FORM 10-K

Caladrius Biosciences, Inc. - CLBS

Filed: March 15, 2016 (period: December 31, 2015)

Annual report with a comprehensive overview of the company

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2015

OR

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

For the Transition Period from _____ to _____

Commission File Number 001-33650

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

DELAWARE	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 ☐ No ☒

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 ☐ No ☒

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes ☒ No ☐

Indicate by check mark 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. ☐

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 ☐	Accelerated filer ☒
Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2015 (the last business day of the most recently completed second fiscal quarter) was approximately $94.6 million, computed by reference to the last sale price of $1.87 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 14, 2016, 59,030,599 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, including expanding our PCT business;
- whether a market is established for our cell-based products and services and our ability to capture a meaningful share of this market;
- scientific and medical developments beyond our control;
- our ability to obtain and maintain, as applicable, appropriate governmental licenses, accreditations or certifications or comply with healthcare laws and regulations or any other adverse effect or limitations caused by government regulation of our business;
- whether any of our current or future patent applications result in issued patents, the scope of those patents and our ability to obtain and maintain other rights to technology required or desirable for the conduct of our business; and our ability to commercialize products without infringing the claims of third party patents;
- whether any potential strategic or financial benefits of various licensing agreements will be realized;
- the results of our development activities;
- our ability to complete our other planned clinical trials (or initiate other trials) in accordance with our estimated timelines due to delays associated with enrolling patients due to the novelty of the treatment, the size of the patient population and the need of patients to meet the inclusion criteria of the trial or otherwise; and
- our ability to satisfy our obligations under our loan agreement.

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

Cell Therapy Development and Manufacturing

PCT is a leading cell therapy development and manufacturing provider (often called a contract development and manufacturing organization, or "CDMO"), specializing in cell and cell-based gene therapies. PCT offers high-quality development and manufacturing capabilities (e.g., current Good Manufacturing Practice (“cGMP”) manufacturing systems and facilities), quality systems, cell and tissue processing, logistics, storage and distribution) and engineering solutions (e.g., process and assay development, optimization and automation) to clients with therapeutic candidates at all stages of development. PCT produces clinical supplies and ultimately, intends also to produce commercial product for its clients. PCT has worked with over 100 clients and produced over 20,000 cell therapy products since it was founded seventeen 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. We currently operate facilities qualified under cGMPs in each of Allendale, New Jersey and Mountain View, California, including EU-compliant production capacity. On March 11, 2016, PCT entered into a strategic collaboration and license agreement with Hitachi Chemical to accelerate the creation of a global commercial cell therapy development and manufacturing enterprise with deep engineering expertise. PCT is positioned to expand its capacity both in the United States and internationally, as needed. As the industry continues to mature and a growing number of cell therapy companies approach commercialization, we believe that PCT is well positioned to serve as an external manufacturing partner of choice for commercial-stage cell therapy companies.

CLBS03

We are developing strategically, through the utilization of our core development and manufacturing expertise, a product candidate that is an innovative therapy for type 1 diabetes mellitus ("TID"). This therapy is based on a proprietary platform technology for immunomodulation. We have selected as an initial target the unmet medical need of pediatric patients who are newly diagnosed with T1D. This program is based on the use of 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 viruses and other foreign antigens. When Tregs function properly, only harmful foreign materials are attacked by T effector cells. In autoimmune disease, however, it is thought that deficient Treg activity and numbers permit the T effector cells to attack the body's own beneficial cells. In the case of T1D, there are currently no curative treatments, only lifelong insulin therapy, which often does not prevent serious co-morbidities. Two Phase 1 clinical trials of this technology in T1D demonstrated safety and tolerance, feasibility of manufacturing, an implied durability of effect and an early indication of efficacy through the preservation of beta cell function. In the first quarter of 2016 we expect to commence patient enrollment in the first of two cohorts in The Sanford Project: T-Rex Study, a Phase 2 prospective, randomized, placebo-controlled, double-blind clinical trial to evaluate the safety and efficacy of our Treg product candidate, CLBS03, in adolescents with recent onset T1D. After the three-month follow-up of the first cohort of 18 patients, which is expected in early 2017, an initial safety analysis of the data and early analysis of immunological biomarkers will be undertaken. Satisfactory evaluation of the safety of the initial cohort as agreed by us, our independent Data Safety Monitoring Board and the U.S. Food and Drug Administration ("FDA") will then prompt the enrollment of the remaining 93 patients. A subsequent interim analysis of efficacy is planned after approximately 50% of patients

reach the six-month follow-up milestone. We have 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.

Additional Technology Platforms

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

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

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.

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 is 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. We are seeking to expand our manufacturing facilities internationally.

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 our in-house team.

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 Chemical has purchased a 19.9% equity interest in PCT for $19.4 million. We retain the remaining 80.1% ownership of PCT. 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 license agreement, Hitachi Chemical will pay PCT $5.6 million in upfront and fee driven payments, each of which is expected to be achieved in 2016. In addition, Hitachi Chemical will pay service fees and royalties on contract revenue in those territories. Under the license arrangement, Hitachi Chemical 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. By leveraging this expanded footprint, we believe PCT's clients will gain access to the cell and cell-based gene therapy markets of tomorrow, where we expect engineering solutions to process optimization and automation will play a seminal role worldwide.

Our Experience and Expertise

Our 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 our 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 17 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: We develop innovative long-term solutions to the unique challenges of cell therapy manufacturing through our Center for Innovation & Engineering. We accelerate 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 continue to shift towards Phase 2 and Phase 3 trials

and into commercial distribution if regulatory approvals are obtained. As this industry continues to develop and mature, we believe PCT is well positioned to capture a meaningful share of this potentially larger, more profitable market. To meet this coming demand, we are exploring opportunities to expand internationally.

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 our Center for Innovation & Engineering, we 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.

We are 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 our internal core of engineering and innovation expertise, we are 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, we believe that we 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, we are 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 2016. 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 compliant quality systems. The Allendale facility also has been designed to be compliant with European Medicines Agency ("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 we do not currently possess, though we are pursuing such. We also face competition from a number of other manufacturers that are somewhat smaller in size and have fewer resources than does 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. To be successful, we 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. Our ability to achieve this and to successfully compete against other manufacturers will depend, in large part, on our success in expanding PCT's 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

We provide 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.

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 2016, the Alliance for Regenerative Medicine recognizes over 670 regenerative medicine companies worldwide, which includes gene and cell therapy developers, and over 630 clinical trials.

All living complex organisms start as a single cell that replicates, differentiates (matures) and perpetuates 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, 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 is 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, comprising a data license and patent license, has advanced our Treg Program to a Phase 2 trial, expected to initiate 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.

The clinical trial provided preliminary safety and feasibility data that support developing 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.

In the first quarter of 2016 we expect to commence patient enrollment 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 in two cohorts comprising of 18 patients and 93 patients, respectively. An initial safety analysis of the data and early analysis of immunological markers will occur after the treatment and the three month follow-up visit of the first 18 patients is completed, which is expected in early 2017. Satisfactory evaluation of the safety of the initial cohort as agreed by us, our independent Data Safety Monitoring Board and the FDA will then prompt the enrollment of the remaining 93 patients. An interim efficacy analysis is expected after approximately 50% of patients reach the six month follow-up milestone.

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 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 therapeutic that can modify the course of T1D will potentially achieve significant cost savings, and thus command high market penetration and premium pricing. 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 in the near term.

Currently, there are no approved therapies for T1D but only treatments designed to address the symptoms of the disease. There are many 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. The pipeline for all novel agents is skewed towards early development, including ultra-low dosing of Interleukin-2, which increases the number of tolerogenic cells and which has been advanced to phase 2 by ILTOO Pharma. Also in early development are beta-cell replacement therapies, such as that of ViaCyte, Inc., which employ technologies that protect transplanted beta-cells from immune attack.

TECHNOLOGY OUT-LICENSING OPPORTUNITIES

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 recently discontinued our Phase 3 clinical investigation of CLBS20, a candidate based on this technology, 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 CLBS 20 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.

Immuno-Oncology Intellectual Property

We own the following intellectual property:

- Portfolio of one foreign issued patent (Singapore), nine granted U.S. patents, approximately 16 U.S. pending patent applications and approximately 85 foreign. 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;
    - 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.

Market Opportunity and Competition

The melanoma therapeutics market across the U.S., EU and Japan was estimated to be $950 million in 2012 and is expected to grow to reach $2.75 billion by 2022, according to Decision Resources' Malignant Melanoma 2013 report. The field of developing treatments for melanoma is highly competitive. Several recently approved approaches have demonstrated improved clinical benefits in melanoma, including ipilimumab, an anti-CTLA-4 antibody (Bristol-Myers Squibb) and anti-PD-1 antibodies, nivolumab and pembrolizumab (Bristol-Myers Squibb and Merck, respectively). These products represent a new class of “immunotherapeutics” and have novel mechanisms of action targeting immune checkpoints. BRAF enzyme inhibitors include vemurafenib, marketed by Roche and dabrafenib from GlaxoSmithKline. Also recently approved is trametinib, a mitogen-activated protein kinase ("MEK") from GlaxoSmithKline. These therapies target critical intracellular protein pathways. In addition to the immune checkpoint modulators, several companies, including Amgen, Northwest Biotherapeutics, ImmunoCellular Therapeutics and Argos Therapeutics are developing therapeutic vaccines that act by priming a person’s immune system to recognize and attack cancer cells.

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 new 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 clinical trial for which we are seeking a partnership to fund execution. We have secured manufacturing space in Kobe, Japan to evaluate a potential CD34 cell therapy program in CLI and a small team of regulatory professionals in Japan who work with us in all interactions with the PMDA and Ministry of Health, Labour and Welfare ("MHLW").

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.

In mid 2015, we entered into an agreement with SPS Cardio, LLC to out-license the patent and commercialization rights to our CD34 ischemic repair technology for the indications of acute myocardial infarction ("AMI") and CHF in selected non-U.S. territories. SPS is a venture capital firm that will fund this technology's further development in these indications and designated countries. SPS intends to initiate, and subsequently to enroll and complete, a Phase 2 proof-of-concept clinical trial in India for the treatment of CHF. This trial will be conducted under internationally-accepted norms of cGMP and in such a fashion that the data will be acceptable for use as part of regulatory submissions to the FDA and other international regulatory authorities. We will be eligible to receive royalties together with a milestone upon successful development and commercialization of any product eventually sold in the territories.

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, refractory angina and Syndrome X.

Ischemic Repair (CD34 Cell) Intellectual Property Platform

Our developed and owned ischemic repair patent portfolio is comprised of the following:

- 9 U.S. patents, 2 EU patents (each filed in 11 individual countries) and 12 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
- 2 U.S. and 12 outside the U.S. patent applications 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 100,000 in the EU and 20,000 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. Pluristem Therapeutics Inc. and Stempeutics Research Pvt. Ltd. are examples of two companies also seeking to launch or evaluating the potential to launch clinical trials in Japan for allogeneic cell therapy product candidates for CLI.

Immune Modulation (T Regulatory Cell Technology)

Our Treg technology platform is potential applicable to multiple autoimmune and allergic diseases beyond our current target indication of TID. Asthma, another condition caused by an imbalance in the immune system, occurs when excessive inflammation is triggered in the lungs resulting in constriction of the airways and difficulty breathing. The causes of asthma are complex, though it is known that over-activity of T-helper type 2 ("Th2") cells is a common feature. Th2 cells secrete the inflammatory signals that lead to the symptoms of asthma. Existing evidence indicates that Treg cells may regulate Th2 activity and therefore may have a beneficial effect on severe asthma. 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 also other indications in which we believe Tregs may have a meaningful therapeutic effect.

Immune Modulation Intellectual Property Platform

We have assembled a patent portfolio through licenses from leaders in the field of Tregs (The University of Pennsylvania/Carl June, Bruce Blazar, et al and the UCSF/Jeffrey Bluestone et al) comprised of:

- 12 patents and 6 pending patent applications;
- Claims covering many facets of Tregs, including:
  - composition claims to engineered antigen presenting cells ("APCs");
  - methods of Treg isolation, expansion and activation/stimulation as sourced from peripheral blood and cord blood; and
  - methods of treating or preventing certain conditions and/or diseases, including Type 1 diabetes, organ transplant rejection, and GVHD using Tregs.
- Patents and applications cover international geographies (U.S., EU, Japan, China, Australia, Canada).
- An option on patent licenses to critical reagents employed in Treg therapeutic development.

Topical Aesthetics (Dermatological Technology)

Our aesthetics program, based on expertise in cellular therapy and manufacturing, developed 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 intends to commercialize 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 will receive royalties on net sales.

Topical Aesthetics Intellectual Property Platform

We own the following intellectual property:

- Portfolio of 3 granted and 6 pending patent applications for manufacturing a dermatological product, including:
  - Stem cell growth media and methods of making and using same;
  - Stem Cell Compositions for Cosmetic and Dermatologic Use
- The portfolio is international, including filings in the U.S., EU, Canada and Hong Kong

Neurological Regeneration

Our intellectual property portfolio provides the opportunity for research collaboration for a variety of neurological disorders such as traumatic brain injury and spinal cord injury.

In February 2015, we licensed to Sacred Cells Research Partners, LLC (Sacred Cells) the exclusive rights in the field of use for spinal cord injury to our neuronal progenitor cell product technology, which technology Sacred Cells intends to develop and make commercially available. We will receive payments throughout its clinical development and royalties on gross sales.

Neurological Regeneration Intellectual Property Platform

We own the following intellectual property:

- Portfolio of 3 granted and 2 pending patent 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 U.S. and the EU.

GOVERNMENT REGULATION

The health care industry is one of the most highly regulated industries in the U.S. 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; 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 meet certain criteria such as if the cells or tissues are more than minimally manipulated or if they are intended for a non-homologous use. 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.

Stem Cell Therapeutic and Research Act of 2005

The Stem Cell Therapeutic and Research Act of 2005 established a national donor bank of cord blood and created a national network for matching cord blood to patients. The National Marrow Donor Program ("NMDP") carries out this legislation, which entails acting as the nation's Cord Blood Coordinating Center and actively recruiting parents for cord blood donations. The NMDP also administers the National Cord Blood Inventory ("NCBI"), which has a goal of collecting 150,000 cord blood units that could be used to treat patients all over the United States. Importantly, the legislation also authorized federal funding to support the legislation's goals for collecting cord blood units.

Pharmaceutical and Biologic Products

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 biological products such as CLBS10, CLBS20 and CLBS03D. 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 CLBS10, CLBS20, CLBS03D 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 biologics are associated with similar approval risks and costs as drugs.

Failure to comply with applicable United States 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.

Pharmaceutical and biologic product development in the U.S. typically involves preclinical laboratory and animal tests, the 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 practice, or GCP, 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; as well as under 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 clinical trials of FDA regulated products, including drugs and biologics, are required to register and disclose certain clinical trial information. 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 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, or IRB, 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*: Studies 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*: Studies 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 studies.

After completion of the required clinical testing, a 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 U.S. 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, the submission of most NDAs or BLAs is additionally subject to a substantial application user fee, currently exceeding $2,335,000, and the manufacturer and/or sponsor under an approved new drug application are also subject to annual product and establishment user fees, currently exceeding $110,000 per product and $569,000 per establishment. These fees are typically increased 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 it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs and BLAs. Most such applications for standard review drug or biologic products are reviewed within ten to twelve months; most applications for priority review drugs or biologics are reviewed in six to eight months. FDA can extend these reviews by three months. Priority review can be applied to drugs or biologics that the FDA determines offer major advances in treatment, or provide

a treatment where no adequate therapy exists. For biologics, priority review is further limited only for products intended to treat a serious or life-threatening disease relative to the 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 it generally follows such recommendations.

Before approving a NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. 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 cGMP - a quality system regulating manufacturing - is satisfactory and the NDA or BLA contains data that provide substantial evidence that the drug or biologic is safe and effective in the indication studied.

After the FDA evaluates the NDA or BLA and the manufacturing facilities, it 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 resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in 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 U.S. 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 product, including cellular therapies comprised of HCT/Ps. These laws and regulations include requirements for cGMP. These requirements are designed to ensure that a facility's processes - and products resulting from those processes - meet defined safety requirements. The cGMP requirements are federal regulations that govern the manufacture, processing, packaging and holding of drug and cell therapy products.

The objective of compliance with cGMP standards is to protect the public health and safety by ensuring that 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.

A central focus of the cGMP requirements is to design and build quality into the manufacturing processes and the facilities in which products are produced and to ensure the consistency, product integrity, and reproducibility of results and product characteristics. This is done by implementing quality systems and processes including 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 cGMPs. 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 requirements of remedial action, and, in the case of failures that are more serious, suspension of manufacturing operations, seizure, 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 can affect us directly 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 U.S. for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent 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 are 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, 2015, we had 221 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 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, 2015, we have incurred aggregate net losses of approximately $372.1 million. Our net losses attributable to common stockholders for the years ended December 31, 2015 and December 31, 2014 were approximately $80.9 million and $54.9 million, respectively. As of December 31, 2015, our cash and cash equivalents were $20.3 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.

Our research and development expenses increased significantly over the past three years as a result of conducting the PreSERVE AMI Phase 2 clinical trial of CLBS10 (formerly NBS10) for which we reported primary analysis results in November 2014. In addition, although we initiated dosing of a Phase 3 clinical trial for CLBS20 for metastatic melanoma in 2015, that trial was subsequently terminated in January 2016. We are preparing for the initiation of a Phase 2 clinical trial of CLBS03D for diabetes 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 do so, we will need to raise additional capital, enter into collaboration agreements with third parties or undertake any combination thereof. If we are unsuccessful in our efforts to raise capital or find collaborative partners, we will likely need to otherwise delay or abandon the trials.

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

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

Compliance with public company obligations, including the securities laws and regulations, is costly and requires significant management resources, and we may fail to comply. We are an "accelerated filer," and no longer qualify to report under smaller reporting company disclosure rules, and as a result are subject to more comprehensive disclosure obligations, with increased compliance costs.

The federal securities laws and regulations, including the corporate governance and other requirements of the Sarbanes-Oxley Act of 2002, impose complex and continually changing regulatory requirements on our operations and reporting. Because the aggregate market value of our public float was in excess of $75 million as of June 30, 2013, we became an "accelerated filer" as of the end of our 2013 fiscal year. As a result, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, our independent registered public accounting firm auditing our financial statements is now required to attest to and report on the effectiveness of our internal controls over financial reporting. The auditor attestation requirement applied to us for the first time with the filing of our Annual Report on Form 10-K for 2013. In addition, beginning with our Form 10-Q for March 31, 2014, we were required to satisfy all of the accelerated filer disclosure requirements. These requirements will increase our legal compliance obligations and costs, which could harm our results of operations and divert management's attention from business operations.

Relatively speaking, we are a small company with limited resources. There can be no assurances that we will be able to comply with the added "accelerated filer" requirements by applicable deadlines and to maintain compliance in the future. If our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal control over financial reporting for future year ends, investors could lose confidence in the reliability of our financial reporting.

RISKS RELATED TO OUR MANUFACTURING BUSINESS

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 studies, 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 cGMP. Manufacturers of cell-based product candidates such as CLBS03 also must comply with cGTP. In addition, therapeutic products may be required to modify their manufacturing process 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 Co. America, Ltd. and Hitachi Chemical Co., Ltd. (collectively "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 U.S. 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 Chemical will lead development and commercialization activities in Asia for our PCT business. Failure by Hitachi Chemical 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 Chemical 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 Chemical 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 Chemical 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 Chemical 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 Chemical 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 Chemical 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 type 1 diabetes (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 critical limb ischemia (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.

We plan to initiate in early 2016 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 studies 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 study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required Institutional Review Board, or 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's good clinical practices requirements, or cGCPs, or applicable requirements in other countries;
- 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 studies 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. For example, we expect to initiate enrollment for the Phase 2 trial of CLBS03 in the first quarter of 2016, but this could fail to occur for any number of reasons. 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 U.S. 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 submitted a request to the FDA for Fast Track designation for CLBS03 in February 2016. The FDA may take up to 60 days to release its decision with respect to a Fast Track application. 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.

PCT will exclusively provide 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 CLBS10 and 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 studies 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.

Despite being in business for over eight years, 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 recent onset Type 1 diabetes, 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. Current approaches include immune modulatory agents aiming to improve metabolic function by rescuing insulin producing beta cells, as well as regenerative agents that are hoping to replace beta cells altogether. There are many novel agents in early development, including ultra-low dose of Interleukin-2, which has been advanced to phase 2 by ILTOO Pharma. Also in early development are beta-cell replacement therapies such as that of ViaCYTE, Inc., which employ technologies that protect transplanted beta-cells from immune attack. 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 prospects.

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 its safety and efficacy, 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, generally 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 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
- 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, as well as 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 comprised of 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, or 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 a serious adverse event 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 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, 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.

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. Therefore there is a risk 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, 2015 through March 14, 2016 our common stock traded as low as $0.48 per share and as high as $4.17 per share; in 2014, our common stock traded as low as $3.08 per share and as high as $8.29 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, 2015, there were 56,733,012 shares of our common stock outstanding. In addition, there were outstanding stock options and warrants representing the potential issuance of an additional 9,877,303 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.

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. Commencing January 2016 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 (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. 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 three cell therapy manufacturing facilities, in Allendale, New Jersey, in Mountain View, California, and in Irvine, 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 comprised of (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 the third quarter of 2016. 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 2017. 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%.

The Irvine facility is approximately 16,000 square feet. It consists of office space and is also a manufacturing facility with four clean rooms. It maintains test methods and proprietary media that enable controlled, cGMP-compliant production of critical, high-purity cell product(s). The base monthly rent is approximately $38,000. With the discontinuation of CLBS20, which was being manufactured principally in this location, we have engaged a broker to seek a sublease or assign the leasehold on the Irvine space to a new tenant.

Subject to having sufficient capital resources, our longer-term plans include the acquisition and development of other facilities within and outside of the United States, to be developed into replicable and scalable manufacturing facilities, strategically located to best serve our and our clients' needs. Inherent in the nature of cell therapy today is the biologic shelf life of the cell therapy product itself. This limits the transit times between the time the cell product is extracted from a patient until it arrives at a manufacturing facility and the time that a processed product leaves the manufacturing facility and arrives for re-infusion in the patient. Therefore, it is preferable for cell therapy manufacturing facilities to be located in major population centers and within close proximity of major airport hubs.

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.

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.

2015	High	Low
First Quarter	$4.26	$2.53
Second Quarter	$3.47	$1.80
Third Quarter	$2.03	$1.10
Fourth Quarter	$1.56	$1.01

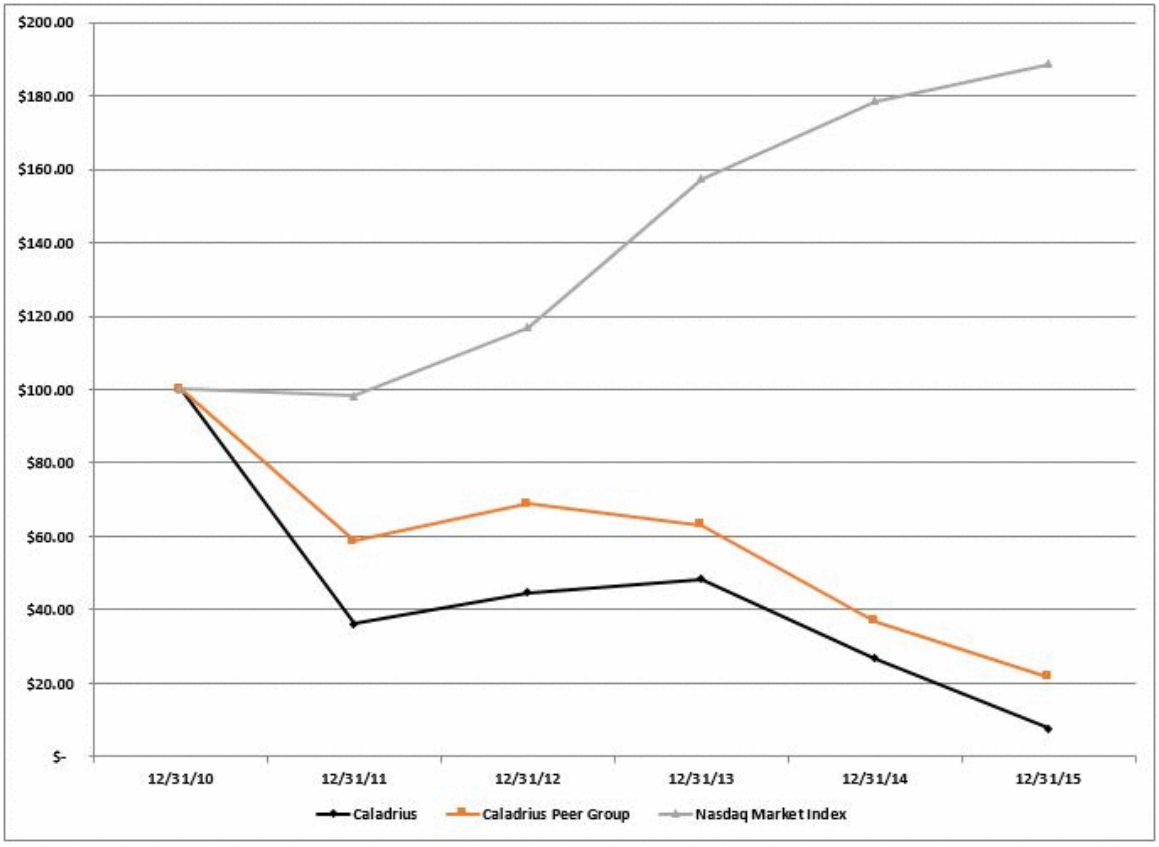
2014	High	Low
First Quarter	$8.29	$6.23
Second Quarter	$7.39	$4.56
Third Quarter	$6.68	$5.10
Fourth Quarter	$7.22	$3.08

On March 14, 2016, the last reported price of our common stock was $0.95 per share.

Performance Graph

Set forth below is a line graph comparing changes in the cumulative total return over the past five years on (i) Caladrius's common stock, (ii) a broad market index (the NASDAQ Market Index), and (iii) a peer group consisting the following companies in the biotechnology industry: Aastrom Biosciences, Inc., Athersys, Inc., Cytori Therapeutics, Inc., Immunocellular Therapeutics Ltd., Opexa Therapeutics, Inc., and Stemcells, Inc. (the "Peer Group"), for the period commencing on December 31, 2010 and ending on December 31, 2015 (1).

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
Assumes Initial Investment of $100



*$100 invested on 12/31/10 in stock or index, including reinvestment of dividends.

Caladrius/Market/Index	12/31/2010	12/31/2011	12/31/2012	12/31/2013	12/31/2014	12/31/2015
Caladrius, Inc.	$100.00	$36.17	$44.68	$48.37	$26.74	$7.66
NASDAQ Market Index	$100.00	$58.70	$68.83	$63.01	$36.76	$21.61
Peer Group	$100.00	$98.20	$116.88	$157.44	$178.53	$188.75

(1) Assumes that $100 was invested on December 31, 2010 in our common stock and each index, and that all dividends were reinvested. No cash dividends have been declared on our common stock. Shareholder returns over the indicated period should not be considered indicative of future shareholder returns.

Holders

As of February 29, 2016, 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, 2015 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)	6,663,270	$6.46	5,459,206	(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

None

ITEM 6. SELECTED FINANCIAL DATA.

The following selected financial data are derived from our consolidated financial statements. Unless otherwise noted, all information in the discussion and references to years are based on our fiscal year, which ends on December 31. The following data should be read in conjunction with Item 7., "Management's Discussion and Analysis of Financial Condition and Results of Operations," and Item 8., "Financial Statements and Supplementary Data." These items include discussions of factors affecting comparability of the information shown below.

(in thousands, except per share data)	Year Ended December 31,				
Consolidated Statement of Income Data:	**2015**	**2014**	**2013**	**2012**	**2011**
Revenues	$ 22,488	$ 17,939	$ 14,668	$ 14,330	$ 10,050
Total operating costs and expenses	$ 136,337	$ 75,680	$ 51,477	$ 44,716	$ 44,055
Net loss from continuing operations	$ (81,011)	$ (55,466)	$ (39,485)	$ (36,101)	$ (34,566)
Net loss from continuing operations attributable to Caladrius Biosciences, Inc. common stockholders	$ (80,886)	$ (54,873)	$ (38,981)	$ (35,814)	$ (34,267)
Basic and diluted loss from continuing operations per share attributable to Caladrius Biosciences, Inc. common stockholders	$ (1.67)	$ (1.68)	$ (1.90)	$ (2.59)	$ (3.87)
Weighted average common shares outstanding	48,508	32,756	20,496	13,842	8,860

Consolidated Balance Sheet Data:	**2015**	**2014**	**2013**	**2012**	**2011**
Cash, cash equivalents, and marketable securities	$ 20,318	$ 26,254	$ 46,134	$ 13,737	$ 3,935
Assets related to discontinued operations (current and long-term)	$ —	$ —	$ —	$ —	$ 107,938
Total assets	$ 57,205	$ 126,275	$ 89,816	$ 54,406	$ 155,328
Long-term debt (current and long-term)	$ 15,000	$ 15,000	$ —	$ —	$ —
Mortgages payable (current and long-term)	$ —	$ —	$ 3,237	$ 3,438	$ 3,635
Notes payable (current and long-term)	$ 1,776	$ 1,643	$ 912	$ 374	$ 148
Convertible Redeemable Series E Preferred Stock	$ —	$ —	$ —	$ —	$ 4,811
Liabilities for acquisition-related contingent consideration	$ —	$ 18,260	$ 9,450	$ 7,550	$ 3,130
Liabilities related to discontinued operations (current and long-term)	$ —	$ —	$ —	$ —	$ 54,554
Total stockholders' equity	$ 23,714	$ 58,074	$ 62,026	$ 32,820	$ 80,133

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

Cell Therapy Development and Manufacturing

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

CLBS03

We are developing strategically, through the utilization of or core development and manufacturing expertise, a product candidate that is an innovative therapy for type 1 diabetes mellitus ("TID"). This therapy is based on a proprietary platform technology for immunomodulation. We have selected as an initial target the unmet medical need of pediatric patients who are newly diagnosed with T1D. This program is based on the use of 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 viruses and other foreign antigens. When Tregs function properly, only harmful foreign materials are attacked by T effector cells. In autoimmune disease, however, it is thought that deficient Treg activity and numbers permit the T effector cells to attack the body's own beneficial cells. In the case of T1D, there are currently no curative treatments, only lifelong insulin therapy, which often does not prevent serious co-morbidities. Two Phase 1 clinical trials of this technology in T1D demonstrated safety and tolerance, feasibility of manufacturing, an implied durability of effect and an early indication of efficacy through the preservation of beta cell function. In the first quarter of 2016 we expect to commence patient enrollment in the first of two cohorts in The Sanford Project: T-Rex Study, a Phase 2 prospective, randomized, placebo-controlled, double-blind clinical trial to evaluate the safety and efficacy of our Treg product candidate, CLBS03, in adolescents with recent onset T1D. After the

three-month follow-up of the first cohort of 18 patients, which is expected in early 2017, an initial safety analysis of the data and early analysis of immunological biomarkers will be undertaken. Satisfactory evaluation of the safety of the initial cohort as agreed by us, our independent Data Safety Monitoring Board and the U.S. Food and Drug Administration ("FDA") will then prompt the enrollment of the remaining 93 patients. A subsequent interim analysis of efficacy is planned after approximately 50% of patients reach the six-month follow-up milestone. We have 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.

Additional Technology Platforms

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

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

Results of Operations

Year Ended December 31, 2015 Compared to Year Ended December 31, 2014

Net loss for the year ended December 31, 2015 was approximately $81.0 million compared to $55.5 million for the year ended December 31, 2014. 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).

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, 2015, total revenues were approximately $22.5 million compared to $17.9 million for the year ended December 31, 2014, representing an increase of $4.5 million, or 25%. Revenues were comprised of the following (in thousands):

	Year Ended December 31,	
	2015	2014
Clinical Services	$ 14,830.9	$ 10,442.9
Clinical Services Reimbursables	3,432.2	3,725.0
Processing and Storage Services	4,104.4	3,770.9
Other	$ 120.0	$ —
	$ 22,487.6	$ 17,938.8

- Clinical Services, representing *process development* and *clinical manufacturing* services provided at PCT to its various clients, were approximately $14.8 million for the year ended December 31, 2015, compared to $10.4 million for the year ended December 31, 2014, representing an increase of approximately $4.4 million or 42%. The increase was primarily due to $4.1 million of higher clinical manufacturing revenue (which is recognized as services are rendered), and to a lesser extent, $0.3 million of higher process development revenue (such revenue being recognized on a "completed contract" basis).

    - *Clinical Manufacturing Revenue* - Clinical manufacturing revenues were approximately $10.5 million for the year ended December 31, 2015, compared to $6.4 million for the year ended December 31, 2014. 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 $4.4 million for the year ended December 31, 2015, compared to $4.0 million for the year ended December 31, 2014. During the year ended December 31, 2015, 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, 2015, approximately $4.9 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, representing reimbursement of expenses for certain consumables incurred on behalf of our clinical service revenue clients, were approximately $3.4 million for the year ended December 31, 2015, compared to $3.7 million for the year ended December 31, 2014, representing a decrease of approximately $0.3 million or 8%. 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, primarily representing revenues from our oncology stem cell processing, were approximately $4.1 million for the year ended December 31, 2015, compared to $3.8 million for the year ended December 31, 2014, representing an increase of approximately $0.3 million or 9%. The increase is primarily due to increased volume and pricing for the processing services.

Operating Costs and Expenses of Revenues

For the year ended December 31, 2015, operating expenses totaled $136.3 million compared to $75.7 million for the year ended December 31, 2014, representing an increase of $60.7 million or 80%. Operating expenses were comprised of the following:

- Cost of revenues were approximately $20.2 million for the year ended December 31, 2015, compared to $15.7 million for the year ended December 31, 2014, representing an increase of $4.5 million or 29%. The increase is primarily due to increased clinical services costs to support our customer's process development and clinical manufacturing efforts, as well as additional investment in our internal facilities and capabilities. Overall, gross profit for the year ended December 31, 2015 was $2.3 million or 10% of 2015 revenues, compared to gross profit for the year ended December 31, 2014 of $2.3 million or 13% of 2014 revenues. Gross profit percentages generally will increase as clinical service revenue increases. 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 were approximately $23.9 million for the year ended December 31, 2015 compared to $29.2 million for the year ended December 31, 2014, representing a decrease of approximately $5.3 million, or 18%.

    - *Immuno-oncology* - Immuno-oncology expenses, which are primarily associated with the Intus Phase 3 clinical trial for the immunotherapy product candidate CLBS20, were $9.9 million for the year ended December 31, 2015, representing an increase of $3.0 million compared to the year ended December 31, 2014. The targeted cancer immunotherapy program was acquired in the acquisition (the "CSC Acquisition") of California Stem Cell, Inc. ("CSC") in May 2014. In January 2016, we discontinued the clinical development of CLBS20.

- *Ischemic Repair* - Ischemic repair expenses were $6.5 million for the year ended December 31, 2015, representing a decrease of approximately $4.7 million compared to the year ended December 31, 2014. The decrease is primarily due to lower costs associated with the PreServe AMI Phase 2 clinical trial for CLBS10, and partially offset by expenses associated with a potential critical limb ischemia development program in Japan.

- *Immune Modulation* - Immune modulation expenses, including our efforts focused on initiating our Phase 2 clinical trial of CLBS03 in type 1 diabetes, were $4.0 million for the year ended December 31, 2015, representing a decrease of $3.0 million compared to the year ended December 31, 2014.

- *Other* - Other research and development expenses were $3.4 million for the year ended December 31, 2015, representing a decrease of approximately $0.6 million compared to the year ended December 31, 2014. Equity-based compensation included in research and development expenses for the year ended December 31, 2015, was approximately $1.8 million, representing a decrease of $0.2 million, compared to the year ended December 31, 2014.

- Impairment of intangible assets 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 were approximately $30.0 million for the year ended December 31, 2015, compared to $30.8 million for the year ended December 31, 2014, representing a decrease of approximately $0.8 million, or 3%. Equity-based compensation included in selling, general and administrative expenses for the year ended December 31, 2015, was approximately $7.4 million, compared to approximately $8.7 million for the year ended December 31, 2014, representing a decrease of $1.3 million. The decrease in equity-based compensation was due to its broader use during the year ended December 31, 2014. Equity-based compensation expense will continue to fluctuate in future years as equity-linked instruments are used to compensate employees, consultants and other service providers. Non-equity-based general and administrative expenses for the year ended December 31, 2015 were approximately $22.6 million, compared to approximately $22.1 million for the year ended December 31, 2014. The increase was related to higher corporate development activities, and expenses associated with the additional CSC operating activities since the acquisition date on May 8, 2014, and increased corporate infrastructure to support our overall operations.

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, 2015, was $17.7 million, compared with other income, net, of $2.9 million for the year ended December 31, 2014, 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 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 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 $2.1 million for the year ended December 31, 2015, compared with $0.8 million for the year ended December 31, 2014. The increase was primarily due to interest expense associated with the $15.0 million loan from Oxford Finance LLC in September 2014.

Provision for Income Taxes

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. These benefits were partially offset by a tax provision on the taxable temporary differences on the goodwill recognized in the PCT acquisition in 2011, 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.

Noncontrolling Interests

In March 2011, we acquired rights to use patents under licenses from Becton, Dickinson and Company ("BD") in exchange for a 19.9% interest in our Athelos subsidiary. Pursuant to the Stock Purchase Agreement signed in March 2011, BD's ownership will be diluted based on new investment in Athelos (subject to certain anti-dilution provisions). As of December 31, 2015, BD's ownership interest in Athelos was decreased to 2.8%. For the years ended December 31, 2015 and 2014, BD's minority shareholder's share of Athelos' net loss totaled approximately $0.1 million and $0.6 million, respectively.

Year Ended December 31, 2014 Compared to Year Ended December 31, 2013

Net loss for the year ended December 31, 2014, was approximately $55.5 million compared to $39.5 million for the year ended December 31, 2013.

Revenues

For the year ended December 31, 2014, total revenues were approximately $17.9 million compared to $14.7 million for the year ended December 31, 2013, representing an increase of $3.3 million, or 22%. Revenues were comprised of the following (in thousands):

	Year Ended December 31,	
	2014	2013
Clinical Services	$ 10,442.9	$ 9,146.3
Clinical Services Reimbursables	3,725.0	2,085.4
Processing and Storage Services	3,770.9	3,436.8
	$ 17,938.8	$ 14,668.5

- Clinical Services, representing *process development* and *clinical manufacturing* services provided at PCT to its various clients, were approximately $10.4 million for the year ended December 31, 2014, compared to $9.1 million for the year ended December 31, 2013, representing an increase of approximately $1.3 million or 14%. The increase was primarily due to $2.0 million of higher process development revenue (such revenue being recognized on a "completed contract" basis) as a result of an increase in the number of new process development agreements with our existing clients, which was partially offset by $0.6 million of lower clinical manufacturing revenue (which is recognized as services are rendered).
    - *Process Development Revenue* - Process development revenues were approximately $4.0 million for the year ended December 31, 2014, compared to $2.0 million for the year ended December 31, 2013. During the year ended December 31, 2014, 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, 2014, approximately $3.9 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 Manufacturing Revenue* - Clinical manufacturing revenues were approximately $6.4 million for the year ended December 31, 2014, compared to $7.0 million for the year ended December 31, 2013. The decrease is primarily due to lower enrollment of patients being treated in our customers' clinical trials.

- Clinical Services Reimbursables, representing reimbursement of expenses for certain consumables incurred on behalf of our clinical service revenue clients, were approximately $3.7 million for the year ended December 31, 2014 compared to $2.1 million for the year ended December 31, 2013, representing an increase of approximately $1.6 million or 79%. 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, primarily representing revenues from our oncology stem cell processing, were approximately $3.8 million for the year ended December 31, 2014 compared to $3.4 million for the year ended December 31, 2013, representing an increase of approximately $0.3 million or 10%. The increase is primarily due to increased volume and pricing for the processing services.

Operating Costs and Expenses of Revenues

For the year ended December 31, 2014, operating expenses totaled $75.7 million compared to $51.5 million for the year ended December 31, 2013, representing an increase of $24.2 million or 47%. Operating expenses were comprised of the following:

- Cost of revenues were approximately $15.7 million for the year ended December 31, 2014, compared to $12.9 million for the year ended December 31, 2013, representing an increase of $2.7 million or 21%. The increase is primarily due to increased clinical services costs to support our customer's process development and clinical manufacturing efforts, as well as additional investment in our internal facilities and capabilities. Overall, gross profit for the year ended December 31, 2014 was $2.3 million or 13% of 2014 revenues, compared to gross profit for the year ended December 31, 2013 of $1.7 million or 12% of 2013 revenues. Gross profit percentages generally will increase as clinical service revenue increases. 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 were approximately $29.2 million for the year ended December 31, 2014, compared to $16.9 million for the year ended December 31, 2013, representing an increase of approximately $12.3 million, or 73%. Research and development expenses associated with our targeted cancer immunotherapy program, including the initiation of the Intus Phase 3 clinical trial for our lead immunotherapy product candidate CLBS20, were $6.9 million for the year ended December 31, 2014. The targeted cancer immunotherapy program was acquired in the CSC merger on May 8, 2014. Research and development expenses related to our ischemic repair program, including expenses associated with the Preserve AMI Phase 2 clinical trial for our product candidate CLBS10, increased by approximately $0.2 million for the year ended December 31, 2014, compared to the prior year period. The increase reflects costs related to evaluating additional potential therapeutic indications in the ischemic repair program, which were partially offset by lower expenses in the Preserve AMI Phase 2 clinical trial which completed patient enrollment in the fourth quarter of 2013. Research and development expenses associated with our immune modulation program increased by approximately $4.3 million, and was primarily due to our efforts to develop Tregs. Other research and development expenses associated with engineering and innovation initiatives at PCT to improve scale up, automation, and integration capabilities increased during year ended December 31, 2014 compared to the prior year. Equity-based compensation included in research and development expenses for the year ended December 31, 2014 and December 31, 2013 were approximately $2.1 million and $0.8 million, respectively.

- Selling, general and administrative expenses were approximately $30.8 million for the year ended December 31, 2014, compared to $21.6 million for the year ended December 31, 2013, representing a decrease of approximately $9.1 million, or 43%. Equity-based compensation included in selling, general and administrative expenses for the year ended December 31, 2014, was approximately $8.7 million, compared to approximately $5.7 million for the year ended December 31, 2013, representing a decrease of $2.9 million. The increase in equity-based compensation was due to its broader use during the year ended December 31, 2014, and in particular, equity awards issued as a bonus for the successful completion of the CSC Acquisition. Equity-based compensation expense will continue to fluctuate in future years as equity-linked instruments are used to compensate employees, consultants and other service providers. Non-equity-based general and administrative expenses for the year ended December 31, 2014, were approximately $22.1 million, compared

to approximately $15.9 million for the year ended December 31, 2013. The increase was related to higher corporate development activities, expenses associated with the additional CSC operating activities since the acquisition date on May 8, 2014, and increased corporate infrastructure to support our expanded clinical activities.

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, 2014, totaled approximately $2.9 million, and primarily represented the decrease in the estimated fair value of our contingent consideration liability associated with potential earn out payments on the net sales of our lead product candidate CLBS10 (in the event of and following the date of first commercial sale of CLBS10), which was partially offset by an increase in the fair value of our contingent consideration for potential future milestone payments related to the CSC acquisition. Other expense, net for the year ended December 31, 2013 totaled approximately $1.6 million, and primarily represented an increase in the estimated fair value of our contingent consideration liability associated with potential earn out payments on the net sales of CLBS10.

For the year ended December 31, 2014, interest expense was $0.8 million compared with $0.3 million for the year ended December 31, 2013. The increase is primarily due to the $15.0 million loan from Oxford Finance LLC in September 2014, which bears an annual interest rate of 8.5%, amortization of related debt issuance costs, and accretion of the 8% final payment fee due in September 2018. Interest expense in each period also relates to mortgage payables, which were fully repaid in September 2014.

Provision for Income Taxes

The provision for income taxes for the years ended December 31, 2014 and December 31, 2013 primarily relate to the taxable temporary differences on the goodwill recognized in the PCT acquisition in 2011, which is being amortized over 15 years for tax purposes. 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.

Noncontrolling Interests

In March 2011, we acquired rights to use patents under licenses from Becton, Dickinson and Company ("BD") in exchange for a 19.9% interest in our Athelos subsidiary. Pursuant to the Stock Purchase Agreement signed in March 2011, BD's ownership will be diluted based on new investment in Athelos (subject to certain anti-dilution provisions). As of December 31, 2014, BD's ownership interest in Athelos was decreased to 3.8%. For the years ended December 31, 2014 and 2013, BD's minority shareholder's share of Athelos' net loss totaled approximately $0.6 million and $0.5 million, respectively.

Analysis of Liquidity and Capital Resources

At December 31, 2015, we had cash, cash equivalents, and marketable securities of approximately $20.3 million, working capital of approximately $8.3 million, and stockholders' equity of approximately $23.7 million.

During the year ended December 31, 2015, we met our immediate cash requirements through revenue generated from our PCT operations, existing cash balances, offerings of our common stock (which raised an aggregate of approximately $36.5 million), and the use of equity and equity-linked instruments to pay for services and compensation.

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

	Year Ended December 31,		
	2015	2014	2013
Net cash used in operating activities	$ (39,258.3)	$ (46,895.2)	$ (27,101.7)
Net cash (used in) provided by investing activities	3,798.4	(10,736.7)	(2,691.5)
Net cash provided by financing activities	36,604.3	30,672.2	62,189.5

Operating Activities

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, impairments of 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.

Our cash used in operating activities in the year ended December 31, 2014 totaled approximately $46.9 million, which is the sum of (i) our net loss from continuing operations of $55.5 million, and adjusted for non-cash expenses totaling $10.2 million (which includes adjustments for equity-based compensation, depreciation and amortization, and changes in acquisition-related contingent consideration), and (ii) changes in operating assets and liabilities of approximately $1.7 million.

Our cash used in operating activities in the year ended December 31, 2013 totaled approximately $27.1 million, which is the sum of (i) our net loss from continuing operations of $39.5 million, and adjusted for non-cash expenses totaling $10.8 million (which includes adjustments for equity-based compensation, depreciation and amortization, and changes in acquisition-related contingent consideration), and (ii) changes in operating assets and liabilities of approximately $1.6 million.

Investing Activities

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 net sales of marketable securities available for sale during year ended December 31, 2015.

During the year ended December 31, 2014, we spent approximately $3.7 million for property and equipment. In addition, we spent approximately $7.1 million for net purchases of marketable securities available for sale during year ended December 31, 2014.

During the year ended December 31, 2013, we spent approximately $2.7 million for property and equipment.

Financing Activities

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 14.4 million shares of our common stock at a public offering price of $2.00 per share in May 2015.
- We raised gross proceeds of approximately $9.7 million through the issuance of approximately 4.4 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.

During the year ended December 31, 2014, our financing activities consisted of the following:

- We raised gross proceeds of approximately $15.0 million from loan proceeds from Oxford Finance LLC in September 2014. In connection with the loan, we repaid all outstanding amounts due under two loans from TD Bank, N.A. in the amount of approximately $3.1 million. In addition, debt offering/issuance costs of $0.5 million were paid in connection with the loan.
- We raised gross proceeds of approximately $16.5 million through the issuance of approximately 2.8 million shares of our common stock under the provisions of our Common Stock Purchase Agreements with Aspire.
- We raised approximately $0.3 million from the exercise of 48,987 options.
- We raised approximately $1.7 million from the exercise of 333,250 warrants.

- We received proceeds of $1.8 million from the issuance of notes payable relating to certain insurance policies and equipment financings, less repayments of $1.1 million.

During the year ended December 31, 2013, our financing activities consisted of the following:

- We raised $11.5 million (or $10.5 million in net proceeds after deducting underwriting discounts and commissions and offering expenses) through an underwritten offering of 2.3 million shares of our common stock at a public offering price of $5.00 per share in April 2013.
- We raised $40.3 million (or $37.1 million in net proceeds after deducting underwriting discounts and commissions and offering expenses) through an underwritten offering of 5.75 million shares of our common stock at a public offering price of $7.00 per share in October 2013.
- We raised gross proceeds of approximately $11.1 million through the issuance of approximately 1.6 million shares of common stock under the provisions of our common stock purchase agreement with Aspire.
- We raised approximately $0.2 million from the exercise of 0.03 million options.
- We raised approximately $3.0 million from the exercise of 0.6 million warrants. To induce the exercise of certain of these warrants, we provided consideration to the warrant holders in the form of cash.

Liquidity and Capital Requirements Outlook

Liquidity

We anticipate requiring additional capital to grow the PCT business, to fund the development of CLBS03 and other operating expenses, and to make principle and interest payments on our loan with Oxford Finance. To meet our short and long term liquidity needs, we currently expect to use existing cash balances, our revenue generating activities, and a variety of other means.

On March 11, 2016, PCT entered into a global collaboration that includes licensing, development and equity, with Hitachi Chemical Co., LTD ("Hitachi Chemical"), a Japanese-based global conglomerate with a growing franchise in life sciences including regenerative medicine ("Hitachi Transaction"), and will receive an aggregate of $25.0 million in cash, of which $19.4 million was received in March 2016, and the remainder is expected to be received before the end of 2016. PCT will retain $10 million of the $25.0 million proceeds, and Caladrius will receive $15 million of the proceeds.

In September 2014, we entered into a Loan and Security Agreement with Oxford Finance LLC and received $15.0 million in gross proceeds. We have been making interest-only payments on the outstanding amount of the loan on a monthly basis at a rate of 8.50% per annum. On March 11, 2016, upon execution of the Hitachi Transaction, the Company and Oxford Finance LLC entered into an amendment to the Loan and Security Agreement whereby (i) the Company paid $7.0 million to Oxford Finance LLC, comprised of principal, interest and early termination fees, (ii) the Company's subsidiaries PCT, PCT Allendale, LLC, and NeoStem Family Storage, LLC (collectively the "Removed Borrowers") were removed as borrowers under the Loan, (iii) Oxford Finance LLC's security interests in any and all assets of the Removed Borrowers were released, (iv) the interest only period on the remaining outstanding Loan balance is extended until January 1, 2017, and (v) in the event the Company receives 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 Oxford Finance LLC, up to a $3.0 million total. If 20% of such proceeds in aggregate is less than $3.0 million by March 31, 2017, then the Company will make a lump sum payment equal to the difference by March 31, 2017. The loan matures on September 1, 2018.

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 11.0 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.

In June 2015, 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 14.4 million shares of common stock at a public offering price of $2.00 per share.

On March 10, 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 1.4 million shares of common stock and a two-year warrant to purchase up to an aggregate of 1.4 million shares of Caladrius' common stock, at an exercise price of $1.00 per share. The unit purchase price for a share of Caladrius common stock and warrant to purchase one share of Caladrius common stock was $0.705 per unit, with $1 million of gross proceeds received by us.

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.

We believe that the proceeds received in the Hitachi Transaction, along with our current cash, our revenue generating activities, and our access to funds under our agreement with Aspire Capital, will be sufficient to fund our operations for the next twelve months.

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.

Commitments and Contingencies

The following table summarizes our obligations to make future payments under current contracts as of December 31, 2015 (in thousands):

	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Contractual Obligations					
Notes Payable	$ 1,775.7	$ 1,192.7	$ 583.0	$ —	$ —
Long Term Debt	16,200.0	4,171.5	12,028.5	—	—
Purchase Obligations	500.4	333.6	166.8	—	—
Operating Lease Obligations	6,910.1	2,062.0	2,898.5	1,781.5	168.1
	$ 25,386.2	$ 7,759.8	$ 15,676.8	$ 1,781.5	$ 168.1

Other significant commitments and contingencies include the following:

- Under agreements with external clinical research organizations (“CROs”), we will incur expenses relating to our clinical trials for our therapeutic product candidates in development. The timing and amount of these expenses are based on performance of services rendered and expenses as incurred by the CROs and therefore, we cannot reasonably estimate the timing of these payments.

- Under certain license, collaboration, and merger agreements, we are required to pay royalties, milestone and/or other payments upon successful development and commercialization of products. However, successful research and development of pharmaceutical products is high risk, and most products fail to reach the market. Therefore, at this time the amount and timing of the payments, if any, are not known.

- From time to time, we are 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, we do not believe that the outcome of any pending claims will have a material adverse effect on our financial condition or operating results.

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 out 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.

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 and Other Intangible Assets

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. Intangible assets related to in process research and development ("IPR&D") projects are considered to be indefinite-lived until the completion or abandonment of the associated R&D efforts. If and when development is complete, which generally occurs if and when regulatory approval to market a product is obtained, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives at that point in time.

We review goodwill and indefinite-lived intangible assets at least annually, or at the time a triggering event is identified for possible impairment. Goodwill and indefinite-lived intangible assets are 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 or the IPR&D below its carrying value. We test our goodwill and indefinite-lived intangible assets each year on December 31. We review the carrying value of goodwill and indefinite-lived intangible assets 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 and IPR&D's estimated fair value. If these estimates or related assumptions change in the future, we may be required to record impairment charges.

Amortized intangible assets consist of customer lists, manufacturing technology, and tradename, as well as patents and rights associated primarily with the VSEL™ Technology. These intangible assets are amortized on a straight line basis over their respective useful lives.

Definite-lived Intangible Assets

Definite-lived intangible assets consist of customer lists, manufacturing technology, tradenames, patents and rights. These intangible assets are amortized on a straight line basis over their respective useful lives. We review definite-lived intangibles 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.

Recognizing and Measuring Assets Acquired and Liabilities Assumed in Business Combinations at Fair Value

We account for acquired businesses using the purchase method of accounting, which requires that assets acquired and liabilities assumed be recorded at date of acquisition at their respective fair values. The consolidated financial statements and results of operations reflect an acquired business after the completion of the acquisition. The fair value of the consideration paid, including contingent consideration, is assigned to the underlying net assets of the acquired business based on their respective fair values. Any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill. Amounts

allocated to IPR&D are included on the balance sheet. Intangible assets, including IPR&D assets upon successful completion of the project and approval of the product, are amortized on a straight-line basis to amortize expense over the expected life of the asset. Significant judgments are used in determining the estimated fair values assigned to the assets acquired and liabilities assumed and in determining estimates of useful lives of long-lived assets. Fair value determinations and useful life estimates are based on, among other factors, estimates of expected future net cash flows, estimates of appropriate discount rates used to present value expected from future net cash flow streams, the timing of approvals for IPR&D projects and the timing of related product launch dates, the assessment of each asset's life cycle, the impact of competitive trends on each asset's life cycle and other factors. These judgments can materially impact the estimates used to allocate acquisition date fair values to assets acquired and liabilities assumed and the resulting timing and amount charged to, or recognized in current and future operating results. For these and other reasons, actual results may vary significantly from estimated results.

We determine the acquisition date fair value of contingent consideration obligations based on a probability-weighted income approach derived from revenue estimates, post-tax gross profit levels and a probability assessment with respect to the likelihood of achieving contingent obligations including contingent payments such as milestone obligations, royalty obligations and contract earn-out criteria, where applicable. The fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement as defined in fair value measurement accounting. The resulting probability-weighted cash flows are discounted using an appropriate effective annual interest rate. At each reporting date, the contingent consideration obligation will be revalued to estimated fair value at that time and changes in fair value will be reflected as income or expense in our consolidated statement of operations. Changes in the fair value of the contingent consideration obligations may result from changes in discount periods and rates, changes in the timing and amount of revenue estimates and changes in probability assumptions with respect to the likelihood of achieving the various contingent payment obligations. Changes in assumptions utilized in our contingent consideration fair value estimates could result in an increase or decrease in our contingent consideration obligation and a corresponding charge to operating loss or income.

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

Market risk is the risk of change in fair value of a financial instrument due to changes in interest rates, equity prices, creditworthiness, financing, exchange rates or other factors. Our primary market risk exposure relates to changes in interest rates. Our earnings and cash flows are subject to fluctuations due to changes in interest rates, principally in connection with our investments in marketable securities, which consist primarily of short-term money market funds and municipal debt securities. However, as of December 31, 2015, we do not believe we are materially exposed to changes in interest rates given the short-term duration of the securities. Additionally, our outstanding $15.0 million Long-Term Loan with Oxford Finance LLC, representing our largest component of debt, has a fixed interest rate until 2018, and is not subject to interest rate exposure. As a result, we do not believe we have material exposure to market risk related to interest rate changes as of December 31, 2015.

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 Bioscience, Inc.

We have audited the accompanying consolidated balance sheets of Caladrius Bioscience, Inc., a Delaware corporation, and subsidiaries (the "Company") as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, equity, and cash flows for each of the three years in the period ended December 31, 2015. 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes 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 Bioscience, Inc. and subsidiaries as of December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2015, based on criteria established in the 2013 *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 15, 2016 expressed an unqualified opinion.

/s/ GRANT THORNTON LLP

New York, New York
March 15, 2016

CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2015	December 31, 2014
ASSETS		
Current Assets		
Cash and cash equivalents	$ 20,318,411	$ 19,174,061
Marketable securities	—	7,080,053
Accounts receivable trade, net of allowance for doubtful accounts of $0 and $385,362 respectively	2,566,101	3,111,274
Deferred costs	2,911,743	2,566,989
Prepaids and other current assets	3,476,177	4,349,167
Total current assets	29,272,432	36,281,544
Property, plant and equipment, net	17,064,900	15,960,731
Goodwill	7,013,315	25,209,336
Intangible assets, net	2,877,880	47,560,406
Other assets	976,768	1,263,375
Total assets	$ 57,205,295	$ 126,275,392
LIABILITIES AND EQUITY		
Current Liabilities		
Accounts payable	$ 4,107,388	$ 5,661,173
Accrued liabilities	6,198,488	4,322,901
Long-term debt, current	4,171,456	1,109,612
Notes payable	1,192,666	816,776
Unearned revenues	5,345,225	4,334,120
Total current liabilities	21,015,223	16,244,582
Deferred income taxes	932,662	18,176,190
Notes payable	583,041	825,897
Long term debt	10,828,544	13,890,388
Acquisition-related contingent consideration	—	18,260,000
Other long-term liabilities	562,001	804,546
Total liabilities	33,921,471	68,201,603
Commitments and Contingencies		
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, 2015 and December 31, 2014	100	100
Common stock, $.001 par value, authorized 500,000,000 shares; issued and outstanding, 56,733,012 and 36,783,857 shares, at December 31, 2015 and December 31, 2014, respectively	56,733	36,784
Additional paid-in capital	396,496,341	350,428,903
Treasury stock, at cost; 110,799 shares at December 31, 2015, and 109,989 shares at December 31, 2014	(707,637)	(705,742)
Accumulated deficit	(372,132,490)	(291,246,538)
Accumulated other comprehensive income	486	1,329
Total Caladrius Biosciences, Inc. stockholders' equity	23,713,533	58,514,836
Noncontrolling interests	(429,709)	(441,047)
Total equity	23,283,824	58,073,789
	$ 57,205,295	$ 126,275,392

See accompanying notes to consolidated financial statements.

CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2015	2014	2013
Revenues	$ 22,487,566	$ 17,938,790	$ 14,668,455
Expenses:			
Cost of revenues	20,158,828	15,678,475	12,947,217
Research and development	23,899,026	29,194,262	16,917,396
Impairment of goodwill and intangible assets	62,273,336	—	—
Selling, general, and administrative	30,005,542	30,806,807	21,612,793
Operating Expenses	136,336,732	75,679,544	51,477,406
Operating loss	(113,849,166)	(57,740,754)	(36,808,951)
Other income (expense):			
Other income (expense), net	17,723,579	2,926,003	(1,614,858)
Interest expense	(2,128,442)	(755,697)	(281,421)
	15,595,137	2,170,306	(1,896,279)
Loss from before (benefit) provision for income taxes and noncontrolling interests	(98,254,029)	(55,570,448)	(38,705,230)
(Benefit) provision for income taxes	(17,243,528)	(104,202)	780,104
Net loss	(81,010,501)	(55,466,246)	(39,485,334)
Less - loss attributable to noncontrolling interests	(124,549)	(593,313)	(504,090)
Net loss attributable to Caladrius Biosciences, Inc. common stockholders	$ (80,885,952)	(54,872,933)	(38,981,244)
Basic and diluted loss per share attributable to Caladrius Biosciences, Inc. common stockholders	$ (1.67)	$ (1.68)	$ (1.90)
Weighted average common shares outstanding	48,508,106	32,756,102	20,495,771

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,		
	2015	2014	2013
Net loss	$ (81,010,501)	$ (55,466,246)	$ (39,485,334)
Other comprehensive income (loss):			
Available for sale securities - net unrealized gain (loss)	(843)	1,329	—
Total other comprehensive income (loss)	(843)	1,329	—
Comprehensive loss	(81,011,344)	(55,464,917)	(39,485,334)
Comprehensive loss attributable to noncontrolling interests	(124,549)	(593,313)	(504,090)
Comprehensive net loss attributable to Caladrius Biosciences, Inc. common stockholders	$ (80,886,795)	$ (54,871,604)	$ (38,981,244)

See accompanying notes to consolidated financial statements.

CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EQUITY

	Series B Convertible Preferred Stock		Common Stock								
	Shares	Amount	Shares	Amount	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
Balance at December 31, 2012	10,000	$ 100	16,375,365	$ 16,375	$231,218,615	$ —	$(197,392,361)	$(665,600)	$ 33,177,129	$ (356,970)	$32,820,159
Net loss	—	—	—	—	—	—	(38,981,244)	—	(38,981,244)	(504,090)	(39,485,334)
Share-based compensation	—	—	513,912	514	6,878,187	—	—	(40,142)	6,838,559	—	6,838,559
Proceeds from issuance of common stock	—	—	9,712,724	9,713	58,726,453	—	—	—	58,736,166	—	58,736,166
Proceeds from option exercises	—	—	31,369	31	150,627	—	—	—	150,658	—	150,658
Proceeds from warrant exercises	—	—	563,167	564	3,027,677	—	—	—	3,028,241	—	3,028,241
Warrant inducements	—	—	—	—	(62,014)	—	—	—	(62,014)	—	(62,014)
Change in Ownership in Subsidiary	—	—	—	—	(345,020)	—	—	—	(345,020)	345,020	—
Balance at December 31, 2013	10,000	$ 100	27,196,537	$ 27,197	$299,594,525	$ —	$(236,373,605)	$(705,742)	$ 62,542,475	$ (516,040)	$62,026,435
Net loss	—	—	—	—	—	—	(54,872,933)	—	(54,872,933)	(593,313)	(55,466,246)
Unrealized gain/loss on marketable securities	—	—	—	—	—	1,329	—	—	1,329	—	1,329
Share-based compensation	—	—	916,359	916	11,208,626	—	—	—	11,209,542	—	11,209,542
Net proceeds from issuance of common stock	—	—	2,959,214	2,959	16,707,686	—	—	—	16,710,645	—	16,710,645
Proceeds from option exercises	—	—	48,987	49	270,959	—	—	—	271,008	—	271,008
Proceeds from warrant exercises	—	—	333,250	333	1,720,392	—	—	—	1,720,725	—	1,720,725
Shares issued in CSC merger	—	—	5,329,510	5,330	21,595,021	—	—	—	21,600,351	—	21,600,351
Change in Ownership in Subsidiary	—	—	—	—	(668,306)	—	—	—	(668,306)	668,306	—
Balance at December 31, 2014	10,000	$ 100	36,783,857	$ 36,784	$350,428,903	$ 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	—	—	928,000	928	9,751,077	—	—	(1,895)	9,750,110	—	9,750,110
Net proceeds from issuance of common stock	—	—	19,021,155	19,021	36,452,248	—	—	—	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	56,733,012	$ 56,733	$396,496,341	$ 486	$(372,132,490)	$(707,637)	$ 23,713,533	$ (429,709)	$23,283,824

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,		
	2015	2014	2013
Cash flows from operating activities:			
Net loss	$ (81,010,501)	$ (55,466,246)	$ (39,485,334)
Adjustments to reconcile net loss to net cash used in operating activities:			
Common stock, stock options and warrants issued as payment for compensation, services rendered	9,750,110	11,209,542	6,838,559
Depreciation and amortization	2,686,779	2,186,949	1,605,608
Changes in fair value of derivative liability	—	(23,175)	(77,981)
Changes in acquisition-related contingent consideration	(18,260,000)	(3,080,000)	1,900,000
Impairment of goodwill and intangible assets	62,273,336	—	—
Bad debt (recovery) expense	—	(6,467)	(234,225)
Deferred income taxes	(17,243,528)	(104,202)	780,104
Amortization/Accretion on Marketable Securities	95,095	51,517	—
Changes in operating assets and liabilities:			
Prepaids and other current assets	872,990	(2,768,062)	(758,798)
Accounts receivable	545,173	(1,198,844)	(573,005)
Deferred costs	(344,753)	(1,296,766)	(157,198)
Unearned revenues	1,011,104	2,517,520	348,260
Other assets	286,607	613,175	(204,422)
Accounts payable, accrued liabilities and other liabilities	79,257	469,821	2,916,739
Net cash used in operating activities	(39,258,331)	(46,895,238)	(27,101,693)
Cash flows from investing activities:			
Cash received in acquisitions	—	50,894	—
Purchase of short term investments	(6,081,900)	(8,043,241)	—
Sales of marketable securities	13,066,014	913,000	—
Acquisition of property and equipment	(3,185,737)	(3,657,352)	(2,691,471)
Net cash provided by (used in) investing activities	3,798,377	(10,736,699)	(2,691,471)
Cash flows from financing activities:			
Proceeds from exercise of options	—	271,008	150,658
Proceeds from exercise of warrants	—	1,720,725	3,028,241
Net proceeds from issuance of capital stock	36,471,269	16,710,645	58,736,165
Proceeds from long term debt	—	15,000,000	—
Debt issuance costs	—	(523,830)	—
Repayment of mortgage loan	—	(3,236,721)	(201,754)
Proceeds from notes payable	1,087,361	1,827,413	1,041,347
Repayment of notes payable	(954,326)	(1,097,001)	(503,172)
Payment for warrant inducement	—	—	(62,014)
Net cash provided by financing activities	36,604,304	30,672,239	62,189,471
Net (decrease) increase in cash and cash equivalents	1,144,350	(26,959,698)	32,396,307
Cash and cash equivalents at beginning of year	19,174,061	46,133,759	13,737,452
Cash and cash equivalents at end of year	$ 20,318,411	$ 19,174,061	$ 46,133,759
Supplemental Disclosure of Cash Flow Information:			
Cash paid during the period for:			
Interest	$ 1,497,845	$ 232,500	$ 274,100
Taxes	—	—	—
Supplemental schedule of non-cash financing activities			
Common stock and contingent consideration issued with the acquisition of CSC	—	33,490,351	—

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

Cell Therapy Development and Manufacturing

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

CLBS03

We are developing strategically, through the utilization of or core development and manufacturing expertise, a product candidate that is an innovative therapy for type 1 diabetes mellitus ("TID"). This therapy is based on a proprietary platform technology for immunomodulation. We have selected as an initial target the unmet medical need of pediatric patients who are newly diagnosed with T1D. This program is based on the use of 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 viruses and other foreign antigens. When Tregs function properly, only harmful foreign materials are attacked by T effector cells. In autoimmune disease, however, it is thought that deficient Treg activity and numbers permit the T effector cells to attack the body's own beneficial cells. In the case of T1D, there are currently no curative treatments, only lifelong insulin therapy, which often does not prevent serious co-morbidities. Two Phase 1 clinical trials of this technology in T1D demonstrated safety and tolerance, feasibility of manufacturing, an implied durability of effect and an early indication of efficacy through the preservation of beta cell function. In the first quarter of 2016 we expect to commence patient enrollment in the first of two cohorts in The Sanford Project: T-Rex Study, a Phase 2 prospective, randomized, placebo-controlled, double-blind clinical trial to evaluate the safety and efficacy of our Treg product candidate, CLBS03, in adolescents with recent onset T1D. After the three-month follow-up of the first cohort of 18 patients, which is expected in early 2017, an initial safety analysis of the data and early analysis of immunological biomarkers will be undertaken. Satisfactory evaluation of the safety of the initial cohort as agreed by us, our independent Data Safety Monitoring Board and the U.S. Food and Drug Administration ("FDA") will then prompt the

enrollment of the remaining 93 patients. A subsequent interim analysis of efficacy is planned after approximately 50% of patients reach the six-month follow-up milestone. We have 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.

Additional Technology Platforms

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

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

Financial Information & Liquidity

On March 11, 2016, PCT entered into a global licensing, development and equity collaboration with Hitachi Chemical Co., LTD ("Hitachi Chemical"), a Japanese-based global conglomerate with a growing franchise in life sciences including regenerative medicine ("Hitachi Transaction"), and will receive an aggregate of $25.0 million in cash, of which $19.4 million was received in March 2016, and the remainder expected to be received before the end of 2016 (see Note 18). PCT will retain $10 million of the $25.0 million proceeds, and Caladrius will receive $15 million of the proceeds. Concurrent with the Hitachi Transaction, Caladrius will use $7.0 million of the proceeds to repay a portion of the outstanding loan with Oxford Finance (see Note 18). In addition to the Hitachi Transaction, 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. 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. We believe that the proceeds received in the Hitachi Transaction, along with our current cash, our revenue generating activities, and our access to funds under our agreement with Aspire Capital, will be sufficient to fund our operations for the next twelve months. 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 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.

In February 2016, we received written notification from 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. We have 180 days after the date of the Nasdaq notification to regain compliance by maintaining a minimum closing bid price of $1.00 for ten consecutive trading days. If we are unable to regain compliance, NASDAQ will provide us with written notification that our common stock is subject to delisting. We may also elect to apply to transfer our common stock to the Nasdaq Capital Market if we satisfy all requirements, other than the minimum bid price requirement, for initial inclusion in this market. If we make such an election and our transfer application is approved, we will be eligible to regain compliance with the minimum closing bid price requirement until 180 days after the end of the first 180 day period. If, at the conclusion of either or both of the 180-day periods,

we have not achieved compliance, we may appeal NASDAQ's determination to delist our securities. We cannot assure you that we will be successful in regaining compliance with the Nasdaq Global Market listing requirements or that, if we choose to apply for transfer to the Nasdaq Capital Market, we would be successful in our application.

Basis of Presentation

The accompanying Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("generally accepted accounting principles"). 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, 2015 and 2014, and the results of its operations and its cash flows for the years ended December 31, 2015, 2014, and 2013.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements. Estimates also affect the reported amounts of revenues and expenses during the reporting period. The Company bases its estimates on historical experience and other assumptions believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. The Company makes critical estimates and assumptions in determining the fair values of goodwill for potential goodwill impairments for our reporting units, fair values of In-Process R&D assets, fair values of acquisition-related contingent considerations, useful lives of our 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
NeoStem Therapies, 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	100%	United States of America
NeoStem Family Storage, LLC	100%	United States of America
Athelos Corporation (1)	97%	United States of America
PCT Allendale, LLC	100%	United States of America
NeoStem Oncology, LLC	100%	United States of America

(1) As of December 31, 2015, Becton Dickinson's ownership interest in Athelos Corporation was 2.8%.

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, 2015, four customers represented 17%, 14%, 10%, and 8% respectively, of total revenues recognized. As of December 31, 2015, four customers represented 60% of our accounts receivable.

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 either cash equivalents or marketable securities. 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 and Indefinite-Lived Intangible Assets

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. Intangible assets related to in process research and development ("IPR&D") projects are considered to be indefinite-lived until the completion or abandonment of the associated R&D efforts. If and when development is complete, which generally occurs if and when regulatory approval to market a product is obtained, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives at that point in time.

The Company reviews goodwill and indefinite-lived intangible assets at least annually, or at the time a triggering event is identified for possible impairment. Goodwill and indefinite-lived intangible assets are 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 or the IPR&D below its carrying value. The Company tests its goodwill and indefinite-lived intangible assets each year on December 31. The Company reviews the carrying value of goodwill and indefinite-lived intangible assets 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 and IPR&D'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 and IPR&D for impairment as of December 31, 2015, June 30, 2015, and December 31, 2014 for its two reporting units. As of June 30, 2015, the Company determined that IPR&D valued at $9.4 million was impaired (see Note 9). As of December 31, 2015, the Company determined that IPR&D valued at $34.3 million million and goodwill valued at $18.2 million were impaired (see Note 9). As of December 31, 2014, the Company concluded there was no goodwill impairment.

Definite-lived Intangible Assets

Definite-lived intangible assets consist of customer lists, manufacturing technology, tradenames, patents and rights. These intangible assets are amortized on a straight line basis over their respective useful lives. The Company reviews definite-lived intangibles 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 2015, 2014, and 2013.

Recognizing and Measuring Assets Acquired and Liabilities Assumed in Business Combinations at Fair Value

The Company accounts for acquired businesses using the purchase method of accounting, which requires that assets acquired and liabilities assumed be recorded at date of acquisition at their respective fair values. The consolidated financial statements and results of operations reflect an acquired business after the completion of the acquisition. The fair value of the consideration paid, including contingent consideration, is assigned to the underlying net assets of the acquired business based on their respective fair values. Any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill. Amounts allocated to IPR&D are included on the balance sheet . Intangible assets, including IPR&D assets upon successful completion of the project and approval of the product, are amortized on a straight-line basis to amortization expense over the expected life of the asset. Significant judgments are used in determining the estimated fair values assigned to the assets acquired and liabilities assumed and in determining estimates of useful lives of long-lived assets. Fair value determinations and useful life estimates are based on, among other factors, estimates of expected future net cash flows, estimates of appropriate discount rates used to present value expected from future net cash flow streams, the timing of approvals for IPR&D projects and the timing of related product launch dates, the assessment of each asset's life cycle, the impact of competitive trends on each asset's life cycle and other factors. These judgments can materially impact the estimates used to allocate acquisition date fair values to assets acquired and liabilities assumed and the resulting timing and amount charged to, or recognized in current and future operating results. For these and other reasons, actual results may vary significantly from estimated results.

The Company determines the acquisition date fair value of contingent consideration obligations based on a probability-weighted income approach derived from revenue estimates, post-tax gross profit levels and a probability assessment with respect to the likelihood of achieving contingent obligations including contingent payments such as milestone obligations, royalty obligations and contract earn-out criteria, where applicable. The fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement as defined in fair value measurement accounting. The resulting probability-weighted cash flows are discounted using an appropriate effective annual interest rate. At each reporting date, the contingent consideration obligation will be revalued to estimated fair value at that time and changes in fair value will be reflected as income or expense in our consolidated statement of operations. Changes in the fair value of the contingent consideration obligations may

result from changes in discount periods and rates, changes in the timing and amount of revenue estimates and changes in probability assumptions with respect to the likelihood of achieving the various contingent payment obligations. Changes in assumptions utilized in our contingent consideration fair value estimates could result in an increase or decrease in our contingent consideration obligation and a corresponding charge to operating loss or income.

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, 2015, 2014, and 2013, clinical services reimbursements were $3.4 million, $3.7 million, and $2.1 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.

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 ASU 2014-09, "*Revenue from Contracts with Customers (Topic 606).*" The new revenue recognition standard provides a five-step analysis to determine when and how revenue is recognized. The standard requires that a company recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. This ASU is effective for annual periods beginning after December 15, 2016 and will be applied retrospectively to each period presented or as a cumulative-effect adjustment as of the date of adoption. The Company is currently evaluating the impact of the pending adoption of ASU 2014-09 on its consolidated financial statements.

In August 2014, FASB issued Accounting Standards Update (ASU) No. 2014-15 Preparation 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 is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The Company is currently evaluating the adoption of this ASU and its impact on the consolidated financial statements.

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 will be effective for us beginning in our first quarter of 2017. Early adoption is permitted. We do not expect this adoption to 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.

In February 2016, the FASB issued ASU No. 2016-02 “Leases” (“ASU 2016-02”), which is effective for the fiscal years beginning after December 15, 2018. ASU 2016-02 requires entities to report a right of use asset and liability for the obligation to make payments for all leases with the exception of those leases with a term of twelve months or less. The adoption of this standard, is not expected to have a material impact on the Company’s consolidated financial statements.

Note 3 – Acquisition

On May 8, 2014, the Company closed (the “Closing”) its acquisition of CSC (the “CSC Acquisition”), pursuant to the terms of the Agreement and Plan of Merger, dated as of April 11, 2014 (the “Merger Agreement”), by and among the Company and its acquisition subsidiaries (collectively, "Subco"), CSC, and Jason Livingston, solely in his capacity as CSC stockholder representative (together with his permitted successors, the “CSC Representative”). At Closing, Fortis Advisors LLC succeeded to the duties of the CSC Representative pursuant to the Merger Agreement. Pursuant to the Merger Agreement, on the Closing Date, Subco was merged with CSC (the “Merger”), with Subco surviving the Merger as a wholly-owned subsidiary of the Company. At Closing, Subco changed its legal name to NeoStem Oncology, LLC.

Aggregate Merger Consideration

Pursuant to the terms of the Merger Agreement, all shares of CSC common stock (CSC Common Stock) and CSC preferred stock (“CSC Preferred Stock”, and collectively with the CSC Common Stock, the “CSC Capital Stock”) outstanding immediately prior to the Closing, and all outstanding unexercised options to purchase CSC Common Stock (CSC Options) (treated as if a net exercise had occurred), were canceled and converted into the right to receive, in the aggregate (and giving effect to the liquidation preferences accorded to the CSC Preferred Stock):

(1) An aggregate of 5,329,593 shares of our common stock (subject to payment of nominal cash in lieu of fractional shares) (the “Closing Merger Consideration”); and

(2) if payable after the Closing, certain payments in an amount of up to $90 million in the aggregate, payable in shares of the Company's Common Stock or cash, in the Company’s sole discretion, in the event of the successful completion of certain milestone events in connection with the CSC Acquisition (the “Milestone Payments”, and together with the Closing Merger Consideration, the “Merger Consideration”).

The fair value of the net assets acquired in the CSC Acquisition was $19.4 million. The fair value of the consideration paid by the Company was valued at $33.5 million, resulting in the recognition of goodwill in the amount of $14.1 million. The consideration paid was comprised of equity issued and milestone payments. The fair value of the equity issued by the Company was valued at $21.6 million. The fair value of the milestone payments was valued at $11.9 million, and is contingent on the achievement of certain milestones associated with the future development of the acquired programs. Such contingent consideration has been classified as a liability and will be subject to remeasurement at the end of each reporting period.

The fair value of assets acquired and liabilities assumed on May 8, 2014 is as follows (in thousands):

Cash and cash equivalents	$ 51
Accounts receivable trade, net	45
Prepaids and other current assets	19
Property, plant and equipment, net	1,041
Other assets	201
Goodwill	14,092
In-Process R&D	34,290
Accounts payable	(333)
Accrued liabilities	(2,014)
Deferred tax liability	(13,901)
	$ 33,491

The total cost of the acquisition has been allocated to the assets acquired and the liabilities assumed based upon their estimated fair values at the date of the acquisition. The final allocation was completed during the measurement period which was one year from the date of acquisition.

Pro Forma Financial Information (unaudited)

The following supplemental table presents unaudited consolidated pro forma financial information as if the closing of the acquisition of CSC had occurred on January 1, 2013 (in thousands, except per share amounts):

	Twelve Months Ended December 31, 2014		Twelve Months Ended December 31, 2013	
	(As Reported)	(Proforma - Unaudited)	(As Reported)	(Proforma - Unaudited)
Revenues	$ 17,939	$ 18,649	$ 14,668	$ 15,471
Net loss	$ (55,467)	$ (57,964)	$ (39,485)	$ (44,790)
Net loss attributable to Caladrius	$ (54,873)	$ (57,371)	$ (38,981)	$ (44,286)
Net loss per share attributable to Caladrius	$ (1.68)	$ (1.51)	$ (1.90)	$ (1.71)

The unaudited supplemental pro forma financial information should not be considered indicative of the results that would have occurred if the acquisition of CSC had been consummated on January 1, 2013, nor are they indicative of future results.

Note 4 – Available-for-Sale-Securities

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

	December 31, 2015				December 31, 2014			
	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	$ 249.0	$ —	$ —	$ 249.0
Corporate debt securities	1,047.2	—	—	1,047.2	—	—	—	—
Money market funds	837.7	—	—	837.7	12,791.9	—	—	12,791.9
Municipal debt securities	4,740.9	0.8	—	4,741.7	9,317.3	1.3	—	9,318.6
Total	$ 6,874.8	$ 0.8	$ —	$ 6,875.6	$ 22,358.2	$ 1.3	$ —	$ 22,359.5

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, 2015	December 31, 2014
Cash and cash equivalents	$ 6,875.6	$ 15,279.4
Marketable securities	—	7,080.1
Total	$ 6,875.6	$ 22,359.5

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

	December 31, 2015	
	Amortized Cost	Estimated Fair Value
Less than one year	$ 6,874.8	$ 6,875.6
Greater than one year	—	—
Total	$ 6,874.8	$ 6,875.6

Note 5 – Deferred Costs

Deferred costs representing work in process for costs incurred on process development contracts that have not been completed, were $2.9 million and $2.6 million as of December 31, 2015 and December 31, 2014, respectively. The Company also has deferred revenue of approximately $4.9 million and $3.9 million of progress billings received as of December 31, 2015 and December 31, 2014, respectively, related to these contracts.

Note 6 – Property, Plant and Equipment

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

	December 31,	
	2015	2014
Building and improvements	$ 11,478.6	$ 11,298.7
Machinery and equipment	68.3	68.3
Lab equipment	7,461.2	6,324.7
Furniture and fixtures	2,320.9	1,166.3
Software	445.7	312.4
Leasehold improvements	2,831.5	2,219.6
Property, plant and equipment, gross	24,606.2	21,390.0
Accumulated depreciation	(7,541.4)	(5,429.3)
Property, plant and equipment, net	$ 17,064.8	$ 15,960.7

The Company's results included depreciation expense of approximately $2.1 million, $1.6 million and $1.0 million for the years ended December 31, 2015, 2014, and 2013, respectively.

Note 7 – Loss Per Share

For the years ended December 31, 2015, 2014, and 2013 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, 2015, 2014, and 2013 the Company excluded the following potentially dilutive securities:

	December 31,		
	2015	2014	2013
Stock Options	6,663,270	4,427,276	2,932,191
Warrants	3,214,033	3,550,956	4,898,266
Restricted Shares	202,776	280,481	78,500

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 classifies the fair value of the warrant derivative liabilities as level 3 inputs. These inputs require material subjectivity because value is derived through the use of a lattice model that values the derivatives based on probability weighted discounted cash flows. In May 2014, the warrants expired and the value of the warrant derivative liabilities were written off and recorded in other expenses in our consolidated statement of operations.

The Company classifies the fair value of contingent consideration obligations as level 3 inputs. The Company has recognized contingent consideration obligations related to the following:

- In October 2011, in connection with the acquisition (the "Amorcyte Acquisition") of Amorcyte, LLC ("Amorcyte"), contingent consideration obligations were recognized relating to earn out payments equal to 10% of the net sales of the lead product candidate CLBS10 (in the event of and following the date of first commercial sale of CLBS10, a CD34 therapy), provided that in the event the Company sublicenses CLBS10, the applicable earn out payment will be equal to 30% of any sublicensing fees, and provided further that the Company will be entitled to recover direct out-of-pocket clinical development costs not previously paid or reimbursed and any costs, expenses, liabilities and settlement amounts arising out of claims of patent infringement or otherwise challenging Amorcyte's right to use intellectual property, by reducing any earn out payments due by 50% until such costs have been recouped in full (the "Earn Out Payments"). As of June 30, 2015, based on a thorough analysis of the available data from the PreSERVE-AMI Phase 2 clinical study for CLBS10, an updated commercial assessment, and consultation with the Company's scientific advisory board and the Science and Technology Committee of the Board of Directors, the Company determined that it will not pursue further development of CLBS10. As a result, the Amorcyte Acquisition contingent consideration fair value decreased from $5.5 million as of December 31, 2014 to $0 as of June 30, 2015, since the contingent consideration is based solely on future revenues of CLBS10. The change in estimated fair value has been recorded in other expense (income), net in our consolidated statement of operations.

- In May 2014, in connection with the CSC Acquisition, contingent consideration obligations were recognized relating to milestone payments of up to $90 million, based on the achievement of certain milestones associated with the future development of the acquired programs, including CLBS20, a Phase 3 clinical study as a monotherapy for treatment of recurrent Stage III or Stage IV metastatic melanoma. As of December 31, 2015, the Company determined that the treatment paradigm in metastatic melanoma was transformed during the course of 2015 by the accelerating adoption of multiple immune checkpoint inhibitors used as monotherapy and in combination treatments. These new drugs have significantly improved outcomes in metastatic melanoma and therefore have altered the opportunity for a monotherapy such as CLBS20 in a landscape that is quickly converting to combination therapies, and as a result, the Company discontinued the ongoing CLBS20 Phase 3 clinical study. As a result, the CSC Acquisition contingent consideration fair value decreased from $12.8 million as of December 31, 2014 to $0 as of December 31, 2015. The change in estimated fair value has been recorded in other expenses in our consolidated statement of operations.

The fair value of contingent consideration obligations is based on discounted cash flow models using a probability-weighted income approach. The measurements are based upon unobservable inputs supported by little or no market activity based on our own assumptions and experience. The Company bases the timing to complete the development and approval programs on the current development stage of the product and the inherent difficulties and uncertainties in developing a product candidate, such as obtaining U.S. Food and Drug Administration (FDA) and other regulatory approvals. In determining the probability of regulatory approval and commercial success, we utilize data regarding similar milestone events from several sources, including industry

studies and our own experience. These fair value measurements represent Level 3 measurements as they are based on significant inputs not observable in the market. Significant judgment is employed in determining the appropriateness of these assumptions as of the acquisition date and for each subsequent period. Accordingly, changes in assumptions could have a material impact on the amount of contingent consideration expense we record in any given period.

The following table sets forth by level within the fair value hierarchy the Company's financial assets and liabilities that were accounted for at fair value on a recurring basis as of December 31, 2015, and December 31, 2014 (in thousands):

	December 31, 2015				December 31, 2014			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Marketable securities - available for sale	$ —	$ —	$ —	$ —	$ —	$ 7,080.0	$ —	$ 7,080.0
	$ —	$ —	$ —	$ —	$ —	$ 7,080.0	$ —	$ 7,080.0
Liabilities:								
Contingent consideration	—	—	—	—	—	—	18,260.0	18,260.0
	$ —	$ —	$ —	$ —	$ —	$ —	$ 18,260.0	$ 18,260.0

There were no transfers of financial instruments to or from Levels 1, 2 or 3 during the periods presented. For those financial instruments with significant Level 3 inputs, the following table summarizes the activity for the year ended December 31, 2015 by type of instrument (in thousands):

	Year Ended December 31, 2015	
	Contingent Consideration	Total
Beginning liability balance	$ 18,260.0	$ 18,260.0
Change in fair value recorded in operations	(18,260.0)	(18,260.0)
Ending liability balance	$ —	$ —

Some of the Company's financial instruments are not measured at fair value on a recurring basis, but are recorded at amounts that approximate fair value due to their liquid or short-term nature, such as cash and cash equivalents, accounts receivable, and accounts payable. Our long-term debt and notes payable are carried at cost and approximate fair value due to their variable or fixed interest rates, which are consistent with the interest rates in the market.

Note 9 – Goodwill and Other Intangible Assets

The following table summarizes the changes in the carrying amount of goodwill (in thousands):

	Total
Balance as of December 31, 2014	$ 25,209.3
Goodwill impairment	(18,196.0)
Balance as of December 31, 2015	$ 7,013.3

Goodwill impairment of $18.2 million is based on the Company's annual review for goodwill impairment as of December 31, 2015, and related to the Company's Research and Development reporting unit. The impairment is directly attributable to the Company's decision to discontinue its CLBS20 Phase 3 study. The Company evaluated whether goodwill was impaired in the Research and Development reporting unit as of June 30, 2015 in connection with its decision to no longer pursue further development of CLBS10, and concluded there was no goodwill impairment. The remaining goodwill is solely related to the PCT reporting unit.

The Company's intangible assets and related accumulated amortization as of December 31, 2015 and December 31, 2014 consisted of the following (in thousands):

	Useful Life	December 31, 2015 Gross	December 31, 2015 Accumulated Amortization	December 31, 2015 Net	December 31, 2014 Gross	December 31, 2014 Accumulated Amortization	December 31, 2014 Net
Customer list	10 years	$ 1,000.0	$ (495.1)	$ 504.9	$ 1,000.0	$ (395.1)	$ 604.9
Manufacturing technology	10 years	3,900.0	(1,930.9)	1,969.1	3,900.0	(1,540.9)	2,359.1
Tradename	10 years	800.0	(396.1)	403.9	800.0	(316.1)	483.9
In process R&D	Indefinite	—	—	—	43,690.0	—	43,690.0
Patent rights	19 years	—	—	—	669.0	(246.5)	422.5
Total Intangible Assets		$ 5,700.0	$ (2,822.1)	$ 2,877.9	$ 50,059.0	$ (2,498.6)	$ 47,560.4

The Company's IPR&D programs were acquired in the Amorcyte Acquisition (CD34 technology) and CSC Acquisition (tumor cell/dendritic cell technology).

- *CD34 Technology:* The Company determined as of June 30, 2015, based on a thorough analysis of the available data from the PreSERVE-AMI Phase 2 clinical study, an updated commercial assessment, and consultation with the Company's scientific advisory board and the Science and Technology Committee of the Board of Directors, that it will not pursue further development of CLBS10 for the acute myocardial infarction indication upon completion of the ongoing PreSERVE-AMI Phase 2 clinical study. However, it intends to explore other potential and more commercially viable indications of chronic heart failure and/or critical limb ischemia for its CD34 cell technology platform. These other indications are early stage opportunities, and would require external funding and/or partnerships to proceed to the next step in clinical development. As a result, and given the early stage and funding constraints of these other potential opportunities, the Company determined that IPR&D valued at $9.4 million was fully impaired as of June 30, 2015.

- *Tumor Cell/Dendritic Cell Technology:* In May 2014, in connection with the CSC Acquisition, the Company acquired CLBS20, a Phase 3 clinical study as a monotherapy for treatment of recurrent Stage III or Stage IV metastatic melanoma.The Company determined as of December 31, 2015, that the treatment paradigm in metastatic melanoma was transformed during the course of 2015 by the accelerating adoption of multiple immune checkpoint inhibitors used as monotherapy and in combination treatments. These new drugs have significantly improved outcomes in metastatic melanoma and therefore have altered the opportunity for a monotherapy such as CLBS20 in a landscape that is quickly converting to combination therapies, and as a result, the Company discontinued the ongoing CLBS20 Phase 3 clinical study. As a result, given the changing competitive landscape and funding constraints of advancing this program, and a thorough evaluation of these factors by the Company's management in the fourth quarter of 2015, the Company determined that IPR&D valued at $34.3 million was fully impaired as of December 31, 2015.

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

	Year Ended December 31, 2015	2014	2013
Cost of revenue	$ 309.1	$ 316.8	$ 390.0
Research and development	116.1	108.4	35.2
Selling, general and administrative	180.0	180.0	180.0
Total	$ 605.2	$ 605.2	$ 605.2

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

2016	$ 570.0
2017	570.0
2018	570.0
2019	570.0
2020	570.0
Thereafter	27.9
	$ 2,877.9

Note 10 – Accrued Liabilities

Accrued liabilities were as follow (in thousands):

	December 31,	
	2015	2014
Salaries, employee benefits and related taxes	$ 2,771.2	$ 2,807.2
Professional fees	480.7	495.4
Other	2,946.5	1,020.3
	$ 6,198.4	$ 4,322.9

Note 11 – Debt

Notes Payable

As of December 31, 2015 and December 31, 2014, the Company had notes payable of approximately $1.8 million and $1.6 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”). After repayment of all outstanding amounts due under two loans from TD Bank, N.A. in the amount of approximately $3.1 million, and deductions for debt offering/issuance costs and interim period interest, the net proceeds from Loan were $11.3 million. 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. The proceeds from the Loan may be used to satisfy the Company’s future working capital needs, including the development of its cell therapy product candidates.

The Company has been making interest only payments on the outstanding amount of Loan on a monthly basis at a rate of 8.50% per annum. On April 29, 2015, with the Company's announcement that the first patient in the Intus Study had been randomized, the interest-only payment period on the Loan was extended from October 1, 2015 to April 1, 2016, which was in accordance with the Loan and Security Agreement. In March 2016, the interest-only payment period was extended through January 1, 2017 (see Note 18). Commencing on January 1, 2017, the Company will make 21 consecutive monthly payments of principal and interest. The Loan matures on September 1, 2018. At its option, the Company may prepay all amounts owed under the Loan and Security Agreement (including all accrued and unpaid interest), subject to a prepayment fee that is determined based on the date the loan is prepaid. The Company is also required to pay Lender a final payment fee equal to 8% of the Loan. The final payment fee will be amortized to interest expense throughout the life of the Loan using the effective interest rate method. The Company paid a facility fee in the amount of $100,000 in connection with Loan.

Under the Loan and Security Agreement and a related mortgage, the Company granted to Lender a security interest in all of the Company’s real property and personal property now owned or hereafter acquired, excluding intellectual property, and certain other assets and exemptions. The Company also entered into a Mortgage and Absolute Assignment of Leases and Rents (the "Mortgage"). The Company also granted Lender a security interest in the shares of 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 its business or property; 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 with the Loan and Security Agreement. As of December 31, 2015, the Company was in compliance with all covenants under the Loan and Security Agreement.

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

Years Ending December 31,		(in millions)
2016	$	5.3
2017		6.7
2018		6.2
Total	$	18.2

During the years ended December 31, 2015 and 2014, the Company recognized $1.3 million and $0.3 million of interest expense related to the Loan and Security Agreement.

Note 12 – Stockholders' Equity

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 4,400,000 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 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) 176,000 shares, which equals four percent (4%) of the initial reserve of 4,400,000 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 380,000 to 975,000. 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 1,375,000. At a Special Meeting of Stockholders of the Company held on January 18, 2011, the stockholders approved an amendment to increase this number to 1,775,000. 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 2,375,000. At the 2012 Annual Meeting of Stockholders of the Company held on October 5, 2012, the stockholders approved an amendment to (i) merge the 570,000 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 450,000 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 5,995,000. 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 8,995,000.

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 8,995,000 shares of common stock of the Company (as of December 31, 2015) 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, 2015:

	2003 Equity Plan	2009 Equity Plan	2015 Equity Plan
Shares Authorized for Issuance	250,000	8,995,000	4,400,000
Outstanding Stock Options	(108,745)	(6,113,425)	(441,100)
Exercised Stock Options	(9,250)	(80,856)	—
Restricted stock or equity grants issued under Equity Plans	(88,993)	(1,601,033)	—
Shares Expired	(43,012)	—	—
Total common shares remaining to be issued under the Equity Plans	—	1,199,686	3,958,900

The Company adopted an employee stock purchase plan effective January 1, 2013, and authorized 500,000 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, 2015, 133,939shares were issued under the employee stock purchase plan. At December 31, 2015, the Company had 300,620 shares of the Company's common stock available for future grant in connection with this plan.

Equity Issuances

June 2015 Public Offering

In June 2015, the Company completed an underwritten offering of 12.5 million shares of the Company's common stock, at a public offering price of $2.00 per share. The underwriters also exercised their entire over-allotment option of 1.875 million shares. The Company received gross proceeds of $28.8 million, before deducting underwriting discounts and commissions and offering expenses payable by the Company.

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 11.0 million shares, unless stockholder approval is obtained or certain minimum sale price levels are reached) of the Company's common stock over a 24-month term. As consideration for entering into the Purchase Agreement, the Company issued 842,696 shares of its common stock to Aspire Capital. During the years ended December 31, 2015, the Company issued 200,000 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 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 at any time.

We are party to two existing agreements with Aspire Capital (the "May 2015 Purchase Agreement" and the "March 2014 Purchase Agreement", or collectively, the "Previous Purchase Agreements"). The registration statement we previously filed with the SEC to cover offerings of shares of our common stock subject to the previous 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 Previous 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 364,837 shares of its common stock to Aspire Capital. The Company has not issued any additional shares under the May 2015 Purchase Agreement. Under the March 2014 Purchase Agreement, Aspire Capital is committed to purchase up to an aggregate of $30 million of shares. As consideration for entering into the March 2014 Purchase Agreement, the Company issued 150,000 shares of its common stock to Aspire Capital. During the years ended December 31, 2015, the Company issued 3.0 million shares of common stock under the March 2014 Purchase Agreement with Aspire for gross proceeds of $9.4 million. Overall, the Company issued 5.1 million shares under the March 2014 Purchase Agreement for gross proceeds of $20.3 million.

Stock Options and Warrants

The following table summarizes the activity for stock options and warrants for the year ended December 31, 2015:

	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, 2014	4,427,234	$ 9.19	6.93	$ 28.6	3,550,956	$ 14.12	2.12	$ 1.0
Changes during the Year:								
Granted	3,414,388	$ 3.01			—	$ —		
Exercised	—	$ —			—	$ —		
Forfeited	(437,770)	$ 4.92			—	$ —		
Expired	(740,372)	$ 7.83			(336,923)	$ 17.91		
Outstanding at December 31, 2015	6,663,480	$ 6.46	6.88	$ 0.1	3,214,033	$ 13.72	1.26	$ —
Vested at December 31, 2015 or expected to vest in the future	6,663,480	$ 6.58	6.79	$ 0.1	3,214,033	$ 13.72	1.26	$ —
Exercisable at December 31, 2015	4,837,711	$ 7.46	6.12	$ —	3,214,033	$ 13.72	1.26	$ —

The total intrinsic value of stock options exercised during the years ended December 31, 2015 and December 31, 2014 was $0 and $61,641, respectively.

During the years ended December 31, 2015 and 2014, the Company did not issue warrants for services.

Restricted Stock

During the years ended December 31, 2015 and 2014, the Company issued restricted stock for services as follows ($ in thousands, except share data):

	2015	2014
Number of Restricted Stock Issued	928,000	917,907
Value of Restricted Stock Issued	$ 2,488.6	$ 4,996.3

The weighted average estimated fair value of restricted stock issued for services in the years ended December 31, 2015 and 2014 was $2.68 and $5.44 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 13 – Share-Based Compensation

Share-based Compensation

We utilize share-based compensation in the form of stock options, warrants and restricted stock. The following table summarizes the components of share-based compensation expense for the years ended December 31, 2015, 2014 , and 2013 ($ in thousands):

	Year Ended December 31,		
	2015	2014	2013
Cost of revenues	$ 545.3	$ 494.2	$ 314.0
Research and development	1,811.5	2,058.2	822.2
Selling, general and administrative	7,393.3	8,657.1	5,702.5
Total share-based compensation expense	$ 9,750.1	$ 11,209.5	$ 6,838.7

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, 2015 were as follows ($ in thousands):

	Stock Options	Warrants	Restricted Stock
Unrecognized compensation cost	$ 3,078.6	$ —	$ 332.0
Expected weighted-average period in years of compensation cost to be recognized	3.17	0.00	1.95

Total fair value of shares vested and the weighted average estimated fair values of shares grant for the year ended December 31, 2015, 2014, and 2013 were as follows ($ in thousands):

	Stock Options			Warrants		
	Year Ended December 31,			Year Ended December 31,		
	2015	2014	2013	2015	2014	2013
Total fair value of shares vested	$ 6,133.0	$ 5,387.1	$ 3,375.7	$ —	$ 9.6	$ 129.0
Weighted average estimated fair value of shares granted	1.95	4.56	4.29	—	—	3.71

Valuation Assumptions

The fair value of stock options and warrants at the date of grant was estimated using the Black-Scholes option pricing model. The expected volatility is based upon historical volatility of the Company's stock. The expected term for the options is based upon observation of actual time elapsed between date of grant and exercise of options for all employees. The expected term for the warrants is based upon the contractual term of the warrants.

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

	Stock Options			Warrants		
	Year Ended December 31,			Year Ended December 31,		
	2015	2014	2013	2015	2014	2013
Expected term - minimum (in years)	2	0	1	0	3	2
Expected term - maximum (in years)	10	10	10	0	3	5
Expected volatility - minimum	71%	62%	61%	—	66%	73%
Expected volatility - maximum	75%	77%	79%	—	66%	79%
Weighted Average volatility	74%	74%	83%	—	74%	82%
Expected dividend yield	—	—	—	—	—	—
Risk-free interest rate - minimum	1.19%	0.12%	0.13%	—	0.79%	0.32%
Risk-free interest rate - maximum	2.14%	3.00%	2.67%	—	0.79%	1.73%

Note 14 – 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,		
	2015	2014	2013
United States	$ (98,254.0)	$ (55,570.4)	$ (38,705.2)
	$ (98,254.0)	$ (55,570.4)	$ (38,705.2)

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

	Years Ended December 31,		
	2015	2014	2013
Current			
U.S. Federal	$ —	$ —	$ —
State and local	—	—	—
	$ —	$ —	$ —
Deferred			
U.S. Federal	$ (14,695.5)	$ 159.0	$ 476.9
State and local	(2,548.0)	(263.2)	303.2
	$ (17,243.5)	$ (104.2)	$ 780.1
Total			
U.S. Federal	$ (14,695.5)	$ 159.0	$ 476.9
State and local	(2,548.0)	(263.2)	303.2
	$ (17,243.5)	$ (104.2)	$ 780.1

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,		
	2015	2014	2013
U.S. Federal benefit at statutory rate	$ (33,406.4)	$ (18,894.0)	$ (13,159.8)
State and local benefit net of U.S. federal tax	(4,926.9)	(3,435.0)	(3,430.9)
Permanent non deductible expenses for U.S. taxes	706.4	1,094.6	1,798.2
True-up of prior year net operating loss	(556.5)	(25.5)	(91.4)
Return to actual	—	—	(3,822.9)
Effect of change in deferred tax rate	1.3	1,075.7	(1,094.8)
Valuation allowance for deferred tax assets	20,938.6	20,080.0	20,581.7
Tax provision	$ (17,243.5)	$ (104.2)	$ 780.1

Deferred income taxes at December 31, 2015, 2014 and 2013 consist of the following ($ in thousands):

	December 31,		
	2015	2014	2013
Deferred Tax Assets:			
Accumulated net operating losses (tax effected)	$ 86,537.8	$ 69,047.0	$ 25,727.7
Deferred revenue	—	—	23.1
Deferred rent	11.1	(7.8)	15.2
Share-based compensation	12,764.3	9,577.2	5,466.7
Intangibles	899.7	715.1	287.3
Accumulated depreciation	—	—	348.7
Charitable contributions	423.3	409.8	391.8
Bad debt provision	297.4	296.9	239.7
Capital loss carry-forward	6,973.0	6,925.1	6,644.5
Other	652.1	609.7	—
Deferred tax assets prior to tax credit carryovers	108,558.7	87,573.0	39,144.7
Deferred Tax Liabilities:			
Accumulated depreciation	$ (66.0)	$ (18.8)	$ —
Intangible and indefinite lived assets	(932.7)	(18,176.3)	(3,599.1)
Deferred tax liabilities	(998.7)	(18,195.1)	(3,599.1)
	107,560.0	69,377.9	35,545.6
Valuation reserve	(108,492.7)	(87,554.1)	(39,144.7)
Net deferred tax liability	$ (932.7)	$ (18,176.2)	$ (3,599.1)

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, 2015 and 2014, the Company had approximately $221.5 million and $177.2 million, respectively of Federal NOLs available to offset future taxable income expiring from 2026 through 2035. In accordance with Section 382 of the Internal Revenue code, the usage of the Company's NOLs could be limited in the event of a change in ownership. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period when those temporary differences become deductible. If a change of ownership did occur there would be an annual limitation on the usage of the Company's losses which are available through 2035.

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, 2015, 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 Federal tax returns are currently being audited for the years 2012 and 2013. For years prior to 2011 the federal statute of limitations is closed. Most of the remaining states remain open to examination for a period of 3 to 4 years from date of filing. The Company files tax returns in all of the foreign jurisdictions that it has a permanent establishment and the tax filings remain subject to examination for 4 to 5 years.

Note 15 – Related Party Transactions

In December 2013, the Company modified both the First Mortgage and Second Mortgage with TD Bank, N.A. (see Note 11). Pursuant to the Loan Modifications, Andrew L. Pecora, M.D., Regional Cancer Care Associates LLC (Dr. Pecora's medical practice), and certain partners in such practice, including Dr. Pecora, had been released as guarantors of the Second Mortgage Loan, and Caladrius had become a guarantor of the Loans pursuant to a Guaranty of Payment delivered by Caladrius to the Lender. Dr. Pecora, currently serves as a Caladrius director.

Note 16 – Commitments and Contingencies

Lease Commitments

We entered into an assignment agreement with an unaffiliated third party, effective February 19, 2015, for general office space located in Basking Ridge, NJ. This property is used as the Company's corporate headquarters. The space is approximately 18,000 rentable square feet. The base monthly rent is currently $31,875and the lease term ends July 31, 2020. In addition, there are two (2) five (5) year renewal options. In connection with the assumption of the lease, the third party (a) conveyed its rights in various scheduled furniture and equipment and (b) paid the Company approximately $580,000. The amount paid to the Company included a security deposit of approximately $115,000. The Company also leases facilities in New York, NY, Irvine, CA, and Mountain View, CA, of which certain have escalation clauses and renewal options, and also leases equipment under certain noncancelable operating leases that expire from time to time through 2021.

A summary of future minimum rental payments required under operating leases that have initial or remaining terms in excess of one year as of December 31, 2015 are as follows (in thousands):

Years ended	Operating Leases
2016	2,062.0
2017	1,863.8
2018	1,034.7
2019	989.4
2020 and thereafter	960.2
Total minimum lease payments	$ 6,910.1

Expense incurred under operating leases were approximately $1.7 million , $1.3 million , and $1.1 million for the years ended December 31, 2015, 2014, and 2013, 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: Trex 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 is expected to commence as early as the first quarter of 2016. We will be initially responsible for the supply of all study drug to the first 18 enrolled patients upon commencement of the study.

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

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

Note 17 – Quarterly Financial Data (unaudited)

The tables below summarize the Company's unaudited quarterly operating results for the years ended December 31, 2015 and 2014, respectively.

(in thousands, except per share data)	Three Months Ended March 31, 2015	June 30, 2015	September 30, 2015	December 31, 2015
Revenues	$ 3,172	$ 5,867	$ 5,888	$ 7,560
Total operating costs and expenses	$ 21,260	$ 31,536	$ 16,271	$ 67,269
Net loss	$ (19,231)	$ (17,158)	$ (11,393)	$ (33,228)
Net loss attributable to Caladrius Biosciences, Inc. common stockholders	$ (19,187)	$ (17,126)	$ (11,376)	$ (33,197)
Basic and diluted loss per share attributable to Caladrius Biosciences, Inc. common stockholders	$ (0.51)	$ (0.38)	$ (0.21)	$ (0.59)

(in thousands, except per share data)	Three Months Ended March 31, 2014	June 30, 2014	September 30, 2014	December 31, 2014
Revenues	$ 4,056	$ 4,489	$ 4,118	$ 5,276
Total operating costs and expenses	$ 17,555	$ 16,919	$ 20,376	$ 20,830
Net loss	$ (13,830)	$ (12,769)	$ (17,177)	$ (11,691)
Net loss attributable to Caladrius Biosciences, Inc. common stockholders	$ (13,682)	$ (12,605)	$ (16,974)	$ (11,612)
Basic and diluted loss per share attributable to Caladrius Biosciences, Inc. common stockholders	$ (0.49)	$ (0.40)	$ (0.48)	$ (0.32)

Note 18 – Subsequent Events

Hitachi Transaction

On March 11, 2016, PCT entered into a global collaboration that includes licensing, development and equity components with Hitachi Chemical Co., LTD ("Hitachi Chemical"), a Japanese-based global conglomerate with a growing franchise in life sciences including regenerative medicine ("Hitachi Transaction") to develop our PCT business outside of the U.S. This collaboration consists of an equity investment in, and a license agreement with, PCT.

Under the equity investment agreement, Hitachi Chemical purchased a 19.9% membership interest in PCT for $19.4 million of which $15.0 million will be distributed to Caladrius from PCT and $4.4 million will remain at PCT, which will be used for the continued expansion and improvements at PCT in support of commercial product launch readiness as well as for general corporate purposes. Caladrius remains the majority shareholder retaining an 80.1% ownership interest.

PCT and Hitachi Chemical also entered into an exclusive license agreement for Asia pursuant to which PCT will receive $5.6 million from Hitachi Chemical in three fee driven payments throughout 2016. PCT licensed certain cell therapy technology and know-how (including an exclusive license in Asia) and agreed to provide Hitachi Chemical with certain training and support. As additional consideration, Hitachi Chemical will pay PCT royalties on contract revenue generated in Asia for a minimum of 10 years.

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

Oxford Debt Repayment

On March 11, 2016, upon execution of the Hitachi Transaction, the Company and Oxford Finance LLC entered into an amendment to the Loan and Security Agreement whereby (i) the Company paid $7.0 million to Oxford Finance LLC, comprised of principal, interest and early termination fees, (ii) the Company's subsidiaries PCT, PCT Allendale, LLC, and NeoStem Family Storage, LLC (collectively the "Removed Borrowers") were removed as borrowers under the Loan, (iii) Oxford Finance LLC's security interests in any and all assets of the Removed Borrowers were released, (iv) the interest only period on the remaining outstanding Loan balance is extended until January 1 2017, and (v) in the event the Company receives 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 Oxford Finance LLC, up to a $3.0 million maximum. If 20%

of such proceeds in aggregate is less than $3.0 million by March 31, 2017, then the Company will make a lump sum payment equal to the difference by March 31, 2017.

Common Stock and Warrant Issuances

On March 10, 2016, the Company entered into a securities purchase agreement with certain investors, pursuant to which Caladrius issued and sold in a private placement an aggregate of 1.4 million shares of common stock and a two-year warrant to purchase up to an aggregate of 1.4 million shares of Caladrius' common stock, at an exercise price of $1.00 per share. The unit purchase price for a share of Caladrius common stock and warrant to purchase one share of Caladrius common stock was $0.705 per unit, with $1 million of gross proceeds received by Caladrius.

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, 2015, 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, 2015. 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, 2015, 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, 2015 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Attestation Report of the Registered Public Accounting Firm

Our independent registered public accounting firm, Grant Thornton LLP, audited our internal control over financial reporting as of December 31, 2015. Their attestation report, dated March 15, 2016 and which appears below, expressed an unqualified opinion on our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTRED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
Caladrius Biosciences, Inc.

We have audited the internal control over financial reporting of Caladrius Bioscience, Inc., a Delaware corporation, and subsidiaries (the "Company") as of December 31, 2015, based on criteria established in the 2013 *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 directors of the company; and (3) 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 the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on criteria established in the 2013 *Internal Control-Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements of the Company as of and for the year ended December 31, 2015, and our report dated March 15, 2016 expressed an unqualified opinion on those financial statements.

/s/ GRANT THORNTON LLP

New York, New York
March 15, 2016

ITEM 9B. OTHER INFORMATION.

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Pursuant to Paragraph G(3) of the General Instructions to Form 10-K, the information required by Part III (Items 10, 11, 12, 13 and 14) is being incorporated by reference herein from our definitive proxy statement (or an amendment to our Annual Report on Form 10-K) to be filed with the SEC within 120 days of the end of the fiscal year ended December 31, 2015 in connection with our 2016 Annual Meeting of Stockholders.

ITEM 11. EXECUTIVE COMPENSATION

See Item 10.

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

See Item 10.

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

See Item 10.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

See Item 10.

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

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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
2.1	Agreement and Plan of Merger dated as of May 8, 2014, by and among the Company, California Stem Cell, Inc., NBS Acquisition Sub I, Inc. and NBS Acquisition Sub II, LLC (filed as Exhibit 2.1 to the Company's Current Report on Form 8-K dated April 14, 2014).
2.2	Equity Purchase Agreement, dated as of June 18, 2012, by and among the Company, China Biopharmaceuticals Holdings, Inc., Fullbright Finance Limited, Suzhou Erye Economy & Trading Co., Ltd., and Suzhou Erye Pharmaceutical Co., Ltd. (filed as Exhibit 2.1 to the Company's Current Report on Form 8-K dated June 18, 2012).
2.3	Amendment to Equity Purchase Agreement, dated as of August 14, 2012, by and among the Company, China Biopharmaceuticals Holdings, Inc., Highacheive Holdings Limited, Fullbright Finance Limited, Suzhou Erye Economy & Trading Co., Ltd. and Suzhou Erye Pharmaceutical Co., Ltd. (filed as Exhibit 2.1 to the Company's Current Report on Form 8-K dated August 23, 2012).
2.4	Agreement and Plan of Merger, dated as of July 13, 2011, by and among the Company, Amo Acquisition Company I, Inc., Amo Acquisition Company II, LLC and Amorcyte, Inc. (filed as Exhibit 2.1 to the Company's Current Report on Form 8-K dated July 11, 2011).
2.5	Agreement and Plan of Merger, dated as of September 23, 2010, by and among the Company, NBS Acquisition Company LLC, and PCT (filed as Exhibit 2.1 to the Company's Current Report on Form 8-K dated September 23, 2010).
3.1	Amended and Restated Certificate of Incorporation of the Company, filed with the Secretary of State of the State of Delaware on October 3, 2013 (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K dated October 3, 2013).
3.2	Amended and Restated By-Laws dated January 5, 2015 (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K on January 5, 2015).
3.3	Amendment to the By-Laws of the Company - Forum Selection Clause (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on June 5, 2015).
3.4	Certificate of Amendment to Certificate of Incorporation of the Company dated May 29, 2015 (effective June 8, 2015) (filed as Exhibit 3.2 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).
4.1	Form of Redeemable Service Provider Warrant (filed as Exhibit 4.19 to the Company's Registration Statement on Form S-3/A, File No. 333.173853, filed with the SEC on September 16, 2011).
4.2	Form of 2011 Redeemable Service Provider Warrant (filed as Exhibit 4.20 to the Company's Registration Statement on Form S-3/A, File No. 333-173853, filed with the SEC on September 16, 2011).
4.3	Form of Redeemable Service Provider Warrant with cashless exercise rights (filed as Exhibit 4.21 to the Company's Registration Statement on Form S-3/A, File No. 333-173853, filed with the SEC on September 16, 2011).
4.4	Form of 2010/2011 Redeemable Service Provider Warrant with cashless exercise rights (filed as Exhibit 4.22 to the Company's Registration Statement on Form S-3/A, File No. 333-173853, filed with the SEC on September 16, 2011).
4.5	Letter Agreement dated December 18, 2008 between the Company and RimAsia Capital Partners, L.P. (filed as Exhibit 4.1 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 as filed with the SEC on March 31, 2009).
4.6	Specimen Certificate for Common Stock (filed as Exhibit 4.1 to the Company's Registration Statement on Form S-3, File No. 333-145988, filed with the SEC on September 11, 2007).
4.7	Form of Placement Agent Warrant from June 2010 (filed as Exhibit 4.2 to the Company's Current Report on Form 8-K dated June 25, 2010 and filed with the SEC on June 28, 2010).
4.8	Amended and Restated Warrant, dated March 15, 2010, issued to RimAsia Capital Partners, L.P. (filed as Exhibit 4.1 to the Company's Current Report on Form 8-K dated March 15, 2010 and filed with the SEC on March 18, 2010).
4.9	Form of Warrant from the November 2010 Common Stock Offering (filed as Exhibit 4.1 to the Company's Current Report on Form 8-K dated and filed with the SEC on November 16, 2010).

4.10 Warrant Agreement, dated as of January 19, 2011, between the Company, and Continental Stock Transfer & Trust Company, with the forms of $3.00 Warrant and $5.00 Warrant attached thereto (filed as Exhibit 4.1 to the Company's Current Report on Form 8-K dated January 18, 2011 and filed with the SEC on January 24, 2011).

4.11 Warrant Agreement, dated as of July 22, 2011, between the Company and Continental Stock Transfer & Trust Company, with the form of Series NA Warrant attached thereto (filed as Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011 as filed with the SEC on November 10, 2011).

4.12 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).

4.13 Warrant Agreement, dated as of October 17, 2011, between the Company and Continental Stock Transfer & Trust Company, with the form of Global Series AMO Warrant attached thereto (filed as Exhibit 4.1 to the Company's Current Report on Form 8-K dated October 14, 2011).

4.14 Form of Common Stock Purchase Warrant from the March 2012 Underwritten Offering (filed as Exhibit 4.1 to the Company's Current Report on Form 8-K dated March 29, 2012).

4.15 Form of Common Stock Purchase Warrant for the May-July 2012 private placement (filed as Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2012 as filed with the SEC on August 14, 2012).

4.16 Form of New Warrant from July 2012 (filed as Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2012 as filed with the SEC on August 14, 2012).

4.17 Form of Warrant from August 2012 private placement (filed as Exhibit 4.6 to the Company's Registration Statement on Form S-3, File No. 333-183542, filed with the SEC on August 24, 2012).

4.18 Form of 2011/2012 Service Provider Warrant (filed as Exhibit 4.10 to the Company's Registration Statement on Form S-3, File No. 333-183542, filed with the SEC on August 24, 2012).

4.19 Warrant issued to Aspire Capital Fund, LLC in August 2012 (filed as Exhibit 4.9 to the Company's Registration Statement on Form S-3, File No. 333-183542, filed with the SEC on August 24, 2012).

4.20 Form of Warrant for November 2012 Unit private placement (filed as Exhibit 4.4 to the Company's Registration Statement on Form S-3, File No. 333-185346, filed with the SEC on December 7, 2012).

4.21 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).

4.22 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).

4.23 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).

10.1 Consulting Agreement, dated as of May 11, 2010 between the Company and RimAsia Capital, Partners, LP (filed as Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010 as filed with the SEC on August 6, 2010).

10.2 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).

10.3 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).

10.4 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).

10.5 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).

10.6 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).

10.7 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).

10.8 Stock Purchase and Assignment Agreement dated March 28, 2011, by and among PCT, Athelos Corporation and Becton Dickinson and Company (filed as Exhibit 10.3 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).

10.9 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).

10.10 The Company 2003 Equity Participation Plan, as amended (filed as Exhibit 10.2 to the Company's Registration Statement on Form S-1/A, File No. 333-137045, filed with the SEC on November 3, 2006). +

10.11 Form of Stock Option Agreement (filed as Exhibit 10.2 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2003 as filed with the SEC on March 30, 2004). +

10.12 Form of Option Agreement dated July 20, 2005 (filed as Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2005 as filed with the SEC on August 15, 2005). +

10.13 Amended and Restated Company 2009 Equity Compensation Plan, as amended (filed as Annex A to the Company's Definitive Proxy Statement on Schedule 14A filed on August 29, 2014). +

10.14 Form of Stock Option Grant Agreement under the Company 2009 Equity Compensation Plan (filed as Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010 as filed with the SEC on August 16, 2010). +

10.15 Description of the Company's Board of Directors Compensation Plan (incorporated by reference to the first paragraph of Item 5.02 contained within the Company's Current Report on Form 8-K dated January 4, 2012, and the last paragraph appearing under Item 11 of this Annual Report on Form 10-K for the fiscal year ended December 31, 2012). +

10.16 The Company's 2012 Employee Stock Purchase Plan (filed as Appendix A to the Company's Definitive Proxy Statement on Schedule 14A for the 2012 Annual Meeting of Stockholders as filed with the SEC on September 7, 2012).+

10.17 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).

10.18 Employment Agreement between the Company and Dr. Robin L. Smith, dated May 26, 2006 (filed as Exhibit 10.4 to the Company's Current Report on Form 8-K dated June 2, 2006). +

10.19 January 26, 2007 Amendment to Employment Agreement of Dr. Robin L. Smith (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K dated January 26, 2007). +

10.20 September 27, 2007 Amendment to Employment Agreement of Dr. Robin L. Smith (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K dated September 27, 2007). +

10.21 Letter agreement dated January 9, 2008 with Dr. Robin L. Smith (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K dated January 9, 2008). +

10.22 Amendment dated July 29, 2009 to Employment Agreement dated May 26, 2006 between the Company and Dr. Robin L. Smith (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K dated July 29, 2009). +

10.23 Amendment dated April 4, 2011 to Employment Agreement dated May 26, 2006 between the Company and Dr. Robin L. Smith (filed as Exhibit 10.66 to the Company's Annual Report on From 10-K for the fiscal year ended December 31, 2010 as filed with the SEC on April 6, 2011). +

10.24 Amendment dated November 13, 2012 to Employment Agreement dated May 26, 2006 between the Company and Dr. Robin L. Smith (filed as Exhibit 10.43 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2012 as filed with the SEC on March 8, 2013). +

10.25 Letter Agreement dated March 11, 2014 to Employment Agreement dated May 26, 2006 between the Company and Dr. Robin L. Smith (filed as Exhibit 10.49 to the Company's Annual Report on Form 10-K filed with the SEC on March 13, 2014). +

10.26 Amendment dated as of January 1, 2015, to Employment Agreement by and between the Company and Dr. Robin L. Smith, dated May 26, 2006 (filed as Exhibit 10.1 on the Company's Current Report on Form 8-K filed with the SEC on January 5, 2015). +

10.27 Amendment, dated as of January 16, 2015, to Amendment dated as of January 1, 2015 to Employment Agreement by and between the Company and Dr. Robin L. Smith (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on January 16, 2015). +

10.28 Consulting Agreement, dated as of December 18, 2015 by and between the Company and Dr. Robin L. Smith (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on December 23, 2015).

10.29 January 26, 2007 Employment Agreement with Catherine M. Vaczy, Esq. (filed as Exhibit 10.4 to the Company's Current Report on Form 8-K dated January 26, 2007). +

10.30 Letter agreement dated January 9, 2008 with Catherine M. Vaczy, Esq. (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K dated January 9, 2008). +

10.31 Letter Agreement dated July 8, 2009 between the Company and Catherine M. Vaczy, Esq. (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K dated July 6, 2009). +

10.32 Letter Agreement dated July 7, 2010 between the Company and Catherine M. Vaczy, Esq. (filed as Exhibit 10(a) to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2010 as filed with the SEC on November 12, 2010). +

10.33 Letter Agreement dated January 6, 2012 between the Company and Catherine M. Vaczy, Esq. (filed as Exhibit 10.92 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011 as filed with the SEC on March 20, 2012). +

10.34 Letter Agreement dated November 13, 2012 between the Company and Catherine M. Vaczy, Esq. (filed as Exhibit 10.57 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2012 as filed with the SEC on March 8, 2013). +

10.35 Letter Agreement, dated July 12, 2013, between the Company and Catherine M. Vaczy, Esq. (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K dated July 12, 2013). +

10.36 Letter Agreement, dated March 11, 2014, between the Company and Catherine M. Vaczy, Esq. (filed as Exhibit 10.57 to the Company's Annual Report on Form 10-K filed with the SEC on March 13, 2014).+

10.37 Letter Agreement, dated August 4, 2014, between the Company and Catherine M. Vaczy, Esq. (filed as Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q with the SEC on August 7, 2014).

10.38 Letter Agreement, dated October 27, 2014, between the Company and Catherine M. Vaczy, Esq. (filed as Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed with the SEC on October 30, 2014).+

10.39 Letter Agreement dated January 2, 2015, between the Company and Catherine M. Vaczy, Esq. (filed as Exhibit 10.39 to the Company's Annual Report on Form 10-K/A filed with the SEC on April 30, 2015).+

10.40 Letter Agreement, dated February 5, 2015, between the Company and Catherine M. Vaczy, Esq. (filed as Exhibit 10.40 to the Company's Annual Report on Form 10-K/A filed with the SEC on April 30, 2015).+

10.41 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). +

10.42 Amendment dated August 17, 2011 to Employment Agreement dated September 23, 2010 and effective January 19, 2011 between PCT, the Company, and Andrew L. Pecora, M.D., F.A.C.P. (filed as Exhibit 10.95 to the Company's Registration Statement on Form S-4, File No. 333-176673, filed with the SEC on September 2, 2011). +

10.43 Letter Agreement dated April 11, 2012 between the Company and Andrew Pecora, M.D., F.A.C.P. (filed as Exhibit 10.107 to the Company's Annual Report on Form 10-K/A for the year ended December 31, 2011 as filed with the SEC on April 27, 2012). +

10.44 Amendment dated July 31, 2013 and effective August 5, 2013, by and among Andrew L. Pecora, M.D., FACP, the Company, PCT, and Amorcyte, LLC (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K dated August 5, 2013). +

10.45 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). +

10.46 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). +

10.47 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).+

10.48 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).

10.49 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).+

10.50†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.+

10.51 Employment Agreement, dated as of July 15, 2013, by and between the Company and Stephen W. Potter (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K dated July 15, 2013).+

10.52 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).+

10.53 Employment Agreement, dated as of August 16, 2013 and effective August 19, 2013, by and between the Company and Robert Dickey IV (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K dated August 19, 2013).+

10.54 Offer Letter dated August 14, 2013 and effective August 19, 2013, by and between the Company and Larry May (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K dated August 19, 2013).+

10.55 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).+

10.56 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).+

10.57 Employment Agreement, dated as of January 5, 2015 and effective on January 5, 2015, by and between the Company. and Robert S. Vaters (filed as Exhibit 10.3 to the Company's Current Report on Form 8-K filed on January 5, 2015).+

10.58 Amendment, dated as of January16, 2015, to Employment Agreement, dated as of January 5, 2015 and effective on January 5, 2015, by and between the Company and Robert S. Vaters (filed as Exhibit 10.3 to the Company's Current Report on Form 8-K filed on January 16, 2015).+

10.59†Separation Agreement, dated as of October 5, 2015, to Employment Agreement, dated January 5, 2015, by and between Company and Robert S. Vaters.+

10.60 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).

10.61 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).

10.62 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).

10.63 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).

10.64 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).

10.65 Consulting Agreement, dated December 18, 2015, between the Company and Dr. Robin L. Smith (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on December 23, 2015). +

10.66 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). +

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

32.1† Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

32.2† Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

101.INS† XBRL Instance Document

101.SCH†XBRL Taxonomy Extension Schema

101.CAL†XBRL Taxonomy Extension Calculation Linkbase

101.DEF†XBRL Taxonomy Extension Definition Linkbase

101.LAB†XBRL Taxonomy Extension Label Linkbase

101.PRE† XBRL Taxonomy Extension Presentation Linkbase

\+ 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.

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 15, 2016.

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, PhD. David J. Mazzo, PhD.	Director, and Chief Executive Officer (Principal Executive Officer)	March 15, 2016
/s/ Joseph Talamo Joseph Talamo	Senior Vice President, and Chief Financial Officer (Principal Financial and Accounting Officer)	March 15, 2016
/s/ Steven S. Myers Steven S. Myers	Executive Chair of the Board of Directors	March 15, 2016
/s/ Richard Berman Richard Berman	Director	March 15, 2016
/s/ Robert A. Preti Robert A. Preti	Director, President, Senior Vice President, Manufacturing and Technical Operations, and Chief Technology Officer	March 15, 2016
/s/ Eric Wei Eric Wei	Director	March 15, 2016
/s/ Andrew L. Pecora, M.D. Andrew L. Pecora, M.D.	Director	March 15, 2016
/s/ Steven M. Klosk Steven M. Klosk	Director	March 15, 2016
/s/ Peter Traber Peter Traber	Director	March 15, 2016

Exhibit 10.50

October 6, 2015

Joseph Talamo
27 Brushy Ridge Road
New Canaan, CT 06840

Dear Joe,

This letter serves as an amendment to your offer letter dated June 28, 2011, and confirms your appointment to Senior Vice President & Chief Financial Officer of Caladrius Biosciences, Inc., (the "Company"), reporting to the Chief Executive Officer. This appointment is effective October 6, 2015.

In accordance with your appointment, your annual base salary shall be $300,000.00 and your target bonus shall be up to 30% of base salary. With your appointment, you shall serve as a member of the Company's Executive Committee.

Should the Company terminate your employment without cause, or should you realize a reduction in duties, title, authority or responsibility that occurs by virtue of the Company being acquired, you will be entitled to receive severance in the amount of six (6) months' base salary and benefits continuation for the severance period.

All other terms and conditions of your employment shall remain the same.

Congratulations on your well-deserved appointment! We look forward to your continued efforts and success.

Caladrius Biosciences, Inc.

By: /s/ David Schloss
David Schloss
Vice President, Human Resources

Acknowledged and Agreed:

/s/ Joseph Talamo

Date: October 6, 2015

Exhibit 10.59

SEPARATION AGREEMENT AND GENERAL RELEASE

THIS SEPARATION AGREEMENT AND GENERAL RELEASE (this "Agreement") is made as of the 5th day of October 2015 (the "Effective Date"), by and between Robert S. Vaters ("Executive") and Caladrius Biosciences, Inc. ("Caladrius" or the "Company").

WHEREAS, the Company has employed Executive as its President and Chief Financial Officer since January 5, 2015 pursuant to the terms of an employment agreement dated January 5, 2015 and an amendment thereto dated January 16, 2015 (collectively, the "Employment Agreement"); and

WHEREAS, the Executive has also served as a Director on the Company's Board of Directors since January 22, 2015; and

WHEREAS, Executive and Caladrius (formerly NeoStem, Inc.) entered into an Executive Confidentiality and Inventions Assignment Agreement dated January 5, 2015, in connection with the commencement of his employment, a copy of which is attached hereto (the "Restrictive Covenant Agreement"); and

WHEREAS, Executive's employment with the Company is being terminated effective October 5, 2015; and

WHEREAS, Executive is resigning as a Director on the Company's Board of Directors effective October 5, 2015; and

WHEREAS, Executive and the Company desire to settle fully and finally any differences, rights and duties arising between them, including, but in no way limited to, any differences, rights and duties that have arisen or might arise out of or are in any way related to Executive's employment with the Company and the termination of his employment;

NOW, THEREFORE, in consideration of the payment, benefits and other covenants contained in this Agreement, which Executive acknowledges are in excess of any benefits to which Executive would otherwise be entitled, the parties agree as follows:

1. **Termination**. Executive's employment with the Company terminated effective October 5, 2015 (the "Termination Date") and Executive resigned as a member of the Company's Board of Directors on the Termination Date.

2. **Separation Payment**. Pursuant to the terms of the Employment Agreement, provided that Executive executes and does not revoke this Agreement, the Company agrees to pay Executive a separation amount of $425,000, an amount equal to one year of Executive's current base salary, less all applicable withholdings (the "Separation Payment"). The Separation Payment will include any accrued salary. The Separation Payment will be paid to Executive in accordance with Company standard payroll practices beginning on the first regular payroll following the eighth (8th) day after Executive signs and returns this Agreement to the Company. However, in the event of a change in control, to be defined by the Company, the remaining Separation Payment owed the Executive will be paid in a lump sum within thirty (30) days of the change in control. Executive acknowledges and agrees that other than as

specifically set forth in the Agreement, he is not due any additional compensation, including without limitation, compensation for unpaid salary, bonus, severance, incentive or performance pay.

3. **2015 Bonus.** Executive shall be eligible for a pro-rata bonus for 2015, if at year end, (i) the Compensation Committee determines that the Company has met its annual objectives; and (ii) the Compensation Committee awards bonuses to other executives of the Company. Any pro-rata bonus award shall be consistent with Executive's target bonus under his Employment Agreement and the overall corporate performance score as determined by the Compensation Committee. Executive's bonus shall be paid to Executive at the time all other 2015 company bonuses are paid.

4. Stock Options and Restricted Stock Awards. All of Executive's unvested stock options and restricted stock awards shall immediately vest upon the Termination Date and all vested options shall remain exercisable for a period of ninety (90) days' from the Termination Date in accordance with the terms of Caladrius' 2009 Amended and Restated Equity Compensation Plan.

5. Executive Benefits. Executive's participation in any Company-sponsored Executive benefit plans will terminate on October 31, 2015. Executive will be eligible to continue his health, dental and vision care coverage pursuant to the provisions of the Consolidated Omnibus Reconciliation Act of 1985 ("COBRA") for an 18 month period. The Company shall reimburse Executive a portion of the cost of such coverage through June 30, 2016, which payments will be equal to the amount of the monthly premium for such coverage, less the amount that Executive would have been required to pay if he would have remained an employee of the Company. Executive will be required to pay the full monthly premium thereafter. If Executive secures new employment and becomes eligible for and elects benefits under a new employer's group health plan, his right to reimbursement shall terminate and he must immediately notify the Company of the start date of that insurance, by letter addressed to David Schloss, VP Human Resources, Caladrius Biosciences, Inc., 106 Allen Road, 4TH Floor, Basking Ridge, NJ 07920. Executive will receive information about continuing his health coverage under COBRA in a later mailing, including a form by which he may elect continued coverage. If Executive applies for unemployment, Caladrius will not oppose it.

6. **Expenses**. As per Executive's Employment Agreement, the Company will reimburse Executive for all expenses incurred by him on or prior to the Termination Date in connection with his duties, provided he submits an expense report and receipts in accordance with the Company's normal expense reimbursement policy within ten (10) business days following the Termination Date. Company also shall reimburse Executive up to $10,000 for legal and/or accounting fees associated with the negotiation of this Agreement.

7. Release.

(a) In consideration of the payments, benefits and covenants contained in this Agreement, Executive, for himself and for his children, heirs, administrators, representatives, executors, successors and assigns, releases and gives up any and all claims and rights which Executive has, may have or hereafter may have against Caladrius, its owners, members, subsidiaries, affiliates, predecessors, successors, assigns, officers, directors, shareholders, Executives and agents and all of their predecessors, successors and assigns (the "Releasees") from the beginning of the world until the Termination Date, including, but not limited to, any and all charges, complaints, claims, liabilities, obligations, promises, agreements, controversies, damages, remedies, actions, causes of action, suits, rights, demands, costs, losses, debts and expenses (including attorneys' fees and costs) of any nature whatsoever, whether known or unknown, whether in law or equity (collectively, "Claims"), including, but not limited to, any Claims

(i) arising out of or related to Executive's employment with Caladrius; (ii) arising out of or related to the termination of his employment with Caladrius, (iii) based on contract whether express or implied, written or oral, or (iv) arising under or related to the United States and/or State Constitutions, federal and/or common law, and/or rights arising out of alleged violations of any federal, state or other governmental statutes, regulations or ordinances or the laws of any country or jurisdiction including, without limitation, the National Labor Relations Act, Title VII of the Civil Rights Act of 1964, the Age Discrimination in Employment Act of 1967, the Older Workers' Benefit Protection Act of 1990, the Americans with Disabilities Act of 1990, the Civil Rights Act of 1871, the Civil Rights Act of 1991, the Equal Pay Act of 1963, the Worker Adjustment and Retraining Notification Act of 1988, the Executive Retirement Income Security Act of 1974, the New York Labor Law, the New York State Human Rights Law and the New York City Human Rights Law, the New Jersey Law Against Discrimination, New Jersey's Conscientious Executive Protection Act, New Jersey's Family Leave Act, the California Fair Employment and Housing Act, the California Family Rights Act, the provisions of the California Labor Code, all as amended. This Section releases all Claims related, but not limited to, the right to the payment of wages, bonuses, vacation, pension benefits or any other Executive benefits, and any other rights arising under federal, state or local laws prohibiting discrimination and/or harassment on the basis of race, color, religion, religious creed, sex, sexual orientation, national origin, ancestry, age, mental retardation, learning disability or blindness, mental or physical disability, disorder or handicap, alienage or citizenship status, marital status or domestic partnership status, genetic information, military status or any other basis prohibited by law.

(b) This release does not waive or release any Claims that Executive may have against Caladrius or any of the Releasees related to: (i) vested benefits under the Company's 401(k) plan; (ii) events occurring after the Termination Date; or (iii) enforcing the terms of this Agreement; (iv) rights to defense and indemnity from Caladrius; or (v) rights to coverage under any liability insurance policy (e.g., directors' and officers' liability insurance).

(c) Executive represents that he has not filed against Caladrius or any of the Releasees or any of its affiliates any Claims with any governmental or administrative agency, arbitral tribunal, administrative tribunal, self-regulatory body, or any court arising out of or related to his employment by Caladrius or any other matter arising on or prior to the date hereof. Executive covenants and agrees that he will not, directly or indirectly, commence or prosecute, or assist in the filing, commencement or prosecution in any court any Claim brought either by Executive or by any person or entity, against Caladrius or any of the Releasees, arising out of any of the matters set forth in this Agreement or based upon any Claim. Executive further waives his right to any monetary recovery in connection with a local, state or federal governmental agency proceeding and his right to file a claim seeking monetary damages in any court. This Agreement does not (i) prohibit or restrict Executive from communicating, providing relevant information to or otherwise cooperating with the EEOC or any other governmental authority with responsibility for the administration of fair employment practices laws regarding a possible violation of such laws or responding to any inquiry from such authority, including an inquiry about the existence of this Agreement or its underlying facts, or (ii) require Executive to notify Caladrius of such communications or inquiry.

8. Confidentiality, Intellectual Property and Non-Compete. The Restrictive Covenant Agreement shall survive the execution of this Agreement and shall remain in full force and effect. The non-compete clause contained within the Restrictive Covenant Agreement shall remain in effect for twelve (12) months following the Termination Date. Executive certifies that he has fully complied with all of his obligations under the Restrictive Covenant Agreement as of the Termination Date, including without limitation, his obligation to return to Caladrius all information and documents related to Inventions or Proprietary Information (as those terms are defined in the Restrictive Covenant Agreement).

Executive further certifies that he has returned, or will return within five (5) business days following the Termination Date, all Caladrius property, including without limitation, computers, data bases, cell phones, office, door and file keys, identification cards, credit cards, business cards, computer access codes and instructional manuals. Executive represents and covenants that he will fully comply with his obligations under the Restrictive Covenant Agreement following the Termination Date. Executive may disclose the terms of the Restrictive Covenant Agreement to others with whom he may enter into a business relationship.

9. Non-Disparagement.

(a) Executive and Company each agree to not (and shall not encourage or induce others to), in any manner, directly or indirectly, make or publish any statement (orally or in writing) that would libel, slander, disparage, denigrate, ridicule or criticize the other party (which in the case of Caladrius includes any of its affiliates or affiliates respective executives, officers or directors). Executive further agrees that without Caladrius' prior, written consent, he will not: (i) hold himself out as continuing to be affiliated or associated with Caladrius or any of its affiliates in any way after the Termination Date (which prohibition shall not preclude Executive from representing his employment with Caladrius prior to the Termination Date); or (ii) make any statements concerning Caladrius, any of its affiliates or any of Caladrius' or an affiliate's respective Executives, officers or directors in the public domain, including without limitation statements in, or intended for use in, publications, print, electronic media, advertising or public presentations.

(b) Provided Executive directs requests for future references to David Schloss or to his designee, Caladrius agrees to confirm in response to such request only Executive's last title and dates of employment.

(c) Nothing in this paragraph, however, shall preclude Executive from giving truthful testimony under oath in response to a subpoena or other lawful process and truthful answers in response to questions from a government investigator.

10. Cooperation; Consultancy. Executive agrees to cooperate, to a reasonable extent, with and assist Caladrius, its affiliates and legal counsel and provide information to Caladrius, its affiliates and legal counsel as to matters in which Executive was involved prior to the Termination Date, including, without limitation, information needed in connection with any claim or litigation, investigation, administrative proceeding, arbitration or enforcement action by or against Caladrius or any of its affiliates relating to any matter in which he was involved or about which he had knowledge, and will testify as a witness in connection with such matters if requested by Caladrius or any one of its affiliates, at which time, Executive would be entitled to reasonable compensation for such services.

11. Public Disclosures. Executive and Company shall review and agree upon language that may be contained in a Form 8-K to be filed with the SEC on behalf of the Company and a press release to be disseminated by the Company, each in connection with Executive's termination.

12. No Admission of Liability. This Agreement does not constitute or imply an admission of liability or wrongdoing by the Company or any of the Releasees.

13. Confidentiality. The terms of this Agreement are **CONFIDENTIAL**. Executive and Caladrius each agree not to tell anyone about this Agreement and not to disclose any information contained in this Agreement to anyone, other than to their respective lawyers, financial advisors or

Executive's immediate family members, except as necessary to administer this Agreement, to enforce the terms of this Agreement, as required by law, including without limitation, Caladrius' disclosure obligations under the United States securities laws and regulations or to respond to a valid subpoena or other legal process. If Executive does tell his lawyer, financial advisor or immediate family members about this Agreement or its contents, he must immediately tell them that they must keep it confidential as well.

14. Breach.

(a) If Caladrius determines in good faith that Executive has breached, is breaching or threatens to breach the Restrictive Covenant Agreement, in addition to any other rights to injunctive relief and monetary damages available under that agreement or at common law, Executive shall repay the Separation Payment to Caladrius. To the extent that Caladrius has not yet paid the Separation Payment, Caladrius may immediately suspend such payment. The prevailing party in any action arising out of or related to a breach of the Restrictive Covenant Agreement shall be entitled to an award of reasonable attorneys' fees and costs in addition to any other legal and equitable relief.

(b) Excluding any breach of the Restrictive Covenant Agreement, the parties may only institute an action for specific enforcement of the terms of this Agreement and seek damages resulting from such breach. Executive may not institute any proceeding based on claims related to Executive's employment with Caladrius or the termination thereof.

15. No Reliance. Executive represents that, in executing this Agreement, he does not rely and has not relied upon any representation or statement not set forth in this Agreement that Caladrius or any of its members, agents, representatives, or attorneys may have made with regard to the subject matter, basis or effect of this Agreement. Caladrius asserts that it has made no representation or statement that is not reflected in this Agreement. No other promises, agreements or modifications shall be binding unless in writing and signed after the Effective Date.

16. Governing Law and Jurisdiction. This Agreement shall be construed in accordance with the laws of the State of New York without regard to any state's conflict of law provisions. Any dispute arising out of or related to this Agreement shall be submitted to the New York State Supreme Court, New York County. Executive and Caladrius each consent to the exercise of personal jurisdiction over him or it for this purpose and waives any objection to the exercise of jurisdiction based on improper venue or inconvenient forum. **Each of Executive and Caladrius waives any right to resolve any dispute arising under or related to this Agreement before a jury**.

17. Severability. If at any time after the date of the execution of this Agreement, any provision of this Agreement shall be held in any court or agency of competent jurisdiction to be illegal, void, or unenforceable, such provision shall be deemed to be restated to reflect, as nearly as possible, the original intentions of the parties in accordance with applicable law. The invalidity or unenforceability of any provision of this Agreement, however, shall not affect the validity or enforceability of any other provision of this Agreement.

18. Entire Agreement. This Agreement and the Restrictive Covenant Agreement set forth the entire agreement between the parties with respect to the subject matter hereof. This Agreement and the Restrictive Covenant Agreement collectively supersede any and all prior understandings and agreements between the parties. Neither party shall have any obligation toward the other except as set forth in this

Agreement and the Restrictive Covenant Agreements. This Agreement may not be modified except in a writing signed by all parties.

19. **Enforceability**. Executive is bound by this Agreement. Anyone who succeeds to his rights and responsibilities, such as his heirs or the executors of his estate, is also bound. This Agreement is made for Caladrius' benefit and all who succeed Caladrius' rights and responsibilities, such as Caladrius' successors or assigns.

20. **Headings**. The headings contained in this Agreement are for the convenience of reference only and are not intended to define, limit, expand or describe the scope or intent of any provision of this Agreement.

21. **Warranties**. By signing this Agreement, Executive acknowledges the following:

(a) He understands that this Agreement is **LEGALLY BINDING** and by signing it he gives up certain rights.

(b) Executive has sixty (60) days from the Termination Date to consider his rights and obligations under this Agreement (although he may execute and return this Agreement at any time) and whether to execute the Agreement.

(c) Caladrius advises him to consult with an attorney and/or any other advisors of his choice before signing this Agreement.

(d) By executing this Agreement, Executive warrants that he has voluntarily chosen to enter into this Agreement and has not been forced or pressured in any way to sign it.

(e) He acknowledges and agrees that the payments and benefits set forth in Sections 2, 3, 4 and 5 of this Agreement and the other benefits and covenants contained herein are contingent on him executing this Agreement and **KNOWINGLY AND VOLUNTARILY RELEASING** all Claims against Caladrius and the other Releasees that he may have, known or unknown, and that these benefits are in addition to any benefit he would have otherwise received if he did not sign this Agreement.

(f) This Agreement shall have no force and effect and he will not be entitled to the payments and benefits set forth in Section 2, 3, 4 and 5 of this Agreement, unless he signs and delivers this Agreement on or before sixty (60) days after the Termination Date.

(g) He has seven (7) days after he signs this Agreement to revoke it by notifying the Company in writing to the attention of David Schloss at Caladrius Biosciences, Inc., 106 Allen Road, 4th Floor, Basking Ridge, NJ 07920 so that the revocation notice is received by Caladrius Biosciences, Inc. on or before the end of the seventh day. The Agreement will not become effective or enforceable until the seven (7) day revocation period has expired.

(h) This Agreement includes a **waiver of all rights and claims** he may have under the Age Discrimination in Employment Act of 1967 (29 U.S.C. §621 *et seq.*); and

(i) This Agreement does not waive any rights or claims that may arise after this Agreement becomes effective, which is seven (7) days after Executive signs it, provided that he does not exercise his right to revoke this Agreement

IN WITNESS WHEREOF, the parties have executed this Agreement as of the Effective Date.

ROBERT S. VATERS

/s/ Robert S. Vaters
Dated: October 5, 2015

CALADRIUS BIOSCIENCES, INC.

By:
/s/ David J. Mazzo, PhD

Name: David J. Mazzo
Title: Chief Executive Officer

Exhibit 21.1

Subsidiaries of Caladrius Biosciences, Inc.

Entity	Percentage of Ownership	Location
Caladrius Biosciences, Inc.	100%	United States of America
NeoStem Therapies, 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, 2015, Becton Dickinson's ownership interest in Athelos Corporation was 2.8%.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our reports dated March 15, 2016, with respect to the consolidated financial statements and internal control over financial reporting included in the Annual Report of Caladrius Biosciences, Inc. on Form 10-K for the year ended December 31, 2015. We hereby consent to the incorporation by reference of said reports in the Registration Statements of Caladrius Biosciences, Inc. on Forms S-3 (File No. 333-145988, File No. 333-173853, File No. 333-173855, File No. 333-176673, File No. 333-183542, File No. 333-183543, File No. 333-185346, File No. 333-188486, File No. 333-196702 and File No. 333-206175) 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 and File No. 333-205662).

/s/ GRANT THORNTON LLP

New York, New York
March 15, 2016

Exhibit 31.1

CERTIFICATION

I, David J. Mazzo, PhD, 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 15, 2016

/s/ David J. Mazzo, PhD
Name: David J. Mazzo, PhD
Title: Chief Executive Officer of Caladrius Biosciences, Inc.

A signed original of this written statement required by Section 302 has been provided to Caladrius Biosciences, Inc. and will be retained by Caladrius Biosciences, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 31.2

CERTIFICATION

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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 15, 2016

/s/ Joseph Talamo
Name: Joseph Talamo
Title: Chief Financial Officer of Caladrius Biosciences, Inc.

A signed original of this written statement required by Section 302 has been provided to Caladrius Biosciences, Inc. and will be retained by Caladrius Biosciences, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.1

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

In connection with the Annual Report of Caladrius Biosciences, Inc. (the "Company") on Form 10-K for the year ended December 31, 2015 filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David J. Mazzo, PhD, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and the results of operations of the Company.

Dated: March 15, 2016

/s/ David J. Mazzo, PhD
David J. Mazzo, PhD
Chief Executive Officer

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

A signed original of this written statement required by Section 906 has been provided to Caladrius Biosciences, Inc. and will be retained by Caladrius Biosciences, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

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

In connection with the Annual Report of Caladrius Biosciences, Inc. (the "Company") on Form 10-K for the year ended December 31, 2015 filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph Talamo, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as amended ; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and the results of operations of the Company.

Dated: March 15, 2016

/s/ Joseph Talamo
Joseph Talamo
Chief Financial Officer

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

A signed original of this written statement required by Section 906 has been provided to Caladrius Biosciences, Inc. and will be retained by Caladrius Biosciences, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.