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, 2016

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.)
106 ALLEN ROAD, FOURTH FLOOR BASKING RIDGE, NJ	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 o No x

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" and "smaller reporting 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

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, 2016 (the last business day of the most recently completed second fiscal quarter) was approximately $32.0 million, computed by reference to the last sale price of $5.90 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 16, 2017, 8,308,264 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;
- our ability to integrate our acquired businesses successfully and grow such acquired businesses as anticipated;
- whether a market is established for our cell-based products and services and our ability to capture a meaningful share of this market;
- scientific and medical developments beyond our control;
- our ability to obtain and maintain, as applicable, appropriate governmental licenses, accreditations or certifications or comply with healthcare laws and regulations or any other adverse effect or limitations caused by government regulation of our business;
- whether any of our current or future patent applications result in issued patents, the scope of those patents and our ability to obtain and maintain other rights to technology required or desirable for the conduct of our business; and our ability to commercialize products without infringing the claims of third party patents;
- whether any potential strategic or financial benefits of various licensing agreements will be realized;
- the results of our development activities;
- our ability to complete our other planned clinical trials (or initiate other trials) in accordance with our estimated timelines due to delays associated with enrolling patients due to the novelty of the treatment, the size of the patient population and the need of patients to meet the inclusion criteria of the trial or otherwise;
- our ability to satisfy our obligations under our loan agreement; and
- our ability to consummate any announced strategic transactions, including the sale of our remaining ownership stake in PCT, LLC.

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 our internal specialized cell therapy clinical development expertise to select and develop early-stage cell therapy candidates with the intention of partnering these candidates post proof-of-concept in humans. Our current lead product candidate, CLBS03, is an autologous ex vivo polyclonal T regulatory cell ("Treg") clinical phase 2 therapy targeting adolescents with recent-onset type 1 diabetes mellitus (“T1D”). Our subsidiary, PCT, LLC, a Caladrius Company™ (“PCT”), is a leading provider of development and manufacturing services to the cell and cell-based gene therapy industry. PCT has significant cell therapy-specific experience and expertise, an expansive list of noteworthy clients and significant revenue growth over the past three years. Notably, PCT and Hitachi Chemical Co. America, Ltd. ("Hitachi America") and Hitachi Chemical Co., Ltd. (“Hitachi” and, together with Hitachi America, "Hitachi Chemical") are engaged in a strategic collaboration to accelerate the creation of a global commercial cell therapy development and manufacturing enterprise with deep engineering expertise.

Proposed Sale of Remaining Interest in PCT to Hitachi America

On March 16, 2017 (the “Effective Date”), Caladrius entered into an interest purchase agreement (the "Purchase Agreement"), by and among Caladrius, PCT and Hitachi America, pursuant to which Hitachi America has agreed to acquire the 80.1% membership interest in PCT that it does not already own from Caladrius for $75.0 million in cash (the “Sale”), subject to potential adjustment, including based on PCT’s cash and outstanding indebtedness as of the closing of the Sale, and a potential future milestone payment (the “Purchase Price”). Pursuant to the terms of the Purchase Agreement, at the Effective Date, Hitachi America will pay Caladrius $5.0 million of the Purchase Price (the “Initial Payment”). At the closing of the Sale (the “Closing”), an additional $5.0 million of the Purchase Price will be deposited into an escrow account to cover potential indemnification claims of Hitachi America, if any. The Closing is subject to customary closing conditions, including approval of Caladrius’ stockholders, and is expected to occur during the second quarter of 2017. However, we cannot provide assurance as to when the Sale will be completed, or whether it will be completed at all. See “Item 1A. Risk Factors-Risks Related to the Sale.

As part of the Purchase Price, Hitachi will pay Caladrius $5.0 million (the “Milestone Payment”) if PCT achieves $125.0 million in Cumulative Revenue (excluding clinical service reimbursables) (the “Milestone”) for the period from January 1, 2017 through December 31, 2018. For purposes of the Milestone, “Cumulative Revenue” will be calculated based on PCT’s revenue from all customers (including Caladrius and its subsidiaries) in accordance with the financial accounting and reporting standards set forth in the statements and pronouncements of the Financial Accounting Standards Board (“FASB”), consistently applied.

PCT is a well-known cell therapy development and manufacturing provider (often called a contract development and manufacturing organization, or "CDMO"), specializing in cell and cell-based gene therapies. PCT offers high-quality development and manufacturing capabilities (e.g., current Good Manufacturing Practice (“cGMP”) manufacturing systems and facilities), quality systems, cell and tissue processing, logistics, storage and distribution) and engineering solutions (e.g., process and assay development, optimization and automation) to clients with therapeutic candidates at all stages of development. PCT produces clinical supplies. Following completion of the Sale, we will no longer be involved in the CDMO business, but will continue to develop cell therapy product candidates (the “Retained Business”). For additional information related to the Sale and related transactions, see footnote 18 to our audited financial statements appearing in Item 8 below.

CLBS03

We are developing strategically, through the utilization of our core development and manufacturing expertise, a product candidate that is 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 below 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 T effector 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 T effector cells. In autoimmune disease, however, it is thought that deficient Treg activity and numbers permit the T effector cells to attack the body's own beneficial cells. In the case of T1D, 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, only lifelong insulin therapy, which therapy often does not prevent serious co-morbidities. Two Phase 1 clinical trials of this technology in T1D demonstrated safety and tolerance, feasibility of manufacturing, an implied durability of effect as well as an early indication of potential therapeutic effect through the preservation of beta cell function. In the first quarter of 2016, we commenced patient enrollment in the first of two

cohorts in The Sanford Project: T-Rex Study, a Phase 2 prospective, randomized, placebo-controlled, double-blind clinical trial (the "TRex Study") to evaluate the safety and efficacy of CLBS03 in adolescents with recent onset T1D. 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 of early therapeutic effect is planned after approximately 50% of patients reach the six-month follow-up milestone, which analysis is expected in late 2017 or early 2018. 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 total $12.2 million amount will become payable upon the achievement of certain milestones which are still under negotiation. We expect to receive $5.7 million in initial funding on April 1, 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").

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 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"). Published reports in *Circulation Cardiovascular Interventions*, *Atherosclerosis*, *Stem Cells and Circulation Journal*, provide preliminary evidence that CD34 cell therapy is safe and can exert significant therapeutic effects in patients with CLI, a condition in which blood flow to the legs is severely impaired, causing pain and non-healing ulcers and, ultimately, potentially resulting in the need for amputation. Our Clinical Trial Notification for a pivotal Phase 2 trial investigating CLBS12 (a candidate for CLI) was submitted to the Japanese Pharmaceutical and Medical Device Agency ("PMDA") and was cleared to proceed. The protocol design was agreed with PMDA and if successful, could provide the basis for conditional approval under Japan's favorable regenerative medicine law. We are seeking to collaborate on CLBS12 with development and/or manufacturing partners. We submitted multiple grant applications in an effort to seek non-dilutive financing to investigate the CD34 technology for additional clinical indications in the United States and expect to learn the results of those applications in the first half of 2017.

We intend to develop this platform if capital becomes available through grants, partnerships or licensing, as well as potentially using reasonable amounts of our own capital as it becomes available.

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, a platform using tumor cell/dendritic cell technology for immuno-oncology and additional indications for our CD34 cell technology. The immuno-oncology program has the benefit of promising Phase 2 clinical data and applicability to multiple indications. This platform is based on our extensive intellectual property portfolio. In 2016, we completed multiple out-licensing agreements for this and other technology platforms in an effort to monetize non-core assets.

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

Cell Therapy Development and Manufacturing

PCT is a leading CDMO, specializing in cell and cell-based gene therapies. PCT offers high-quality development and manufacturing capabilities (e.g., cGMP manufacturing systems and facilities, quality systems, cell and tissue processing, logistics, storage and distribution) and engineering solutions (e.g., process and assay development, optimization and automation) to clients with therapeutic candidates at all stages of development. PCT produces clinical supplies and ultimately, intends also to produce commercial product for its clients. PCT has worked with over 100 clients and produced over 20,000 cell therapy products since it was founded 18 years ago. PCT’s manufacturing services are designed to reduce the capital investment and time required by clients to advance their development programs compared to conducting process development and manufacturing in-house. PCT has demonstrated regulatory expertise, including the support of over 50 U.S. and European Union ("EU") regulatory filings for clients and expertise across multiple cell types and therapeutic applications, including immunotherapy (e.g. CAR-T therapies), neuro/endocrine therapies, hematopoietic replacement and tissue repair/regeneration. PCT offers a complete development pathway for its clients, with services supporting preclinical through commercial phase, all underpinned by timely process optimization and automation support. PCT currently operates facilities qualified under cGMPs in each of Allendale, New Jersey and Mountain View, California, including EU-compliant production capacity in the Allendale facility. On March 11, 2016, PCT entered into a technology license agreement with Hitachi (the "Hitachi License Agreement") to accelerate the creation of a global commercial cell therapy development and manufacturing enterprise with deep engineering expertise, at which time Caladrius sold 19.9% of its ownership

stake in PCT to Hitachi America. As discussed above, on March 16, 2017, we entered into the Purchase Agreement to sell our remaining 80.1% membership interest in PCT to Hitachi America for the Purchase Price.

Reverse Stock Spli

On July 28, 2016, we implemented a one-for-ten reverse split of our issued and outstanding shares of our 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 our common stock, except to the extent that the Reverse Stock Split resulted in any of our stockholders owning a fractional share, which was rounded up to the next highest whole share. In connection with the Reverse Stock Split, there was no change in the nominal par value per share of $0.001. The Reverse Stock Split was effectuated in order to increase the per share trading price of our common stock to satisfy the $1.00 minimum bid price requirement for continued listing on The NASDAQ Capital Market.

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.

Corporate Information

We incorporated in 1980 as a Delaware corporation and our principal executive offices are located at 106 Allen Road, Fourth 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®, Athelos™, and PCT, LLC™. 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, devices and diagnostics and aesthetic medicine. In 2017, the Alliance for Regenerative Medicine recognizes over 759 regenerative medicine companies worldwide, which includes 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, first bone marrow and then 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 that are used to treat many cancers. These types of cell therapies are standard of practice world-wide and are typically 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, and much of the business of PCT, 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 Therapy ("OSCT"), donor cells are expanded many fold in tissue culture and large banks of cells are frozen in individual aliquots 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 and/or from the process of aging.

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 efficacy of autologous Tregs in 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 reported that, in the clinical trial, 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 were deemed unrelated 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 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 based product similar to CLBS03 and provided additional information on the safety and feasibility of this approach in new onset children with T1D.

We are currently enrolling patients in the T-Rex Study, a Phase 2 prospective, randomized, placebo-controlled, double-blind clinical trial to evaluate the safety and efficacy of our Treg product candidate, CLBS03, in adolescents with recent onset T1D. We have entered into a strategic collaboration with Sanford Research to support the execution of this trial. Sanford Research is a non-profit research organization that is part of Sanford Health and supports an emerging translational research center focused on finding a cure for T1D. The T-Rex study is expected to enroll a total of 111 subjects. An analysis of a broad panel of immunological markers suggested by our Scientific Advisory Board will occur after subject treatment at a variety of timepoints throughout the study. Satisfactory evaluation of the safety of the initial cohort of 19 patients based on one month follow-up from our independent Data Safety Monitoring Board was received in October 2016. An interim analysis of early therapeutic effect is expected to be completed in late 2017 or early 2018 after approximately 50% of patients reach the six month follow-up milestone. On February 23, 2017, the California Institute for Regenerative Medicine ("CIRM") awarded us funds of up to $12.2 million to support the CLBS03 Phase 2 TID Study. The total $12.2 million amount will become payable upon the achievement of certain milestones which are

still under negotiation. We expect to receive $5.7 million in initial funding on April 1, 2017. CLBS03 has been granted Fast Track and orphan drug designations from the FDA as well as ATMP classification from the EMA

Market Opportunity and Competition

In 2015, *The International Diabetes Foundation Atlas*, 7th Ed., reported an estimated 86,000 children younger than 15 develop T1D annually worldwide, with annual increase 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 will 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 to progressively penetrate the market as the magnitude and durability of their therapeutic effect becomes well characterized.

Currently, there are no approved therapies for newly onset T1D or potential curative approaches 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 Phaarmaceuticals 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.

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, Neuromyelitis optica spectrum disorder ("NMO") is an autoimmune disease and demyelination disorder. Although NMO pathogenesis has some similarities to multiple sclerosis, NMO is a distinct disorder. It is a serious debilitating disease with no current options for curative treatment. Certain evidence also suggests that a failure of Tregs may be important in the development systemic lupus erythematosis ("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, lupus, rheumatoid arthritis, chronic obstructive pulmonary disease and inflammatory bowel disease are other indications in 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 from leaders in the field of Tregs (UCSF/Jeffrey Bluestone et al, Centenary Institute) comprising:

- Seven patents and nine 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)

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 improve through 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 efficacy. We have 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"). These consultations have led to an agreement on the design for a 35-patient open-label clinical trial for which we are seeking a partnership to fund execution as well as considering potentially using reasonable amounts of our own capital as it becomes available.

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 would have potential in treating chronic heart failure ("CHF"). Published reports have provided evidence that CD34 cells administered into the coronary arteries of patients with CHF can improve survival compared to patients treated with standard medical therapy.

We believe that the platform technology is also potentially applicable across several other indications including ST-segment elevation myocardial infarction ("STEMI"), non-ST-segment elevation myocardial infarction ("N-STEMI"), stroke, claudication, chronic heart failure, refractory angina and Syndrome X. We have submitted multiple grant applications in an effort to seek non-dilutive financing to investigate the CD34 technology for additional clinical indications in the United States and expect to learn the results of those applications in 2017

Ischemic Repair (CD34 Cell) Intellectual Property Platform

Our developed and owned ischemic repair patent portfolio comprising 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/CXCR4 stem cells that move in response to SDF-1 or VEGF, together with a stabilizing amount of serum, and that can be delivered parenterally through a catheter to repair an injury caused by vascular insufficiency.
- Issued and pending claims can be applied to 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 patent are pending.

Market Opportunity and Competition for CLI

In Japan there are roughly 44,000 patients with CLI, of whom roughly 21,000 are not candidates for revascularization, making them the addressable population for CLBS12. The addressable population is roughly 54,000 in the EU and 55,000 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.

Immuno-Oncology (Tumor Cell/Dendritic Cell Technology)

It has been well established that the human immune system can provide a powerful response in the treatment of cancer if the immune system can be properly "educated" to attack cancerous cells while leaving the normal tissue unharmed. It is thought that many recurrences of cancers treated with the standard of care are the result of tumor or cancer initiating cells (commonly referred to as "cancer stem cells") that evade the initial therapy and initiate tumor re-growth. Targeting tumor or cancer initiating cells after medically induced tumor regression remains a seminal goal of cancer therapeutics. It is believed by some that eradication of such cells could lead to long-term disease-free survival, better overall survival and potential cures. The treatment paradigm in oncology, however, was transformed during 2015 by accelerating adoption of multiple immune checkpoint inhibitors used as monotherapy and in combination treatments. Therefore, we discontinued development of our tumor cell/dendritic cell therapy product candidate, CLBS20, for the treatment of metastatic melanoma as a monotherapy. Our emphasis regarding CLBS20 is now to secure a partner or an out-licensing arrangement with a third party to continue the development of CLBS20 as a combination therapy. We believe that this proprietary tumor cell/dendritic cell technology has the capability to be a potent immunotherapy for other oncology

indications, such as ovarian cancer, colon cancer, lung cancer and hepatocellular cancer. In May 2016, we out-licensed our tumor cell/dendritic cell technology to AiVita Biomedical, Inc. ("AiVita") for ovarian cancer (candidate CLBS23) for worldwide use.

Immuno-Oncology Intellectual Property

We own the following intellectual property:

- Ten granted patents and approximately 88 pending patents. Pending patent applications covering most facets of the dendritic cell vaccine product and manufacture process, including:
  - Pluripotent Germ Lay Origin Antigen Presenting Cancer Vaccine;
  - Antigen-presenting cancer vaccines, methods of manufacturing vaccines and methods of treating disease using the vaccines; and
  - Methods of making individualized high purity carcinoma initiating (stem) cells for target indications.
- The portfolio is international in scope, including filings in the United States, Europe, Japan, China, Hong Kong, Australia, New Zealand, Israel, Singapore, China, Korea and Canada.

Topical Aesthetics (Dermatological Technology)

Our aesthetics technology, based on expertise in cellular therapy and manufacturing, consists of a topical skin application using growth factors secreted by stem cells. The growth factors are harvested from a proprietary manufacturing process that includes a complex composition of human stem cells of epidermal originating lineages cultured in a controlled microenvironment to promote healthy skin cell biology.

In February 2016, our subsidiary, NeoStem Oncology, licensed to AiVita the exclusive rights to our cell-derived dermatological product technology, which technology AiVita is commercializing through a distribution agreement with ALPHAEON Corporation, a social commerce company in lifestyle healthcare. ALPHAEON has an established board-certified physician community of more than 10,000 members coupled with e-commerce capabilities. We receive royalties on net sales.

Topical Aesthetics Intellectual Property Platform

We own the following intellectual property:

- Portfolio of three granted and six pending patent applications for manufacturing a dermatological product, including:
  - Stem cell growth media and methods of making and using same; and
  - Stem Cell Compositions for Cosmetic and Dermatologic Use.
- The portfolio is international, including filings in the United States, Switzerland, Germany, France, United Kingdom, Ireland, Sweden, Canada and Hong Kong.

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.

PCT: A PREMIER CELL THERAPY SERVICE PROVIDER

Through our subsidiary, PCT, we provide high quality manufacturing capabilities and innovative engineering solutions in the development of cell-based therapies. Our strategy has been to leverage our core expertise in the support of cell therapy developers, biotechnology companies and pharmaceutical companies that recognize our ability to improve their manufacturing processes and to provide value-added manufacturing services.

We operate two state-of-the-art, accredited and certified U.S. facilities, one in Allendale, New Jersey, and one in Mountain View, California.

Our in-house expertise provides us with know-how and resources to cost-effectively and efficiently develop our own selected cell therapy product candidates, as well as to translate our own proprietary technologies into stable, reproducible, well-characterized, commercially viable cell therapy products candidates for clients. We believe that this expertise provides us with an advantage in the advancement and development of our own product candidates. With respect to those product candidates to date, including our CLBS03 Phase 2 product candidate, all manufacturing has been carried out by PCT.

On March 11, 2016, PCT entered into a global collaboration with Hitachi Chemical that includes licensing, development and equity components. As part of the collaboration, Hitachi America purchased a 19.9% equity interest in PCT for $19.4 million. In addition, PCT has licensed its cell therapy technology and know-how to Hitachi Chemical for cell therapy manufacturing in certain Asian territories, including Japan, where the Pharmaceuticals and Medical Devices Agency ("PMDA") has introduced more favorable legislation to stimulate the growth of regenerative medicine development in Japan. Under the Hitachi License Agreement, Hitachi paid PCT $5.6 million in upfront and fee driven payments in 2016. In addition, Hitachi will pay PCT service fees and royalties on contract revenue in those territories. Under the license arrangement, Hitachi is responsible for all capital and operational expenses associated with establishment and operation of the Asian business on which PCT is entitled to royalty payments. Outside of the license agreement, PCT and Hitachi Chemical have agreed to explore the establishment of a joint venture in Europe.

As discussed above, on March 16, 2017, we entered into the Purchase Agreement to sell our remaining 80.1% membership interest in PCT to Hitachi America for the Purchase Price.

Our Experience and Expertise

PCT's management team has extensive and unique experience in domestic and internationally regulated cell therapy development, including contract research, development and manufacturing across a broad range of science, technologies and process operations. Members of PCT's management include recognized and credentialed experts in all aspects of clinical and product development, characterization, manufacturing, delivery and use of cellular products and have extensive experience designing, validating and operating cGMP/GLP cell therapy manufacturing facilities.

PCT's expertise is focused on advancing product candidates from conception through commercialization by reducing manufacturing risks, shortening the time to regulatory approval and lowering the overall costs of a clinical development program. With its established facilities and infrastructure, PCT offers expertise at all stages of the product development lifecycle and cost-effective development and manufacturing services that meet applicable quality standards.

During its approximately 18 years in operation, PCT has produced more than 20,000 different cell therapy products based on many cell types, including neuronal and skin based cells for brain and spinal cord repair, myoblasts, mesenchymal cells and bone marrow derived cells for heart disease, T cells (such as T Regulatory cell, CAR-T and TCR therapies), tumor, dendritic cells and monocytes for cancer treatment, cord blood, peripheral blood, bone marrow CD34 selected cells for transplantation and islet cells for diabetes.

PCT's expertise is in high quality delivery of cell therapy, including:

- Manufacturing: Manufacturers of cell therapy-based products and specifically those manufacturing patient-specific cell therapies, face a number of challenges, including limited unit sizes and process scalability, short processing turnaround times and stringent and evolving regulatory requirements. PCT addresses these challenges by leveraging its established cGMP infrastructure and quality systems.
- Innovation and Engineering: PCT develops innovative long-term solutions to the unique challenges of cell therapy manufacturing through our Center for Innovation & Engineering. PCT accelerates the use of automation, integration, closed processing and other strategies to address scale up, cost of goods, quality control and robustness of manufacturing process. In order to utilize our expertise and further reduce cost of goods sold for products, PCT continually seeks innovation drivers, including new opportunities for automation in its manufacturing operations.
- Manufacturing Development: PCT develops, optimizes, implements and validates various aspects of cell therapy product and process development. PCT also provides analytical development, such as the creation of quality assays.
- Cell and Tissue Processing: PCT provides cost-effective cell processing services that meet current Good Tissue Practices ("cGTP") standards.

Over the next several years, we anticipate that the number of companies in the cell therapy field will continue to increase and the relative distribution of stage of development of the therapeutics will shift towards Phase 2 and Phase 3 trials and into commercial distribution if regulatory approvals are obtained.

Improving Deliverability of Cell Therapy Products through PCT's Center for Innovation & Engineering

As the field of regenerative medicine matures and an increasing number of products reach the marketplace, valuable lessons are being learned about the strengths and weaknesses of various business models that may allow for therapies to be delivered to large numbers of patients. At the Center for Innovation & Engineering, PCT's experts are thinking beyond current practices to accelerate the use of automation, integration and other engineering strategies to address the important issues of scale up, cost of goods, and improved robustness of manufacturing process in anticipation of commercial production.

PCT is applying engineering principles to transition cell therapy science to manufacturing at scale and applying development by design principles, as well as structured development methodology focused on unit operations to increase the chance of successful commercial-scale manufacturing. In addition to building its internal core of engineering and innovation expertise, PCT is partnering with solutions providers and academic institutions to leverage existing expertise and develop novel closed systems, single-use disposables, automation, and integration. In this way, PCT believes that it will be able to support the manufacture of high quality products at a reasonable cost of goods and meet product demand in a scalable manner as it grows throughout the commercial life of the therapeutic. For example, Caladrius, through PCT, is collaborating with Invetech Pty Ltd, ("Invetech") to develop a new closed processing system for cell therapy manufacturing whereby Invetech has provided system design and engineering development and we have developed applications for performing closed cell processing manipulations.

Facilities

With more than 50,000 square feet in its Allendale, New Jersey and Mountain View, California facilities, PCT is a cGMP cell therapy center of excellence with facilities on both the east and the west coasts of the United States. These facilities include 5,500 square feet of controlled environment rooms ("CERs" or "clean rooms") that are unidirectional-flow, negative-pressure, and International Organization for Standardization ("ISO") designation 7 ("ISO7") classified and ISO 6/EU Grade B, which allows products to be sent to the EU for clinical trials. We are currently in the process of increasing our clean room capacity at the Allendale facility by 60% while developing and implementing cell therapy-specific pharmaceutical grade quality systems to support commercial manufacturing for the United States and Europe, with the build-out expected to complete in 2017. Each CER has controlled access, live facility and equipment monitoring with automated alarm call-out, dedicated HVAC systems and an uninterruptible power supply ("UPS") connection maintained by an external diesel-fueled back-power generator. Each facility also contains cell and tissue cryogenic storage rooms with controlled access, live facility and equipment monitoring with automated alarm call-out, and UPS connection to ensure high levels of quality control and risk mitigation for product storage.

Our facilities are accredited by the Foundation for the Accreditation of Cellular Therapy ("FACT"), hold all requisite licensures, are registered with the FDA as human cells, tissues, and cellular and tissue-based products ("HCT/Ps") facilities and maintain cGMP and cGTP compliant quality systems. The Allendale facility also has been designed to be compliant with the EMA standards for the manufacture of human cells for therapeutic use.

Competition

PCT's manufacturing business faces competition from other third party contract manufacturers as well as more general competition from companies and academic and research institutions that may choose to self-manufacture rather than utilize a contract manufacturer. Two of the larger third party contract manufacturer competitors in the field of cell therapy are Lonza Group Ltd. and WuXi AppTec. Both of these companies are well-established manufacturers with financial, technical, research and development and sales and marketing resources that are significantly greater than those of PCT. In addition, both companies have international capabilities that PCT does not currently possess, though it is pursuing such. PCT also faces competition from a number of other manufacturers that are somewhat smaller in size and have fewer resources than does PCT.

More generally, PCT faces competition inherent in any third party manufacturer's business: namely, that potential customers may instead choose to invest in their own facilities and infrastructure. To be successful, PCT will need to convince potential customers that PCT's capabilities can mitigate their risk of high product cost of goods due to the potential for idle capacity, are more innovative, of higher-quality and more cost-effective than could be achieved through internal manufacturing and that our experience and expertise is unique in the industry. PCT's ability to achieve this and to successfully compete against other manufacturers will depend, in large part, on PCT's success in expanding its commercial manufacturing-ready capacity and by developing superior automation technologies that improve both the quality and profitability associated with cell therapy manufacturing.

Cell Processing and Storage

PCT provides cell therapy processing and storage services in support of stem cell transplant programs at select hospitals throughout the country on a contract basis, where such hospitals do not have their own laboratory and processing services. Such services are provided in compliance with cGMP standards, consistent with applicable national standards.

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.

HCT/P Regulations

Manufacturing facilities that produce cellular therapies are subject to extensive regulation by the FDA. In particular, FDA regulations set forth requirements pertaining to establishments that manufacture human cells, tissues, and cellular and tissue-based products (“HCT/Ps”). Title 21, Code of Federal Regulations, Part 1271 provides for a unified registration and listing system, donor-eligibility, current Good Tissue Practice ("cGTP"), and other requirements that are intended to prevent the introduction, transmission, and spread of communicable diseases by HCT/Ps. More specifically, key elements of Part 1271 include:

- Registration and listing requirements for establishments that manufacture HCT/Ps;
- Requirements for determining donor eligibility, including donor screening and testing;
- cGTP requirements, which include requirements pertaining to the manufacturer's quality program, personnel, procedures, manufacturing facilities, environmental controls, equipment, supplies and reagents, recovery, processing and process controls, labeling, storage, record-keeping, tracking, complaint files, receipt, pre-distribution shipment, distribution, and donor eligibility determinations, donor screening, and donor testing;
- Adverse reaction reporting;
- Labeling of HCT/Ps;
- Specific rules for importing HCT/Ps; and
- FDA inspection, retention, recall, destruction, and cessation of manufacturing operations.

PCT currently collects, processes, stores and manufactures HCT/Ps, including the manufacture of cellular therapy products. NeoStem Family Storage also collects, processes, and stores HCT/Ps. Therefore, both PCT and NeoStem Family Storage must comply with cGTP and with the current Good Manufacturing Practices ("cGMP") requirements that apply to biological products. Cell and tissue based products may also be subject to the same approval standards, including demonstration of safety and efficacy, as other biologic and drug products if they fail to meet all HCT/P criteria set forth in Title 21, Code of Federal Regulations, Section 1271.10. Management believes that requirements pertaining to premarket approval do not currently apply to PCT or NeoStem Family Storage because those entities are not currently investigating, marketing or selling cellular therapy products. If either PCT or NeoStem Family Storage changes its business operations in the future, the FDA requirements that apply to PCT or NeoStem Family Storage may also change.

State Regulation of Cell Therapy

Certain state and local governments regulate cell-processing facilities by requiring them to obtain other specific licenses. As required under applicable state law, PCT's New Jersey and California facilities are licensed, respectively, as a blood bank in New Jersey and as a biologics manufacturing facility in California. PCT also maintains licenses with respect to states that require licensure of out-of-state facilities that process cell, tissue and/or blood samples of residents of such states (e.g., New York and Maryland). PCT has the relevant state licenses needed for processing and is AABB (American Association of Blood Banks) accredited for this purpose. Management believes that it is in material compliance with currently applicable federal, state, and local laboratory licensure requirements and intends to continue to comply with new licensing requirements that may become applicable in the future.

Certain states may also have enacted laws and regulations, or may be considering laws and regulations, regarding the use and marketing of stem cells or cell therapy products, such as those derived from human embryos. While these laws and regulations should not directly affect PCT's business, they could affect the business of some of PCT's clients and therefore the amount of business PCT receives from these clients.

Federal Regulation of Clinical Laboratories

The Clinical Laboratory Improvement Amendments (“CLIA”) extends federal oversight to clinical laboratories that examine or conduct testing on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of disease or for the assessment of the health of human beings. CLIA requirements apply to those laboratories that handle biological matter. CLIA requires that these laboratories be certified by the government, satisfy governmental quality and personnel standards, undergo proficiency testing, be subject to biennial inspections and remit fees. The sanctions for failure to comply with CLIA include suspension, revocation, or limitation of a laboratory's CLIA certificate necessary to conduct business, fines, or criminal penalties. Additionally, CLIA certification may sometimes be needed when an entity, such as PCT or NeoStem Family Storage, desires to obtain accreditation, certification, or license from non-government entities for cord blood collection, storage and processing. PCT has obtained CLIA certification for its facilities in New Jersey. We have been advised that, currently, CLIA certification is not required for our PCT facilities in California. However, to the extent that any of the activities of PCT or NeoStem Family Storage (for example, with regard to processing or testing blood and blood products) require CLIA certification, PCT intends to obtain and maintain such certification and/or licensure.

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. 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 or any future product candidates. In addition, these regulations may change and our product candidates may be subject to new legislation 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 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 a notice of claimed investigational exemption or an investigational new drug application (“IND”), which must become effective before clinical testing can commence and 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 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 preclinical or 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 applicable clinical trials (as defined in the Food and Drug Administration Amendments Act) 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"), a committee that reviews research involving human subjects to ensure compliance with applicable research and ethical guidelines, for approval. 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, or may impose other conditions.

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 phase may be required.

- *Phase 1*: Trials in this phase are initially conducted in a limited population 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 possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted indications and to determine dose tolerance and optimal dosage. 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 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 undertaken in large patient populations 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, 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. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.
- *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. Such post approval trials are typically referred to as Phase 4 trials.

After completion 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, currently exceeding $2,038,000, and the manufacturer and/or sponsor under an approved new drug application are also subject to annual product and establishment user fees, currently exceeding $97,000 per product and $512,000 per establishment. 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 generally follows such recommendations.

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.

Additional Controls

The PHS Act also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

Current Good Manufacturing Practices (cGMP) Standards

The FD&C Act and FDA regulations govern the quality control, manufacture, packaging, and labeling procedures of products regulated as a drug or biological products, including cellular therapies comprising HCT/Ps. These laws and regulations include requirements for regulated entities to comply with cGMPs applicable to the specific product(s). The cGMPs are designed to ensure that a facility's processes - and products resulting from those processes - meet defined safety requirements.

The FDA's objective in requiring compliance with cGMP standards is to protect the public health and safety by ensuring that regulated products (i) have the identity, strength, quality and purity that they purport or are represented to possess; (ii) meet their specifications; and (iii) are free of objectionable microorganisms and contamination.

As a central focus of the cGMP requirements regulated entities must design and build quality assurance safeguards into the manufacturing processes and the production facilities for regulated products and must ensure the consistency, product integrity, and reproducibility of results and product characteristics. This is done by implementing quality systems and processes including appropriate, controlled procedures, specifications and documentation.

In addition, drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with applicable cGMPs. The FDA may also initiate for-cause investigations of manufacturing facilities if it learns of possible serious regulatory violations at such facilities. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain compliance with cGMPs. Failure to comply with applicable FDA requirements can result in regulatory inspections and associated observations, warning letters, other enforcement measures requiring remedial action, and, in the case of failures that are more serious, suspension of manufacturing operations, seizure of product, injunctions, product recalls, fines, and other penalties. We believe that our facilities are in material compliance with applicable, existing FDA requirements.

Additionally, FDA, other regulatory agencies, or the U.S. Congress may be considering, and may enact laws or regulations regarding the use and marketing of stem cells, cell therapy products, or products derived from human cells or tissue. These laws and regulations may directly affect us or the business of some of PCT's clients and therefore the amount of business PCT receives from these clients.

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 NDA holders a six-month extension of any exclusivity-patent or non-patent-for a drug if certain conditions are met. 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. Under the BPCA, BLA-holders may obtain a six-month extension of non-patent market exclusivity for a biologic if certain conditions are met.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition - generally a 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.

EMPLOYEES

As of December 31, 2016, we had 209 full-time employees, including the employees of our subsidiaries. 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 THE SALE

The announcement and pendency of the Sale, whether or not completed, may adversely affect the PCT business and the Retained Business.

The announcement and pendency of the Sale may adversely affect the trading price of our common stock, our business and our relationships with clients, customers, suppliers and employees. Third parties may be unwilling to enter into material agreements with respect to the PCT business. New or existing customers, suppliers and business partners may prefer to enter into agreements with our competitors who have not expressed an intention to sell their business because customers, suppliers and business partners may perceive that such competitors are likely to be more stable. Additionally, employees working in the Retained Business may become concerned about the future of the Retained Business, and lose focus or seek other employment, especially in light of the fact that the PCT business accounts for substantially all of our revenues. In addition, while the completion of the Sale is pending, we may be unable to attract and retain key personnel and our management's focus and attention and employee resources may be diverted from operational matters.

If we fail to complete the Sale, our business and financial performance may be adversely affected.

The completion of the Sale is subject to the satisfaction or waiver of various conditions, including the approval of the Sale by our stockholders and the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, which may not be satisfied in a timely manner or at all

If the Sale is not completed, we may have difficulty recouping the costs incurred in connection with negotiating the Sale. Our directors, executive officers and other employees will have expended extensive time and effort and will have experienced significant distractions from their work during the pendency of the Sale, and we will have incurred significant third party transaction costs, in each case, without any commensurate benefit, which may have a material and adverse effect on our stock price and results of operations.

In addition, if the Sale is not completed, our board of directors, in discharging its fiduciary obligations to our stockholders, may evaluate other strategic alternatives including, but not limited to, continuing to operate the PCT business with Hitachi America as a significant minority investor for the foreseeable future or an alternative sale transaction relating to PCT. An alternative sale transaction, if available, may yield lower consideration than the proposed Sale, be on less favorable terms and conditions than those contained in the Purchase Agreement and involve significant delay. Any future sale of substantially all of the assets of Caladrius or other transactions may be subject to further stockholder approval.

Finally, if the Sale is not completed, the announcement of the termination of the Purchase Agreement may adversely affect our relationships with customers, suppliers and employees, which could have a material adverse impact on our ability to effectively operate our business. In addition, if the Purchase Agreement is terminated under certain circumstances, Caladrius will be required to repay the $5.0 million Initial Payment and pay a termination fee of $5.0 million. If such payments are not made within 90 days, Hitachi America's membership interest in PCT will increase from 19.9% to 32.22% and Hitachi America will have the right to nominate another director on the PCT board of managers. If the Purchase Agreement is terminated under certain other circumstances, Caladrius will be required to return the $5.0 million Initial Payment, and, if does not do so within 90 days, Hitachi America's membership interest in PCT will increase from 19.9% to 26.06% and Hitachi America will have the right to nominate another director on the PCT board of managers. Each of these scenarios could have adverse effects on our business, results of operations and the trading price of our common stock.

The failure to effectively utilize the proceeds from the Sale may adversely affect the Retained Business.

The proceeds from the Sale will be received by Caladrius, not Caladrius' stockholders. Caladrius will use a portion of the proceeds to pay the remaining balance owed pursuant to the loan and security agreement, dated as of September 19, 2014, among Oxford Finance LLC, as collateral agent and lender, Caladrius and certain subsidiaries of Caladrius, and to pay for transaction costs associated with the Sale. The remainder of the proceeds may be used, at the discretion of our board of directors, for working capital and other general corporate purposes, including, among other things, to complete our currently enrolling Phase 2 trial (the Sanford Project: T-Rex Study) for our lead product candidate, CLBS03 for the treatment of recent-onset type 1 diabetes, and to judiciously and opportunistically identify and acquire, or partner on the development of, other product candidates. However, we

do not have agreements or commitments for any such acquisitions or partnerships at this time. Our failure to effectively utilize the proceeds from the Sale could adversely affect our ability to develop cell therapy candidates, which could cause the value of your investment in Caladrius to decline.

Our executive officers may have interests in the Sale other than, or in addition to, the interests of our stockholders generally.

Our executive officers may have interests in the Sale that are different from, or are in addition to, the interests of our stockholders generally. In connection with entering into the Purchase Agreement, Caladrius entered into a retention agreement with Robert A. Preti, a Caladrius director and a co-founder and the President of PCT, and certain other employees of PCT. Dr. Preti and certain of our other employees have entered into employment agreements with Hitachi that will be effective upon the closing of the Sale. Under the terms of our equity compensation plans, the approval of the Sale by our stockholders will result in the acceleration of all of the equity awards granted under our equity compensation plans. Our board of directors was aware of these interests and considered them, among other matters, in approving the Purchase Agreement. For additional information regarding the retention agreement we entered into with Dr. Preti, please see footnote 18 to our audited financial statements appearing in Item 8 below.

The Purchase Agreement limits our ability to pursue alternatives to the Sale.

The Purchase Agreement contains provisions that may make it more difficult for us to sell Caladrius or for PCT to enter into any transaction other than the Sale. These provisions include the prohibition on our ability to solicit competing proposals and the requirement that we repay Hitachi America the Initial Payment and pay Hitachi America a termination fee of $5.0 million under certain circumstances if the Purchase Agreement is terminated after our board of directors have determined that a third-party proposal is a superior proposal to the Sale and does not recommend that our stockholders approve the Sale. In the case where our board of directors changes its recommendation, Caladrius remains obligated to solicit the approval of the Sale from its stockholders.

These provisions could make it less advantageous for a third party that might have an interest in acquiring Caladrius or PCT to consider or propose an alternative transaction, even if that party were prepared to pay consideration with a higher value than the consideration to be paid by Hitachi America.

Because Caladrius is expected to have almost no revenue and significantly fewer assets following the Sale of PCT, there is a possibility that such lack of revenues and diminished assets may affect our ability to satisfy the continued listing standards of the Nasdaq, which could result in the delisting of our common stock.

The continued listing standards of the Nasdaq include, among other things, requirements that we maintain certain levels of stockholders' equity, market capitalization and/or minimum trading price. Even though we currently satisfy these requirements, following the Sale our business will be smaller with almost no revenue and significantly fewer assets, which may cause us to fail to satisfy the continued listing standards of the Nasdaq. In the event that we are unable to satisfy such continued listing standards, our common stock may be delisted from the Nasdaq. Any delisting of our common stock from such market could adversely affect our ability to attract new investors, decrease the liquidity of our outstanding shares of common stock, reduce our flexibility to raise additional capital, reduce the price at which our common stock trades and increase the transaction costs inherent in trading such shares with overall negative effects for our stockholders. In addition, delisting of our common stock could deter broker-dealers from making a market in or otherwise seeking or generating interest in our common stock, and might deter certain institutions and persons from investing in our securities at all. For these reasons and others, delisting could adversely affect the price of our common stock and our business, financial condition and results of operations.

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 date of the Purchase Agreement (the "Effective Date"), 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 the Retained 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 the Retained Business during the Non-Competition Period that may otherwise be favorable to Caladrius' stockholders.

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

Pursuant to the terms of the Purchase Agreement, Hitachi America will pay Caladrius $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 Caladrius will receive the $5.0 million Milestone Payment contemplated by the Purchase Agreement.

Caladrius is become 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, Caladrius is 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 will be 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 use by Caladrius.

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 Caladrius stock will 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.

If the Sale is completed, our actual results of operations will differ materially from any expectations or financial guidance provided by us concerning future financial results and our future financial results will be dependent on our ability to grow the Retained Business.

PCT accounts for substantially all of our revenues. Accordingly, if the Sale is completed, our financial results will differ materially from the guidance we have previously provided. In addition, if the Sale is completed, our future financial results will be dependent solely on our ability to grow the Retained Business. See "-Risks Related To Our Cell Therapy Product Development Efforts" below for a description of the risks related to the Retained Business.

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, 2016, we have incurred aggregate net losses of approximately $404.8 million. Our net losses attributable to common stockholders for the years ended December 31, 2016 and December 31, 2015 were approximately $32.7 million and $80.9 million, respectively. As of December 31, 2016, our cash and cash equivalents were $14.7 million. The revenues generated in our cell therapy services business have not been, and are not expected in the foreseeable future 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 cell therapy services business for us 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, or expansion of our manufacturing operations 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 the operation, enhancement and expansion of our manufacturing operations 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:

- our ability to complete the sale of our remaining membership interest in PCT to Hitachi America;
- 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 and manufacturing operations, including but not limited to the costs of expanded facilities, equipment costs, engineering and innovation initiatives 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, use of our common stock purchase agreement with Aspire Capital, 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 facilities, including our Oxford debt facility, 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, including growing our own manufacturing capabilities and infrastructure;
- 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.

Our recurring losses from operations raise substantial doubt regarding our ability to continue as a going concern.

Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern. There is no assurance that sufficient financing will be available when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

Our independent registered public accounting firm issued its report dated March 16, 2017 in connection with the audit of our financial statements as of December 31, 2016, which included an explanatory paragraph describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern.

RISKS RELATED TO OUR MANUFACTURING BUSINESS

On March 16, 2017, we entered the Purchase Agreement to sell our remaining membership interest in PCT to Hitachi America for the Purchase Price. If the sale is consummated, Hitachi America will own 100% of PCT, and we will no longer have any ownership interest in PCT. See "Item 1. Business-Overview- Proposed Sale of Remaining Interest in PCT to Hitachi America." Once the Sale of our remaining ownership stake in PCT is completed, these risk factors related to our manufacturing business will no longer apply.

Cell therapy is in its early stages; it is still a developing field and a significant global market for manufacturing services may never emerge.

Cell therapy is in its early stages and is still a developing area of research, with few cell therapy products approved for clinical use. Many of the existing cellular therapy candidates are based on novel cell technologies that are inherently risky and may not be understood or accepted by the marketplace, making it difficult for their own funding to enable them to continue their business. In addition to providing in-house process development and manufacturing expertise for our own product candidates in development, PCT provides consulting and manufacturing of cell and tissue-based therapeutic products in clinical trials and processing of stem cell products for transplantation programs for third parties. The number of people who may use cell or tissue-based therapies, and thus the demand for cell processing services, is difficult to forecast. If cell therapies under development by us or by others to treat disease are not proven safe and effective, demonstrate unacceptable risks or side effects or, where required, fail to receive regulatory approval, our manufacturing business will be significantly impaired. While the therapeutic application of cells to treat serious diseases is currently being explored by a number of companies, to date there are only a handful of approved cell therapy products in the U.S. Ultimately, our success in deriving revenue from manufacturing depends on the development and growth of a broad

and profitable global market for cell-, gene- and tissue-based therapies and services and our ability to capture a share of this market through PCT.

PCT's revenues may vary dramatically from period to period making it difficult to forecast future results.

The nature and duration of PCT's contracts with customers often involve regular renegotiation of the scope, level and price of the services we are providing. If our customers reduce the level of their spending on research and development or marketing or are unsuccessful in attaining or retaining product sales due to market conditions, reimbursement issues or other factors, our results of operations may be materially impacted. In addition, other factors, including the rate of enrollment for clinical trials, will directly impact the level and timing of the products and services we deliver. As such, the levels of our revenues and profitability can fluctuate significantly from one period to another and it can be difficult to forecast the level of future revenues with any certainty.

We have a finite manufacturing capacity at PCT, which could inhibit the long-term growth prospects of this business.

We currently provide services and produce materials for clinical trials at our existing manufacturing facilities in Allendale, New Jersey and Mountain View, California. 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 services and products could exceed our existing manufacturing capacity. We expect 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 capabilities for cell therapy services and products in the future, which may require us to invest significant amounts of capital and to obtain regulatory approvals. In this regard, we are reviewing opportunities for expansion to both commercial level and international manufacturing capabilities. If we are unable to meet rising demand for products and services on a timely basis or unable to maintain cGMP compliance standards, then it is likely that our clients and potential clients will elect to obtain the products and services from competitors and the progress of our own programs will be impaired which could materially and adversely affect the level of our revenue, growth prospect and 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 subjects companies to 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 PCT in order to establish cost of goods levels that will permit approved products to succeed commercially.

PCT 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. We cannot provide assurances that we 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 we are unsuccessful in our efforts to develop these improvements, we may be unable to develop for ourselves or for our customers commercially viable products, which would impair our ability to continue our operations.

We face competition from other third party contact manufacturers, as well as more general competition from companies and academic and research institutions that may choose to self-manufacture rather than utilize a contract manufacturer.

The two largest third party contract manufacturer competitors in the field of cell therapy are Lonza Group Ltd. and WuXi AppTec. Both of these companies are large, well-established manufacturers with financial, technical, research and development and sales and marketing resources that are significantly greater than those of PCT. In addition, both Lonza and WuXi have international capabilities that we do not currently possess though we are pursuing. We also face competition from a number of other manufacturers that are smaller in size or have fewer resources than PCT.

More generally, we face competition inherent in any third party manufacturer’s business: namely, that potential customers may instead choose to invest in their own facilities and infrastructure, affording them greater control over their products and the hope of long-term cost savings compared to a third party contract manufacturer. To be successful, we will need to convince potential customers that PCT’s capabilities are more innovative, of higher-quality and more cost-effective than could be achieved through internal manufacturing and that our experience and expertise is unique in the industry. Our ability to achieve this and to successfully compete against other manufacturers will depend, in large part, on our success in developing superior automation technologies that improve both the quality and profitability associated with cell therapy manufacturing. If we are unable to successfully compete against other manufacturers, we may not be able to develop our PCT operations which may harm our business, financial condition and results of operations.

We have a limited marketing personnel and budget for our PCT operations, which could limit our ability to grow this business.

The degree of market acceptance of our products and services depends upon a number of factors, including the strength of our sales and marketing support. If our marketing is not effective, our ability to generate revenues could be significantly impaired. The newness of the industry and capital constraints provide challenges to our marketing and sales activities at PCT, and the failure to attract a sufficient base of customers will affect our ability to increase our revenues and operate profitably.

The logistics associated with the distribution of materials produced by PCT are significant, complex and expensive and may negatively impact our ability to generate and meet future demand for our products and improve profitability.

Current cell therapy products and product candidates, including our own, have a limited shelf life, in certain instances limited to fewer than 12 hours. Thus, it is necessary to minimize the amount of time between when the cell product is extracted from a patient, arrives at one of our facilities for processing, and is returned for infusion in the patient.

To do so, we need our cell therapy facilities to be located in major population centers in which patients are likely to be located and within close proximity of major airports. In the future, it may be necessary to build new facilities, which would require a significant commitment of capital and may not then be available to us. Even if we are able to establish such new facilities, we may experience challenges in ensuring that they are compliant with cGMP standards, FDA requirements, and/or applicable state or local regulations. We cannot be certain that we would be able to recoup the costs of establishing a facility in a given market. Given these risks, we could choose not to expand our cell processing and manufacturing services into new geographic markets which will limit our future growth prospects.

To effectively and efficiently deliver 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 customers' and our own needs.

PCT has entered into a global collaboration with Hitachi Chemical that includes licensing, development and equity components and we may not recognize the benefits of this collaboration.

PCT has entered into a global collaboration with Hitachi Chemical that includes licensing, development and equity components to develop our PCT business outside of the United States. This collaboration is subject to numerous risks, including the following:

- Hitachi Chemical has discretion in determining the efforts and resources that they will apply to the collaboration, which efforts and resources may prove inadequate;
- Hitachi Chemical may not pursue development and commercialization of our PCT business in Asia or Europe, or may elect not to continue or renew development or commercialization programs based on 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;
- Hitachi Chemical could independently develop, or develop with third parties, products that compete directly or indirectly with our PCT business;
- Hitachi Chemical may not commit sufficient resources to the marketing and development of the PCT business in Asia or Europe;
- disputes may arise between us and Hitachi Chemical that could cause the delay or termination of the research, development or commercialization of our PCT business, or that results in costly litigation or arbitration that diverts management attention and resources; and
- our collaboration with Hitachi Chemical may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of our PCT business.

Although we still control development and commercialization activities in North America for our PCT business, Hitachi will lead development and commercialization activities in Asia for our PCT business. Failure by Hitachi to meet its obligations under the license agreement and any additional co-development or co-commercialization agreement we may enter into, or failure by Hitachi to apply sufficient efforts at developing and commercializing our PCT business, may materially adversely affect our business and our results of operations. Hitachi Chemical could independently develop, or develop with its other third party collaborators, products or product candidates that compete directly or indirectly with our products or product candidates, and that competition could adversely impact our PCT business in North America.

In addition, Hitachi will also require and we are obligated to provide some level of assistance from us with respect to training and support for the PCT licensed cell therapy technology and know-how, and this assistance could be burdensome on our organization and resources and disrupt our own development and commercialization activities for our PCT business for which we retain rights or in geographies where we are responsible for leading development and commercialization.

We may form or seek further strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our PCT business and any future product candidates that we may develop. Such alliances will be subject to many of the risks set forth above. Moreover, 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 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.

As a result of these risks, we may not be able to realize the benefit of our existing collaborations or any future collaborations or licensing agreements we may enter into. Any delays in entering into new collaborations or strategic partnership agreements related to our PCT business or 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.

If Hitachi terminates its agreement with us or fails to perform its obligations under its agreement with us, or fails to comply with applicable law, the development and commercialization of our PCT business could be delayed or terminated.

Our global collaboration agreement with Hitachi allows for, and we expect that any future collaborations and licenses will allow, either party to terminate the agreement for specified material breaches by the other party. If Hitachi or any other future collaborator or licensee terminates its agreement with us for breach or otherwise, it may be difficult for us to attract new collaborators or licensees and could adversely affect how we or our reputation are perceived in the business and financial communities. In addition, Hitachi could determine that it is in its financial interest to:

- pursue alternative technologies or develop alternative products, either on its own or jointly with others, that may be competitive with the PCT business on which it is collaborating with us and has licensed from us, which could affect its commitment to us;
- pursue higher-priority programs or change the focus of its development programs, which could affect their commitment to us; or
- choose to devote fewer resources to the marketing and development of our PCT business.

If any of these events occur, the development and commercialization of our PCT business could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue such development and commercialization on our own.

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 seeking a partner to take it into the clinic, being considered for clinical development in Japan, 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 TID. We are also actively seeking a partner to take CLBS12 into the clinic and thereby take advantage of the paradigm of 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. 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, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in obtaining required IRB approval at each clinical trial site;
- 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, other third parties, or us to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA or international GCP requirements;
- 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 or CLBS12 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 10-30 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.

Products 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 PCT will provide exclusively the cell processing services necessary for clinical production for our CLBS03 Phase 2 T1D trial. PCT also provides services and produces materials for clinical trials on behalf of unaffiliated third parties. To date, PCT has not produced any products at commercial scale quantities. We expect that PCT would need to expand significantly its manufacturing capabilities to meet potential commercial demand for CLBS03 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 we increase our manufacturing capabilities, it is possible that we 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 a third-party supplier for CLBS03 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. While PCT historically has provided services in connection with our development activities, we cannot assure you that our management will successfully oversee our clinical development efforts and our plans to capture a piece of the cell therapy market.

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, 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 or potential curative approaches 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 Phaarmaceuticals 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 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 our PCT 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 preclinical and nonclinical animal 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 governmental healthcare 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. We also are required to comply with FDA's cGTP regulations. If we fail to register or update registration information in a timely way, or fail to comply with cGTP regulations, we will be out of compliance with FDA regulations which could adversely affect our business.

Our manufacture of certain cellular therapy products for ourselves or at PCT on behalf of our customers triggers additional FDA requirements applicable to HCT/Ps, or products comprising HCT/Ps, which are regulated as a drug, biological product, or medical device. 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. We must comply with cGMP or QSR requirements including quality control, quality assurance and the maintenance of records and documentation for certain products. We 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 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 subjects 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, 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. On March 23, 2010, healthcare reform legislation was approved by Congress and has been signed into law. 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.

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, and methods of making and using dendritic cell-based vaccines. 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 changes 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, 2016 through March 16, 2017 our common stock traded as low as $2.65 per share and as high as $13.30 per share; in 2015, our common stock traded as low as $10.10 per share and as high as $42.60 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, 2016, there were 8,205,790 shares of our common stock outstanding. In addition, there were outstanding stock options and warrants representing the potential issuance of an additional 1,080,539 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 to Aspire Capital pursuant to our Purchase Agreement may cause substantial dilution to our existing stockholders and the sale of the shares of common stock acquired by Aspire Capital could cause the price of our common stock to decline.

We entered into a Purchase Agreement with Aspire Capital Fund, LLC in November 2015, pursuant to which Aspire Capital committed to the purchase of up to $30 million of shares of our common stock over the term of that Agreement, subject to certain terms and conditions. Under that Purchase Agreement, in November 2015 we drew down approximately $253,000 causing dilution to outstanding shares and we may draw down incremental funds under the Purchase Agreement in the future, further diluting, potentially substantially, our outstanding common stock.

Pursuant to the agreement, after Aspire Capital acquires shares under the Purchase Agreement, it may sell all or some of those shares. Sales to Aspire Capital by us pursuant to the Purchase 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 to Aspire Capital, 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 to Aspire Capital and the Purchase Agreement 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 the Company's 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 the Aspire Purchase Agreement or 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.

Corporate Headquarters and other office space

Our corporate headquarters are located in Basking Ridge, New Jersey. In early 2015, we entered into an assignment agreement for general office space located in Basking Ridge, New Jersey. The space is approximately 18,467 rentable square feet. The base monthly rent is $32,000 and the lease term ends July 31, 2020. In addition, there are two five-year renewal options. In connection with the assumption of the lease, the third party assignor (i) conveyed its rights in various scheduled furniture and equipment and (ii) paid us approximately $580,000, which amount offset the rental payments paid by us. A security deposit of approximately $115,000 payable by us will offset the amount payable by the third party assignor. With the additional space, we believe the total leased space is sufficient for the near future. In January 2014, we executed a fourth modification and additional space agreement (the “fourth modification”) modifying to our existing lease in order to (i) obtain additional office space adjacent to our current, third floor offices in New York, NY and (ii) extend the lease term for both the existing office space and the additional, adjacent space through January 31, 2018. The base monthly rent for our offices is approximately $43,000 per month for 10,000 square feet, a portion of which is currently subleased at approximately $10,000 per month.

Cell Therapy Manufacturing Facilities

We presently operate two cell therapy manufacturing facilities, in Allendale, New Jersey and in Mountain View, California.

We own the Allendale property, of which 26,250 square feet of its approximate 30,000 square feet have been developed, allowing for the possibility of future expansion. The Allendale facility is comprising (i) four ISO Class 7 manufacturing suites, (ii) one ISO Class 6 manufacturing suite that is designed to meet EU production standards and (iii) quality control, research and development laboratories and support facilities. The Allendale facility and systems have been designed to meet the accreditation requirements of the Foundation for the Accreditation of Cellular Therapy (FACT) and to comply with the FDA’s requirements, including applicable cGMP regulations, and to meet the standards of the American Association of Blood Banks (AABB). The Allendale facility is also in compliance with a range of state and federal regulatory and licensing requirements. We recently completed an expansion of the facility in 2014, adding laboratory, clean room suites and support facilities. During fourth quarter of 2015, we commenced with activities to provide for additional facility expansion and enhancements that are planned to complete in 2017. This latest expansion includes upgrades to our warehousing and document storage areas, enhancements to our QC laboratory, and the commissioning of an additional three controlled-environment (clean room) manufacturing rooms. At completion, the facility upgrades will enable Grade B infrastructure suitable to provide for EU manufacturing from three of the eight clean rooms. Further, we expect that these modifications provide the basis to position us for commercial manufacturing from the Allendale facility.

The Mountain View facility is also a licensed cell therapy manufacturing facility, of which all 25,024 square feet is developed. This property is used for manufacturing client products. Mountain View is equipped with six ISO Class 7 manufacturing suites and quality control, research and development laboratories and support facilities. The Mountain View facility is subject to a lease agreement, as amended to date, having a current term that extends through June 2019. The base monthly rent is currently $45,000 subject to annual cost of living adjustments provided, however, that each such annual rental adjustment will not be less than 3% or more than 7%.

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 SAFTEY 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.

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

2015	High	Low
First Quarter	$42.60	$25.30
Second Quarter	$34.70	$18.00
Third Quarter	$20.30	$11.00
Fourth Quarter	$15.60	$10.10

On March 16, 2017, the last reported price of our common stock was $5.14 per share.

Holders

As of March 16, 2017, there were approximately 1,410 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, 2016 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”) and our 2012 Employee Stock Purchase Plan (the “2012 ESPP Plan”) and our 2015 Equity Compensation Plan (the "2015 Plan").

	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)	952,790	$39.90	61,661	(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 2012 ESPP Plan and the 2015 Plan.

(3) Includes shares available for future issuance under the 2009 Plan and the 2012 ESPP Plan.

Recent Sales of Unregistered Securities

On November 18, 2016 we issued an aggregate of 16,000 shares of restricted common stock, $0.001 par value, to MDM Worldwide Solutions, 50% of which shares vested immediately and the remainder of which will vest 50% at the end of the twelve month period after issuance.

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 our internal specialized cell therapy clinical development expertise to select and develop early-stage cell therapy candidates with the intention of partnering these candidates post proof-of-concept in humans. Our current lead product candidate, CLBS03, is an autologous ex vivo polyclonal T regulatory cell ("Treg") clinical phase 2 therapy targeting adolescents with recent-onset type 1 diabetes mellitus ("T1D"). Our subsidiary, PCT, LLC, a Caladrius Company™ ("PCT"), is a leading provider of development and manufacturing services to the cell and cell-based gene therapy industry. PCT has significant cell therapy-specific experience and expertise, an expansive list of noteworthy clients and significant revenue growth over the past three years. Notably, PCT and Hitachi are engaged in a strategic collaboration to accelerate the creation of a global commercial cell therapy development and manufacturing enterprise with deep engineering expertise.

Proposed Sale of Remaining Interest in PCT to Hitachi America

On March 16, 2017, Caladrius entered into Purchase Agreement, by and among Caladrius, PCT and Hitachi America, pursuant to which Hitachi America has agreed to acquire the 80.1% membership interest in PCT that it does not already own from Caladrius for $75.0 million in cash, subject to potential adjustment, including based on PCT's cash and outstanding indebtedness as of the closing of the Sale, and a potential future milestone payment. Pursuant to the terms of the Purchase Agreement, at the Effective Date, Hitachi America will pay Caladrius $5.0 million of the Purchase Price. At the closing of the Sale, an additional $5.0 million of the Purchase Price will be deposited into an escrow account to cover potential indemnification claims of Hitachi America, if any. The Closing is subject to customary closing conditions, including approval of Caladrius' stockholders, and is expected to occur during the second quarter of 2017. However, we cannot provide assurance as to when the Sale will be completed, or whether it will be completed at all. See "Item 1A. Risk Factors-Risks Related to the Sale."

As part of the Purchase Price, Hitachi will pay Caladrius $5.0 million if PCT achieves $125.0 million in Cumulative Revenue (excluding clinical service reimbursables) (the "Milestone") for the period from January 1, 2017 through December 31, 2018. For purposes of the Milestone, "Cumulative Revenue" will be calculated based on PCT's revenue from all customers (including Caladrius and its subsidiaries) in accordance with the financial accounting and reporting standards set forth in the statements and pronouncements of the Financial Accounting Standards Board, consistently applied.

PCT is a well-known CDMO, specializing in cell and cell-based gene therapies. PCT offers high-quality development and manufacturing capabilities (e.g., cGMP manufacturing systems and facilities), quality systems, cell and tissue processing, logistics, storage and distribution) and engineering solutions (e.g., process and assay development, optimization and automation) to clients with therapeutic candidates at all stages of development. PCT produces clinical supplies and expects to produce commercial product for its clients in the future. Following completion of the Sale, we will no longer be involved in the CDMO business, but will continue to develop cell therapy product candidates. For additional information related to the Sale and related transactions, see footnote 18 to our audited financial statements appearing in Item 8 below.

CLBS03

We are developing strategically, through the utilization of or core development and manufacturing expertise, a product candidate that is an innovative therapy for type 1 diabetes mellitus T1D. This therapy is based on a proprietary platform technology for immunomodulation. We have selected as an initial target the unmet medical need of pediatric patients who are newly diagnosed with T1D, most of whom will be below 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 T effector 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 T effector cells. In autoimmune disease, however, it is thought that deficient Treg activity and numbers permit the T effector cells to attack the body's own beneficial cells. In the case of T1D, 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, only lifelong insulin therapy, which therapy often does not prevent serious co-morbidities. Two Phase 1 clinical trials of this technology in T1D demonstrated safety and tolerance, feasibility of manufacturing, an implied durability of effect as well

as an early indication of potential therapeutic effect through the preservation of beta cell function. In the first quarter of 2016, we commenced patient enrollment in the first of two cohorts in The Sanford Project: T-Rex Study, a Phase 2 prospective, randomized, placebo-controlled, double-blind clinical trial (the "TRex Study") to evaluate the safety and efficacy of CLBS03 in adolescents with recent onset T1D. 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 of early therapeutic effect is planned after approximately 50% of patients reach the six-month follow-up milestone, which analysis is expected in late 2017 or early 2018. 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 total $12.2 million amount will become payable upon the achievement of certain milestones which are still under negotiation. We expect to receive $5.7 million in initial funding on April 1, 2017. CLBS03 has been granted Fast Track and orphan drug designations from the FDA as well as Advanced Therapeutic Medicinal Product ("ATMP") classification from the European Medicines Agency ("EMA").

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 increase blood flow to the impacted area. We believe that conditions caused by underlying ischemic injury can improve through our CD34 cell technology, including critical limb ischemia ("CLI"). Published reports in *Circulation Cardiovascular Interventions*, *Atherosclerosis*, *Stem Cells and Circulation Journal*, provide preliminary evidence that CD34 cell therapy is safe and can exert significant therapeutic effects in patients with CLI, a condition in which blood flow to the legs is severely impaired, causing pain and non-healing ulcers and, ultimately, potentially resulting in the need for amputation. Our Clinical Trial Notification for a pivotal Phase 2 trial investigating CLBS12 (a candidate for CLI) was submitted to the Japanese Pharmaceutical and Medical Device Agency ("PMDA") and was cleared to proceed. The protocol design was agreed with PMDA and if successful, could provide the basis for conditional approval under Japan's favorable regenerative medicine law. We are seeking to collaborate on CLBS12 with development and/or manufacturing partners. We submitted multiple grant applications in an effort to seek non-dilutive financing to investigate the CD34 technology for additional clinical indications in the United States and expect to learn the results of those applications in the first half of 2017.

We intend to develop this platform if capital becomes available through grants, partnerships or licensing, as well as potentially using reasonable amounts of our own capital as it becomes available.

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, a platform using tumor cell/dendritic cell technology for immuno-oncology and additional indications for our CD34 technology. The immuno-oncology program has the benefit of promising Phase 2 clinical data and applicability to multiple indications. This platform is based on our extensive intellectual property portfolio. In 2016 we completed multiple out-licensing agreements for these and other technology platforms in an effort to monetize non-core assets.

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

Cell Therapy Development and Manufacturing

PCT is a leading cell therapy development and manufacturing provider (often called a contract development and manufacturing organization, or "CDMO"), specializing in cell and cell-based gene therapies. PCT offers high-quality development and manufacturing capabilities (e.g., current Good Manufacturing Practice (“cGMP”) manufacturing systems and facilities), quality systems, cell and tissue processing, logistics, storage and distribution) and engineering solutions (e.g., process and assay development, optimization and automation) to clients with therapeutic candidates at all stages of development. PCT produces clinical supplies and ultimately, intends also to produce commercial product for its clients. PCT has worked with over 100 clients and produced over 20,000 cell therapy products since it was founded 18 years ago. PCT’s manufacturing services are designed to reduce the capital investment and time required by clients to advance their development programs compared to conducting process development and manufacturing in-house. PCT has demonstrated regulatory expertise, including the support of over 50 U.S. and European Union ("EU") regulatory filings for clients and expertise across multiple cell types and therapeutic applications, including immunotherapy (e.g. CAR-T therapies), neuro/endocrine therapies, hematopoietic replacement and tissue repair/regeneration. PCT offers a complete development pathway for its clients, with services supporting preclinical through commercial phase, all underpinned by timely process optimization and automation support. PCT currently operates facilities qualified under cGMPs in each of Allendale, New Jersey and Mountain View, California, including EU-compliant production capacity in the Allendale

facility. On March 11, 2016, PCT entered into a strategic collaboration and license agreement with Hitachi Chemical to accelerate the creation of a global commercial cell therapy development and manufacturing enterprise with deep engineering expertise, at which time we sold 19.9% of our ownership stake in PCT to Hitachi America. As discussed above, on March 16, 2017, we entered into the Purchase Agreement to sell our remaining 80.1% membership interest in PCT to Hitachi America for the Purchase Price (see "Item 1. Business-Overview- Proposed Sale of Remaining Interest in PCT to Hitachi America").

Reverse Stock Split

On July 28, 2016, we implemented a one-for-ten reverse split of our issued and outstanding shares of our common stock (the "Reverse Stock Split"), as authorized at the annual meeting of stockholder 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 our common stock, except to the extent that the Reverse Stock Split resulted in any of our stockholders owning a fractional share, which was rounded up to the next highest whole share. In connection with the Reverse Stock Split, there was no change in the nominal par value per share of $0.001. The Reverse Stock Split was effectuated in order to increase the per share trading price of our common stock to satisfy the $1.00 minimum bid price requirement for continued listing on The NASDAQ Capital Market.

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.

Results of Operations

Description of the Company's Business Segments

The Company is organized into two business segments: the R&D Segment and the PCT Segment. The R&D Segment develops early-stage cellular therapeutic candidates to treat certain diseases with the intention of partnering these candidates post proof-of-concept in humans. The R&D Segment recognizes less than 1% of the Company's revenues, which are primarily associated with outlicensing agreements, and all of the Company's research and development efforts. The PCT Segment provides development

and manufacturing services to the cell and cell-based gene therapy industry. The PCT Segment recognizes over 99% of the Company's revenues, and all cost of revenues.

Year Ended December 31, 2016 Compared to Year Ended December 31, 2015

Net loss for the year ended December 31, 2016 was approximately $33.3 million compared to $81.0 million for the year ended December 31, 2015. The lower net loss was primarily due to continued clinical services revenue growth coupled with significant reductions in overall operating expenses during the year ended December 31, 2016 compared with the year ended December 31, 2015. In addition, the net loss for the year ended December 31, 2015 included the impact of two corporate decisions regarding the discontinuation of our CLBS10 and CLBS20 clinical development programs, and goodwill impairment related to these decisions. The net impact of these decisions increased the net loss in 2015 by $24.7 million.

In the second quarter of 2015, we decided to no longer pursue development of CLBS10 upon completion of the ongoing PreSERVE-AMI Phase 2 clinical trial. Based on this decision, we determined that in process research and development ("IPR&D") valued at $9.4 million was fully impaired (recorded in impairment of intangible assets in our consolidated statement of operations), and the associated deferred tax liability of $3.7 million was reversed (recorded in benefit from income taxes in our consolidated statement of operations). In addition, the fair value of contingent consideration associated with earn out payments on CLBS10 future revenues was reduced from $5.6 million to $0 as of June 30, 2015 (recorded in other income in our consolidated statement of operations).

In the fourth quarter of 2015, following a comprehensive review of the CLBS20 clinical development program, including current market dynamics and current and expected future competitive therapies, we decided to discontinue the Phase 3 clinical trial of CLBS20 as a monotherapy for metastatic melanoma. Based on this decision, we determined that IPR&D valued at $34.3 million was fully impaired (recorded in impairment of intangible assets in our consolidated statement of operations), and the associated deferred tax liability of $13.9 million was reversed (recorded in benefit from income taxes in our consolidated statement of operations). In addition, the fair value of contingent consideration associated with future milestone payments on CLBS20 future development and follow on therapies was reduced from $13.9 million to $0 as of December 31, 2015 (recorded in other income in our consolidated statement of operations). Goodwill was also impaired by $18.2 million as of December 31, 2015, based on the decision to discontinue CLBS20.

The overall $24.7 million increase in net loss in 2015 resulting from the CLBS10 and CLBS20 clinical development program discontinuation decisions, and goodwill impairment are summarized as follows (in thousands):

	Year Ended December 31, 2015			
	CLBS10	CLBS20	Goodwill	Total
IPR&D Impairment	$ 9,400.0	$ 34,290.0	$ —	$ 43,690.0
IPR&D Impairment (Tax Effect)	(3,750.0)	(13,901.2)	—	(17,651.2)
Goodwill Impairment	—	—	18,196.0	18,196.0
Contingent Consideration Adjustment	(5,630.0)	(13,880.0)	—	(19,510.0)
Loss Included in Overall Net Loss	$ 20.0	$ 6,508.8	$ 18,196.0	$ 24,724.8

Revenues

For the year ended December 31, 2016, total revenues were approximately $35.3 million compared to $22.5 million for the year ended December 31, 2015, representing an increase of $12.8 million, or 57%. Revenues were comprised of the following (in thousands):

	Year Ended December 31,	
	2016	2015
Clinical Services	$ 23,815.1	$ 14,830.9
Clinical Services Reimbursables	6,444.6	3,432.2
Processing and Storage Services	4,557.5	4,104.4
Other	466.7	120.0

	$ 35,283.9	$ 22,487.6

- Clinical Services (provided by the PCT Segment), representing *process development* and *clinical manufacturing* services provided at PCT to its various clients, were approximately $23.8 million for the year ended December 31, 2016, compared

to $14.8 million for the year ended December 31, 2015, representing an increase of approximately $9.0 million or 61%. The increase was primarily due to $6.8 million of higher clinical manufacturing revenue (which is recognized as services are rendered), and $2.2 million of higher process development revenue (such revenue being recognized on a "completed contract" basis).

- *Clinical Manufacturing Revenue* - Clinical manufacturing revenues were approximately $17.2 million for the year ended December 31, 2016, compared to $10.5 million for the year ended December 31, 2015. The increase is primarily due to higher enrollment of patients being treated in our customers' clinical trials.
- *Process Development Revenue* - Process development revenues were approximately $6.6 million for the year ended December 31, 2016, compared to $4.4 million for the year ended December 31, 2015. During the year ended December 31, 2016, the number of process development contracts initiated and completed were higher compared to the prior year period. In accordance with our revenue recognition policy, process development revenue is recognized upon contract completion (i.e., when the services under a particular contract are completed). As of December 31, 2016, approximately $4.0 million process development revenue has been deferred to future periods for contracts that have been initiated but not yet completed. This revenue will be recognized in future periods upon completion of those contracts. Process development revenue will continue to fluctuate from period to period as a result of this revenue recognition policy.

- Clinical Services Reimbursables (provided by the PCT Segment), representing reimbursement of expenses for certain consumables incurred on behalf of our clinical service revenue clients, were approximately $6.4 million for the year ended December 31, 2016, compared to $3.4 million for the year ended December 31, 2015, representing an increase of approximately $3.0 million or 88%. Generally, clinical services reimbursables correlate with clinical services revenues. However, differences in the cost of supplies to be reimbursed can vary greatly from contract to contract based on the cost of supplies needed for each client's manufacturing and development process, and may impact this correlation. In addition, our terms for billing reimbursable expenses do not include a significant mark up in the acquisition cost of such consumables, and as a result, changes in this revenue category have little impact on our gross profit and net loss.
- Processing and Storage Services (provided by the PCT Segment), primarily representing revenues from our oncology stem cell processing, were approximately $4.6 million for the year ended December 31, 2016, compared to $4.1 million for the year ended December 31, 2015, representing an increase of approximately $0.5 million or 11%. The increase is primarily due to increased volume and pricing for the processing services.

Operating Costs and Expenses

For the year ended December 31, 2016, operating expenses totaled $66.6 million compared to $136.3 million for the year ended December 31, 2015, representing a decrease of $69.7 million or 51%. Operating expenses were comprised of the following:

- Cost of revenues (incurred in the PCT Segment) were approximately $31.1 million for the year ended December 31, 2016, compared to $20.2 million for the year ended December 31, 2015, representing an increase of $11.0 million or 54%. Overall, gross margin for the year ended December 31, 2016 was $4.1 million or 12%, compared to $2.3 million or 10% year ended December 31, 2015. Gross margin percentages generally will increase/decrease as clinical service revenue increases/decreases. However, gross profit percentages will also fluctuate from period to period due to the mix of service and reimbursable revenues and costs.
- Research and development expenses (incurred in the R&D Segment) were approximately $15.1 million for the year ended December 31, 2016 compared to $23.9 million for the year ended December 31, 2015, representing a decrease of approximately $8.8 million, or 37%.
  - *Immune Modulation* - Immune modulation expenses, including expenses associated with our Phase 2 study of CLBS03 in T1D, were $8.3 million for the year ended December 31, 2016, representing an increase of $4.2 million compared to the year ended December 31, 2015.
  - *Immuno-oncology* - Immuno-oncology expenses, which are primarily associated with the close-out activities for the Intus Phase 3 clinical trial for the immunotherapy product candidate CLBS20, were $2.6 million for the year ended December 31, 2016, representing a decrease of $7.1 million compared to the year ended December 31, 2015. In January 2016, we discontinued the clinical development of CLBS20.
  - *Ischemic Repair* - Ischemic repair expenses were $2.2 million for the year ended December 31, 2016, representing a decrease of approximately $4.3 million compared to the year ended December 31, 2015. The decrease is primarily due to lower program expenses associated with the decision to only conduct clinical study activity for a critical limb ischemia development program in Japan with a partner, and lower expenses associated with the close-out activities of the PreServe AMI Phase 2 clinical trial for CLBS10.

- *Other* - Other research and development expenses were $2.1 million for the year ended December 31, 2016, representing a decrease of approximately $1.6 million compared to the year ended December 31, 2015. Equity-based compensation included in research and development expenses for the year ended December 31, 2016, was approximately $0.3 million, representing a decrease of $1.5 million, compared to the year ended December 31, 2015.

- Impairment of intangible assets (incurred in the R&D Segment) of $62.3 million for the year ended December 31, 2015 were primarily related to the following:
  - The full impairment of IPR&D associated with CLBS10 valued at $9.4 million, based on our decision that we will not pursue further development of CLBS10 upon completion of the ongoing PreSERVE-AMI Phase 2 clinical trial.
  - The full impairment of IPR&D associated with CLBS20 valued at $34.3 million, based on our decision to discontinue the Phase 3 study of CLBS20 as a monotherapy for metastatic melanoma.
  - Goodwill impairment of $18.2 million, based on the our annual review for goodwill impairment as of December 31, 2015. The impairment was directly attributable to our decision to discontinue our CLBS20 Phase 3 clinical trial.

- Selling, general and administrative expenses (incurred and shared in both the PCT and R&D Segments) were approximately $20.4 million for the year ended December 31, 2016, compared to $30.0 million for the year ended December 31, 2015, representing a decrease of approximately $9.6 million, or 32%. Equity-based compensation included in selling, general and administrative expenses for the year ended December 31, 2016, was approximately $1.8 million, compared to approximately $7.4 million for the year ended December 31, 2015, representing a decrease of $5.6 million. Non-equity-based general and administrative expenses for the year ended December 31, 2016 were approximately $18.5 million, compared to approximately $22.6 million for the year ended December 31, 2015. 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.

Other Income (Expense)

Other income, net for the year ended December 31, 2016, was $0.02 million, compared with other income, net, of $17.7 million for the year ended December 31, 2015, and primarily relates to changes in the estimated fair value of our contingent consideration liabilities. The year ended December 31, 2015 amounts include the revaluation of the contingent consideration related to CLBS10 which decreased from $5.6 million to $0, and the revaluation of the contingent consideration associated with future milestone payments on CLBS20 future development and follow on therapies which decreased from $13.9 million to $0. The write down of these liabilities is directly related to the discontinuation of the related programs discussed above.

Interest expense was $1.9 million for the year ended December 31, 2016, compared with $2.1 million for the year ended December 31, 2015, and is primarily related to interest expense on the loan from Oxford Finance LLC.

Provision for Income Taxes

The provision from income taxes for the year ended December 31, 2016 and the year ended December 31, 2015 relates to the taxable temporary differences on the goodwill recognized in the PCT acquisition in 2011 and reported in the PCT Segment, which is being amortized over 15 years for tax purposes.

The benefit from income taxes for the year ended December 31, 2015, relates primarily to the reversal of the deferred tax liability of $3.7 million associated with the impairment of the CLBS10 IPR&D intangible asset valued at $9.4 million, and the reversal of the deferred tax liability of $13.9 million associated with the impairment of the CLBS20 IPR&D intangible asset valued at $34.3 million, both of which were reported in the R&D Segment. These benefits were partially offset by a tax provision on the taxable temporary differences on the goodwill recognized in the PCT acquisition in 2011 and reported in the PCT Segment, which is being amortized over 15 years for tax purposes. A tax provision will continue to be recognized each period over the amortization period, and will only reverse when the goodwill is eliminated through a sale, impairment, or reclassification from an indefinite-lived asset to a finite-lived asset.

Analysis of Liquidity and Capital Resources

At December 31, 2016, we had cash, cash equivalents, and marketable securities of approximately $14.7 million, working capital of approximately $5.1 million, and stockholders’ equity of approximately $4.9 million.

During the year ended December 31, 2016, we met our immediate cash requirements through revenue generated from our PCT operations, cash received from the transaction with Hitachi (net of repayments on our long-term debt to Oxford Finance LLC), proceeds from the issuances of our common stock, and existing cash balances. Additionally, we used equity and equity-linked instruments to pay for services and compensation.

Net cash provided by or used in operating, investing and financing activities were as follows (in thousands):

	Year Ended December 31,	
	2016	2015
Net cash used in operating activities	$ (23,667.7)	$ (39,258.3)
Net cash (used in) provided by investing activities	(2,849.3)	3,798.4
Net cash provided by financing activities	20,903.6	36,604.3

Operating Activities

Our cash used in operating activities in the year ended December 31, 2016 totaled approximately $23.7 million, which is the sum of (i) our net loss of 33.3 million, and adjusted for non-cash income and expenses totaling $6.1 million (which includes adjustments for equity-based compensation, depreciation and amortization, loss on disposal of assets, and deferred taxes), and (ii) changes in operating assets and liabilities of approximately $3.6 million.

Our cash used in operating activities in the year ended December 31, 2015 totaled approximately $39.3 million, which is the sum of (i) our net loss of $81.0 million, and adjusted for non-cash income and expenses totaling $39.3 million (which includes adjustments for equity-based compensation, depreciation and amortization, impairment of goodwill and intangible assets, and changes in acquisition-related contingent consideration liabilities and deferred taxes), and (ii) changes in operating assets and liabilities of approximately $2.5 million.

Investing Activities

During the year ended December 31, 2016, we spent approximately $2.8 million for property and equipment.

During the year ended December 31, 2015, we spent approximately $3.2 million for property and equipment. In addition, we received approximately $7.0 million from the sale of marketable securities (net of purchases) during year ended December 31, 2015.

Financing Activities

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

- In September 2016, we raised $4.0 million in a registered direct offering through the issuance of 0.8 million shares of our common stock, and $6.6 million in concurrent private placement offerings through the issuance of 1.4 million shares of our common stock.
- In March 2016, Hitachi Chemical purchased a 19.9% membership interest in PCT for $19.4 million.
- In March 2016, we paid $6.3 million in principal payments on our long term debt to Oxford Finance LLC upon our sale of a 19.9% membership interest in PCT to Hitachi America and our entry into the Hitachi License Agreement (collectively, the "March 2016 Hitachi Transaction"), and ,in September 2016, we paid an additional $3.0 million in principal payments on our long term debt to Oxford Finance LLC.
- In March 2016, 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 $1.0 million from the issuance of notes payable relating to certain insurance policies and equipment financings, less repayments of $1.6 million.

During the year ended December 31, 2015, our financing activities consisted of the following:

- We raised $28.8 million (or $26.5 million in net proceeds after deducting underwriting discounts and commissions and offering expenses) through an underwritten offering of 1.44 million shares of our common stock at a public offering price of $20.00 per share in May 2015.
- We raised gross proceeds of approximately $9.7 million through the issuance of approximately 0.4 million shares of our common stock under the provisions of our Common Stock Purchase Agreements with Aspire.
- We received proceeds of $1.1 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

Liquidity (assuming Sale Closes in the Second Quarter of 2017)

The Sale may constitute the sale of substantially all of the Company's property and assets under Delaware law, and the Company is therefore seeking the approval of the Sale by the Company's stockholders which is expected in the second quarter of 2017. The Company expects to receive the Initial Payment in the first quarter of 2017. If the Sale closes, the Company expencts to receive the remainder of the Purchase Price (other than the $5.0 million paid into escrow and the milestone payment) in the second quarter of 2017. We believe that the expected cash on hand from the Sale 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, as well as to repay our outstanding loan with Oxford Finance in 2017.

Liquidity (assuming the Sale Does Not Close)

If we do not consummate the Sale, we will require additional capital to fund the development of CLBS03 and other operating expenses, to grow the PCT business, and to make principal and interest payments on our loan with Oxford Finance. To meet our short and long term liquidity needs, we expect to use existing cash balances, additional cash that may be received if certain milestones are met (as described below) pursuant to the private placement purchase agreements we entered into in September 2016, to use cash from our revenue generating activities, and a variety of other means, including raising capital through our common stock purchase agreements with Aspire Capital. Other sources of liquidity could include additional potential issuances of debt or equity securities in public or private financings, partnerships and/or collaborations and/or sale of assets. In addition, we will continue to seek, as appropriate, grants for scientific and clinical studies from various governmental agencies and foundations.

In September 2016, we entered into a securities purchase agreement with a single institutional investor pursuant to which we issued in a registered direct offering, an aggregate of 0.8 million shares of 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 an aggregate of 4.4 million shares of common stock, at a purchase price of $4.72 per share. The investments were 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 our Phase 2 CLBS03 clinical trial, in a second closing (the “Second Closing”). As of December 31, 2016, $6.6 million of the Initial Closing tranche was received, and 1,398,305 shares of common stock had been issued. As of December 31, 2016, the remaining $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. It is doubtful that any funds will be received from this investor, or whether we would agree to accept those funds on the original terms if offered.

On March 2016, PCT and Caladrius entered into a global collaboration that includes licensing, development and equity, with Hitachi, a Japanese-based global conglomerate with a growing franchise in life sciences including regenerative medicine, for an aggregate of $25.0 million in cash, which was received in 2016.

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

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

In September 2014, we entered into a Loan and Security Agreement with Oxford Finance LLC and received $15.0 million in gross proceeds. We have been making interest-only payments on the outstanding amount of the loan on a monthly basis at a rate of 8.50% per annum. On March 11, 2016, upon execution of the March 2016 Hitachi Transaction, we and Oxford Finance LLC 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 LLC's security interests in any and all assets of the Removed Borrowers were released, (iv) the interest only period on the remaining outstanding Loan balance 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. The loan matures on September 1, 2018. As of December 31, 2016, the outstanding principal amount under the loan was $5.7 million.

Other sources of liquidity could include additional potential issuances of debt or equity securities in public or private financings, additional warrant exercises, option exercises, partnerships and/or collaborations, and/or sale of assets. Our history of operating

losses and liquidity challenges, may make it difficult for us to raise capital on acceptable terms or at all. The demand for the equity and debt of biopharmaceutical companies like ours is dependent upon many factors, including the general state of the financial markets. During times of extreme market volatility, capital may not be available on favorable terms, if at all. Our inability to obtain such additional capital could materially and adversely affect our business operations.

While we continue to seek capital through a number of means, there can be no assurance that additional financing will be available on acceptable terms, if at all, and our negotiating position in capital generating efforts may worsen as existing resources are used. Additional equity financing may be dilutive to our stockholders; debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate as a business; our stock price may not reach levels necessary to induce option or warrant exercises; and asset sales may not be possible on terms we consider acceptable. If we are unable to access capital necessary to meet our long-term liquidity needs, we may have to delay or discontinue the development of CLBS03, and/or the expansion of our business or raise funds on terms that we currently consider unfavorable. Our recurring losses and our need to raise substantial capital raise substantial doubt about our ability to continue as a going concern for the next 12 months following the issuance of the financial statements.

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.

Revenue Recognition

Clinical Services: We recognize revenue for our (i) cell process development and (ii) cell manufacturing services based on the terms of individual contracts.

We recognize revenues for cell development services when all of the following conditions are met:

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

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

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

Cell manufacturing services are generally distinct arrangements whereby we are paid for time and materials or for fixed monthly amounts. Revenue is recognized when efforts are expended or contractual terms have been met.

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

Clinical Services Reimbursements: We separately charge the customers for the expenses associated with certain consumable resources (reimbursable expenses) that are specified in each clinical services contract. On a monthly basis, we bill customers for reimbursable expenses and immediately recognizes these billings as revenue, as the revenue is deemed earned as reimbursable expenses are incurred.

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

License Fees: PCT and Hitachi Chemical also entered into an exclusive license agreement for Asia pursuant to which PCT received $5.6 million from Hitachi Chemical in 2016. PCT licensed to Hitachi Chemical certain cell therapy technology and know-how (including an exclusive license to use the PCT brand in Asia) and agreed to provide Hitachi Chemical certain training and support. As additional consideration, Hitachi Chemical will pay PCT royalties on contract revenue generated in Asia for a minimum of 10 years. The initial term of the Hitachi License Agreement is 10 years and may be automatically extended for successive additional two year terms. We recognize the payments as revenue on a straight-line basis over the initial 10-year term.

Share-Based Compensation

We expense all share-based payment awards to employees, directors, advisors 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. Advisor and 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.

Goodwill

Goodwill is the excess of purchase price over the fair value of identified net assets of businesses acquired. Intangible assets with an indefinite lives are measured at their respective fair values as of the acquisition date. We do not amortize goodwill and intangible assets with indefinite useful lives.

We review goodwill at least annually, or at the time a triggering event is identified for possible impairment. Goodwill is reviewed for possible impairment between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of the reporting unit below its carrying value. We test our goodwill each year on December 31. We review the carrying value of goodwill utilizing an income approach model, and, where appropriate, a market value approach is also utilized to supplement the discounted cash flow model. We make assumptions regarding estimated future cash flows, discount rates, long-term growth rates and market values to determine each reporting unit’s estimated fair value. If these estimates or related assumptions change in the future, we may be required to record impairment charges.

Long-lived Assets

Long-lived assets consist of customer lists, manufacturing technology, tradenames, patents and rights, as well as 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.

We have audited the accompanying consolidated balance sheets of Caladrius Biosciences, Inc., a Delaware corporation, and subsidiaries (the “Company”) as of December 31, 2016 and 2015, and the related consolidated statements of operations, comprehensive loss, equity, and cash flows for each of the two years in the period ended December 31, 2016. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company’s internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Caladrius Biosciences Inc. and subsidiaries as of December 31, 2016 and 2015, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2016 in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring losses from operations and as of December 31, 2016 has an accumulated deficit of $404.8 million. These conditions, along with other matters as set forth in Note 1, raise substantial doubt about the Company’s ability to continue as a going concern. Management’s plans in regard to these matters are also discussed in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ GRANT THORNTON LLP

New York, New York
March 16, 2017

CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2016	December 31, 2015
ASSETS		
Current Assets		
Cash and cash equivalents	$ 14,705,008	$ 20,318,411
Accounts receivable trade, net of allowance of $0 at December 31, 2016 and 2015, respectively	2,891,723	2,566,101
Deferred costs	3,582,298	2,911,743
Prepaid and other current assets	3,469,932	3,476,177
Total current assets	24,648,961	29,272,432
Property, plant and equipment, net	17,149,241	17,064,900
Goodwill	7,013,315	7,013,315
Intangible assets, net	2,307,880	2,877,880
Other assets	713,451	976,768
Total assets	$ 51,832,848	$ 57,205,295
LIABILITIES, REDEEMABLE SECURITIES - NON-CONTROLLING INTERESTS AND EQUITY		
Current Liabilities		
Accounts payable	$ 4,366,753	$ 4,107,388
Accrued liabilities	6,062,569	6,198,488
Long-term debt, current	3,126,457	4,171,456
Notes payable, current	847,327	1,192,666
Unearned revenues, current	5,098,193	5,345,225
Total current liabilities	19,501,299	21,015,223
Deferred income taxes	1,070,700	932,662
Notes payable	292,217	583,041
Unearned revenues, long-term	4,587,397	—
Long term debt	2,524,897	10,828,544
Other long-term liabilities	389,858	562,001
Total liabilities	28,366,368	33,921,471
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, 2016 and December 31, 2015	100	100
Common stock, $.001 par value, authorized 500,000,000 shares; issued and outstanding, 8,205,791 and 5,673,302 shares, at December 31, 2016 and December 31, 2015, respectively	8,206	5,673
Additional paid-in capital	410,372,049	396,547,401
Treasury stock, at cost; 11,080 shares at December 31, 2016 and December 31, 2015 respectively	(707,637)	(707,637)
Accumulated deficit	(404,788,809)	(372,132,490)
Accumulated other comprehensive income	—	486
Total Caladrius Biosciences, Inc. stockholders' equity	4,883,909	23,713,533
Noncontrolling interests	(817,429)	(429,709)
Total equity	4,066,480	23,283,824
	$ 51,832,848	$ 57,205,295

See accompanying notes to consolidated financial statements.

CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2016	**2015**
Revenues	$ 35,283,868	$ 22,487,566
Expenses:		
Cost of revenues	31,136,129	20,158,828
Research and development	15,108,528	23,899,026
Impairment of goodwill and intangible assets	—	62,273,336
Selling, general, and administrative	20,374,969	30,005,542
Operating expenses	66,619,626	136,336,732
Operating loss	(31,335,758)	(113,849,166)
Other income (expense):		
Other income (expense), net	21,957	17,723,579
Interest expense	(1,857,694)	(2,128,442)
	(1,835,737)	15,595,137
Loss before provision (benefit) for income taxes and noncontrolling interests	(33,171,495)	(98,254,029)
Provision (benefit) for income taxes	138,038	(17,243,528)
Net loss	(33,309,533)	(81,010,501)
Less - loss attributable to noncontrolling interests	(653,214)	(124,549)
Net loss attributable to Caladrius Biosciences, Inc. common stockholders	$ (32,656,319)	(80,885,952)
Basic and diluted loss per share attributable to Caladrius Biosciences, Inc. common stockholders	$ (4.99)	$ (16.67)
Weighted average common shares outstanding	6,548,251	4,850,811

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,	
	2016	2015
Net loss	$ (33,309,533)	$ (81,010,501)
Other comprehensive loss:		
Available for sale securities - net unrealized loss	(486)	(843)
Total other comprehensive loss	(486)	(843)
Comprehensive loss	(33,310,019)	(81,011,344)
Comprehensive loss attributable to noncontrolling interests	(653,214)	(124,549)
Comprehensive net loss attributable to Caladrius Biosciences, Inc. common stockholders	$ (32,656,805)	$ (80,886,795)

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, 2014	10,000	$ 100	3,678,386	$ 3,678	$ 350,462,009	$ 1,329	$ (291,246,538)	$ (705,742)	$ 58,514,836	$ (441,047)	$ 58,073,789
Net loss	—	—	—	—	—	—	(80,885,952)	—	(80,885,952)	(124,549)	(81,010,501)
Unrealized gain/loss on marketable securities	—	—	—	—	—	(843)	—	—	(843)	—	(843)
Share-based compensation	—	—	92,800	93	9,751,912	—	—	(1,895)	9,750,110	—	9,750,110
Net proceeds from issuance of common stock	—	—	1,902,116	1,902	36,469,367	—	—	—	36,471,269	—	36,471,269
Change in Ownership in Subsidiary	—	—	—	—	(135,887)	—	—	—	(135,887)	135,887	—
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 gain/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

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,	
	2016	2015
Cash flows from operating activities:		
Net loss	$ (33,309,533)	$ (81,010,501)
Adjustments to reconcile net loss to net cash used in operating activities:		
Equity-based compensation expense	2,604,291	9,750,110
Depreciation and amortization	2,743,648	2,686,779
Changes in acquisition-related contingent consideration	—	(18,260,000)
Impairment of goodwill and intangible assets	—	62,273,336
Loss on disposal of assets	591,307	—
Deferred income taxes	138,038	(17,243,528)
Amortization/Accretion on Marketable Securities	—	95,095
Changes in operating assets and liabilities:		
Prepaid and other current assets	6,245	872,990
Accounts receivable	(325,622)	545,173
Deferred costs	(670,555)	(344,753)
Unearned revenues	4,340,366	1,011,104
Other assets	262,830	286,607
Accounts payable, accrued liabilities and other liabilities	(48,697)	79,257
Net cash used in operating activities	(23,667,682)	(39,258,331)
Cash flows from investing activities:		
Purchase of short term investments	—	(6,081,900)
Sales of marketable securities	—	13,066,014
Acquisition of property and equipment	(2,849,296)	(3,185,737)
Net cash (used in) provided by investing activities	(2,849,296)	3,798,377
Cash flows from financing activities:		
Tax withholding payments on net share settlement equity awards	(72,010)	—
Net proceeds from issuance of capital stock	11,560,394	36,471,269
Repayment of long-term debt	(9,348,646)	—
Proceeds from notes payable	979,579	1,087,361
Repayment of notes payable	(1,615,742)	(954,326)
Sale of ownership interest in subsidiary	19,400,000	—
Net cash provided by financing activities	20,903,575	36,604,304
Net (decrease) increase in cash and cash equivalents	(5,613,403)	1,144,350
Cash and cash equivalents at beginning of year	20,318,411	19,174,061
Cash and cash equivalents at end of year	$ 14,705,008	$ 20,318,411
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the period for:		
Interest	$ 1,823,424	$ 1,497,845
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 our internal specialized cell therapy clinical development expertise to select and develop early-stage cell therapy candidates with the intention of partnering these candidates post proof-of-concept in humans. Our current lead product candidate, CLBS03, is an autologous ex vivo polyclonal T regulatory cell ("Treg") clinical phase 2 therapy targeting adolescents with recent-onset type 1 diabetes mellitus (“T1D”). Our subsidiary, PCT, LLC, a Caladrius Company™ (“PCT”), is a leading provider of development and manufacturing services to the cell and cell-based gene therapy industry. PCT has significant cell therapy-specific experience and expertise, an expansive list of noteworthy clients and significant revenue growth over the past three years. Notably, PCT and Hitachi Chemical Co. America, Ltd. ("Hitachi America") and Hitachi Chemical Co., Ltd. ("Hitachi" and together with Hitachi America, “Hitachi Chemical”) are engaged in a strategic collaboration to accelerate the creation of a global commercial cell therapy development and manufacturing enterprise with deep engineering expertise.

CLBS03

We are developing strategically, through the utilization of or core development and manufacturing expertise, a product candidate that is an innovative therapy for TID. 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 below the age of 18. This program is based on the use of T regulatory cells ("Tregs") to treat diseases caused by imbalances in an individual's immune system. This novel approach seeks to restore immune balance by enhancing Treg number and function. Tregs are a natural part of the human immune system and regulate the activity of T effector cells; the cells that are responsible for protecting the body from pathogens and foreign antigens. When Tregs function properly, only harmful foreign materials are attacked by T effector cells. In autoimmune disease, however, it is thought that deficient Treg activity and numbers permit the T effector cells to attack the body's own beneficial cells. In the case of T1D, 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, only lifelong insulin therapy, which therapy often does not prevent serious co-morbidities. Two Phase 1 clinical trials of this technology in T1D demonstrated safety and tolerance, feasibility of manufacturing, an implied durability of effect as well as an early indication of potential therapeutic effect through the preservation of beta cell function. In the first quarter of 2016, we commenced patient enrollment in the first of two cohorts in The Sanford Project: T-Rex Study, a Phase 2 prospective, randomized, placebo-controlled, double-blind clinical trial (the "TRex Study") to evaluate the safety and efficacy of CLBS03 in adolescents with recent onset T1D. In October 2016 we received a satisfactory safety evaluation by our independent Data Safety Monitoring Board based on the safety data then available from the first 19 patients enrolled in the trial. A subsequent interim analysis of early therapeutic effect is planned after approximately 50% of patients reach the six-month follow-up milestone, which analysis is expected in late 2017 or early 2018. 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 total $12.2 million amount will become payable upon the achievement of certain milestones which are still under negotiation. We expect to receive $5.7 million in initial funding on April 1, 2017. CLBS03 has been granted Fast Track and orphan drug designations from the FDA as well as Advanced Therapeutic Medicinal Product ("ATMP") classification from the European Medicines Agency ("EMA")

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 increase blood flow to the impacted area. We believe that conditions caused by underlying ischemic injury can improve through our CD34 cell technology, including critical limb ischemia ("CLI"). Published reports in *Circulation Cardiovascular Interventions*, *Atherosclerosis*, *Stem Cells and Circulation Journal*, provide preliminary evidence that CD34 cell therapy is safe and can exert significant therapeutic effects in patients with CLI, a condition in which blood flow to the legs is severely impaired, causing pain and non-healing ulcers and, ultimately, potentially resulting in the need for amputation. Our Clinical Trial Notification for a pivotal Phase 2 trial investigating CLBS12 (a candidate for CLI) was submitted to the Japanese Pharmaceutical and Medical Device Agency ("PMDA") and was cleared to proceed. The protocol design was agreed with PMDA and if successful, could provide the basis for conditional

approval under Japan's favorable regenerative medicine law. We are seeking to collaborate on CLBS12 with development and/or manufacturing partners. We submitted multiple grant applications in an effort to seek non-dilutive financing to investigate the CD34 technology for additional clinical indications in the United States and expect to learn the results of those applications in the first half of 2017.

We intend to develop this platform if capital becomes available through grants, partnerships or licensing, as well as potentially using reasonable amounts of our own capital as it becomes available.

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, a platform using tumor cell/dendritic cell technology for immuno-oncology and additional indications for our CD34 cell technology. The immuno-oncology program has the benefit of promising Phase 2 clinical data and applicability to multiple indications. This platform is based on our extensive intellectual property portfolio. In 2016 we completed multiple out-licensing agreements for these and other technology platforms in an effort to monetize non-core assets.

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

Cell Therapy Development and Manufacturing

PCT is a leading cell therapy development and manufacturing provider (often called a contract development and manufacturing organization, or "CDMO"), specializing in cell and cell-based gene therapies. PCT offers high-quality development and manufacturing capabilities (e.g., current Good Manufacturing Practice (“cGMP”) manufacturing systems and facilities), quality systems, cell and tissue processing, logistics, storage and distribution and engineering solutions (e.g., process and assay development, optimization and automation) to clients with therapeutic candidates at all stages of development. PCT produces clinical supplies and ultimately, intends also to produce commercial product for its clients. PCT has worked with over 100 clients and produced over 20,000 cell therapy products since it was founded 18 years ago. PCT’s manufacturing services are designed to reduce the capital investment and time required by clients to advance their development programs compared to conducting the process development and manufacturing in-house. PCT has demonstrated regulatory expertise, including the support of over 50 U.S. and European Union ("EU") regulatory filings for clients, and expertise across multiple cell types and therapeutic applications, including immunotherapy (e.g. CAR-T therapies), neuro/endocrine therapies, hematopoietic replacement and tissue repair/regeneration. PCT offers a complete development pathway for its clients, with services supporting preclinical through commercial phase, all underpinned by timely process optimization and automation support. PCT currently operate facilities qualified under cGMPs in each of Allendale, New Jersey and Mountain View, California, including EU-compliant production capacity in the Allendale facility. On March 11, 2016, PCT entered into a strategic collaboration and license agreement with Hitachi Chemical to accelerate the creation of a global commercial cell therapy development and manufacturing enterprise with deep engineering expertise, at which time Caladrius sold 19.9% of its ownership stake in PCT to Hitachi Chemical.

On March 16, 2017 (the "Effective Date"), Caladrius entered into an interest purchase agreement (the "Purchase Agreement"), by and among Caladrius, PCT and Hitachi America, pursuant to which Hitachi America has agreed to acquire the 80.1% membership interest in PCT that it does not already own from Caladrius for $75.0 million in cash (the “Sale”), subject to potential adjustment, including based on PCT’s cash and outstanding indebtedness as of the closing of the Sale, and a potential future milestone payment (the “Purchase Price”). Pursuant to the terms of the Purchase Agreement, at the Effective Date, Hitachi America will pay Caladrius $5.0 million of the Purchase Price (the “Initial Payment”). At the closing of the Sale (the “Closing”), an additional $5.0 million of the Purchase Price will be deposited into an escrow account to cover potential indemnification claims of Hitachi America, if any, under the Purchase Agreement. The Closing is subject to customary closing conditions, including approval of Caladrius’ stockholders, and is expected to occur during the second quarter of 2017. However, we cannot provide assurance as to when the Sale will be completed, or whether it will be completed at all.

As part of the Purchase Price, Hitachi will pay Caladrius $5.0 million (the “Milestone Payment”) 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. For purposes of the Milestone, “Cumulative Revenue” will be calculated based on PCT’s revenue from all customers (including Caladrius and its subsidiaries) in accordance with the financial accounting and reporting standards set forth in the statements and pronouncements of the Financial Accounting Standards Board (“FASB”), consistently applied (see Note 18).

Financial Information & Liquidity

Liquidity (assuming the Sale Closes in the Second Quarter of 2017) - see Note 18

The Sale may constitute the sale of substantially all of the Company's property and assets under Delaware law, and the Company is therefore seeking the approval of the Sale by the Company's stockholders which is expected in the second quarter of 2017. The

Company expects to receive the Initial Payment in the first quarter of 2017. If the Sale closes, the Company expects to receive the remainder of the Purchase Price (other than the $5.0 million paid into escrow and the milestone payment) in the second quarter of 2017. We believe that the expected cash on hand from the Sale 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, as well as to repay our outstanding loan with Oxford Finance in 2017.

We cannot provide assurance as to when the Sale will be completed, or whether it will be completed at all. In addition, if the Purchase Agreement is terminated under certain circumstances, Caladrius will be required to repay the $5.0 million Initial Payment and pay a termination fee of $5.0 million. If such payments are not made within 90 days, Hitachi America's membership interest in PCT will increase from 19.9% to 32.22%. If the Purchase Agreement is terminated under certain other circumstances, Caladrius will be required to return the $5.0 million Initial Payment, and, if does not do so within 90 days, Hitachi America's membership interest in PCT will increase from 19.9% to 26.02%. Each of these scenarios could have adverse effects on our business, results of operations and the trading price of our common stock.

Liquidity (assuming Sale Does Not Close)

During the year ended December 31, 2016, the Company incurred a net loss of $33.3 million and used $23.7 million of net cash in operating activities. As of December 31, 2016, the Company's accumulated deficit was $404.8 million. We anticipate requiring additional capital in order to grow our PCT business, to fund the development of CLBS03, to fund other operating expenses, and to make principal and interest payments on our loan with Oxford Finance. To meet our short and long term liquidity needs, we currently expect to use existing cash and cash equivalents balances, our revenue generating activities and a variety of other means, including our common stock purchase agreements with Aspire Capital (see Note 13). Other sources of liquidity could include additional potential issuances of debt or equity securities in public or private financings, option exercises, partnerships and/or collaborations and/or sale of assets. In addition, we will continue to seek as appropriate grants for scientific and clinical studies from various governmental agencies and foundations. While we continue to seek capital through a number of means, there can be no assurance that additional financing will be available to us on acceptable terms, if at all. If we are unable to access capital necessary to meet our liquidity needs, we may have to delay or discontinue the development of CLBS03, and/or the expansion of our business or raise funds on terms that we may consider unfavorable.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern for at least the next 12 months following the issuance of our financial statements; however, the above conditions raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments to reflect the possible future effects on the recoverabilty and classification of assets or the amounts and classifications of liabilities that may result should the Company be unable to continue as a going concern.

Reverse Stock Split

On July 28, 2016, we implemented a one-for-ten reverse split of our issued and outstanding shares of our 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 our common stock, except to the extent that the Reverse Stock Split resulted in any of our stockholders owning a fractional share, which was rounded up to the next highest whole share. In connection with the Reverse Stock Split, there was no change in the nominal par value per share of $0.001. The Reverse Stock Split was effectuated in order to increase the per share trading price of our common stock to satisfy the $1.00 minimum bid price requirement for continued listing on The NASDAQ Capital Market.

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.

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, 2016 and 2015, and the results of its operations and its cash flows for the years ended December 31, 2016 and 2015.

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 periods. The Company bases its estimates on historical experience and other assumptions believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. The Company makes critical estimates and assumptions in determining the fair values of goodwill for potential goodwill impairments, useful lives of our long-lived tangible and intangible assets, allowances for doubtful accounts, and stock-based awards values. Accordingly, actual results could differ from those estimates and assumptions.

Principles of Consolidation

The Consolidated Financial Statements include the accounts of Caladrius Biosciences, Inc. and its wholly owned and partially owned subsidiaries and affiliates as listed below. All intercompany activities have been eliminated in consolidation.

Entity	Percentage of Ownership	Location
Caladrius Biosciences, Inc.	100%	United States of America
Amorcyte, LLC	100%	United States of America
PCT, LLC, a Caladrius Company (1)	80.1%	United States of America
NeoStem Family Storage, LLC (1)	80.1%	United States of America
PCT Allendale, LLC (1)	80.1%	United States of America
Athelos Corporation (2)	98.4%	United States of America
NeoStem Oncology, LLC	100%	United States of America

(1) As of December 31, 2016, Hitachi America's ownership interest was 19.9%
(2) As of December 31, 2016, Becton Dickinson's ownership interest in Athelos Corporation was 1.6%.

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

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

For the year ended December 31, 2016, three customers represented 46% of total revenues recognized, the largest of which was 19%. As of December 31, 2016, three customers represented 40% of our accounts receivable, the largest of which was 19%.

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.

Accounts Receivable

Accounts receivable are carried at original invoice amount less an estimate made for doubtful accounts. The Company applies judgment in connection with establishing the allowance for doubtful accounts. Specifically, the Company analyzes the aging of accounts receivable balances, historical bad debts, customer concentration and credit-worthiness, current economic trends and changes in the Company's customer payment terms. Significant changes in customer concentrations or payment terms, deterioration of customer credit-worthiness or weakening economic trends could have a significant impact on the collectability of the receivables and the Company's operating results. If the financial condition of the Company's customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required. Management regularly reviews the aging of receivables and changes in payment trends by its customers, and records a reserve when it believes collection of amounts due are at risk.

Deferred Costs

The Company, through its PCT subsidiary, regularly enters into contracts with clients for services that have multiple stages and are dependent on one another to complete the contract and recognize revenue. The Company's deferred costs represents work in process for costs incurred on such projects at PCT that have not been completed. The Company reviews these projects periodically to determine that the value of each project is stated at the lower of cost or market.

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:

Building and improvements	25-30 years
Machinery and equipment	8-12 years
Lab equipment	5-7 years
Furniture and fixtures	5-12 years
Software	3-5 years
Leasehold improvements	Life of lease

Goodwill

Goodwill is the excess of purchase price over the fair value of identified net assets of businesses acquired. Intangible assets with indefinite useful lives are measured at their respective fair values as of the acquisition date. The Company does not amortize goodwill and intangible assets with indefinite useful lives.

The Company reviews goodwill at least annually, or at the time a triggering event is identified for possible impairment. Goodwill is reviewed for possible impairment between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of the reporting unit below its carrying value. The Company tests its goodwill each year on December 31. The Company reviews the carrying value of goodwill utilizing an income approach model, and, where appropriate, a market value approach is also utilized to supplement the discounted cash flow model. The Company makes assumptions regarding estimated future cash flows, discount rates, long-term growth rates and market values to determine each reporting unit's estimated fair value. If these estimates or related assumptions change in the future, the Company may be required to record impairment charges. In accordance with its accounting policy, the Company tested goodwill as of December 31, 2016 and concluded there was no goodwill impairment. As of December 31, 2015, the Company determined that goodwill valued at $18.2 million was impaired (see Note 9).

Long-lived Assets

Long-lived assets consist of customer lists, manufacturing technology, tradenames, patents and rights, as well as 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. There were no impairments in 2016 and 2015.

Share-Based Compensation

The Company expenses all share-based payment awards to employees, directors, consultants, including grants of stock options, warrants, and restricted stock, over the requisite service period based on the grant date fair value of the awards. Consultant awards

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

Loss Per Share

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

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 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.

Revenue Recognition

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

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

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

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

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

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

Some client agreements include multiple elements, comprised of cell process development and cell manufacturing services. The Company believes that process development and clinical manufacturing services each have stand-alone value because these services can be provided separately by other companies. In accordance with ASC Update No. 2009-13, "Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements," the Company (1) separates deliverables into separate units of

accounting when deliverables are sold in a bundled arrangement and (2) allocates the arrangement's consideration to each unit in the arrangement based on its relative selling price.

Clinical Services Reimbursements: The Company separately charges the customers for the expenses associated with certain consumable resources (reimbursable expenses) that are specified in each clinical services contract. On a monthly basis, the Company bills customers for reimbursable expenses and immediately recognizes these billings as revenue, as the revenue is deemed earned as reimbursable expenses are incurred. For the years ended December 31, 2016 and 2015, clinical services reimbursements were $6.4 million and $3.4 million, respectively.

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

License Fees: PCT and Hitachi also entered into an exclusive license agreement for Asia pursuant to which PCT received $5.6 million from Hitachi in 2016. PCT licensed to Hitachi certain cell therapy technology and know-how (including an exclusive license to use the PCT brand in Asia) and agreed to provide Hitachi with certain training and support. As additional consideration, Hitachi will pay PCT royalties on contract revenue generated in Asia for a minimum of 10 years. The initial term of the Hitachi License Agreement is 10 years and may be automatically extended for successive additional two year terms. The Company recognizes the payments as revenue on a straight-line basis over the initial 10-year term. For the year ended December 31, 2016, the Company recognized $0.5 million of license fee revenue. As of December 31, 2016, $0.6 million of Hitachi license fees were included in unearned revenue, and $4.6 million was included in unearned revenue - long-term.

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 Pronouncement

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, “Revenue from Contracts with Customers” (ASU 2014-09) and has subsequently issued a number of amendments to ASU 2014-09. The new standard, as amended, provides a single comprehensive model to be used in the accounting for revenue arising from contracts with customers and supersedes current revenue recognition guidance, including industry-specific guidance. The standard’s stated core principle is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve this core principle, ASU 2014-09 includes provisions within a five-step model that includes identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations, and recognizing revenue when, or as, an entity satisfies a performance obligation. In addition, the standard requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The new standard will be effective for us beginning January 1, 2018 and permits two methods of adoption: the full retrospective method, which requires the standard to be applied to each prior period presented, or the modified retrospective method, which requires the cumulative effect of adoption to be recognized as an adjustment to opening retained earnings in the period of adoption. The Company is currently evaluating the impact of the pending adoption of ASU 2014-09 on its consolidated financial statements and has not yet selected the transition method. The Company anticipates assigning internal resources to assist with the evaluation and implementation of the new standard, and will continue to provide updates during 2017.

In August 2014, FASB issued Accounting Standards Update (ASU) No. 2014-15 Presentation of Financial Statements - Going Concern (Subtopic 205-40), Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. Under generally accepted accounting principles (GAAP), continuation of a reporting entity as a going concern is presumed as the basis for preparing financial statements unless and until the entity's liquidation becomes imminent. Preparation of financial statements under this presumption is commonly referred to as the going concern basis of accounting. If and when an entity's liquidation becomes imminent, financial statements should be prepared under the liquidation basis of accounting in accordance with Subtopic 205-30, Presentation of Financial Statements - Liquidation Basis of Accounting. Even when an entity's liquidation is not imminent, there may be conditions or events that raise substantial doubt about the entity's ability to continue as a going concern. In those situations, financial statements should continue to be prepared under the going concern basis of accounting, but the provisions in this ASU

should be followed to determine whether to disclose information about the relevant conditions and events. The ASU was effective for us as of December 31, 2016.

In April 2015, the FASB issued ASU 2015-03, which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This ASU requires retrospective adoption and was effective for us beginning in our first quarter of 2016. The adoption of this standard did not have a material impact on our financial statements.

In November 2015, the FASB issued ASU 2015-17, Income Taxes (Topic 740). The ASU improves on the classification of deferred taxes on the balance sheet by eliminating the current requirement. The current requirement presents deferred tax liabilities and assets as current and noncurrent in a classified balance sheet or statement of financial position. Under the ASU, organizations will now be required to classify all deferred tax assets and liabilities as noncurrent. The amendments apply to all organizations that present a classified balance sheet. For public companies, these amendments are effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. The adoption of this standard did not have a material impact on our financial statements.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, "Leases" (ASU 2016-02). ASU 2016-02 provides accounting guidance for both lessee and lessor accounting models. Among other things, lessees will recognize a right-of-use asset and a lease liability for leases with a duration of greater than one year. For income statement purposes, ASU 2016-02 will require leases to be classified as either operating or finance. Operating leases will result in straight-line expense while finance leases will result in a front-loaded expense pattern. The new standard will be effective for us on January 1, 2019 and will be adopted using a modified retrospective approach which will require application of the new guidance at the beginning of the earliest comparative period presented. We are currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures.

Note 3 – Collaboration and Hitachi License Agreement

Hitachi

On March 11, 2016, PCT entered into a global collaboration with Hitachi. 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. Caladrius remains the majority stockholder retaining an 80.1% ownership interest.

PCT and Hitachi Chemical also entered into an exclusive license agreement for the acceleration of the creation of a global commercial cell therapy development and manufacturing expertise in Asia pursuant to which PCT received $5.6 million from Hitachi Chemical in three fee-driven payments during 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 will pay PCT royalties on contract revenue generated in Asia for a minimum of 10 years.

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

Note 4 – Available-for-Sale-Securitie

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, 2016				December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Certificate of deposits	$ —	$ —	$ —	$ —	$ 249.0	$ —	$ —	$ 249.0
Corporate debt securities	—	—	—	—	1,047.2	—	—	1,047.2
Money market funds	4,426.8	—	—	4,426.8	837.7	—	—	837.7
Municipal debt securities	—	—	—	—	4,740.9	0.8	—	4,741.7
Total	$ 4,426.8	$ —	$ —	$ 4,426.8	$ 6,874.8	$ 0.8	$ —	$ 6,875.6

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

	December 31, 2016	December 31, 2015
Cash and cash equivalents	$ 4,426.8	$ 6,875.6
Marketable securities	—	—
Total	$ 4,426.8	$ 6,875.6

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

	December 31, 2016	
	Amortized Cost	Estimated Fair Value
Less than one year	$ 4,426.8	$ 4,426.8
Greater than one year	—	—
Total	$ 4,426.8	$ 4,426.8

Note 5 – Deferred Costs

Deferred costs representing work in process for costs incurred on process development contracts that have not been completed, were $3.6 million and $2.9 million as of December 31, 2016 and December 31, 2015, respectively. The Company also has deferred revenue of approximately $4.0 million and $4.9 million of progress billings received as of December 31, 2016 and December 31, 2015, respectively, related to these contracts.

Note 6 – Property, Plant and Equipment

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

	December 31,	
	2016	2015
Building and improvements	$ 12,968.4	$ 11,478.6
Machinery and equipment	68.3	68.3
Lab equipment	8,045.5	7,461.2
Furniture and fixtures	2,288.8	2,320.9
Software	442.1	445.7
Leasehold improvements	1,753.8	2,831.5
Property, plant and equipment, gross	25,566.9	24,606.2
Accumulated depreciation	(8,417.8)	(7,541.4)
Property, plant and equipment, net	$ 17,149.1	$ 17,064.8

The Company’s results included depreciation expense of approximately $1.8 million and $2.1 million for the years ended December 31, 2016 and 2015, respectively.

Note 7 – Loss Per Share

For the years ended December 31, 2016 and 2015 the Company incurred net losses and therefore no common stock equivalents were utilized in the calculation of loss per share as they are anti-dilutive in the periods presented. At December 31, 2016 and 2015 the Company excluded the following potentially dilutive securities:

	December 31,	
	2016	2015
Stock Options	953,690	666,327
Warrants	388,062	321,403
Restricted Shares	126,849	20,278

Note 8 – 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 had no financial assets and liabilities that were accounted for at fair value on a recurring basis as of December 31, 2016 and December 31, 2015.

Note 9 – Goodwill and Other Intangible Assets

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

The Company's intangible assets and related accumulated amortization, all of which resides in the PCT reporting segment, as of December 31, 2016 and December 31, 2015 consisted of the following (in thousands):

		December 31, 2016			December 31, 2015		
	Useful Life	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Customer list	10 years	$ 1,000.0	$ (595.1)	$ 404.9	$ 1,000.0	$ (495.1)	$ 504.9
Manufacturing technology	10 years	3,900.0	(2,320.9)	1,579.1	3,900.0	(1,930.9)	1,969.1
Tradename	10 years	800.0	(476.1)	323.9	800.0	(396.1)	403.9
Total Intangible Assets		$ 5,700.0	$ (3,392.1)	$ 2,307.9	$ 5,700.0	$ (2,822.1)	$ 2,877.9

As of December 31, 2015, the Company determined that IPR&D valued at $34.3 million and goodwill valued at $18.2 million were impaired, as a result of the discontinuation of the Company's CLBS20 Phase 3 clinical study. As of June 30, 2015, the Company determined that IPR&D valued at $9.4 million was impaired as a result of the Company's decision that it would not pursue further development of CLBS10. Total intangible amortization expense was classified in the operating expense categories for the periods included below as follows (in thousands):

	Year Ended December 31,	
	2016	2015
Cost of revenue	$ 314.2	$ 316.8
Research and development	75.8	108.4
Selling, general and administrative	180.0	180.0
Total	$ 570.0	$ 605.2

Estimated intangible amortization expense on an annual basis for the succeeding five years is as follow (in thousands):

2017	$ 570.0
2018	570.0
2019	570.0
2020	570.0
2021	27.9
	$ 2,307.9

Note 10 – Accrued Liabilities

Accrued liabilities were as follow (in thousands):

	December 31,	
	2016	2015
Salaries, employee benefits and related taxes	$ 4,209.7	$ 2,771.2
Professional fees	224.5	480.7
Other	1,628.5	2,946.5
	$ 6,062.7	$ 6,198.4

Note 11 – Debt

Notes Payable

As of December 31, 2016 and December 31, 2015, the Company had notes payable of approximately $1.1 million and $1.8 million, respectively. The notes relate to certain insurance policies and equipment financings, require monthly payments, and mature within one to three years.

Long-Term Debt

On September 26, 2014, the Company entered into a loan and security agreement (the “Loan and Security Agreement”) with Oxford Finance LLC (together with its successors and assigns, the “Lender”) pursuant to which the Lender disbursed $15.0 million (the “Loan”). The debt offering/issuance costs have been recorded as debt issuance costs in other assets in the consolidated balance sheet, and will be amortized to interest expense throughout the life of the Loan using the effective interest rate method.

On March 11, 2016, upon the sale of a 19.9% membership interest in PCT to Hitachi America and our entry into a technology license agreement with Hitachi America (collectively, the “March 2016 Hitachi Transaction”), the Company and the Lender entered into an amendment to the Loan and Security Agreement whereby (i) the Company paid $7.0 million to Lender, comprising principal, interest and early termination fees, (ii) the Company's subsidiaries PCT, PCT Allendale, LLC, and NeoStem Family Storage, LLC (collectively the "Removed Borrowers") were removed as borrowers under the Loan, (iii) Lender's security interests in any and all assets of the Removed Borrowers were released, (iv) the interest only period on the remaining outstanding Loan balance was extended until January 1, 2017, and (v) in the event the Company received gross proceeds from the sale or issuance of any equity securities or subordinated debt, or any partnership, licenses, collaboration, dividend, grant or asset sale through March 31, 2017, 20% of such proceeds will be paid to Lender, up to a $3.0 million maximum as additional partial repayment of Loan. On September 14, 2016, concurrent with the Company's September 2016 Registered Direct Offering and Concurrent Private Placement (see Note 13), the Company repaid $3.0 million of such proceeds to the Lender. The outstanding balance was approximately $5.7 million and $15.0 million at December 31, 2016 and December 31, 2015, respectively.

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

Under the Loan and Security Agreement, the Lender holds a security interest ("Lenders' Security Interest") in all of the Company’s property, excluding the security interests in any and all assets of the Removed Borrowers, and excluding intellectual property and certain other assets and exemptions. The Lender also holds a security interest in the shares owned by the Company in the Company’s subsidiaries. The Loan and Security Agreement restricts the ability of the Company to: (a) convey, lease, sell, transfer or otherwise dispose of any part of Lenders' Security Interest and (b) incur any additional indebtedness. The Loan and

Security Agreement provides for standard indemnification of Lender and contains representations, warranties and certain covenants of the Company. Upon the occurrence of an event of default by the Company under the Loan and Security Agreement, Lender will have customary acceleration, collection and foreclosure remedies. There are no financial covenants associated to the Loan and Security Agreement. As of December 31, 2016, the Company was in compliance with all covenants under the Loan and Security Agreement.

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

Years Ending December 31,		(in thousands)
2017	$	3,126.5
2018		2,524.9
Total	$	5,651.4

During the years ended December 31, 2016 and 2015, the Company recognized $1.7 million and $1.3 million of interest expense related to the Loan and Security Agreement.

Note 12 – Redeemable Securities - Non-Controlling Interests

Under the March 2016 Hitachi Transaction (see Note 3), Hitachi America may, at any time following the tenth anniversary of the March 2016 Hitachi Transaction closing date on March 11, 2016, have the right on one occasion to require Caladrius or PCT to purchase all or some of the equity securities in PCT then held by Hitachi Chemical ("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 Chemical ownership interests increases subsequent to its initial ownership interest, and it offers to sell its equity holdings in excess of 21% of PCT's outstanding equity securities, then the Company shall be required to purchase all such equity holdings of Hitachi Chemical but in no event shall 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.

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

Note 13 – 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, 2016) 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, 2016:

	2003 Equity Plan	2009 Equity Plan	2015 Equity Plan
Shares Authorized for Issuance	25,000	899,500	440,000
Evergreen increase of shares	—	—	226,932
Outstanding Stock Options	(9,524)	(460,156)	(484,010)
Exercised Stock Options	(925)	(8,093)	—
Restricted stock or equity grants issued under Equity Plans	(8,922)	(156,467)	(125,715)
Shares Expired	(5,629)	(274,784)	—
Total common shares remaining to be issued under the Equity Plans	—	—	57,207

The Company adopted an employee stock purchase plan effective January 1, 2013, and authorized 50,000 shares under the plan. 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. During the year ended December 31, 2016, 25,535 shares were issued under the employee stock purchase plan. At December 31, 2016, the Company had 4,454 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 December 31, 2016, $6.6 million of the Initial Closing tranche was received, and 1,398,305 shares of common stock had been issued. As of December 31, 2016, the remaining $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. It is doubtful that any funds will be received from this investor, or whether we would agree to accept those funds on the original terms if offered.

Aspire Purchase Agreements

In November 2015, the Company entered into a common stock purchase agreement (the "Purchase Agreement") with Aspire Capital Fund, LLC, an Illinois limited liability company (“Aspire Capital”), which provides that, subject to certain terms and conditions and Nasdaq rules, Aspire Capital is committed to purchase up to an aggregate of $30 million of shares (limited to a maximum of approximately 1.1 million shares, unless stockholder approval is obtained or certain minimum sale price levels are reached) of the Company's common stock over a 24-month term. As of December 31, 2016, the Company has issued 109,270 shares of common stock under the Purchase Agreement with Aspire for gross proceeds of $0.3 million.

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

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

Stock Options and Warrants

The following table summarizes the activity for stock options and warrants for the year ended December 31, 2016, as adjusted for the Reverse Stock Split:

	Stock Options				Warrants			
	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (In Thousands)	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (In Thousands)
Outstanding at December 31, 2015	666,348	$ 64.60	6.88	$ 0.1	321,404	$ 137.20	1.26	$ —
Changes during the Year:								
Granted	464,815	$ 5.30			171,845	$ 9.30		
Exercised	—	$ —			—	$ —		
Forfeited	(70,513)	$ 32.70			251	$ 700.00		
Expired	(107,860)	$ 48.30			(105,438)	$ 152.70		
Outstanding at December 31, 2016	952,790	$ 39.90	7.60	$ —	388,062	$ 76.50	1.24	$ —
Vested at December 31, 2016 or expected to vest in the future	938,889	$ 40.3	7.58	$ —	388,062	$ 76.50	1.24	$ —
Exercisable at December 31, 2016	769,224	$ 46.2	7.27	$ —	388,062	$ 76.50	1.24	$ —

There were no options exercised during the years ended December 31, 2016 and December 31, 2015.

During the years ended December 31, 2016 and 2015, the Company did not issue warrants for services.

Restricted Stock

During the years ended December 31, 2016 and 2015, the Company issued restricted stock for services as follows ($ in thousands, except share data):

	2016	2015
Number of Restricted Stock Issued	126,849	92,800
Value of Restricted Stock Issued	$ 698.1	$ 2,488.6

The weighted average estimated fair value of restricted stock issued for services in the years ended December 31, 2016 and 2015 was $5.50 and $26.82 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 within one year.

Note 14 – 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, 2016 and 2015 ($ in thousands):

	Year Ended December 31,	
	2016	2015
Cost of revenues	$ 333.7	$ 545.3
Research and development	339.1	1,811.5
Selling, general and administrative	1,931.6	7,393.3
Total share-based compensation expense	$ 2,604.4	$ 9,750.1

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, 2016 were as follows ($ in thousands):

	Stock Options	Restricted Stock
Unrecognized compensation cost	$ 1,245.5	$ 382.3
Expected weighted-average period in years of compensation cost to be recognized	1.80	1.76

Total fair value of shares vested and the weighted average estimated fair values of shares granted for the years ended December 31, 2016 and 2015 were as follows ($ in thousands):

	Stock Options	
	Year Ended December 31,	
	2016	2015
Total fair value of shares vested	$ 2,359.8	$ 6,133.0
Weighted average estimated fair value of shares granted	3.23	19.50

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,	
	2016	2015
Expected term - minimum (in years)	5	2
Expected term - maximum (in years)	10	10
Expected volatility - minimum	73%	71%
Expected volatility - maximum	76%	75%
Weighted Average volatility	72%	74%
Expected dividend yield	—	—
Risk-free interest rate - minimum	1.70%	1.19%
Risk-free interest rate - maximum	2.19%	2.14%

Note 15 – Income Taxes

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,	
	2016	2015
United States	$ (33,171.5)	$ (98,254.0)
	$ (33,171.5)	$ (98,254.0)

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

	Years Ended December 31,	
	2016	2015
Current		
U.S. Federal	$ —	$ —
State and local	—	—
	$ —	$ —
Deferred		
U.S. Federal	$ 109.4	$ (14,695.5)
State and local	28.6	(2,548.0)
	$ 138.0	$ (17,243.5)
Total		
U.S. Federal	$ 109.4	$ (14,695.5)
State and local	28.6	(2,548.0)
	$ 138.0	$ (17,243.5)

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,	
	2016	2015
U.S. Federal benefit at statutory rate	$ (11,278.3)	$ (33,406.4)
State and local benefit net of U.S. federal tax	2,702.5	(4,926.9)
Permanent non deductible expenses for U.S. taxes	80.2	706.4
True-up of prior year net operating loss	(2,371.6)	(556.5)
Effect of change in deferred tax rate	(44.3)	1.3
Valuation allowance for deferred tax assets	11,049.5	20,938.6
Tax provision	$ 138.0	$ (17,243.5)

Deferred income taxes at December 31, 2016 and 2015 consist of the following ($ in thousands):

	December 31,	
	2016	2015
Deferred Tax Assets:		
Accumulated net operating losses (tax effected)	$ 91,455.7	$ 86,537.8
Deferred revenue	1,846.8	—
Deferred rent	314.6	11.1
Share-based compensation	13,747.3	12,764.3
Intangibles	897.8	899.7
Charitable contributions	424.2	423.3
Bad debt provision	—	297.4
Partnership interest	3,857.7	—
Capital loss carry-forward	6,988.1	6,973.0
Other	659.3	652.1
Deferred tax assets prior to tax credit carryovers	120,191.5	108,558.7
Deferred Tax Liabilities:		
Accumulated depreciation	$ (649.4)	$ (66.0)
Intangible and indefinite lived assets	(1,070.7)	(932.7)
Deferred tax liabilities	(1,720.1)	(998.7)
	118,471.4	107,560.0
Valuation reserve	(119,542.1)	(108,492.7)
Net deferred tax liability	$ (1,070.7)	$ (932.7)

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, 2016 and 2015, the Company had approximately $232.7 million and $221.5 million, respectively of Federal NOLs available to offset future taxable income expiring from 2027 through 2036. In accordance with Section 382 of the Internal Revenue code, the usage of the Company's NOLs could be limited in the event of a change in ownership. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period when those temporary differences become deductible. If a change of ownership did occur there would be an annual limitation on the usage of the Company's losses which are available through 2036.

The Company 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, 2016, management does not believe the Company has any material uncertain tax positions that would require it to measure and reflect the potential lack of sustainability of a position on audit in its financial statements. The Company will continue to evaluate its uncertain tax positions in future periods to determine if measurement and recognition in its financial statements is necessary. The Company does not believe there will be any material changes in its unrecognized tax positions over the next year.

The Company 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 16 – Segment Information

In connection with the contemplated sale of the remaining interest in PCT to Hitachi Chemical, we reorganized our financial reporting into two distinct reportable operating segments.

- The R&D Segment which develops early-stage cellular therapeutic candidates to treat certain diseases with the intention of partnering these candidates post proof-of-concept in humans.
- The PCT Segment which provides development and manufacturing services to the cell and cell-based gene therapy industry.

Each operating segment is individually reviewed and evaluated by our Chief Operating Decision Maker (CODM), who allocates resources and assesses performance of each segment individually. The CODM evaluates segment performance primarily based on loss from operations. The Company's Chief Executive Officer has been identified as the CODM.

The following table shows, by segment: net revenue, cost of sales, operating profit, depreciation and amortization, interest expense, income tax benefit (expense), and assets for the years ended December 31, 2016 and 2015 ($ in thousands):

	Year Ended December 31, 2016			Year Ended December 31, 2015		
	R&D Segment	PCT Segment	Total	R&D Segment	PCT Segment	Total
Net revenues	$ 14.0	$ 35,269.8	$ 35,283.9	$ 154.4	$ 22,333.1	$ 22,487.6
Cost of revenues	—	31,136.1	31,136.1	—	20,158.8	20,158.8
Operating loss	(29,502.0)	(1,833.8)	(31,335.8)	(112,181.1)	(1,668.1)	(113,849.2)
Depreciation and amortization	450.3	2,293.4	2,743.6	496.8	2,190.0	2,686.8
Interest expense	1,779.7	78.0	1,857.7	1,945.2	183.2	2,128.4
Provision (benefit) for income taxes	—	138.0	138.0	(17,430.1)	186.5	(17,243.5)
Total assets	$ 11,403.6	$ 40,429.3	$ 51,832.8	$ 23,635.0	$ 33,570.3	$ 57,205.3

Note 17 – Commitments and Contingencies

Lease Commitments

We lease facilities under various operating lease agreements in Basking Ridge, NJ, New York, NY, Irvine, CA, and Mountain View, 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, 2016 are as follows (in thousands):

Years ended	Operating Leases
2017	2,216.3
2018	1,723.5
2019	1,332.7
2020	792.1
2020 and thereafter	168.1
Total minimum lease payments	$ 6,232.7

Expense incurred under operating leases were approximately $2.1 million and $1.7 million for the years ended December 31, 2016 and 2015, respectively.

Contingencies

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

expense associated with general clinical monitoring services. For the remaining 92 patients in the study, we will continue to be responsible for the supply of all study drug and the costs of study enrollment for sites outside of the Sanford centers.

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

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

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

Note 18 – Subsequent Events

March 2017 Hitachi Transaction

Hitachi Chemical purchased a 19.9% membership interest in PCT on March 11, 2016 (see Note 3). On March 16, 2017, Caladrius entered into the Purchase Agreement, by and among Caladrius, PCT and Hitachi America, pursuant to which Hitachi America has agreed to acquire the 80.1% membership interest in PCT that it does not already own from Caladrius for $75.0 million in cash, subject to potential adjustment, based on PCT's cash and outstanding indebtedness as of the closing of the Sale, and a potential future milestone payment. Pursuant to the terms of the Purchase Agreement, at the Effective Date, Hitachi America will pay Caladrius $5.0 million Initial Payment. At the Closing, an additional $5.0 million of the Purchase Price will be deposited into an escrow account to cover potential indemnification claims of Hitachi America, if any. The Closing is subject to customary closing conditions, including approval of Caladrius' stockholders, and is expected to occur during the second quarter of 2017.

As part of the Purchase Price, Hitachi will pay Caladrius the $5.0 million Milestone Payment if PCT achieves $125.0 million in Cumulative Revenue (excluding clinical service reimbursables) for the period from January 1, 2017 through December 31, 2018. For purposes of the Milestone, "Cumulative Revenue" will be calculated based on PCT's revenue from all customers (including Caladrius and its subsidiaries) in accordance with the financial accounting and reporting standards set forth in the statements and pronouncements of the FASB, consistently applied.

Generally, in the event of a Change in Control of Caladrius (as defined in the 2009 Plan and the 2015 Equity Plan, and, together with the 2009 Plan, the "Equity Compensation Plans"), (a) all outstanding options and stock appreciation rights of each participant granted prior to the change in control shall be fully vested and immediately exercisable in their entirety, and (b) all unvested stock awards, restricted stock units, restricted stock, performance-based awards, and other awards shall become fully vested, including without limitation, the following: (i) the restrictions to which any shares of restricted stock granted prior to the change in control are subject shall lapse as if the applicable restriction period had ended upon such change in control, and (ii) the conditions required for vesting of any unvested performance-based awards shall be deemed to be satisfied upon such change in control. The approval of the Sale by our stockholders will result in a Change in Control under our Equity Compensation Plans. Accordingly, all outstanding unvested equity awards will be accelerated if the Sale is approved by our stockholders.

Retention Agreement with Robert A. Preti in Connection with the Sale

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 supersedes all prior agreements and understandings between Dr. Preti and Caladrius regarding the subject matter of the Retention Agreement. Among other things, the Retention Agreement provides for:

- Simultaneously with the Closing, Caladrius will pay to Dr. Preti $1.375 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 $1.375 million for the period from Closing until the date one year after the date of the Closing (the "Anniversary Date"), subject to Dr. Preti's continued employment with PCT through the Anniversary Date (the "Second Retention Payment").
- Dr. Preti will be entitled to 5% of the Milestone Payment if it is successfully earned.

All payments are contingent on Closing of the Sale.

California Institute of Regenerative Medicine Grant Award

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 total $12.2 million amount will become payable upon the achievement of certain milestones which are still under negotiation. We expect to receive $5.7 million in initial funding on April 1, 2017. CLBS03 has been granted Fast Track and orphan drug designations from the FDA as well as Advanced Therapeutic Medicinal Product ("ATMP") classification from the European Medicines Agency ("EMA").

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, 2016, we carried out an evaluation, with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of 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, 2016. 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, 2016, 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, 2016 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 "Managemetn 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 2017 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 2017 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 2017 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 2017 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

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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

54
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).
4.1	Registration Rights Agreement, dated as of March 10, 2014, by and between the Company and Aspire Capital Fund, LLC. (Filed as Exhibit 4.18 to the Company's Annual Report on Form 10-K filed with the SEC on March 13, 2014).
4.2	Registration Rights Agreement, dated as of May 4, 2015, by and between the Company and Aspire Capital Fund, LLC (filed as Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, as filed with the SEC on May 6, 2015).
4.3	Form of Trust Indenture (filed as Exhibit 4.5 to the Company's Registration Statement on Form S-3, filed no. 333-206175, filed with the SEC on August 6, 2015).
4.4	Form of Trust Indenture (filed as Exhibit 4.5 to the Company's Registration Statement on Form S-3, filed no. 333-206175, filed with the SEC on August 6, 2015).
4.5	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).
10.1	Common Stock Purchase Agreement, dated as of March 11, 2014, by and between the Company and Aspire Capital Fund, LLC. Filed as Exhibit 10.10 to the Company's Annual Report on Form 10-K filed on March 13, 2014).
10.2	Escrow Agreement, dated as of October 17, 2011, among the Company, Amorcyte, Inc., Paul J. Schmitt, as Amorcyte Representative, and Continental Stock Transfer & Trust Company, as Escrow Agent (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K dated October 14, 2011).
10.3	Lease dated September 1, 2005 between Vanni Business Park, LLC and PCT, as amended by First Amendment of Lease effective as of July 1, 2006 (filed as Exhibit 10.48 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 as filed with the SEC on April 6, 2011).
10.4	Second Amendment of Lease, executed July 11, 2011 and effective July 1, 2011, by and between Vanni Business Park, LLC and Progenitor Cell Therapy, LLC (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K dated July 11, 2011).
10.5	Guaranty of Lease, executed July 11, 2011 and effective as of July 1, 2011, by the Company for the benefit of Vanni Business Park, LLC (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K dated July 11, 2011).
10.6	First Amendment to Office Lease dated December 10, 2010, by and between WW VKO Owner, LLC and California Stem Cell, Inc; Second Amendment to Office Lease dated February 1, 2012, by and between CGGL 18301 LLC, and California Stem Cell, Inc. Third Amendment to Office Lease dated February 28, 2014, by and between CGGL 18301 LLC, and California Stem Cell, Inc.; and Fourth Amendment to Office Lease Agreement, executed December 19, 2014, effective April 1, 2015, by and between NeoStem, Inc. and CGGL 18301 LLC. (filed as Exhibit 10.9 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).
10.7	Stockholders' Agreement dated March 28, 2011, by and among PCT, Athelos Corporation and Becton Dickinson and Company (filed as Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2011 as filed with the SEC on May 17, 2011).
10.8†	Description of the Company's Board of Directors Compensation Policy. +
10.9	Loan and Security Agreement, dated September 26, 2014, by and between the Company and Oxford Finance LLC. (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K dated September 26, 2014).
10.10	Employment Agreement, dated as of September 23, 2010 and effective on January 19, 2011, by and between PCT, the Company, and Andrew L. Pecora, M.D., F.A.C.P. (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K dated January 18, 2011 and filed with the SEC on January 24, 2011). +

10.11 Employment Agreement, dated as of September 23, 2010 and effective on January 19, 2011, by and between PCT, the Company, and Robert A. Preti, PhD (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K dated January 18, 2011 and filed with the SEC on January 24, 2011). +

10.12 First Amendment to Employment Agreement, dated as of October 27, 2014, to Employment Agreement dated as of September 23, 2010 and effective on January 9, 2011, by and between PCT, the Company, and Robert A. Preti, PhD. (filed as Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 as filed with the SEC on October 30, 2014). +

10.13 Employment Agreement dated and effective as of December 22, 2015, to First Amendment to Employment dated as of October 27, 2014 to Employment Agreement dated as of September 23, 2010 and effective January 19, 2011, by and between the Company and Robert A. Preti, PhD (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K dated December 23, 2015).+

10.14 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).

10.15 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).+

10.16 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.+

10.17 Employment Agreement, dated as of July 23, 2013 and effective August 5, 2013, by and between the Company and Douglas W. Losordo, M.D. (filed as Exhibit 10.1 to the Company’s Current Report on Form 8-K dated August 5, 2013).+

10.18 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).+

10.19 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).+

10.20 Common Stock Purchase Agreement, dated as of May 4, 2015, by and between the Company and Aspire Capital Fund, LLC (filed as Exhibit 10.1 to the Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, as filed with the SEC on May 6, 2015).

10.21 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).

10.22 The Company 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).

10.23 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).

10.24 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).

10.25 Employment Agreement, dated and effective as of December 22, 2015, among PCT, the Company, and Robert Preti, PhD (filed as Exhibit 10.2 to the Company’s Current Report on Form 8-K filed with the SEC on December 23, 2015). +

10.26 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 Form10-Q. for the quarter ended March 31, 2016, filed with the SEC on May 5, 2016).

10.27 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).

10.28 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). (1)

10.29 Amended and Restated Employment Agreement, dated March 11, 2016, by and between Caladrius Biosciences, Inc. and Robert A. Preti, PhD (filed as Exhibit 10.4 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).

10.30 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).

10.31 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).

10.32 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).

10.33 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).

10.34 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).

10.35 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).

10.36 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).

10.37 Amendment to Employment Agreement, dated as of July 25, 2016, by and between the Company and Douglas W. Losordo, MD (filed as Exhibit 10.4 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).

10.38 Employment Agreement, dated as of August 9, 2016, by and between Caladrius Biosciences, Inc. and Douglas W. Losordo, MD (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on August 9, 2016).

10.39 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).

10.40 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).

10.41 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).

10.42 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).

14.1 Code of Ethics for Senior Financial Officers (filed as Exhibit 14.1 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 as filed with the SEC on April 6, 2011).

21.1† Subsidiaries of Caladrius Biosciences, Inc.

23.1† Consent of Grant Thornton LLP

31.1† Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

31.2† Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

32† 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

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+ 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 16, 2017.

CALADRIUS BIOSCIENCES, INC.

By:
/s/ David J. Mazzo, PhD

Name: David J. Mazzo
Title: 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 Chief Executive Officer (Principal Executive Officer)	March 16, 2017
/s/ Joseph Talamo Joseph Talamo	Senior Vice President, and Chief Financial Officer (Principal Financial and Accounting Officer)	March 16, 2017
/s/ Gregory Brown Gregory Brown, MD	Chair of the Board of Directors	March 16, 2017
/s/ Richard Berman Richard Berman	Director	March 16, 2017
/s/ Steven S. Myers Steven S. Myers	Director	March 16, 2017
/s/ Steven M. Klosk Steven M. Klosk	Director	March 16, 2017
/s/ Peter Traber Peter Traber, MD	Director	March 16, 2017
/s/ Eric Wei Eric Wei	Director	March 16, 2017

Exhibit 10.8

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 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 $20,000 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 $5,000 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 $10,000 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 be authorized to receive annually 15,000 stock options and 9,000 restricted stock units, vesting at one year from the grant date; and
- each newly appointed Board member shall be authorized to receive an initial equity grant of 22,500 stock options and 13,500 restricted stock units, with one-third vesting annually on each of the first, second and third anniversaries of the grant date.

Exhibit 21.1

Subsidiaries of Caladrius Biosciences, Inc.

Entity	Percentage of Ownership	Location
Caladrius Biosciences, Inc.	100%	United States of America
Stem Cell Technologies, Inc.	100%	United States of America
Amorcyte, LLC	100%	United States of America
PCT, LLC, a Caladrius Company	80.1%	United States of America
NeoStem Family Storage, LLC	80.1%	United States of America
Athelos Corporation (1)	97%	United States of America
PCT Allendale, LLC	80.1%	United States of America
NeoStem Oncology, LLC	100%	United States of America

(1) As of December 31, 2016, Becton Dickinson's ownership interest in Athelos Corporation was 1.6%.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated March 16, 2017, 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, 2016. 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 and 333-214607) 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 and File No. 333-215455).

/s/ GRANT THORNTON LLP

New York, New York
March 16, 2017

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 16, 2017

/s/ David J. Mazzo
David J. Mazzo, PhD
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 16, 2017

/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, 2016 (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 16, 2017

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

Dated: March 16, 2017

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