to patent applications filed after "first to file" became effective. Post-grant opposition will enable a person who is not the patent owner to initiate proceedings in the Patent office within 9 months after the grant of a patent that can result in cancellation of a patent as invalid. There is a risk, therefore, that any of our patents once granted after the effective date of these provisions of the AIA (March 16, 2013) may be subject to post-grant opposition, which will increase uncertainty on the validity of any newly granted patent or may ultimately result in cancellation of the patent.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents, trademarks and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, and reexamination proceedings before the USPTO and corresponding foreign patent offices and trademark violations. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products and services. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products and services may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to devices, materials, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our products and services. We have conducted freedom to operate analyses with respect to only certain of our products and services, and therefore we do not know whether there are any third-party patents that would impair our ability to commercialize these products and services. We also cannot guarantee that any of our analyses are complete and thorough, nor can we be sure that we have identified each and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of our products and services. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our products or services may infringe.

In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover aspects of our products or services, the holders of any such patents may be able to block our ability to commercialize such products or services unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our products or services. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

RISKS RELATED TO OUR CAPITAL STOCK

Our stock price has been, and will likely continue to be, highly volatile.

The market price of our common stock has been and in the future may continue to be highly volatile. For example, from January 1, 2017 through March 20, 2018 our common stock traded as low as $2.63 per share and as high as $7.79 per share; in 2016, our common stock traded as low as $2.65 per share and as high as $13.30 per share.

The market price for our common stock is highly dependent on, among other things, stock market conditions in general, our clinical development efforts the profitability and growth of our cell therapy services business and the growth of our business in general, the amount of our available cash and investments and our level of cash utilization. Future events could increase the

volatility seen in our common stock and ultimately cause a significant decline in the price of our common stock and ultimately impact our ability to raise additional capital in the future. These events could include the following, among others:

- low levels of trading volume for our shares;
- capital-raising or other transactions that are, or may in the future be, dilutive to existing stockholders or that involve the issuance of debt securities;
- delays in our clinical trials, negative clinical trial results or adverse regulatory decisions relating to our product candidates;
- adverse fluctuations in our revenues or operating results or financial results that otherwise fall below the market's expectations;
- disappointing developments concerning our cell therapy services clients or other collaborators for our product candidates; and
- legal challenges, disputes and/or other adverse developments impacting our patents or other proprietary rights that protect our products.

In addition, broader external events, such as news concerning economic or market conditions in the general economy or within our industry, the activities of our competitors, changes (or the threat of changes) in U.S. or foreign government regulations impacting the life sciences industry or the movement of capital into or out of our industry, are likely to affect the price of our common stock. There can be no assurance that the market price of our common stock will not continue to fluctuate or decline significantly in the future.

In addition to potential dilution associated with future fundraising transactions, we currently have significant numbers of securities outstanding that are exercisable for our common stock, which could result in significant additional dilution and downward pressure on our stock price.

As of December 31, 2017, there were 9,483,911 shares of our common stock outstanding. In addition, there were outstanding stock options and warrants representing the potential issuance of an additional 1,254,407 shares of our common stock. The issuance of these shares in the future would result in significant dilution to our current stockholders and could adversely affect the price of our common stock and the terms on which we could raise additional capital. In addition, the issuance and subsequent trading of shares could cause the supply of our common stock available for purchase in the market to exceed the purchase demand for our common stock. Such supply in excess of demand could cause the market price of our common stock to decline.

Sales of our common stock pursuant to our at-the-market sales agreement with H.C. Wainwright & Co., may cause substantial dilution to our existing stockholders and the sale of such shares of common stock could cause the price of our common stock to decline.

We entered into a Common Stock Sales Agreement with H.C. Wainwright & Co. in February 2018, pursuant to which we may sell up to $12 million of shares of our common stock over the term of that agreement, subject to certain terms and conditions.

Sales by us pursuant to the sales agreement may result in substantial dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of any sales of our shares under the sales agreement and may be terminated by us at any time at our discretion without any cost to us.

Provisions in our amended and restated certificate of incorporation and bylaws and Delaware law may inhibit a takeover of us, which could limit the price investors might be willing to pay in the future for our common stock and could entrench management.

Our amended and restated certificate of incorporation and bylaws contain provisions that may discourage unsolicited takeover proposals that stockholders may consider to be in their best interests. Our board of directors is divided into three classes, each of which will generally serve for a term of three years with only one class of directors being elected in each year. As a result, at a given annual meeting only a minority of the board of directors may be considered for election. Since our staggered board of directors may prevent our stockholders from replacing a majority of our board of directors at any given annual meeting, it may entrench management and discourage unsolicited stockholder proposals that may be in the best interests of stockholders. Moreover, our board of directors has the ability to designate the terms of and issue new series of preferred stock without stockholder approval.

We are also subject to anti-takeover provisions under Delaware law, which could delay or prevent a change of control. Together, these provisions may make more difficult the removal of management and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our securities.

Failure to maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business and stock price.

During the course of testing our disclosure controls and procedures and internal control over financial reporting, we may identify and disclose material weaknesses or significant deficiencies in internal control over financial reporting that will have to be remedied. Implementing any appropriate changes to our internal control may require specific compliance training of our directors, officers and employees, entail substantial costs to modify our existing accounting systems, and take a significant period of time to complete. Such changes may not, however, be effective in maintaining the adequacy of our internal control over financial reporting, and any failure to maintain that adequacy or inability to produce accurate financial statements on a timely basis could result in our financial statements being unreliable, increase our operating costs and materially impair our ability to operate our business.

Failure to achieve and maintain effective internal control over financial reporting could result in a loss of investor confidence in our financial reports and could have a material adverse effect on our stock price. Additionally, failure to maintain effective internal control over our financial reporting could result in government investigation or sanctions by regulatory authorities.

We have already, and could again in the future, fail to comply with the continued listing requirements of the Nasdaq Capital Market, such that our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Our common stock is listed for trading on the Nasdaq Capital Market. We must satisfy Nasdaq's continued listing requirements, including, among other things, a minimum closing bid price requirement of $1.00 per share for 30 consecutive business days. If a company trades for 30 consecutive business days below the $1.00 minimum closing bid price requirement, Nasdaq will send a deficiency notice to the company, advising that it has been afforded a "compliance period" of 180 calendar days to regain compliance with the applicable requirements. Thereafter, if such a company does not regain compliance with the bid price requirement, a second 180-day compliance period may be available. In February 2016, we received such a deficiency notice from the Nasdaq informing us that our stock had traded under $1.00 for thirty (30) consecutive trading days, and that if it does not trade at or above $1.00 for ten (10) consecutive trading days during the next 180 days, our common stock would be delisted absent meeting other conditions for delaying delisting. On July 28, 2016, the Company effected a one-for-ten reverse stock split of its issued and outstanding shares of common stock to increase the per share trading price of our common stock to satisfy the $1.00 minimum bid price requirement. By letter dated August 11, 2016, The Nasdaq Capital Market, Listing Qualification Department, confirmed that our common stock was in compliance with listing requirements.

A delisting of our common stock from Nasdaq could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and fewer business development opportunities.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

Our corporate headquarters are in Basking Ridge, New Jersey. The space is approximately 11,600 rentable square feet. The base monthly rent is approximately $24,000 and the lease term ends July 31, 2020. In addition, there are two five-year renewal options. In February 2018, we executed a two-year lease for approximately 3,400 rentable square feet in Rye Brook, New York. The new office lease will be for administrative staff, and replaces our 10,000 square foot lease in New York, New York, which expired on January 31, 2018. The base monthly rent is approximately $8,400 for our Rye Brook, New York office. In addition, we have the option to renew the lease for a three-year term. We believe the total leased space is sufficient for the near future.

ITEM 3. LEGAL PROCEEDINGS.

We are party to certain legal proceedings in the ordinary course of business. We do not believe that any current legal proceedings are likely to have a material effect on our business, financial condition or results of operations.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

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 at 5:00 pm 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 its 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.

All references in this Annual Report on Form 10-K 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, unless otherwise noted.

Market for Our Common Equity

Our common stock trades on The Nasdaq Capital Market under the symbol “CLBS.” The following table sets forth the high and low sales prices of our common stock for each quarterly period presented, as reported by the Nasdaq.

2017	High	Low
First Quarter	$7.79	$2.85
Second Quarter	$5.54	$4.10
Third Quarter	$4.71	$3.58
Fourth Quarter	$3.93	$2.63

2016	High	Low
First Quarter	$13.30	$4.00
Second Quarter	$7.80	$4.50
Third Quarter	$6.50	$5.10
Fourth Quarter	$5.00	$2.65

On March 20, 2018, the last reported price of our common stock was $5.95 per share.

Holders

As of March 22, 2018, there were approximately 773 stockholders of record of our common stock. The number of record holders was determined from the records of our transfer agent and does not include beneficial owners of our common stock whose shares are held in the names of various security brokers, dealers, and registered clearing agencies.

Dividends and Dividend Policy

We have not paid cash dividends on our common stock during the periods set forth in the stock price table that appears above. The holders of our common stock are each entitled to receive dividends when and if declared by the board of directors out of funds legally available therefor, subject to the terms of any outstanding series of preferred stock. We intend to retain any future earnings to fund the development and growth of our business, and therefore we do not anticipate paying any cash dividends on our common stock in the foreseeable future.

Equity Compensation Plan Information

The following table provides information as of December 31, 2017 regarding shares of our common stock that may be issued under our existing equity compensation plans, including our 2003 Stock Option and Incentive Plan (the “2003 Plan”), 2009 Stock Option and Incentive Plan (the “2009 Plan”), our 2015 Equity Compensation Plan (the "2015 Plan"), our 2012 Employee Stock Purchase Plan (the “2012 ESPP”), and our 2017 Employee Stock Purchase Plan (the "2017 ESPP").

	Equity Compensation Plan Information			
	Number of securities to be issued upon exercise of outstanding options (1)	Weighted Average exercise price of outstanding options and rights	Number of securities remaining available for future issuance under equity compensation plan (excluding securities referenced in column (a))	
Equity compensation plans approved by security holders (2)	1,072,499	$33.50	75,027	(3)

(1) Includes stock options only; does not include purchase rights accruing under the 2012 ESPP Plan because the purchase price (and therefore the number of shares to be purchased) will not be determined until the end of the purchase period.

(2) Consists of the 2003 Plan, the 2009 Plan, the 2015 Plan, the 2012 ESPP, and the 2017 ESPP.

(3) Includes shares available for future issuance under the 2015 Plan and the 2017 ESPP.

Recent Sales of Unregistered Securities

None.

ITEM 6. SELECTED FINANCIAL DATA.

Not applicable.

ITEM 7. 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" and under "Risk Factors" herein.

OVERVIEW

Caladrius Biosciences, Inc. ("we," "us," "our," "Caladrius" or the "Company") is a company developing cellular therapeutics to treat certain diseases. We leverage specialized clinical development expertise to selectively advance therapeutic product candidates to their next significant development milestone and, if appropriate, partner such candidates. Our most advanced product candidate, CLBS03, is an autologous polyclonal regulatory T cell ("Treg") clinical phase 2 therapy targeting children aged 8-17 with recent-onset type 1 diabetes mellitus ("T1D"). We also have phase studies either underway or due to commence shortly involving our CD34 cell therapy for ischemic repair.

Immunomodulation (Treg Technology)

We are developing strategically, through the utilization of our core development expertise, a product candidate (CLBS03) that has the potential to be an innovative therapy for T1D. This therapy is based on a proprietary platform technology for immunomodulation. We have selected as an initial target the unmet medical need of patients who are newly diagnosed with T1D, most of whom will be under the age of 18. This program is based on the use of Tregs to treat diseases caused by imbalances in an individual's immune system. This novel approach seeks to restore immune balance by enhancing Treg number and function. Tregs are a natural part of the human immune system and regulate the activity of effector T cells, the cells that are responsible for protecting the body from pathogens and foreign antigens. When Tregs function properly, only harmful foreign materials are attacked by effector T cells. In autoimmune disease, however, it is thought that deficient Treg activity and numbers permit the effector T cells to attack the body's own beneficial cells. In the case of T1D, the beta cells in the pancreas are attacked, thereby reducing and/or eliminating over time the patient's ability to produce insulin. Insulin is necessary to regulate sugar metabolism and maintain proper sugar levels in the blood. Inconsistent or unnatural insulin levels can lead to many complications, including blindness, vascular disease and, if no insulin supplement is provided, even death. There are currently no curative treatments for TID, only lifelong insulin therapy, which often does not prevent serious co-morbidities. Two Phase 1 clinical trials of Treg technology in T1D, taken together demonstrated safety and tolerance, feasibility of manufacturing, an implied durability of effect as well as an early indication of potential therapeutic effect through the preservation of beta cell function. In the first quarter of 2016, we commenced patient enrollment in the first of two cohorts in The Sanford Project: T-Rex Study, a Phase 2 prospective, randomized, placebo-controlled, double-blind clinical trial (the "TRex Study") to evaluate the safety and efficacy of CLBS03 in adolescents with recent onset TID. We entered into a strategic collaboration with Sanford Research to support the execution of this trial. Sanford Research is a U.S.-based non-profit research organization that supports an emerging translational research center focused on finding a cure for T1D. On February 23, 2017, the California Institute for Regenerative Medicine ("CIRM") awarded us funds of up to $12.2 million to support the T-Rex Study. The funding will be based upon the achievement of certain milestones related to the proportion of subjects enrolled in California, as well as manufacturing and development costs incurred in California. We received $5.7 million in initial funding on May 4, 2017. CLBS03 has been granted Fast Track and orphan drug designations from the U.S. Food and Drug Administration ("FDA") as well as Advanced Therapeutic Medicinal Product ("ATMP") classification from the European Medicines Agency ("EMA"). In October 2016, we received a satisfactory safety evaluation by our independent Data Safety Monitoring Board based on safety data then available from the first 19 patients enrolled in the trial. A subsequent interim analysis was conducted after approximately 50% of patients reached the six-month follow-up milestone, the results of which were publicly released on March 8, 2018 that the therapy continued to be well tolerated and was deemed non-futile for therapeutic effect. On January 18, 2018, we announced completion of enrollment (110 patients) in the TRex Study.

Ischemic Repair (CD34 Cell Technology)

Our CD34 cell technology has led to the development of therapeutic product candidates designed to address diseases and conditions caused by ischemia. Ischemia occurs when the supply of oxygenated blood to healthy tissue is restricted. Through the administration of CD34 cells, we seek to promote the development and formation of new blood vessels and thereby increase blood flow to the impacted area. We believe that conditions caused by underlying ischemic injury can be improved through our CD34 cell technology, including critical limb ischemia ("CLI", coronary microvascular disfunction ("CMD') and refractory angina ("RfA'). Published reports in Circulation Cardiovascular Interventions, Atherosclerosis, Stem Cells and Circulation Journal, provide preliminary evidence that CD34 cell therapy is safe and can exert significant therapeutic effects in patients with CLI, a condition

in which blood flow to the legs is severely impaired, causing pain and non-healing ulcers and, ultimately, potentially resulting in the need for amputation. Our Clinical Trial Notification for a pivotal Phase 2 trial investigating our product candidate in CLI CLBS12 was submitted to the Japanese Pharmaceutical and Medical Device Agency ("PMDA") and was cleared to proceed. The protocol design was agreed to with PMDA, the study was opened for enrollment in December 2017 and treatment of the first patient was announced in March 2018. Based on our discussions with the PMDA, we expect that a successful outcome of this trial will qualify CLBS12 for consideration of early conditional approval in Japan. In anticipation of a successful trial outcome and the possibility of conditional approval, we continue to seek a local partner for CLBS12 in Japan. Furthermore, we submitted grant applications in an effort to seek non-dilutive financing to investigate the CD34 technology for additional clinical indications in the United States and on October 2, 2017 we announced the award of a $1.9 million grant from the National Institutes of Health to support a clinical study of CD34 cells in patients with coronary microvascular dysfunction and we are targeting the initiation of the study by early second quarter 2018.

Additional Out-licensing Opportunities

Our broad intellectual property portfolio of cell therapy assets includes notable programs available for out-licensing in order to continue their clinical development. These include additional indications for our Treg product and additional indications for our CD34 cell technology.

Our current long-term strategy focuses on advancing our therapies through development with the aim of eventually obtaining market authorization, either alone or with partners to provide treatment options to patients suffering from life-threatening medical conditions. We believe that we are positioned to realize potentially meaningful value increases within our own proprietary pipeline if we are successful in advancing our product candidates to their next significant development milestones.

Discontinued Operations

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

Results of Operations

Year Ended December 31, 2017 Compared to Year Ended December 31, 2016

Net loss from continuing operations for the year ended December 31, 2017 was approximately $16.2 million compared to net loss from continuing operations of $31.3 million for the year ended December 31, 2016. Overall net income for the year ended December 31, 2017 was approximately $22.2 million, which included income from discontinued operations of $38.4 million, driven by the gain on sale of PCT of $51.7 million. Overall, net loss for the year ended December 31, 2016 was approximately $33.3 million, which included loss from discontinued operations of $2.1 million.

Operating Expenses

For the year ended December 31, 2017, operating expenses totaled $27.6 million compared to $29.5 million for the year ended December 31, 2016, representing a decrease of $1.9 million or 6%. Operating expenses were comprised of the following:

- Research and development expenses were approximately $15.8 million for the year ended December 31, 2017 compared to $16.7 million for the year ended December 31, 2016, representing a decrease of approximately $0.9 million, or 5%.
    - *Immune Modulation* - Immune modulation expenses, primarily related to expenses associated with our Phase 2 study of CLBS03 in T1D, were $13.4 million for the year ended December 31, 2017, representing an increase of $2.9 million compared to the year ended December 31, 2016. The higher expenses are due to higher clinical trial and manufacturing costs in the current year period compared to the prior year period.

- *Ischemic Repair* - Ischemic repair expenses were $2.7 million for the year ended December 31, 2017, representing an increase of approximately $0.5 million compared to the year ended December 31, 2016. The expenses for the year ended December 31, 2017 are primarily related to initiation-related program expenses associated with our critical limb ischemia development program in Japan. The expenses for the year ended December 31, 2016 are primarily associated with close-out activities of the PreServe AMI Phase 2 clinical trial for CLBS10.
- *Other* - Other research and development expenses during the year ended December 31, 2016 included $2.6 million of close-out activities for the Intus Phase 3 clinical trial for the immunotherapy product candidate CLBS20, announced in January 2016, along with $1.1 million of associated one-time restructuring costs for severance and asset impairments.

- General and administrative expenses were approximately $11.8 million for the year ended December 31, 2017, compared to $12.8 million for the year ended December 31, 2016, representing a decrease of approximately $1.1 million, or 8%. The decrease was 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 as compensation to employees, consultants, directors and other service providers. The use of these instruments has resulted in charges to the results of operations, which has been significant in the past.

Interest Expense

Interest expense was $0.4 million for the year ended December 31, 2017, compared with $1.8 million for the year ended December 31, 2016, and is primarily related to interest expense on the loan from Oxford Finance LLC. Concurrent with the PCT Sale on May 18, 2017, the Oxford loan was fully repaid and retired.

Benefit from Income Taxes

The benefit from income taxes was $11.5 million for the year ended December 31, 2017. We report both continuing and discontinued operations. ASC 740-20-45-7 addresses the income tax accounting treatment when there is a loss from continuing operations and income from discontinuing operations. We must consider the gain from discontinued operations for purposes of allocating a tax benefit to the current year loss from continuing operations. There are three acceptable methods on how a company can record its tax provision. We have adopted a method in which the income from discontinued operations are recognized as a discrete item in the period in which it occurs and applies the concepts of the annual effective tax rate (AETR) during each period in computing the income tax provision from continuing operations. This method results in tax expense for discontinued operations and an income tax benefit for the loss generated from continuing operations.

Discontinued Operations

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

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

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

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

The operations and cash flows of the PCT Segment were eliminated from ongoing operations with the sale of the Company's PCT interest. The operating results of the PCT Segment for the year ended December 31, 2017 and year ended December 31, 2016 were as follows (in thousands):

	Year Ended December 31,	
	2017	2016
Revenue	$ 16,039	$ 42,043
Cost of revenues	(15,321)	(35,519)
Research and development	(257)	(800)
Selling, general, and administrative	(3,251)	(7,558)
Other expense	(14)	(80)
Provision for income taxes	(10,541)	(138)
Gain on sale of segment	51,744	—
Income (loss) from discontinued operations	$ 38,399	$ (2,052)

Analysis of Liquidity and Capital Resources

At December 31, 2017, we had cash, cash equivalents, restricted cash, and marketable securities of approximately $60.1 million, working capital of approximately $51.8 million, and stockholders' equity of approximately $50.5 million.

During the year ended December 31, 2017, we met our immediate cash requirements through cash received from the transaction with Hitachi, 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):

	Year Ended December 31,	
	2017	2016
Net cash used in operating activities - continuing operations	$ (20,237.8)	$ (28,225.3)
Net cash provided by (used in) investing activities - continuing operations	41,459.4	(1,099.5)
Net cash (used in) provided by financing activities - continuing operations	(857.5)	16,912.9

Operating Activities - Continuing Operations

Our cash used in operating activities in the year ended December 31, 2017 totaled approximately $20.2 million, which is the sum of (i) our net income of $22 million, less income from discontinued operations of $38.4 million, and adjusted for non-cash income and expenses totaling $9.2 million (which includes adjustments for equity-based compensation, depreciation and amortization, loss on disposal of assets, deferred taxes, tax benefit, and amortization/accretion of marketable securities), and (ii) changes in operating assets and liabilities of approximately $5.1 million.

Our cash used in operating activities in the year ended December 31, 2016 totaled approximately $28.2 million, which is the sum of (i) our net loss of $33.3 million, less loss from discontinued operation of $2.1 million, and adjusted for non-cash income and expenses totaling $2.8 million (which includes adjustments for equity-based compensation, depreciation and amortization, and loss on disposal of assets), and (ii) changes in operating assets and liabilities of approximately $0.2 million.

Investing Activities - Continuing Operations

Our cash provided by investing activities in the year ended December 31, 2017 totaled approximately $41.5 million. In 2017, we received $74.6 million in net proceeds in connection with the sale of our 80.1% ownership interest in PCT to Hitachi, less $6.7 million of cash held by our PCT subsidiary on the date of the acquisition. We also invested $26.3 million in marketable securities (net), and spent approximately $0.1 million for property and equipment.

Our cash used in investing activities in the year ended December 31, 2016 totaled approximately $1.1 million, representing property and equipment purchases.

Financing Activities - Continuing Operations

During the year ended December 31, 2017, our financing activities consisted of the following:

- We paid $5.7 million in principal payments on our long-term debt to Oxford Finance, which was fully repaid and retired on May 18, 2017.
- We raised gross proceeds of approximately $4.4 million through the issuance of approximately 932,204 shares of our common stock under the conditions of the Second Closing (achievement of the enrollment of 70 subjects in our Phase 2 CLBS03 clinical trial), relating to the September 2016 private placement offering.
- We raised gross proceeds of approximately $1.2 million through the issuance of approximately 210,506 shares of our common stock under the provisions of our Common Stock Purchase Agreement with Aspire which expired in November 2017.
- We received proceeds of $0.4 million from the issuance of notes payable relating to certain insurance policies and equipment financings, less repayments of $1.0 million.

During the year ended December 31, 2016, our financing activities consisted of the following:

- Hitachi purchased a 19.9% membership interest in PCT for $19.4 million, of which $15.0 million of proceeds was distributed to Caladrius from PCT and $4.4 million remained at PCT.
- We raised $4.0 million in a registered direct offering through the issuance of 847,458 shares of our common stock, and $6.6 million in concurrent private placement offerings through the issuance of 1,398,305 shares of our common stock.
- We paid $6.3 million in principal payments on our long term debt to Oxford Finance upon our sale of a 19.9% membership interest in PCT to Hitachi, and, in September 2016, we paid an additional $3.0 million in principal payments on our long term debt to Oxford Finance.
- We raised $1.0 million in a private placement through the issuance of 141,844 shares of our 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.

- We received proceeds of $0.8 million from the issuance of notes payable relating to certain insurance policies and equipment financings, less repayments of $1.0 million.

Liquidity and Capital Requirements Outlook

To meet our short and long-term liquidity needs, we expect to use existing cash balances and a variety of other means. Other sources of liquidity could include additional potential issuances of debt or equity securities in public or private financings, partnerships and/or collaborations and/or sale of assets. Our history of operating losses and liquidity challenges may make it difficult for us to raise capital on acceptable terms or at all. The demand for the equity and debt of biopharmaceutical companies like ours is dependent upon many factors, including the general state of the financial markets. During times of extreme market volatility, capital may not be available on favorable terms, if at all. Our inability to obtain such additional capital could materially and adversely affect our business operations. We will also continue to seek, as appropriate, grants for scientific and clinical studies from various governmental agencies and foundations. We believe that our cash on hand will enable us to fund the development of CLBS03 and other operating expenses for at least the next 12 months following the issuance of our financial statements.

On February 8, 2018, we entered into a Common Stock Sales Agreement with H.C. Wainwright & Co., LLC, as sales agent, in connection with an “at the market offering” under which we from time to time may offer and sell shares of our common stock, having an aggregate offering price of up to $12 million. Subject to the terms and conditions of the sales agreement, H.C. Wainwright & Co., LLC will use its commercially reasonable efforts consistent with its normal trading and sales practices to sell the shares from time to time, based upon our instructions, including any price, time or size limits specified by us. We have provided H.C. Wainwright & Co., LLC with customary indemnification rights, and H.C. Wainwright & Co., LLC will be entitled to a commission at a fixed commission rate equal to 3.0% of the gross proceeds per share sold. In addition, pursuant to the terms of the sales agreement, we agreed to reimburse H.C. Wainwright & Co., LLC for the documented fees and costs of its legal counsel reasonably incurred in connection with (i) entering into the transactions contemplated by the sales agreement in an amount not to exceed $50,000 in the aggregate and (ii) H.C. Wainwright & Co., LLC’s ongoing diligence, drafting and other filing requirements arising from the transactions contemplated by the sales agreement in an amount not to exceed $2,500 in the aggregate per calendar quarter. Sales of the shares, if any, under the sales agreement may be made in transactions that are deemed to be “at the market offerings” as defined in Rule 415 under the Securities Act of 1933, as amended. We have no obligation to sell any of the shares, and may at any time suspend sales under the sales agreement or terminate the sales agreement. The sales agreement will terminate upon the sale of all of the shares under the sales agreement unless terminated earlier by either party as permitted under the sales agreement.

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

In 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 our common stock at a purchase price of $4.72 per share. The gross proceeds to us from the registered direct offering of the shares of common stock were $4.0 million. In concurrent private placements, in September 2016, we entered into Private Placement Purchase Agreements with certain accredited investors for the sale of common stock, at a purchase price of $4.72 per share. The investments were placed in two tranches: (i) $6.6 million upon an initial closing (the “Initial Closing”), and (ii) $4.4 million, subject to certain conditions, including the enrollment of 70 subjects in our Phase 2 CLBS03 clinical trial, in a second closing (the “Second Closing”). We received the Initial Closing tranche in 2016 and issued 1.4 million shares of common stock. In 2017, we received $4.4 million in accordance with the terms of the Second Closing tranche and issued 0.9 million shares of common stock.

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.

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. We have issued 319,776 shares under the Aspire Agreement for gross proceeds of $1.5 million. The Aspire Agreement expired in November 2017.

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 2016, upon execution of the March 2016 Hitachi Transaction, we and Oxford Finance entered

into an amendment to the Loan and Security Agreement whereby (i) we paid $7.0 million to Oxford Finance LLC, comprised of principal, interest and early termination fees, (ii) we subsidiaries PCT, PCT Allendale, LLC, and NeoStem Family Storage, LLC (collectively the "Removed Borrowers") were removed as borrowers under the Loan, (iii) Oxford Finance'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 is extended until January 1, 2017. In September 2016, we paid $3.0 million to repay a portion of the outstanding loan with Oxford Finance. In May 2017, upon execution of the May 2017 Hitachi Transaction, we and Oxford Finance entered into an amendment to the Loan and Security Agreement whereby we paid the remaining $5.7 million long-term debt balance to Oxford Finance LLC.

While we continue to seek capital through a number of means, there can be no assurance that additional financing will be available on acceptable terms, if at all, and our negotiating position in capital generating efforts may worsen as existing resources are used. Additional equity financing may be dilutive to our stockholders; debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate as a business; our stock price may not reach levels necessary to induce option or warrant exercises; and asset sales may not be possible on terms we consider acceptable. If we are unable to access capital necessary to meet our long-term liquidity needs, we may have to delay the expansion of our business or raise funds on terms that we currently consider unfavorable.

SEASONALITY

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

OFF-BALANCE SHEET ARRANGEMENTS

We do not have any off-balance sheet arrangements.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and judgments that affect the amounts reported in the financial statements. On an ongoing basis, we evaluate our estimates and assumptions. We base our 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. Actual results could differ from these estimates.

An accounting policy is considered to be critical if it is important to our financial condition and results of operations and if it requires management’s most difficult, subjective and complex judgments in its application. For a summary of all of our significant accounting policies, see Note 2 to our Consolidated Financial Statements.

Share-Based Compensation

We expense all share-based payment awards to employees, directors, and consultants, including grants of stock options, warrants, and restricted stock, over the requisite service period based on the grant date fair value of the awards. Consultant awards are remeasured each reporting period through vesting. For awards with performance-based vesting criteria, we estimate the probability of achievement of the performance criteria and recognize compensation expense related to those awards expected to vest. We determine 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 our restricted stock and restricted stock units is based on the closing market price of our common stock on the date of grant.

Long-lived Assets

Long-lived assets consist of property, plant and equipment. The assets are amortized on a straight-line basis over their respective useful lives. We review long-lived 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 we expect to hold and use may not be recoverable, we 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.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The financial statements and notes thereto required to be filed under this Item are presented commencing on page

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of this Annual Report on Form 10-K.

Caladrius Biosciences, Inc. and Subsidiaries

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
Caladrius Biosciences, Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of Caladrius Biosciences, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2017 and 2016, the related consolidated statements of operations, comprehensive income (loss), equity, and cash flows for each of the two years in the period ended December 31, 2017, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

Basis for opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ GRANT THORNTON LLP

We have served as the Company's auditor since 2011.

New York, New York
March 22, 2018

CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2017	December 31, 2016
ASSETS		
Current Assets		
Cash and cash equivalents	$ 29,163,200	$ 7,076,651
Restricted cash	5,004,789	—
Marketable securities	25,916,681	—
Accounts receivable trade, net of allowance of $0 at December 31, 2017 and 2016, respectively	234,461	138,774
Prepaid and other current assets	790,514	1,900,493
Assets related to discontinued operations	—	15,533,043
Total current assets	61,109,645	24,648,961
Property, plant and equipment, net	256,905	705,438
Deferred tax assets	575,055	—
Other assets	1,434,077	1,582,209
Assets related to discontinued operations	—	26,577,834
Total assets	$ 63,375,682	$ 53,514,442
LIABILITIES, REDEEMABLE SECURITIES - NON-CONTROLLING INTERESTS AND EQUITY		
Current Liabilities		
Accounts payable	$ 1,343,089	$ 2,226,580
Accrued liabilities	7,810,948	2,659,433
Long-term debt, current	—	3,126,457
Notes payable, current	159,180	563,777
Due to PCT	—	1,681,594
Liabilities related to discontinued operations	—	10,925,052
Total current liabilities	9,313,217	21,182,893
Notes payable	—	159,180
Long term debt	—	2,524,897
Other long-term liabilities	3,872,679	389,858
Liabilities related to discontinued operations	—	5,791,134
Total liabilities	13,185,896	30,047,962
Commitments and Contingencies		
Redeemable Securities - Non-Controlling Interests	—	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, $.01 par value; 825,000 shares designated; issued and outstanding, 10,000 shares at December 31, 2017 and December 31, 2016, respectively	100	100
Common stock, $.001 par value, authorized 500,000,000 shares; issued and outstanding, 9,483,911 and 8,205,790 shares, at December 31, 2017 and December 31, 2016, respectively	9,484	8,206
Additional paid-in capital	433,044,209	410,372,049
Treasury stock, at cost; 11,080 shares at December 31, 2017 and December 31, 2016 respectively	(707,637)	(707,637)
Accumulated deficit	(381,810,109)	(404,788,809)
Accumulated other comprehensive loss	(27,978)	—
Total Caladrius Biosciences, Inc. stockholders' equity	50,508,069	4,883,909
Noncontrolling interests	(318,283)	(817,429)
Total equity	50,189,786	4,066,480
	$ 63,375,682	$ 53,514,442

See accompanying notes to consolidated financial statements.

CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2017	**2016**
Operating Expenses:		
Research and development	$ 15,842,959	$ 16,699,213
General, and administrative	11,750,080	12,802,735
Operating expenses	27,593,039	29,501,948
Operating loss	(27,593,039)	(29,501,948)
Other income (expense):		
Other income (expense), net	273,101	23,854
Interest expense	(377,768)	(1,779,657)
	(104,667)	(1,755,803)
Loss before benefit from income taxes and noncontrolling interests	(27,697,706)	(31,257,751)
Benefit from income taxes	(11,526,557)	—
Net loss from continuing operations	(16,171,149)	(31,257,751)
Discontinued operations - net	38,399,236	(2,051,782)
Net income (loss)	22,228,087	(33,309,533)
Less - net loss from continuing operations attributable to noncontrolling interests	(182,457)	(241,802)
Less - net loss from discontinued operations attributable to noncontrolling interests	(568,156)	(411,412)
Net income (loss) attributable to Caladrius Biosciences, Inc. common shareholders	22,978,700	(32,656,319)
Amounts Attributable to Caladrius Inc. common shareholders:		
Loss from continuing operations	(15,988,692)	(31,015,949)
Income (loss) from discontinued operations - net of taxes	38,967,392	(1,640,370)
Net income (loss) attributable to Caladrius Inc. common shareholders	$ 22,978,700	$ (32,656,319)
Basic and diluted income (loss) per share		
Basic earnings (loss)		
Continuing operations	$ (1.78)	$ (4.74)
Discontinued operations	$ 4.34	$ (0.25)
Caladrius Biosciences, Inc. common shareholders	$ 2.56	$ (4.99)
Diluted earnings (loss)		
Continuing operations	$ (1.78)	$ (4.74)
Discontinued operations	$ 4.34	$ (0.25)
Caladrius Biosciences, Inc. common shareholders	$ 2.56	$ (4.99)
Weighted average common shares outstanding:		
Basic shares	8,968,954	6,548,251
Diluted shares	8,968,954	6,548,251

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,	
	2017	**2016**
Net income (loss)	$ 22,228,087	$ (33,309,533)
Other comprehensive loss:		
Available for sale securities - net unrealized loss	(27,978)	(486)
Total other comprehensive loss	(27,978)	(486)
Comprehensive income (loss)	22,200,109	(33,310,019)
Comprehensive loss attributable to noncontrolling interests	(750,613)	(653,214)
Comprehensive income (loss) attributable to Caladrius Biosciences, Inc. common stockholders	$ 22,950,722	$ (32,656,805)

See accompanying notes to consolidated financial statements.

CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EQUITY

	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	—	—	—	—	—	—	(32,656,319)	—	(32,656,319)	(653,214)	(33,309,533)
Unrealized loss on marketable securities	—	—	—	—	—	(486)	—	—	(486)	—	(486)
Share-based compensation	—	—	114,344	114	2,532,167	—	—		2,532,281	—	2,532,281
Net proceeds from issuance of common stock	—	—	2,418,144	2,419	11,557,975	—	—	—	11,560,394	—	11,560,394
Change in ownership in subsidiary	—	—	—	—	(265,494)	—	—	—	(265,494)	265,494	—
Balance at December 31, 2016	10,000	$ 100	8,205,790	$ 8,206	$ 410,372,049	$ —	$ (404,788,809)	$ (707,637)	$ 4,883,909	$ (817,429)	$ 4,066,480
Net income	—	—	—	—	—	—	22,978,700	—	22,978,700	(750,613)	22,228,087
Unrealized loss on marketable securities	—	—	—	—	—	(27,978)	—	—	(27,978)	—	(27,978)
Share-based compensation	—	—	54,545	55	2,494,416	—	—	—	2,494,471	—	2,494,471
Net proceeds from issuance of common stock	—	—	1,219,741	1,219	5,700,467	—	—	—	5,701,686	—	5,701,686
Proceeds from option exercises	—	—	3,835	4	13,572	—	—	—	13,576	—	13,576
Elimination of equity associated with PCT sale	—	—	—	—	—	—	—	—	—	(3,686,536)	(3,686,536)
Conversion of redeemable securities	—	—	—	—	14,733,908	—	—	—	14,733,908	4,666,092	19,400,000
Change in ownership in subsidiary	—	—	—	—	(270,203)	—	—	—	(270,203)	270,203	—
Balance at December 31, 2017	10,000	$ 100	9,483,911	$ 9,484	$ 433,044,209	$ (27,978)	$ (381,810,109)	$ (707,637)	$ 50,508,069	$ (318,283)	$ 50,189,786

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,	
	2017	2016
Cash flows from operating activities:		
Net income (loss)	$ 22,228,087	$ (33,309,533)
(Income) loss from discontinued operations	(38,399,236)	2,051,782
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Equity-based compensation expense	1,963,202	1,773,691
Depreciation and amortization	372,001	450,266
Loss on disposal of assets	211,813	591,307
Income tax benefit	(11,526,557)	—
Deferred income taxes	(575,055)	—
Amortization/Accretion on marketable securities	339,964	—
Changes in operating assets and liabilities:		
Prepaid and other current assets	1,109,979	457,390
Accounts receivable	(95,686)	(101,882)
Other assets	148,150	222,632
Due to PCT	(1,681,593)	2,784,760
Accounts payable, accrued liabilities and other liabilities	5,667,118	(3,145,758)
Net cash used in operating activities - continuing operations	(20,237,813)	(28,225,345)
Net cash (used in) provided by operating activities - discontinued operations	(638,069)	4,557,663
Net cash used in operating activities	(20,875,882)	(23,667,682)
Cash flows from investing activities:		
Purchase of marketable securities	(60,158,123)	—
Sales of marketable securities	33,873,500	—
Proceeds from PCT sale	74,606,591	—
Net cash sold in PCT sale	(6,727,263)	—
Acquisition of property and equipment	(135,281)	(1,099,460)
Net cash provided by (used in) investing activities - continuing operations	41,459,424	(1,099,460)
Net cash used in investing activities - discontinued operations	(188,794)	(1,749,836)
Net cash provided by (used in) investing activities	41,270,630	(2,849,296)
Cash flows from financing activities:		
Proceeds from exercise of options	13,576	—
Tax withholding payments on net share settlement equity awards	(357,666)	(72,010)
Net proceeds from issuance of capital stock	5,701,686	11,560,394
Repayment of long-term debt	(5,651,354)	(9,348,646)
Proceeds from notes payable	400,998	803,498
Repayment of notes payable	(964,776)	(1,030,351)
PCT dividend to Caladrius	—	15,000,000
Net cash (used in) provided by financing activities - continuing operations	(857,536)	16,912,885
Net cash (used in) provided by financing activities - discontinued operations	(74,231)	3,990,690
Net cash (used in) provided by financing activities	(931,767)	20,903,575
Net increase (decrease) in cash, cash equivalents and restricted cash	19,462,981	(5,613,403)
Cash and cash equivalents at beginning of year - continuing operations	7,076,651	18,657,971
Cash and cash equivalents at beginning of year - discontinued operations	7,628,357	1,660,440
Cash, cash equivalents and restricted cash at end of year	$ 34,167,989	$ 14,705,008
Less cash and cash equivalents of discontinued operations at end of year	—	7,628,357
Cash, cash equivalents and restricted cash of continuing operations at end of year	$ 34,167,989	$ 7,076,651
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the period for:		
Interest	$ 711,901	$ 1,823,424
Taxes	—	—

See accompanying notes to consolidated financial statements.

CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 – The Business

OVERVIEW

Caladrius Biosciences, Inc. (“we,” “us,” "our," “Caladrius” or the “Company”) is a company developing cellular therapeutics to treat certain diseases. We leverage specialized development expertise to selectively advance therapeutic product candidates to their next significant development milestone and, if appropriate, partner such candidates. Our most advanced product candidate, CLBS03, is an autologous polyclonal regulatory T cell ("Treg") clinical phase 2 therapy targeting children aged 8-17 with recent-onset type 1 diabetes mellitus ("T1D"). We also have phase 2 studies either underway or due to commence shortly involving our CD34 cell therapy for ischemic repair.

Immunomodulation (Treg Technology)

We are developing strategically, through the utilization of our core development expertise, a product candidate (CLBS03) that has the potential to be an innovative therapy for T1D. This therapy is based on a proprietary platform technology for immunomodulation. We have selected as an initial target the unmet medical need of patients who are newly diagnosed with T1D, most of whom will be under the age of 18. This program is based on the use of Tregs to treat diseases caused by imbalances in an individual's immune system. This novel approach seeks to restore immune balance by enhancing Treg number and function. Tregs are a natural part of the human immune system and regulate the activity of effector T cells, the cells that are responsible for protecting the body from pathogens and foreign antigens. When Tregs function properly, only harmful foreign materials are attacked by effector T cells. In autoimmune disease, however, it is thought that deficient Treg activity and numbers permit the effector T cells to attack the body's own beneficial cells. In the case of T1D, the beta cells in the pancreas are attacked, thereby reducing and/or eliminating over time the patient's ability to produce insulin. Insulin is necessary to regulate sugar metabolism and maintain proper sugar levels in the blood. Inconsistent or unnatural insulin levels can lead to many complications, including blindness, vascular disease and, if no insulin supplement is provided, even death. There are currently no curative treatments for TID, only lifelong insulin therapy, which often does not prevent serious co-morbidities. Two Phase 1 clinical trials of Treg technology in T1D, taken together demonstrated safety and tolerance, feasibility of manufacturing, an implied durability of effect as well as an early indication of potential therapeutic effect through the preservation of beta cell function. In the first quarter of 2016, we commenced patient enrollment in the first of two cohorts in The Sanford Project: T-Rex Study, a Phase 2 prospective, randomized, placebo-controlled, double-blind clinical trial (the "TRex Study") to evaluate the safety and efficacy of CLBS03 in adolescents with recent onset TID. We entered into a strategic collaboration with Sanford Research to support the execution of this trial. Sanford Research is a U.S.-based non-profit research organization that supports an emerging translational research center focused on finding a cure for T1D. On February 23, 2017, the California Institute for Regenerative Medicine ("CIRM") awarded us funds of up to $12.2 million to support the T-Rex Study. The funding will be based upon the achievement of certain milestones related to the proportion of subjects enrolled in California, as well as manufacturing and development costs incurred in California. We received $5.7 million in initial funding on May 4, 2017. CLBS03 has been granted Fast Track and orphan drug designations from the U.S. Food and Drug Administration ("FDA") as well as Advanced Therapeutic Medicinal Product ("ATMP") classification from the European Medicines Agency ("EMA"). In October 2016, we received a satisfactory safety evaluation by our independent Data Safety Monitoring Board based on safety data then available from the first 19 patients enrolled in the trial. A subsequent interim analysis was conducted after approximately 50% of patients reached the six-month follow-up milestone, the results of which were publicly released on March 8, 2018 that the therapy continued to be well tolerated and was deemed non-futile for therapeutic effect. On January 18, 2018, we announced completion of enrollment (110 patients) of the TRex Study.

Ischemic Repair (CD34 Cell Technology)

Our CD34 cell technology has led to the development of therapeutic product candidates designed to address diseases and conditions caused by ischemia. Ischemia occurs when the supply of oxygenated blood to healthy tissue is restricted. Through the administration of CD34 cells, we seek to promote the development and formation of new blood vessels and thereby increase blood flow to the impacted area. We believe that conditions caused by underlying ischemic injury can be improved through our CD34 cell technology, including critical limb ischemia ("CLI"), coronary microvascular disfunction ("CMD") and refractory angina ("RfA"). Published reports in Circulation Cardiovascular Interventions, Atherosclerosis, Stem Cells and Circulation Journal, provide preliminary evidence that CD34 cell therapy is safe and can exert significant therapeutic effects in patients with CLI, a condition in which blood flow to the legs is severely impaired, causing pain and non-healing ulcers and, ultimately, potentially resulting in the need for amputation. Our Clinical Trial Notification for a pivotal Phase 2 trial investigating our product candidate

in CLI CLBS12 was submitted to the Japanese Pharmaceutical and Medical Device Agency ("PMDA") and was cleared to proceed. The protocol design was agreed to with PMDA, the study was opened for enrollment in December 2017 and treatment or the first patient was announced in March 2018. Based on our discussions with the PMDA, we expect that a successful outcome of this trial will qualify CLBS12 for consideration of early conditional approval in Japan. In anticipation of a successful trial outcome and the possibility of conditional approval, we continue to seek a local partner for CLBS12 in Japan. Furthermore, we submitted grant applications in an effort to seek non-dilutive financing to investigate the CD34 technology for additional clinical indications in the United States and on October 2, 2017 we announced the award of a $1.9 million grant from the National Institutes of Health to support a clinical study of CD34 cells in patients with coronary microvascular dysfunction and we are targeting the initiation of the study by the second quarter of 2018.

Additional Out-licensing Opportunities

Our broad intellectual property portfolio of cell therapy assets includes notable programs available for out-licensing in order to continue their clinical development. These include additional indications for our Treg product and additional indications for our CD34 cell technology.

Our current long-term strategy focuses on advancing our therapies through development with the aim of eventually obtaining market authorization, either alone or with partners, to provide treatment options to patients suffering from life-threatening medical conditions. We believe that we are positioned to realize potentially meaningful value increases within our own proprietary pipeline if we are successful advancing our product candidates to their next significant development milestones.

Discontinued Operations

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

Basis of Presentation

The accompanying Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). In the opinion of management, the accompanying Consolidated Financial Statements of the Company and its subsidiaries include all normal and recurring adjustments considered necessary to present fairly the Company's financial position as of December 31, 2017 and 2016, and the results of its operations and its cash flows for the years then ended.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements. Estimates also affect the reported amounts of revenues and expenses during the reporting period. The Company bases its estimates on historical experience and other assumptions believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. The Company makes critical estimates and assumptions in determining stock-based awards values and income taxes. Accordingly, actual results could differ from those estimates and assumptions.

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

Principles of Consolidation

The Consolidated Financial Statements include the accounts of Caladrius Biosciences, Inc. and its wholly-owned and partially-owned subsidiaries and affiliates, as well as the operations of our former subsidiaries PCT, LLC, a Caladrius company, NeoStem Family Storage, LLC, and PCT Allendale, LLC entities (collectively the "PCT Segment") through May 18, 2017, representing the date which these entities were sold to Hitachi (see Note 3). The PCT Segment is reported in discontinued operations. All intercompany activities have been eliminated in consolidation, except for intercompany activities between Caladrius and the PCT Segment, which are reported without intercompany eliminations in continuing operations and discontinued operations, respectively.

Note 2 – Summary of Significant Accounting Policies

Cash and Cash Equivalents

Cash and cash equivalents include short-term, highly liquid, investments with maturities of ninety days or less when purchased.

Concentration of Risks

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

Marketable Securities

The Company determines the appropriate classification of our marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. All of our marketable securities are considered as available-for-sale and carried at estimated fair values and reported in cash equivalents. Unrealized gains and losses on available-for-sale securities are excluded from net income and reported in accumulated other comprehensive income (loss) as a separate component of stockholders' equity. Other income (expense), net, includes interest, dividends, amortization of purchase premiums and discounts, realized gains and losses on sales of securities and other-than-temporary declines in the fair value of securities, if any. The cost of securities sold is based on the specific identification method. We regularly review all of our investments for other-than-temporary declines in fair value. Our review includes the consideration of the cause of the impairment, including the creditworthiness of the security issuers, the number of securities in an unrealized loss position, the severity and duration of the unrealized losses, whether we have the intent to sell the securities and whether it is more likely than not that we will be required to sell the securities before the recovery of their amortized cost basis. When we determine that the decline in fair value of an investment is below our accounting basis and this decline is other-than-temporary, we reduce the carrying value of the security we hold and record a loss for the amount of such decline.

Property, Plant, and Equipment

The cost of property, plant and equipment is depreciated over the estimated useful lives of the related assets. Depreciation is computed on the straight-line method. Repairs and maintenance expenditures that do not extend original asset lives are charged to expense as incurred. The estimated useful lives of property, plant and equipment are as follows:

Furniture and fixtures	10 years
Computer equipment	3 years
Software	3 years
Leasehold improvements	Life of lease

Long-lived Assets

Long-lived assets consist of property, plant and equipment. The assets are amortized on a straight line basis over their respective useful lives. The Company reviews long-lived 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.

Share-Based Compensation

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

risk-free interest rate, expected volatility, expected dividend yield and expected life of the options or warrants. The fair value of the Company's restricted stock and restricted stock units is based on the closing market price of the Company's common stock on the date of grant.

Income (Loss) Per Share

Basic income (loss) per share is based on the weighted effect of all common shares issued and outstanding, and is calculated by dividing net income (loss) attributable to common stockholders by the weighted average shares outstanding during the period. Diluted loss per share, which is calculated by dividing net income (loss) attributable to common stockholders by the weighted average number of common shares used in the basic income (loss) per share calculation plus the number of common shares that would be issued assuming conversion of all potentially dilutive securities outstanding. Diluted income (loss) per share is not presented as such potentially dilutive securities are anti-dilutive to losses incurred from continuing operations in all periods presented.

Income Taxes

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

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

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

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

Treasury Stock

Treasury stock purchases are accounted for under the cost method whereby the entire cost of the acquired stock is recorded as treasury stock. Gains or losses on the subsequent reissuance of shares are credited or charged to additional paid in capital.

Research and Development Costs

Research and development ("R&D") expenses include salaries, benefits, and other headcount related costs, clinical trial and related clinical manufacturing costs, contract and other outside service fees including sponsored research agreements, and facilities and overhead costs. The Company expenses the costs associated with research and development activities when incurred.

To further drive the Company's cell therapy initiatives, the Company will continue targeting key governmental agencies, congressional committees and not-for-profit organizations to contribute funds for the Company's research and development programs. The Company accounts for such grants as a deduction to the related expense in research and development operating expenses when earned.

New Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). This ASU requires that a lessee recognize lease assets and lease liabilities for those leases classified as operating leases. The guidance is effective for interim and annual periods beginning after December 15, 2018, and will be applied at the beginning of the earliest period presented using a modified retrospective approach. This ASU may have a material impact on the Company's financial statements. The impact on the Company's results of operations is currently being evaluated. The impact of the ASU is non-cash in nature and will not affect the Company's cash position.

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

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. ASU 2016-15 clarifies how companies present and classify certain cash receipts and cash payments in the statement of cash flows where diversity in practice exists. ASU 2016-15 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.

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

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

Note 3 – Collaboration and Hitachi License Agreement

2016 Hitachi Transaction

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

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

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

2017 Hitachi Transaction

On May 18, 2017, the Company sold its remaining 80.1% membership interest in PCT to Hitachi pursuant to the Purchase Agreement, dated March 16, 2017, by and among Caladrius PCT and Hitachi (the "2017 Hitachi Transaction"). The aggregate purchase price to the Company consisted of (i) $75.0 million in cash, (ii) $4.4 million, representing additional consideration based on PCT’s cash and outstanding indebtedness as of the closing date, and (iii) a potential future milestone payment of $5.0 million

if PCT achieves $125 million in cumulative revenue (excluding clinical service reimbursables) (the “Milestone”) for the period from January 1, 2017 through December 31, 2018 (the “Milestone Period”).

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

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

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

Note 4 – Available-for-Sale-Securities

The following table is a summary of available-for-sale securities recorded in cash and cash equivalents in our Consolidated Balance Sheets (in thousands):

	December 31, 2017				December 31, 2016			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities	$ 42,701.0	$ —	$ (28.0)	$ 42,673.0	$ —	$ —	$ —	$ —
Money market funds	9,211.5	—	—	9,211.5	4,426.8	—	—	4,426.8
Total	$ 51,912.5	$ —	$ (28.0)	$ 51,884.5	$ 4,426.8	$ —	$ —	$ 4,426.8

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):

	December 31, 2017	December 31, 2016
Cash and cash equivalents	$ 25,967.8	$ 4,426.8
Marketable securities	25,916.7	—
Total	$ 51,884.5	$ 4,426.8

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

	December 31, 2017	
	Amortized Cost	Estimated Fair Value
Less than one year	$ 51,912.5	$ 51,884.5
Greater than one year	—	—
Total	$ 51,912.5	$ 51,884.5

Note 5 – Property, Plant and Equipment

Property, plant, and equipment consisted of the following (in thousands):

	December 31,	
	2017	2016
Lab equipment	$ —	$ 181.6
Furniture and fixtures	25.4	288.2
Computer equipment	998.3	1,173.4
Software	—	99.5
Leasehold improvements	65.6	115.7
Property, plant and equipment, gross	1,089.3	1,858.4
Accumulated depreciation	(832.4)	(1,153.0)
Property, plant and equipment, net	$ 256.9	$ 705.4

The Company's results included depreciation expense of approximately $0.4 million and $0.5 million for the years ended December 31, 2017 and 2016, respectively.

Note 6 – Loss Per Share

For the years ended December 31, 2017 and 2016 the Company incurred net losses from continuing operations and therefore no common stock equivalents were utilized in the calculation of loss per share as they are anti-dilutive in the periods presented. At December 31, 2017 and 2016 the Company excluded the following potentially dilutive securities:

	December 31,	
	2017	2016
Stock Options	1,072,499	953,690
Warrants	209,818	388,062
Restricted Shares	181,908	126,849
Restricted Stock Units	10,260	—

Note 7 – Fair Value Measurements

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's financial assets and liabilities that were accounted for at fair value on a recurring basis as of December 31, 2017 and December 31, 2016 were as follows (in thousands):

	December 31, 2017				December 31, 2016			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Marketable securities - available for sale	$ —	$ 25,916.7	$ —	$ 25,916.7	$ —	$ —	$ —	$ —
	$ —	$ 25,916.7	$ —	$ 25,916.7	$ —	$ —	$ —	$ —

Note 8 – Accrued Liabilities

Accrued liabilities were as follow (in thousands):

	December 31,	
	2017	2016
Salaries, employee benefits and related taxes	$ 1,389.2	$ 1,406.3
Retention payments	2,233.0	—
Professional fees	286.7	224.5
CIRM upfront funding - current	2,445.9	—
Other	1,456.1	1,028.6
	$ 7,810.9	$ 2,659.4

Note 9 – Debt

Notes Payable

As of December 31, 2017 and December 31, 2016, the Company had notes payable of approximately $0.2 million and $0.7 million, respectively. The notes relate to certain insurance policies and equipment financings, require monthly payments, and mature within one year.

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 were amortized to interest expense throughout the life of the Loan using the effective interest rate method.

In March 2016, concurrent with the 2016 Hitachi Transaction (see Note 3), 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 (see Note 11), the Company repaid $3.0 million of such proceeds to the Lender. The outstanding balance was approximately $5.7 million at December 31, 2016.

In May 2017, concurrent with the 2017 Hitachi Transaction (see Note 3), the Company retired the Loan in full, and paid $4.9 million to Lender, comprising principal, interest and early termination fees. The Company was making interest-only payments on the outstanding amount of the Loan on a monthly basis at a rate of 8.50% per annum. During the years ended December 31, 2017 and 2016, the Company recognized $0.4 million and $1.7 million of interest expense, respectively, related to the Loan and Security Agreement.

Note 10 – Redeemable Securities - Non-Controlling Interests

Under the 2016 Hitachi Transaction (see Note 3), Hitachi, at any time following the tenth anniversary of the 2016 Hitachi Transaction closing date on March 11, 2016, had 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's ownership interests increased subsequent to its initial ownership interest, and it offered to sell its equity holdings in excess of 21% of PCT's outstanding equity securities, then the Company would have been required to purchase all such equity holdings of Hitachi Chemical but in no event would the aggregate purchase price of such Hitachi Chemical equity holdings exceed $20.5 million plus interest at the rate of 2.0% per annum compounded annually.

As of December 31, 2016, since Hitachi had the right to deliver the equity interests in PCT it held in exchange for cash from Caladrius or PCT, the initial $19.4 million value of the non-controlling interest was 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.

Concurrent with 2017 Hitachi Transaction (see Note 3), the Hitachi Put Right was eliminated, and $14.7 million previously classified as Redeemable Securities was classified to Additional Paid in Capital. In addition, the remaining portion classified as Redeemable Securities of $4.7 million was classified to Non-Controlling Interests, representing Hitachi's ownership interest in PCT at the time of the 2016 Hitachi Transaction, which was subsequently eliminated upon the 2017 Hitachi transaction and included the PCT gain on sale.

Note 11 – Stockholders' 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 presented 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 Plans

The Company's 2015 Equity Compensation Plan (the "2015 Equity Plan") was adopted by the stockholders of the Company on July 14, 2015, with 440,000 shares initially reserved for future awards under the 2015 Equity Plan (as adjusted in the manner described below, the "Share Reserve"). These shares will be available for issuance pursuant to non-qualified stock options, incentive stock options, stock appreciation rights, restricted stock, restricted stock units, unrestricted shares, deferred share units, or other kinds of equity based compensation awards. Concurrent with the adoption of the 2015 Equity Plan, no future awards will occur under the 2009 Amended and Restated Equity Compensation Plan (the "2009 Plan"). The 2015 Equity Plan's initial reserve of shares will automatically increase for 10 years, on each January 1st beginning with 2016, by a number of shares equal to the lesser of (i) four percent (4%) of the total number of our shares outstanding on December 31st of the preceding calendar year, (ii) such lesser number as the 2015 Plan's administrator may earlier designate in writing, and (iii) 17,600 shares, which equals four percent (4%) of the initial reserve of 440,000 shares. In addition, the Share Reserve will include shares that are currently subject to awards under our 2009 Equity Plan but that are not issued due to their forfeiture, cancellation, or other settlement.

The 2009 Equity Plan was originally adopted by the stockholders of the Company on May 8, 2009. On October 29, 2009, the stockholders of the Company approved an amendment to the 2009 Equity Plan to increase the number of shares of common stock available for issuance thereunder from 38,000 to 97,500. At the 2010 Annual Meeting of Stockholders of the Company held on June 2, 2010, the stockholders approved an amendment to increase this number to 137,500. At a Special Meeting of Stockholders of the Company held on January 18, 2011, the stockholders approved an amendment to increase this number to 177,500. At the 2011 Annual Meeting of Stockholders of the Company held on October 14, 2011, the stockholders approved an amendment to increase this number to 237,500. At the 2012 Annual Meeting of Stockholders of the Company held on October 5, 2012, the stockholders approved an amendment to (i) merge the 57,000 shares reserved for issuance under the Company's 2009 Non-U.S.

Based Equity Compensation Plan (the "Non-U.S. Plan") with and into the 2009 Equity Plan, and (ii) increase by 45,000 the aggregate number of shares authorized for issuance under the 2009 Equity Plan (the “2009 Amended & Restated Equity Plan”). At the Company's 2013 Annual Meeting held October 3, 2013, the Company's stockholders approved an amendment to the 2009 Amended & Restated Equity Plan to increase the number of shares authorized for issuance to 599,500. At the Company's 2014 Annual Meeting held October 6, 2014, the Company's stockholders approved an amendment to the 2009 Amended & Restated Equity Plan to increase the number of shares authorized for issuance to 899,500.

The Company's 2003 Equity Participation Plan (the “2003 Equity Plan”) expired in 2013 and accordingly, equity awards under the 2003 Equity Plan can no longer be issued. The Company's 2009 Equity Compensation Plan (the “2009 Equity Plan”) makes up to 899,500 shares of common stock of the Company (as of December 31, 2017) available for issuance to employees, consultants, advisors and directors of the Company and its subsidiaries pursuant to incentive or non-statutory stock options, restricted and unrestricted stock awards and stock appreciation rights.

All stock options under the 2003 Equity Plan and 2009 Equity Plan were granted and the 2015 Equity Plan are granted at the fair market value of the common stock at the grant date. Stock options vest either on the date of grant, ratably over a period determined at time of grant, or upon the accomplishment of specified business milestones, and generally expire 2, 3, or 10 years from the grant date depending on the status of the recipient as a consultant, employee or director of the Company.

The number of remaining shares authorized to be issued under the various equity plans are as follows as of December 31, 2017:

	2003 Equity Plan	2009 Equity Plan	2015 Equity Plan
Shares Authorized for Issuance	25,000	899,500	440,000
2016 Evergreen increase of shares	—	—	226,932
2017 Evergreen increase of shares			328,232
Outstanding Stock Options	(5,006)	(432,916)	(634,577)
Exercised Stock Options	(925)	(8,093)	(3,835)
Restricted stock or equity grants issued under Equity Plans	(8,922)	(156,467)	—
Shares Expired	(10,147)	(302,024)	(314,254)
Total common shares remaining to be issued under the Equity Plans	—	—	42,498

The Company adopted an employee stock purchase plan effective January 1, 2013, and authorized 50,000 shares under the plan (the "2012 ESPP"). The plan has two six-month offering periods per year under which eligible employees may contribute up to 15% of their compensation toward the purchase of the Company's common stock per offering period (with a $25,000 cap per calendar year). The employee's purchase price is equal to (i) 85% of the closing price of a share of the Company's common stock on the enrollment date of such offering period or (ii) 85% of the closing price of a share of the Company's common stock on the Exercise Date of such Offering Period, whichever is lower. On May 16, 2017, the Company's stockholders approved an amendment and restatement to the 2012 ESPP (the "2017 ESPP") in order to effect an increase of authorized shares from 50,000 to 100,000. During the year ended December 31, 2017, 21,924 shares were issued under the 2017 ESPP. At December 31, 2017, the Company had 32,530 shares of the Company's common stock available for future grant in connection with this plan.

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 March 31, 2017, $6.0 million of the Initial Closing tranche had not been received from a single investor, who was in breach of his obligations under the Private Placement Purchase Agreement. This investor had also committed to fund $4.0 million in the Second Closing. As a result, the Company terminated the Private Placement Purchase Agreement with this investor in the first quarter of 2017. In 2017, the Company met the conditions of the Second Closing, and received the remaining $4.4 million in proceeds in accordance with the terms of the Second Closing tranche and issued 932,204 shares of common stock.

Aspire Purchase Agreement

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

Stock Options and Warrants

The following table summarizes the activity for stock options and warrants for the year ended December 31, 2017:

	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, 2016	952,790	$ 39.90	7.60	$ —	388,062	$ 76.50	1.24	$ —
Changes during the Year:								
Granted	448,057	$ 11.70			—	$ —		
Exercised	(3,835)	$ 4.70			—	$ —		
Forfeited	(244,413)	$ 18.80			(1,937)	$ 700.00		
Expired	(80,100)	$ 35.80			(176,307)	$ 103.90		
Outstanding at December 31, 2017	1,072,499	$ 33.50	4.76	$ 0.1	209,818	$ 53.20	0.95	$ —
Vested at December 31, 2017 or expected to vest in the future	1,072,107	$ 33.5	4.76	$ 0.1	209,818	$ 53.20	0.95	$ —
Exercisable at December 31, 2017	1,063,759	$ 32.9	4.77	$ 0.1	209,818	$ 53.20	0.95	$ —

Restricted Stock

During the years ended December 31, 2017 and 2016, the Company issued restricted stock for services as follows ($ in thousands, except share data):

	2017	2016
Number of Restricted Stock Issued	181,908	126,849
Value of Restricted Stock Issued	$ 627.7	$ 698.1

The weighted average estimated fair value of restricted stock issued for services in the years ended December 31, 2017 and 2016 was $3.45 and $5.50 per share, respectively. The fair value of the restricted stock was determined using the Company's closing stock price on the date of issuance. The vesting terms of restricted stock issuances are generally between one to four years.

Note 12 – Share-Based Compensation

Share-based Compensation

We utilize share-based compensation in the form of stock options and restricted stock. The following table summarizes the components of share-based compensation expense for the years ended December 31, 2017 and 2016 ($ in thousands):

	Year Ended December 31,	
	2017	2016
Research and development	$ 268.9	$ 262.3
General and administrative	1,694.3	1,511.5
Discontinued operations	888.9	830.6
Total share-based compensation expense	$ 2,852.1	$ 2,604.3

The approval of the 2017 Hitachi Transaction (see Note 3) by our stockholders resulted in a change in control under our equity compensation plans (as defined in the 2009 Plan and the 2015 Equity Plan, and, together with the 2009 Plan, the "Equity Compensation Plans"). Accordingly, all outstanding unvested equity awards were accelerated upon the Closing Date, resulting in an acceleration of $1.9 million of equity compensation for the years ended December 31, 2017. In addition, in connection with the 2017 Hitachi Transaction, the Company agreed to extend the post-termination option exercise period for all PCT employees transitioning to Hitachi from 90 days to the earlier of (i) two years (May 18, 2019) or (ii) the date of the employees' termination from PCT. The post-termination option exercise period modification resulted in an additional expense of $0.3 million which was recorded entirely during the three months ended June 30, 2017 and recorded in discontinued operations, since there were no future service requirements to receive the extended benefit.

Total compensation cost related to nonvested awards not yet recognized and the weighted-average periods over which the awards are expected to be recognized at December 31, 2017 were as follows ($ in thousands):

	Stock Options	Restricted Stock
Unrecognized compensation cost	$ 39.5	$ 97.2
Expected weighted-average period in years of compensation cost to be recognized	0.61	1.84

Total fair value of shares vested and the weighted average estimated fair values of shares granted for the years ended December 31, 2017 and 2016 were as follows ($ in thousands):

	Stock Options	
	Year Ended December 31,	
	2017	2016
Total fair value of shares vested	$ 5,001.7	$ 2,359.8
Weighted average estimated fair value of shares granted	1.72	3.23

Valuation Assumptions

The fair value of stock options 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 range of assumptions made in calculating the fair values of stock options was as follow:

	Stock Options	
	Year Ended December 31,	
	2017	2016
Expected term - minimum (in years)	6	5
Expected term - maximum (in years)	6	10
Expected volatility - minimum	71%	73%
Expected volatility - maximum	74%	76%
Weighted Average volatility	35%	74%
Expected dividend yield	—	—
Risk-free interest rate - minimum	1.99%	1.07%
Risk-free interest rate - maximum	2.28%	2.19%

Note 13 – Research Funding

California Institute of Regenerative Medicine Grant Award

In February 2017, the California Institute for Regenerative Medicine ("CIRM") awarded us funds of up to $12.2 million to support the T-Rex Study. The funding will be based upon the achievement of certain milestones related to the proportion of subjects enrolled in California, as well as manufacturing and development costs incurred in California. We received $5.7 million in initial funding in May 2017, and a $1.9 million milestone payment in December 2017, of which the total will be amortized over the estimated award period through July 2020 as a reduction to the related research and development expenses. As of December 31, 2017, $2.4 million of the funding received is recorded in accrued liabilities, representing the amount expected to be recognized over the next 12 months, and $3.9 million of the funding received is recorded in other long-term liabilities. During the year ended December 31, 2017, the Company amortized and recognized a $1.3 million credit to research and development related to CIRM funds received.

Note 14 – Income Taxes

The Tax Cuts and Jobs Act (“the Act”) was enacted on December 22, 2017. The income tax effects of changes in tax laws are recognized in the period when enacted. The Act provides for significant tax law changes and modifications with varying effective dates, which include reducing the U.S. federal corporate income tax rate from 35% to21%, creating a territorial tax system (with a one-time mandatory repatriation tax on previously deferred foreign earnings), and allowing for immediate capital expensing of certain qualified property acquired and placed in service after September 27, 2017 and before January 1, 2023.

In response to the enactment of the Act in late 2017, the U.S. Securities and Exchange Commission issued Staff Accounting Bulletin No. 118 (“SAB 118”) to address situations where the accounting is incomplete for certain income tax effects of the Tax Act upon issuance of an entity’s financial statements for the reporting period in which the Tax Act was enacted. Under SAB 118, a company may record provisional amounts during a measurement period for specific income tax effects of the Tax Act for which the accounting is incomplete but a reasonable estimate can be determined, and when unable to determine a reasonable estimate for any income tax effects, report provisional amounts in the first reporting period in which a reasonable estimate can be determined. While the Company was able to make reasonable estimates of the impact of the tax effects of the Tax Act, the final impact of the Tax Act may differ from those estimates, including, but not limited to changes in our interpretations and assumptions, additional guidance that may be issued by the IRS, return to provision differences and state rate adjustments. As guidance and technical corrections are issued in the upcoming quarters, the Company will record updates to its original provisional estimates.

The Company remeasured certain U.S. deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future, which is generally 21%. The provisional amount recorded related to the remeasurement of the deferred tax balance was tax expense of $30 million which was offset by a reduction in the valuation allowance resulting in no tax expense.

The provision (benefit) for income taxes is based on loss from operations before provision for income taxes and noncontrolling interests as follows ($ in thousands):

	Years Ended December 31,	
	2017	2016
United States	$ (27,698)	$ (31,258)
	$ (27,698)	$ (31,258)

The provision (benefit) for income taxes was as follows ($ in thousands):

	Years Ended December 31,	
	2017	2016
Current		
U.S. Federal	$ (9,310)	$ —
State and local	(1,641)	—
	$ (10,951)	$ —
Deferred		
U.S. Federal	$ (576)	$ —
State and local	—	—
	$ (576)	$ —
Total		
U.S. Federal	$ (9,886)	$ —
State and local	(1,641)	—
	$ (11,527)	$ —

The provision (benefit) for income taxes is determined by applying the U.S. Federal statutory rate of 34% to income before income taxes as a result of the following ($ in thousands):

	Years Ended December 31,	
	2017	2016
U.S. Federal benefit at statutory rate	$ (9,417)	$ (10,628)
State and local (benefit) / expense net of U.S. federal tax	(1,641)	2,759
Permanent non deductible expenses for U.S. taxes	107	80
AMT credit benefit	(576)	—
True-up of prior year net operating loss	—	(2,371)
Effect of change in deferred tax rate	29,809	(44)
Valuation allowance for deferred tax assets	(29,809)	10,204
Tax provision benefit	$ (11,527)	$ —

Deferred income taxes at December 31, 2017 and 2016 consist of the following ($ in thousands):

	December 31,	
	2017	2016
Deferred Tax Assets:		
Accumulated net operating losses (tax effected)	$ 60,171	$ 79,131
CIRM funding	1,780	—
Deferred rent	3	314
Share-based compensation	2,656	11,562
Intangibles	270	429
Charitable contributions	11	424
Partnership interest	—	3,858
Capital loss carry-forward	—	6,988
Accumulated depreciation	22	—
Accrued payroll	682	—
AMT credit	575	—
Other	526	659
Deferred tax assets	66,696	103,365
Deferred Tax Liabilities:		
Accumulated depreciation	$ —	$ (119)
Deferred tax liabilities	—	(119)
	66,696	103,246
Valuation allowance	(66,121)	(103,246)
Net deferred tax asset	$ 575	$ —

In assessing the realizability of deferred tax assets, including the net operating loss carryforwards (NOLs), the Company assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to utilize its existing deferred tax assets. Based on its assessment, the Company has provided a full valuation allowance against its net deferred tax assets as their future utilization remains uncertain at this time.

As of December 31, 2017 and 2016, the Company had approximately $210.3 million and $232.7 million, respectively of Federal NOLs available to offset future taxable income expiring from 2030 through 2036. In accordance with Section 382 of the Internal Revenue code, the usage of the Company's NOLs could be limited in the event of a change in ownership. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period when those temporary differences become deductible.

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

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

As of December 31, 2017, management does not believe the Company has any material uncertain tax positions that would require it to measure and reflect the potential lack of sustainability of a position on audit in its financial statements. The Company will continue to evaluate its uncertain tax positions in future periods to determine if measurement and recognition in its financial statements is necessary. The Company does not believe there will be any material changes in its unrecognized tax positions over the next year.

The Company completed the audit of its federal tax returns for the years 2012 and 2013 during the fourth quarter of 2016. The audit resulted in an adjustment to the Company's NOL carryforward. For years prior to 2014 the federal statute of limitations is closed for assessing tax. The Company's state tax returns remain open to examination for a period of three to four years from date of filing. The Company ceased doing business in China in 2012. After 2012, the Company had no foreign tax filing obligations. The foreign returns filed for 2012 and prior are subject to examination for five years.

Note 15 – Discontinued Operations

PCT Segment

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

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

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

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

The operations and cash flows of the PCT Segment were eliminated from ongoing operations with the sale of the Company's PCT Interest. The operating results of the PCT Segment for the years ended December 31, 2017 and 2016 were as follows (in thousands):

	Year Ended December 31,	
	2017	2016
Revenue	$ 16,039	$ 42,043
Cost of revenues	(15,321)	(35,519)
Research and development	(257)	(800)
Selling, general, and administrative	(3,251)	(7,558)
Other expense	(14)	(80)
Provision for income taxes	(10,541)	(138)
Gain on sale of segment	51,744	—
Income (loss) from discontinued operations	$ 38,399	$ (2,052)

Note 16 – Commitments and Contingencies

Lease Commitments

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

A summary of future minimum rental payments required under operating leases that have initial or remaining terms in excess of one year as of December 31, 2017 are as follows (in thousands):

Years ended	Operating Leases
2018	910.0
2019	901.2
2020	827.0
2021	474.4
2022 and thereafter	128.6
Total minimum lease payments	$ 3,241.2

Expense incurred under operating leases were approximately $1.4 million and $1.4 million for the years ended December 31, 2017 and 2016, respectively.

Contingencies

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

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

From time to time, the Company is subject to legal proceedings and claims, either asserted or unasserted, that arise in the ordinary course of business. While the outcome of pending claims cannot be predicted with certainty, the Company does not

believe that the outcome of any pending claims will have a material adverse effect on the Company's financial condition or operating results.

Note 17 – Subsequent Events

Common Stock Sales Agreement

On February 8, 2018, we entered into a Common Stock Sales Agreement with H.C. Wainwright & Co., LLC ("HCW"), as sales agent, in connection with an “at the market offering” under which we from time to time may offer and sell shares of our common stock, having an aggregate offering price of up to $12 million. Subject to the terms and conditions of the sales agreement, HCW will use its commercially reasonable efforts consistent with its normal trading and sales practices to sell the shares from time to time, based upon our instructions, including any price, time or size limits specified by us. We have provided HCW with customary indemnification rights, and HCW will be entitled to a commission at a fixed commission rate equal to 3.0% of the gross proceeds per share sold. We have no obligation to sell any of the shares, and may at any time suspend sales under the sales agreement or terminate the sales agreement. The sales agreement will terminate upon the sale of all of the shares under the sales agreement unless terminated earlier by either party as permitted under the sales agreement.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures

Disclosure controls and procedures are the Company's 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 defined in Rules 13a-15(e) and 15d-15(e) 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 Securities and Exchange Commission'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 December 31, 2017, we carried out an evaluation, with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934. 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 the Company in the reports that it files or submits 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.

Internal Control Over Financial Reporting

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934.

Our internal control over financial reporting is a process designed 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 and includes those policies and procedures that:

- Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and the board of directors of the Company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to risk that controls may become inadequate because of changes in conditions or because of declines in the degree of compliance with policies or procedures.

Our management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2017. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in *Internal Control-Integrated Framework (2013).*

As of December 31, 2017, based on management's assessment, the Company's internal control over financial reporting was effective.

Changes in Internal Control over Financial Reporting

There have been no changes in the Company's internal control over financial reporting that occurred during the quarter ended December 31, 2017 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Management and Corporate and Governance Matters," "Section 16(a) Beneficial Ownership Reporting Compliance," and "Code of Conduct and Ethics" in the Company's Proxy Statement for the 2018 Annual Meeting of Stockholders.

ITEM 11. EXECUTIVE COMPENSATION

The response to this item is incorporated by reference from the discussion responsive thereto under the caption “Executive Officer and Director Compensation,” in the Company’s Proxy Statement for the 2018 Annual Meeting of Stockholders.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The response to this item is incorporated by reference from the discussion responsive thereto under the caption[s] “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” in the Company’s Proxy Statement for the 2018 Annual Meeting of Stockholders.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Certain Relationships and Related Transactions” and “Management and Corporate Governance Matters” in the Company’s Proxy Statement for the 2018 Annual Meeting of Stockholders.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The response to this item is incorporated by reference from the discussion responsive thereto under the caption “Independent Public Accountants” in the Company’s Proxy Statement for the 2017 Annual Meeting of Stockholders.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

The following documents are being filed as part of this Report:

(a)(1) FINANCIAL STATEMENTS:

Reference is made to the Index to Financial Statements and Financial Statement Schedule on Page 44 of this Annual Report on Form 10-K.

(a)(2) FINANCIAL STATEMENT SCHEDULE:

Reference is made to the Index to Financial Statements and Financial Statement Schedule on Page 44 of this Annual Report on Form 10-K.

All other schedules have been omitted because the required information is not present or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the Financial Statements or Notes thereto.

(a)(3) EXHIBITS:

The following is a list of exhibits filed (or furnished, where specified) as part of this Annual Report on Form 10-K. Exhibits that were previously filed are described below and are incorporated by reference. For exhibits incorporated by reference, the location of the exhibit in the previous filing is indicated.

Exhibit	Description
3.1	Amended and Restated Certificate of Incorporation of Caladrius Biosciences, Inc., as amended, effective July 27, 2016 (filed as Exhibit 3.1 to the Company's on Form 10-Q for the quarter ended June 30, 2016, filed with the SEC on August 9, 2016).
3.2	Amended and Restated By-Laws of the Caladrius Biosciences, Inc. as amended, effective as of July 27, 2016 (filed as Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, filed with the SEC on August 9, 2016).
3.3	Amendments to Amended and Restated Bylaws of Caladrius Biosciences, Inc., effective as of September 18, 2017 (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on September 21, 2017).
4.1	Form of Trust Indenture (filed as Exhibit 4.5 to the Company's Registration Statement on Form S-3, File No. 333-206175, filed with the SEC on August 6, 2015).
4.2	Form of Warrant (filed as Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 5, 2016).
+	Director Compensation Policy.
10.2	2015 Equity Compensation Plan (filed as Annex A to the Company's Definitive Proxy Statement filed on Schedule 14A, filed with the SEC on June 8, 2015).
+	2017 Employee Stock Purchase Plan (filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 10, 2017).
10.4	Form of Indemnification Agreement for executive officers (filed as Exhibit 10.44 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2014 as filed with the SEC on March 2, 2015).
10.5	First Amendment to Loan and Security Agreement, dated June 17, 2015, by and between the Company and Oxford Finance LLC (filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed with the SEC on August 6, 2015).
10.6	Second Amendment to Loan and Security Agreement, dated September 15, 2015, by and between the Company and Oxford Finance LLC (filed as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed with the SEC on November 5, 2015).
10.7	Consent and Third Amendment to Loan and Security Agreement, dated March 11, 2016, by and between Caladrius Biosciences, Inc., and Oxford Finance LLC (filed as Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q. for the quarter ended March 31, 2016, filed with the SEC on May 5, 2016).
10.8	Form of Securities Purchase Agreement, dated as of September 14, 2016, by and between Caladrius Biosciences, Inc. and the purchaser named therein (registered direct offering) (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on September 15, 2016).
10.9	Form of Securities Purchase Agreement, dated as of September 14, 2016, by and between Caladrius Biosciences, Inc. and the purchaser named therein (private placement) (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on September 15, 2016).
10.10	Form of Securities Purchase Agreement, dated as of September 14, 2016, by and between Caladrius Biosciences, Inc. and the purchaser named therein (private placement) (filed as Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the SEC on September 15, 2016).
10.11	Form of Registration Rights Agreement, dated as of September 14, 2016, by and between Caladrius Biosciences, Inc. and the investors named therein (private placement) (filed as Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the SEC on September 15, 2016).
10.12	Common Stock Purchase Agreement, dated as of November 4, 2015, by and between the Company and Aspire Capital Fund, LLC (filed as Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed with the SEC on November 5, 2015).

10.13 Securities Purchase Agreement, dated March 10, 2016, by and among Caladrius Biosciences, Inc., TJP Opportunities Fund L.L.C., GPP Opportunities Fund L.L.C. and IEA Private Investments LTD (filed as Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q. for the quarter ended March 31, 2016, filed with the SEC on May 5, 2016).

10.14 Registration Rights Agreement, dated March 10, 2016, by and among Caladrius Biosciences, Inc., TJP Opportunities Fund L.L.C., GPP Opportunities Fund L.L.C. and IEA Private Investments LTD (filed as Exhibit 10.8 to the Company's Quarterly Report on Form 10-Q. for the quarter ended March 31, 2016, filed with the SEC on May 5, 2016).

10.15 Unit Purchase Agreement, dated March 11, 2016, by and among Caladrius Biosciences, Inc., PCT, LLC, a Caladrius Company and Hitachi Chemical Co. America, LTD (filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, filed with the SEC on May 5, 2016).

10.16 Amended and Restated Operating Agreement of PCT, LLC, a Caladrius Company, dated March 11, 2016, by and among PCT, LLC, a Caladrius Company, Caladrius Biosciences, Inc. and Hitachi Chemical Co. America, LTD (filed as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, filed with the SEC on May 5, 2016).

10.17 Technology License Agreement, dated March 22, 2016, by and between PCT, LLC, a Caladrius Company and Hitachi Chemical Co. LTD (filed as Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q. for the quarter ended March 31, 2016, filed with the SEC on May 5, 2016).

10.18 Interest Purchase Agreement, by and among Hitachi Chemical Co. America, Ltd., PCT LLC, a Caladrius Company and Caladrius Biosciences, Inc., dated as of March 16, 2017 (filed as Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the SEC on March 17, 2017).

10.19 Warrant for the Purchase of Units of PCT, LLC, a Caladrius Company, effective as of March 16, 2017 (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on March 17, 2017).

10.20 Office Lease Between 110 Allen Road LLC, Landlord and Caladrius Biosciences, Inc. (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on May 17, 2017).

10.21 Lease Termination Agreement Between 106 Allen Road LLC and Caladrius Biosciences, Inc. (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on May 17, 2017).

10.22 Common Stock Sales Agreement, dated February 8, 2018, by and between Caladrius Biosciences, Inc. and H.C. Wainwright & Co., LLC (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on February 8, 2018).

\+ Employment Agreement, dated as of January 5, 2015 and effective on January 5, 2015, by and between the Company and David J. Mazzo, Ph.D. (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed on January 5, 2015).

\+ Amendment, dated as of January 16, 2015, to Employment Agreement, dated as of January 5, 2015 and effective on January 5, 2015, by and between the Company and David J. Mazzo, Ph.D. (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed on January 16, 2015).

\+ Amendment to Employment Agreement, dated as of July 25, 2016, by and between the Company and David J. Mazzo, PhD (filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q. for the quarter ended June 30, 2016, filed with the SEC on August 9, 2016).

\+ Amendment to Employment Agreement with David J. Mazzo, effective September 18, 2017 (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on September 21, 2017).

\+ Employment Agreement, dated as of August 9, 2016, by and between Caladrius Biosciences, Inc. and Douglas W. Losordo, MD (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on August 9, 2016).

\+ Amendment to Employment Letter with Doug Losordo, effective November 1, 2017 (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on November 1, 2017).

\+ Letter Agreement dated June 28, 2011 between the Company and Joseph Talamo (filed as Exhibit 10.10 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011 as filed with the SEC on August 12, 2011).

10.30 + Offer Letter Amendment dated October 6, 2015, to Employment Agreement dated June 28, 2011 and effective October 6, 2015, by and between the Company and Joseph Talamo.

+	Amendment to Letter Agreement, dated as of July 25, 2016, by and between the Company and Joseph Talamo (filed as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, filed with the SEC on August 9, 2016).
+	Employment Agreement, dated March 11, 2016, by and between PCT, LLC, a Caladrius Company and Robert A. Preti, PhD (filed as Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, filed with the SEC on May 5, 2016).
+	Amendment to Employment Agreement, dated as of July 25, 2016, by and between the Company and Robert Preti, PhD (filed as Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, filed with the SEC on August 9, 2016).
+	Retention and Incentive Agreement, by and between Robert A. Preti and Caladrius Biosciences, Inc., dated as of March 16, 2017 (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on March 17, 2017).
†	Code of Ethics for Senior Financial Officers
†	Subsidiaries of Caladrius Biosciences, Inc.
†	Consent of Grant Thornton LLP
†	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
†	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
†	Certification of Chief Executive Officer and 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

+ Management contract or compensatory plan, contract or arrangement required to be filed as an exhibit to this Form 10-K pursuant to Item 15(b) of Form 10-K.

† Filed herewith.

†† Furnished herewith.

(1) Certain portions of this exhibit were omitted based upon a request for confidential treatment, and the omitted portions were filed separately with the SEC on a confidential basis.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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, in the City of New York, State of New York, on March 22, 2018.

CALADRIUS BIOSCIENCES, INC.

By:
/s/ David J. Mazzo, PhD

Name: David J. Mazzo
Title: President and Chief Executive Officer (Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ David J. Mazzo David J. Mazzo, PhD	Director, and President and Chief Executive Officer (Principal Executive Officer)	March 22, 2018
/s/ Joseph Talamo Joseph Talamo	Senior Vice President, and Chief Financial Officer (Principal Financial and Accounting Officer)	March 22, 2018
/s/ Gregory B. Brown Gregory B. Brown, MD	Chairman of the Board of Directors	March 22, 2018
/s/ Steven S. Myers Steven S. Myers	Director	March 22, 2018
/s/ Steven M. Klosk Steven M. Klosk	Director	March 22, 2018
/s/ Peter G. Traber Peter G. Traber, MD	Director	March 22, 2018

Director Compensation Policy

On October 1, 2015 the Compensation Committee of Caladrius Biosciences, Inc. (the "Company"), after consultation with the Board, adopted the Board of Directors Compensation Plan (the "Board of Directors Compensation Plan"), for all non-employee Board members which policy was amended by the Board on May 16, 2017 and December 4, 2017, and currently provides that:

- each Board member shall be authorized to receive an annual cash compensation retainer of $40,000 for his or her service as a Board member;
- the Lead Director shall be authorized to receive an additional annual cash compensation retainer of $10,000 for his or her service as the Lead Director;
- the Non-executive Chair shall be authorized to receive an additional annual cash compensation retainer of $30,000 for his or her service as the Non-executive Chair;
- each member of the Company's Audit Committee shall be entitled to receive annual cash compensation of $8,000 for his or her service on such committee;
- each member of the Company's Compensation Committee shall be entitled to receive annual cash compensation of $6,000 for his or her service on such committee;
- each member of the Company's Nominating and Governance Committee shall be entitled to receive annual cash compensation of $4,500 for his or her service on such committee;
- each member of the Company's Science and Technology Committee shall be entitled to receive annual cash compensation of $4,500 for his or her service on such committee;
- the Audit Committee Chair shall be authorized to receive annual cash compensation of $18,000 for his or her service as the Chair;
- the Compensation Committee Chair shall be authorized to receive annual cash compensation of $12,000 for his or her service as the Chair;
- the Nominating and Governance Committee Chair shall be authorized to receive annual cash compensation of $9,000 for his or her service as the Chair;
- the Science and Technology Committee Chair shall be authorized to receive annual cash compensation of $9,000 for his or her service as the Chair;
- each member of the Board shall receive annually on the second Monday in January a grant of restricted stock with a black scholes value of $30,000 with the number of shares to be issued on the grant date calculated based on the average closing price of the common stock of the Company during the 30 day period of October 15 through November 15 prior to the grant date, vesting at one year from the grant date; and
- each newly appointed Board member shall receive an initial grant of restricted stock with a black scholes value of $60,000 with the number of shares to be issued on the grant date calculated based on the grant date fair value with one-third vesting annually on each of the first, second and third anniversaries of the grant date.

Exhibit 14.1

CODE OF ETHICS FOR SENIOR FINANCIAL OFFICERS

I. PURPOSE

The Board of Directors (the "Board") of Caladrius Biosciences, Inc. (the "Company") has adopted the following Code of Ethics (the "Code") to apply to the Company's Chief Executive Officer, Chief Financial Officer, Chief Accounting Officer or Controller, or persons performing similar functions (the "Senior Financial Officers"). This Code is intended to focus Senior Financial Officers on areas of ethical risk, provide guidance to help them recognize and deal with ethical issues, provide mechanisms to report unethical conduct, foster a culture of honesty and accountability, deter wrongdoing and promote fair and accurate disclosure and financial reporting.

No code or policy can anticipate every situation that may arise. Accordingly, this Code is intended to serve as a source of guiding principles. Senior Financial Officers are encouraged to bring questions about particular circumstances that may involve one or more of the provisions of this Code to the attention of the Audit Committee, who may consult with inside or outside legal counsel as appropriate.

II. INTRODUCTION

Each Senior Financial Officer is expected to adhere to a high standard of ethical conduct. The good name of the Company depends on the way Senior Financial Officers conduct business and the way the public perceives that conduct. Unethical actions, or the appearance of unethical actions, are not acceptable. Senior Financial Officers are expected to be guided by the following principles in carrying out their responsibilities.

- Loyalty. Senior Financial Officers should not be, or appear to be, subject to influences, interests or relationships that conflict with the best interests of the Company.
- Compliance with Applicable Laws. Senior Financial Officers are expected to comply with all laws, rules and regulations applicable to the Company's activities.
- Observance of Ethical Standards. Senior Financial Officers must adhere to high ethical standards in the conduct of their duties. These include honesty and fairness.

III. DUTY TO REPORT VIOLATIONS

You are responsible for reporting in good faith to the Company any circumstances that you believe may constitute a violation of this Code of Conduct. Senior Financial Officers should communicate any suspected violations of this Code promptly to the Chairman of the Audit Committee.an independent director and member of our Audit Committee. The Audit Committee Chair will then inform the other independent directors and they will determine whether a violation has occurred, according to the standards outlined above, hold a formal meeting, if required, to question the officer, employee or director reported, and if necessary recommend a disciplinary remedy or termination of employment, or notify the appropriate legal authorities. Reports may be made to the Company’s secure hotline at (646) 606-2191. The Company’s Whistleblower Policy provides details for reporting illegal or unethical conduct. The Whistleblower Policy is available on the Company’s website. Only the Audit Committee may grant any waivers of this policy.

IV. INTEGRITY OF RECORDS AND FINANCIAL REPORTING

Senior Financial Officers are responsible for the accurate and reliable preparation and maintenance of the Company's financial records. Accurate and reliable preparation of financial records is of critical importance to proper management decisions and the fulfillment of the Company's financial, legal and reporting obligations. Diligence in accurately preparing and maintaining the Company's records allows the Company to fulfill its reporting obligations and to provide stockholders, governmental authorities and the general public with full, fair, accurate, timely and understandable disclosure.

Senior Financial Officers are responsible for establishing and maintaining adequate disclosure controls and procedures, and internal controls and procedures, including procedures that are designed to enable the Company to: (a) accurately document and account for transactions on the books and records of the Company; and (b) maintain reports, vouchers, bills, invoices, payroll and service records, business measurement and performance records and other essential data with care and honesty.

Senior Financial Officers shall immediately bring to the attention of the Audit Committee any information they may have concerning:

1. Defects, deficiencies, or discrepancies related to the design or operation of internal controls which may affect the Company's ability to accurately record, process, summarize, report and disclose its financial data; or

2. Any fraud, whether or not material, that involves management or other employees who have roles in the Company's financial reporting, disclosures or internal controls.

V. CONFLICT OF INTEREST

Senior Financial Officers must avoid any conflicts of interest between themselves and the Company. Any situation that involves, or may involve, a conflict of interest with the Company, should be disclosed promptly to the Audit Committee, who may consult with inside or outside legal counsel as appropriate.

A "conflict of interest" can occur when an individual's personal interest is adverse to or may appear to be adverse to the interests of the Company as a whole. Conflicts of interest also arise when an individual, or a member of his or her family, receives improper personal benefits as a result of his or her position with the Company.

This Code does not attempt to describe all possible conflicts of interest which could develop. Some of the more common conflicts from which Senior Financial Officers must refrain, however, are set forth below:

- Improper conduct and activities. Senior Financial Officers may not engage in any conduct or activities that are inconsistent with the Company's best interests or that disrupt or impair the Company's relationship with any person or entity with which the Company has, or proposes to enter into, a business or contractual relationship.
- Compensation from non-Company Sources. Senior Financial Officers may not accept compensation for services performed for the Company from any source other than the Company.
- Gifts. Senior Financial Officers and members of their immediate families may not accept gifts from persons or entities where any such gift is being made in order to influence their actions in their position with the Company, or where acceptance of the gifts could create the appearance of a conflict of interest.

- Personal use of Company assets. Senior Financial Officers may not use Company assets, labor or information for personal use, other than incidental personal use, unless approved by the Audit Committee or as part of a compensation or expense reimbursement program.
- Financial Interests in other Businesses. Senior Financial Officers should avoid having an ownership interest in any other enterprises, such as a customer, supplier or competitor, if that interest compromises the officer's loyalty to the Company.

VI. CORPORATE OPPORTUNITIES

Senior Financial Officers are prohibited from: (a) taking for themselves personally opportunities related to the Company's business without first presenting those opportunities to the Company and obtaining approval from the Board; (b) using the Company's property, information, or position for personal gain; or (c) competing with the Company for business opportunities.

I. CONFIDENTIALITY

Senior Financial Officers should maintain the confidentiality of information entrusted to them by the Company and any other confidential information about the Company, its business or finances, customers or suppliers that comes to them, from whatever source, except when disclosure is authorized or legally mandated. For purposes of this Code, "confidential information" includes all non-public information relating to the Company, its business or finances, customers or suppliers.

II. COMPLIANCE WITH LAWS, RULES AND REGULATIONS

Senior Financial Officers shall comply with laws, rules and regulations applicable to the Company, including insider trading laws, and all other Company policies.

I. ENCOURAGING THE REPORTING OF ANY ILLEGAL OR UNETHICAL BEHAVIOR

Senior Financial Officers must promote ethical behavior and create a culture of ethical compliance. Senior Financial Officers should foster an environment in which the Company: (a) encourages employees to talk to supervisors, managers and other appropriate personnel when in doubt about the best course of action in a particular situation; (b) encourages employees to report violations of laws, rules and regulations to appropriate personnel; and (c) informs employees that the Company will not allow retaliation for reports made in good faith.

Exhibit 21.1

Subsidiaries of Caladrius Biosciences, Inc.

Entity	Percentage of Ownership	Location
Amorcyte, LLC	100%	United States of America
Athelos Corporation (1)	97%	United States of America
NeoStem Oncology, LLC	100%	United States of America

(1) As of December 31, 2017, Becton Dickinson's ownership interest in Athelos Corporation was 1.6%.

Exhibit 23.1

CONSENT OF INDEPENENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated March 22, 2018, with respect to the consolidated financial statements included in the Annual Report of Caladrius Biosciences, Inc. on Form 10-K for the year ended December 31, 2017. We consent to the incorporation by reference of said report in the Registration Statements of Caladrius Biosciences, Inc. on Forms S-3 (File No. 333-196702, File No. 333-206175, File No. 333-210664, 333-214607 and File No. 333-220354) and on Forms S-8 (File No. 333-107438, File No. 333-144265, File No. 333-159282, File No. 333-162733, File No. 333-173854, File No. 333-181365, File No. 333- 184927, File No. 333-191572, File No. 333-205662, File No. 333-212202, File No. 333-215455, File No. 333-218642 and File No. 333-222410).

New York, New York
March 22, 2018

Exhibit 31.1

CERTIFICATIONS UNDER SECTION 302

I, David J. Mazzo, certify that:

1. I have reviewed this annual report on Form 10-K 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(s) 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(s) 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: March 22, 2018

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

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, Joseph Talamo, certify that:

1. I have reviewed this annual report on Form 10-K 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(s) 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(s) 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: March 22, 2018

/s/ Joseph Talamo
Joseph Talamo
Senior Vice President and Chief Financial Officer
(*Principal Financial Officer*)

Exhibit 32

CERTIFICATIONS UNDER SECTION 906

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), each of the undersigned officers of Caladrius Biosciencs, Inc. a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2017 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 22, 2018

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

Dated: March 22, 2018

/s/ Joseph Talamo
Joseph Talamo
Senior Vice President and Chief Financial Officer
(*Principal Financial Officer*)