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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2019

OR

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

For the Transition Period from _____ to _____

Commission File Number 001-33650

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

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

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

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

Title of Each Class	Trading Symbol (s)	Name of Each Exchange On Which Registered
Common Stock, par value $0.001 per share	CLBS	The Nasdaq Capital Market

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

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

Yes o No x

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

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

Yes x No o

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

Large accelerated filer o	Accelerated filer o
Non-accelerated filer x	Smaller reporting company x
	Emerging growth company o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

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

Yes o No x

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2019 (the last business day of the most recently completed second fiscal quarter) was approximately $20 million, computed by reference to the last sale price of $2.28 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.

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

Class	**Outstanding as of March 5th, 2020**
Common stock, $0.001 par value per share	10,638,771 shares

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 2020 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 annual 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, including, without limitation, all statements related to any expectations of revenues, expenses, cash flows, earnings or losses from operations, cash required to maintain current and planned operations, capital or other financial items; any statements of the plans, strategies and objectives of management for future operations; any plans or expectations with respect to product research, development and commercialization, including regulatory approvals; any other statements of expectations, plans, intentions or beliefs; and any statements of assumptions underlying any of the foregoing. Without limiting the foregoing, the words “plan,” “project,” “forecast,” “outlook,” “intend,” “may,” “will,” “expect,” “likely,” “believe,” “could,” “anticipate,” “estimate,” “continue” or similar expressions or other variations or comparable terminology are intended to identify such forward-looking statements, although some forward-looking statements are expressed differently. We remind readers that forward-looking statements are merely predictions and therefore inherently subject to uncertainties and other factors and involve known and unknown risks that could cause the actual results, performance, levels of activity or our achievements or industry results, to be materially different from any future results, performance, levels of activity or our achievements or industry results expressed or implied by such forward-looking statements. Factors that could cause our actual results to differ materially from anticipated results expressed or implied by forward-looking statements include, among others:

- our ability to obtain sufficient capital or strategic business arrangements to fund our operations and expansion plans, including meeting our financial obligations under various licensing and other strategic arrangements, the funding of our clinical trials for product candidates, and the commercialization of the relevant technology;
- our ability to build and maintain the management and human resources infrastructure necessary to support the growth of our business;
- whether a market is established for our cell-based products and services and our ability to capture a meaningful share of this market;
- scientific, regulatory and medical developments beyond our control;
- our ability to obtain and maintain, as applicable, appropriate governmental licenses, accreditations or certifications or comply with health care 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 on the claims of third-party patents;
- whether any potential strategic or financial benefits of various licensing agreements will be realized;
- the results of our development activities; and
- our ability to complete our other planned clinical trials (or initiate other trials) in accordance with our estimated timelines due to delays associated with enrolling patients due to the novelty of the treatment, the size of the patient population and the need of patients to meet the inclusion criteria of the trial or otherwise.

The factors discussed herein, including those risks described in "Item 1A. Risk Factors" and in the Company's other periodic filings with the SEC, which are available for review at *www.sec.gov* under “Search for Company Filings,” could cause actual results and developments to be materially different from those expressed or implied by such statements. All forward-looking statements attributable to us are expressly qualified in their entirety by these and other factors. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date they were made. Except as required by law, the Company undertakes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

PART I

ITEM 1. BUSINESS.

OVERVIEW

Caladrius Biosciences, Inc. (“we,” “us,” "our," “Caladrius” or the “Company”) is a clinical-stage biopharmaceutical company dedicated to the development of cellular therapies designed to reverse, not manage, cardiovascular disease. We are developing first-in-class therapy products that are based on the notion that our bodies contain finely tuned mechanisms for self-repair. Our technology leverages and enables these mechanisms in the form of specific cells, using formulations unique to each indication.

Our leadership team collectively has decades of biopharmaceutical development experience and world-recognized scientific achievement in the field of cardiovascular disease, among other fields. Our goal is to build a broad portfolio of novel and versatile products that address important unmet medical needs. Our current product candidates include three developmental treatments for ischemic diseases based on our CD34+ cell therapy platform: CLBS12, recipient of SAKIGAKE designation (a Japanese regulatory status that is similar in certain respects to "breakthrough therapy" designation granted by the U.S. Food and Drug Administration (the "FDA") to eligible investigational treatments) and eligible for early conditional approval in Japan for the treatment of critical limb ischemia ("CLI") based on the results of an ongoing clinical trial; CLBS16, a Phase 2 clinical trial in the U.S. for the treatment of coronary microvascular dysfunction ("CMD"); and CLBS14, a Regenerative Medicine Advanced Therapy ("RMAT") designated therapy for which we have finalized with the FDA a protocol for a Phase 3 confirmatory trial in subjects with no-option refractory disabling angina ("NORDA").

Additional Out-licensing Opportunities

Our broad intellectual property portfolio of cell therapy assets includes notable programs available for out-licensing in order to continue their clinical development. Our current long-term strategy is to advance our therapies through development with the ultimate objective of obtaining market authorizations and entering commercialization, either alone or with partners, and to provide treatment options to patients suffering from life-threatening medical conditions. We believe that we are well-positioned to realize potentially meaningful value increases within our own proprietary pipeline if we are successful in advancing our product candidates to their next significant development milestones.

Corporate Information

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

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

This Annual Report on Form 10-K includes the following trademark owned by us: Caladrius®. This trademark is 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.

THE FIELD OF CELL THERAPY

Regenerative medicine is defined as the process of replacing or regenerating human cells, tissues or organs to restore normal function. Among the categories of therapeutic technology platforms within this field are cell therapy, tissue engineering, tools, device diagnostics and aesthetic medicine. All living complex organisms start as a single cell that replicates and then individual groups of cells differentiate (mature into complex cell types), thereby yielding the diversity of organs and organ systems in an adult organism. Cell therapy is a process that uses cells to prevent, treat or cure disease, or to regenerate damaged or aged tissue. Since the 1970s, bone marrow and blood and umbilical cord-derived stem cells have been used to restore bone marrow, as well as blood and immune system cells damaged by the chemotherapy and radiation historically used to treat many cancers. Notably, this approach holds curative potential for patients with otherwise fatal conditions.

There are two general classes of cell therapies: autologous and allogeneic. When cells are collected from a person (donor) and transplanted or used to develop a treatment solely for that same person (recipient or patient) with or without modification,

the treatment paradigm is known as “autologous” cell therapy. For long-term repair of cardiovascular tissues, evidence indicates that the repair cells must remain in the target tissue for a period of time. Since autologous cells are not destroyed by the immune system, autologous cell therapy can be expected to result in long-term residence of the administered cells. When the donor and the recipient are not the same individual, the procedures are referred to as “allogeneic” cell therapy.

Various cell therapies are in clinical development for an array of human diseases, including autoimmune, oncologic, cardiovascular, neurologic and orthopedic diseases, among other indications. While no assurances can be given regarding future medical developments, we believe that the field of cell therapy holds the promise to better the human experience and minimize or ameliorate the pain and suffering from many common and often life-threatening diseases. The FDA has been investing significant resources into policies and organizational changes to advance the cell and gene therapy fields in recent years through what the agency has labeled its “comprehensive regenerative medicine policy framework,” as first announced in late 2017 and incrementally developed since that time through various agency actions.

CELL THERAPY PRODUCT DEVELOPMENT

Ischemic Repair (CD34 Cell Technology)

The CD34+ cell was discovered as a result of the deliberate search for a stem cell capable of stimulating the development and/or repair of blood vessels. All tissues in the body maintain their function by replacing cells over time. In addition to the maintenance function, the body must also be capable of building new blood vessels after injury. A CD34+ cell is a stem cell that has the ability to stimulate new blood vessel formation. No other native cell discovered to date has demonstrated this same capability.

Our CD34+ cell technology has led to the development of therapeutic product candidates designed to address diseases and conditions caused by ischemia. Ischemia occurs when the supply of oxygenated blood to healthy tissue is restricted. Through the administration of CD34+ cells, we seek to promote the development and formation of new microvasculature and thereby increase blood flow to the impacted area. We believe that a number of conditions caused by underlying ischemic injury can be improved through our CD34+ cell technology, including but not limited to, CLI, CMD and NORDA.

While other cell types have been tested by researchers for the treatment of cardiovascular conditions, none have been shown in nature to perform a cardiovascular repair function.

CLBS12 for Treatment of Critical Limb Ischemia

Following detailed discussion and agreement with the Japanese Pharmaceutical and Medical Device Agency ("PMDA"), we treated the first patient in a registration-eligible trial in Japan in March 2018. Based on discussions with the PMDA, we expect CLBS12 will be eligible for early conditional approval in Japan if there is a successful outcome of this trial, thereby effectively making the ongoing trial a potential registration trial in that strategic market. The initial responses observed in the subjects who have reached an endpoint in this open label study are consistent with a positive therapeutic effect and safety profile as reported by previously published clinical trials in Japan and the U.S. Enrollment is ongoing and we anticipate completion by mid-2020 with top line data targeted for late 2020 or early 2021. While the data accumulated to date continue to be encouraging, the final outcome of the trial will be dependent on all data from all subjects. Based on the accelerated review afforded CLBS12 by its SAKIGAKE designation and the current projected timeline to study completion, we expect that CLBS12 could potentially be an approved commercial product in Japan as early as late 2021 or early 2022.

CLBS16 for Treatment of Coronary Microvascular Dysfunction

In October 2017, we announced the award of a $1.9 million grant from the National Institutes of Health to support a clinical study of CD34+ cells in patients with CMD under Award Number R44HL135889. The content of that announcement is solely our responsibility and does not necessarily represent the official views of the National Institutes of Health. This award led to the initiation of development of CLBS16 and enrollment of patients in our ESCaPE-CMD Phase 2 proof-of-concept study at the Mayo Clinic in Rochester, MN and Cedars-Sinai Medical Center in Los Angeles, CA. In June 2019, we announced the completion of enrollment in this study. Results of the first 17 of 20 patients enrolled in this trial who reached 6-month follow-up were presented as a rapid fire oral presentation on November 16, 2019 at the annual meeting of the American Heart Association in Philadelphia, PA by one of the principal investigators, Dr. Noel Bairey Merz, FACC, FAHA, FESC, the director of the Barbra Streisand Women's Heart Center at Cedars-Sinai in Los Angeles, CA. That data set showed a positive therapeutic effect with a statistically significant improvement in angina frequency, coronary flow reserve, Canadian Cardiovascular Society Angina Class and Seattle Questionnaire score, as well as an acceptable safety profile. We are planning to advance the CLBS16 program to its next clinical development step, a Phase 2b study, with a target for first patient enrolled by mid-2020.

CLBS14 for Treatment of No Option Refractory Disabling Angina (NORDA)

We acquired the rights to data and regulatory filings for a CD34+ cell therapy program for refractory angina that had been advanced to Phase 3 by a previous sponsor.

Based on the clinical evidence from the completed studies that a single administration of CLBS14 reduces mortality, improves angina, and increases exercise capacity in patients with otherwise untreatable angina, this product received RMAT designation from the FDA. Working closely with the FDA, we have finalized the design of a confirmatory Phase 3 trial which, in combination with previously filed Phase 1, 2 and 3 data, will be considered for the registration of CLBS14. Notably, this study design includes a 6-month primary endpoint and, with the benefit of the RMAT designation, the biologics license application ("BLA"), once submitted, is expected to receive a 6-month review. We have completed substantially the preparatory work for initiation of this trial. We will not, however, commence enrollment of patients until sufficient capital dedicated to this program is acquired by us, which capital will give us confidence that we can fund the trial uninterrupted through completion.

TECHNOLOGY OUT-LICENSING OPPORTUNITIES

Ischemic Repair (CD34+ Cell Technology)

Our CD34+ Cell Technology is a platform technology with potential application to a broad array of ischemic conditions and we will seek to out-license our technology in geographies or indications where we do not intend to pursue development ourselves.

Intellectual Property Platform

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

- Nine U.S. patents, three EU patents (each filed in 5 individual countries) and 7 other patents in Japan, Canada, Russia and Hong Kong;
- Claims cover, *inter alia*, a pharmaceutical composition that contains a therapeutic concentration of non-expanded CD34+ stem cells that move in response to SDF-1 or VEGF, together with a stabilizing amount of serum, that can be delivered to repair an injury caused by vascular insufficiency;
- Issued and pending claims can be applied to a broad range of conditions caused by underlying ischemia, including: acute myocardial infarction; chronic myocardial ischemia post-AMI; chronic heart failure; critical limb ischemia; and ischemic brain injury;
- Two pending patent applications outside the United States.

Market Opportunity for CLI

In Japan, there are approximately 300,000 patients with CLI, of whom approximately 51,000 are not candidates for revascularization, making them the addressable population for CLBS12. The addressable population is approximately 560,000 patients in the EU and 300,000 in the U.S.

The field of cardiovascular cell therapy development is competitive. There are a number of companies that are developing cell-based therapies for cardiovascular diseases. 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.

Market Opportunity for CMD

In the United States, there are approximately 8,300,000 patients with CMD, while the addressable population is roughly 6,000,000 in the EU and 1,000,000 in Japan.

Market Opportunity for NORDA

In the United States, we have identified fewer than 100,000 patients with no-option refractory disabling angina as candidates for CLBS14, making this an indication of orphan size.

GOVERNMENT REGULATION

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

Premarket Review and Approval of Pharmaceutical and Biological Products in the United States

In the United States, pharmaceutical and biological 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, including biological products, intended for therapeutic uses. Biological products are approved for marketing under provisions of the Public Health Service Act ("PHS Act"). However, biological products that also meet the definition of “drugs” under the FD&C Act are also subject to regulation under FD&C Act provisions and to applicable provisions from two sets of FDA implementing regulations, those for biological products and those for drugs. Another distinction between pharmaceuticals and cellular therapies is that the PHS Act requires the submission of a BLA, rather than a New Drug Application ("NDA"), for market authorization of a cellular therapy candidate like ours. Generally, the application process and requirements for product approval under BLA is similar to those for an NDA, and the review process for biological products is associated with similar approval risks and application costs as for chemical entity drug products.

Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as the FDA refusal to approve pending NDAs or BLAs, withdrawal of an approval, issuance of warning letters and other types of enforcement letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice, or DOJ, or other governmental entities. Under certain circumstances, individual members of company management may also be subject to civil or criminal penalties related to company violations of applicable legal requirements.

An applicant seeking approval to market and distribute a new pharmaceutical or biological product in the United States typically must undertake the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice or GLP regulations;
- submission to the FDA of an IND, which includes the detailed clinical protocol and which must take effect before human clinical trials can commence;
- approval of the clinical trial protocol and the sponsor's safeguards for human subjects by one or more institutional review boards, or "IRBs," depending on the numbers of clinical sites and other features of the study design, before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or "GCPs," to establish the safety and efficacy of the proposed drug or biological product for each proposed indication for which FDA approval is sought;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- preparation and submission to the FDA of an NDA or BLA, as appropriate;
- review of the product by an FDA advisory committee, where appropriate or if applicable, as determined by the FDA at its discretion;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with the regulations establishing current Good Manufacturing Practices, or “cGMPs,” and current Good Tissue Practices or “cGTPs” (if applicable), and to assure that the facilities, methods and controls used for the manufacture, processing and packing of the drug or biological product are adequate to preserve the product’s identity, strength, quality and purity; and
- payment of applicable user fees and securing FDA approval of the NDA or BLA.

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. Moreover, submission of an IND may not result in FDA authorization to initiate a clinical trial if the 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. After a trial is initiated, 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.

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 and GCPs, which are meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors. In addition, sponsors of most clinical trials involving FDA regulated products, including drugs and biologics, are required to register and disclose certain clinical trial information on a public registry and results database managed by the National Institutes of Health called ClinicalTrials.gov. Registration information that must be submitted includes information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial. 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. Failure to comply with applicable clinical trial registration or results reporting obligations can result in civil monetary penalties or the withholding of grant funds from a federally funded grantee.

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

- *Phase 1*: Trials in this phase are initially conducted in a limited population of healthy volunteers to test the product candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients, such as cancer patients, when the drug or biologic is too toxic to be ethically given to healthy individuals.
- *Phase 2*: These clinical trials are generally conducted in a limited patient population to determine the presence and approximate magnitude of therapeutic effect of the product for specific targeted indications and to identify appropriate therapeutic dose and dose frequency as well as any corresponding additional possible adverse effects and safety risks. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- *Phase 3*: These are commonly referred to as pivotal or registration studies. When Phase 2 evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase 3 clinical trials are typically undertaken in a larger patient population to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple and geographically-dispersed clinical trial sites. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug or biologic as a requirement for marketing authorization.
- *Phase 4*: In some cases, the 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.

Submission of an NDA or BLA to the FDA

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product’s chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA or BLA seeking approval to market the drug product for one or more indications. FDA approval of the NDA or BLA is required before marketing of the product may begin in the United States. The cost of preparing and submitting an NDA or BLA is substantial. Under federal law, most NDA or BLA submissions are additionally subject to a substantial application user fee. The current fee for FY2020 is $2,942,965 (some small businesses may qualify for a waiver under certain circumstances) and an annual program fee, currently $325,424, must also be paid for each approved prescription drug or biological product. These fees are typically adjusted annually.

The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be accepted for filing based on the Agency's threshold determination that the application is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. If the application is not sufficiently complete, the FDA may issue a Refusal to File, or RTF, letter, although the FDA may permit an applicant to correct certain easily correctable deficiencies in the NDA/BLA before filing without taking an official RTF action. Under certain NDA and BLA review performance goals to which the FDA has agreed, most applications for standard review of drug or biological products are reviewed within ten to twelve months, and most applications for priority review drugs or biologics are reviewed within six to eight months. If a sponsor submits a major amendment to a filed NDA or BLA at any time during the review cycle, the FDA may extend these reviews by three months although only one such extension is permitted during a review cycle. Priority review can be applied to drugs or biologics that, in the FDA's determination, offer major advances in treatment or provide a treatment for a disease or condition for which no adequate therapy exists. For biologics, priority review is further limited to products intended to treat a serious or life-threatening disease relative to currently approved products. Priority review requests must be submitted in conjunction with the original NDA/BLA for which the sponsor is seeking the designation, and the FDA decision will be made in conjunction with its official action to file the application and begin the substantive review process.

Before approving an NDA or BLA, the FDA will typically inspect one or more clinical trial sites to ensure compliance with GCPs. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. These pre-approval inspections cover all facilities associated with an NDA or BLA submission, including drug component manufacturing (such as active pharmaceutical ingredients), finished drug product manufacturing, and control testing laboratories. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with applicable cGMP and cGTP requirements and are adequate to assure consistent production of the drug or biological product within required specifications and the NDA or BLA contains data that provide substantial evidence that the drug or biologic is safe and effective for the proposed indication.

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

After the FDA fully evaluates the NDA or BLA and the relevant manufacturing facilities, the FDA will issue either an approval/licensure letter or a complete response letter (“CRL”). A CRL generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmitted NDA or BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions within two or six months, depending on the type of information being provided to address the deficiencies in the CRL. Even with the submission of this additional information, however, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a drug or biological product for marketing in the U.S., it may limit the approved indications for use for the product; require that contraindications, warnings or precautions be included in the product labeling; require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug’s safety after approval; require testing and surveillance programs to monitor the product after commercialization; or impose other conditions, including distribution restrictions or other risk management mechanisms, such as a risk evaluation and mitigation strategy or “REMS,” which can materially affect the potential market and profitability of the product. The FDA also may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications or patient populations, making certain types of manufacturing changes or seeking to make additional labeling claims, are subject to further testing requirements and FDA review and approval.

One potential condition of approval is that the FDA may require an applicant to develop a REMS to ensure that the benefits of the drug outweigh its risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. REMS requirements are tailored to the specific risk/benefit profile of a drug and can include requirements such as medication guides for patients, detailed communication plans for health care professionals, and elements to assure safe use, or “ETASU.” ETASU may include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, restricted distribution, and the use of patient registries. The FDA may require a REMS as a condition of approval or may add such a requirement at any point post-approval if it becomes aware of a serious risk associated with use of the product. The requirement for a REMS and the specific components that are involved can materially affect the potential market and profitability of a product. If the FDA concludes an REMS plan is needed, the sponsor of the NDA or BLA must submit a proposed REMS. The FDA will not approve an NDA without an REMS, if required.

Expedited Review Programs (Fast Track, Breakthrough, RMAT) and Accelerated Approval Pathways

The FDA is authorized to facilitate the development and expedite the review of certain drugs or biologics that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the Fast Track Program, the sponsor of an IND for a drug candidate may request that the FDA designate the drug candidate for a specific indication as a Fast Track drug concurrent with, or after, the submission of the IND for the drug candidate. The FDA must determine if the drug candidate qualifies for Fast Track designation within 60 days of receipt of the sponsor’s request. In addition to other benefits such as the ability to engage in more frequent interactions with the FDA, The FDA may initiate review of sections of a Fast Track drug’s NDA or BLA before the application is complete. This "rolling review' is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. The FDA’s time period goal for reviewing an application, however, does not begin until the last section of the NDA/BLA is submitted. Additionally, the Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Separately, under the FDA’s accelerated approval regulations, the FDA may approve a drug for a serious or life-threatening

illness that provides meaningful therapeutic benefit to patients beyond existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw approval of the drug such that accelerated approval also referred to as U.S. "conditional" approval. Products granted accelerated approval also are subject to additional requirements for the pre-dissemination review by the FDA of proposed promotional materials both during the NDA review process and for 120 days after marketing approval.

In addition to the above, the FDA may designate an investigational product as a Breakthrough Therapy or as a Regenerative Medicine Advanced Therapy ("RMAT"), depending on the type of investigational product and its ability to meet applicable eligibility criteria. Breakthrough Therapy designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). The RMAT designation requires similar eligibility criteria to be met, but it is available only to cell therapies, tissue therapies, and other products that meet the statutory definition of a “regenerative medicine therapy.” Specifically, a biological product is eligible for RMAT designation if: (a) the product candidate is a regenerative medicine therapy, which is defined in the FD&C Act as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, except for those regulated solely under the PHS Act (that is, excluding those biological products that are not also regulated as “drugs” under the FD&C Act); (b) the product candidate is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (c) preliminary clinical evidence indicates that the product candidate has the potential to address unmet medical needs for such disease or condition. Both Breakthrough Therapy and RMAT designations are intended to help accelerate product development by allowing more frequent interactions with the FDA and receiving intensive FDA guidance on efficient drug development.

Pediatric Information

Under the Pediatric Research Equity Act ("PREA"), NDAs or BLAs or supplements to NDAs or BLAs must contain data that are adequate to assess the safety and effectiveness of the drug or biologic 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. Sponsors must also submit pediatric trial plans prior to the assessment data, and those plans must contain an outline of the proposed pediatric trial or trials the applicant plans to conduct, including trial objectives and design, any deferral or waiver requests and other information required by regulation. The applicant, the FDA, and the FDA’s internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time. The FDA may grant full or partial waivers or deferrals for submission of data. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation, although the FDA has recently taken steps to limit what it considers abuse of this statutory exemption in PREA by announcing that it does not intend to grant any additional orphan drug designations for rare pediatric subpopulations of what is otherwise a common disease.

The Best Pharmaceuticals for Children Act ("BPCA") provides approved NDA and BLA holders a six-month extension of any exclusivity that attaches to the end of all existing marketing exclusivities and patents for the drug or biologic. Conditions for exclusivity include the FDA’s determination that information relating to the use of a new drug or biologic in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Orphan Drugs

Under the Orphan Drug Act, the FDA may designate a candidate as an orphan drug if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the U.S.) Orphan drug designation must be

requested by an applicant before submitting an NDA or BLA for the relevant drug candidate. If the FDA grants orphan drug designation, the FDA will publicly disclose the generic identity of the drug candidate and its potential orphan use. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation, the product generally will receive orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances comprising methods by which a second sponsor can demonstrate clinical superiority of its drug in comparison to the first approved orphan drug. Regardless of the orphan drug designation, a competitor may receive FDA approval for a different product (i.e., a different therapeutic agent from the orphan drug) for the same indication for which the orphan product has exclusivity and may obtain approval for the same product (i.e., the same therapeutic agent as the orphan drug) but for a different indication. If a designated orphan drug ultimately receives marketing approval for an indication broader than what was described in its orphan drug designation request, it may not be entitled to exclusivity under the Orphan Drug Act. Among the other benefits of orphan drug designation, the sponsor receives a waiver of the NDA or BLA application user fee and is eligible for tax credits for certain research (although the amount of this potential tax credit was decreased from 50% to 25% of qualified clinical testing expenses with the 2017 overhaul of the U.S. Tax Code, effective in 2018).

Post-Approval Requirements

Drugs and biological products manufactured, marketed or distributed pursuant to FDA approval decisions are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion, and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to FDA review and approval before they can be implemented. There also are continuing, annual program fee requirements for any marketed, approved prescription products, as well as new application fees for supplemental applications.

In addition, drug manufacturers and other entities involved in the manufacture of approved drugs are required to register their facilities with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA for compliance with cGMP/cGTP requirements. Prescription drug distribution facilities are also subject to state licensure, including inspections, by the relevant local regulatory authority. Changes to the manufacturing process, specifications or container closure system for an approved drug or biologic are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP or cGTP and impose reporting and documentation requirements upon the sponsor and others involved in the product's manufacturing process. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP/cGTP compliance and ensure ongoing compliance with other statutory requirements the FD&C Act, such as the requirements for making manufacturing changes to an approved NDA or BLA.

Even after a new drug or biologic approval is granted, the FDA may withdraw that approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. If a previously unknown problem, including adverse events of unanticipated severity or frequency, or with manufacturing processes, is discovered or the manufacturer fails to comply with regulatory requirements, the FDA may require revisions to the approved labeling to add new safety information; may impose additional post-market studies or clinical trials to assess new safety risks; or may impose distribution or other restrictions under a REMS program. Other potential consequences of regulatory non-compliance include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs/BLAs or supplements to approved NDAs/BLAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties;
- consent degrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; or
- mandated modification of promotional materials and labeling and the issuance of corrective information.

The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drug and biological products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant penalties. In addition, the distribution of prescription pharmaceutical products is subject to a variety of federal and state laws, the most recent of which is still in the process of being phased into the U.S. supply chain and regulatory framework.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. Most recently, the Drug Supply Chain Security Act, or DSCSA, was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States, including most biological products. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10-year period that is expected to culminate in November 2023. From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. It is impossible to predict whether further legislative or regulatory changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Other Health Care Regulations

If our product candidates are approved in the United States, we will have to comply with various U.S. federal and state laws, rules and regulations pertaining to health care fraud and abuse, including anti-kickback laws and physician self-referral laws, rules and regulations. Violations of the fraud and abuse laws are punishable by criminal and civil sanctions, including, in some instances, exclusion from participation in federal and state health care programs, including Medicare and Medicaid. 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, applicable to the processing and storage of human cells and tissues;
- laws and regulations administered by the United States Department of Health and Human Services, including the Office for Human Research Protections and the Office of Inspector General;
- 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 ("HIPAA"), 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;
- the federal transparency requirements under the Physician Payments Sunshine Act that require manufacturers of FDA-approved drugs, devices, biologics and medical supplies covered by Medicare or Medicaid to report, on an annual basis, to the Department of Health and Human Services information related to payments and other transfers of value physicians, teaching hospitals, and certain advanced non-physician health care practitioners and physician ownership and investment interests;
- 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.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines, or the relevant compliance guidance promulgated by the federal government, in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures to the extent that those laws impose requirements that are more stringent than the Physician Payments Sunshine Act. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

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

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

Under the PMD Act, products under consideration may also be given a SAKIGAKE designation (similar to an FDA "Breakthrough" or "RMAT" designation in certain respects) and/or may be granted a priority review status. Additionally, there is a commitment that the PMDA will facilitate research and development by giving scientific and regulatory advice to sponsors from the early stage of development.

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

EMPLOYEES

As of December 31, 2019, we had 27 full-time employees. Our senior management and professional employees have had prior experience in pharmaceutical or biotechnology companies. None of our employees are 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, 2019, we have incurred aggregate net losses of approximately $417.4 million. Our net losses from continuing operations attributable to common stockholders for the years ended December 31, 2019 and December 31, 2018 were approximately $19.4 million and $16.2 million, respectively. As of December 31, 2019, our cash and cash equivalents and marketable securities were $25.2 million. Our current business has not generated revenues in the past and for the foreseeable future we do not expect it to generate revenue to be sufficient to cover costs attributable to that business or to our operations as a whole, including our development activities associated with our product candidates. Ultimately, we may never generate sufficient revenue from our business to reach profitability, generate positive cash flow or sustain, on an ongoing basis, our current or projected levels of product development and other operations.

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

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

Our clinical activities are expected to continue to grow as our programs are advanced and they will require significant investment over a period of several years before they could potentially be approved by the FDA and commercialized by us, if ever. Even if data from our current clinical trials for our product candidates were deemed positive, we may be required to conduct additional clinical trials of the product candidates, including larger and more expensive pivotal Phase 3 trials, to pursue commercialization of the candidates. To do so, we will need to raise additional capital, enter into collaboration agreements with third parties or undertake any combination thereof. If we are unsuccessful in our efforts to raise capital or find collaborative partners, we will likely need to otherwise delay or abandon the trials.

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

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

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, utilization of our at-the-market ("ATM") sales agreement with H.C. Wainwright & Co., equity sales pursuant to our purchase agreement with Lincoln Park Capital Fund, L.L.C., potential issuances of other debt or equity securities in public or private financings and/or sale or licensing of assets. If we raise capital through the sale of equity, or securities convertible into equity, it will result in dilution to our

then-existing stockholders. Servicing the interest and principal repayment obligations under debt we incur, or whether any such debt is called, would divert funds that might 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 diminish our share in the future revenues associated with the partnered product.

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

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

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

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

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

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

Section 404(b) of the Sarbanes-Oxley Act of 2002 requires an independent registered public accounting firm to test the internal control over financial reporting of public companies, and to report on the effectiveness of such controls, for each fiscal year ending after June 15, 2010. Under the Dodd Frank Wall Street Reform and Consumer Protection Act of 2010, we

are exempt from Section 404(b) as long as we remain a smaller reporting company or a non-accelerated filer. If our status as a smaller reporting company changes, we may be required to comply with this auditor attestation requirement.

In addition, we may in the future discover areas of our internal controls that need improvement, particularly with respect to businesses that we may acquire. If so, we cannot be certain that any remedial measure we take will ensure that we have adequate internal controls over our financial processes and reporting in the future. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could harm our operating results or cause us to fail to meet our reporting obligations. If we are unable to conclude that we have effective internal controls over financial reporting, or if it becomes necessary for our independent registered public accounting firm to provide us with an unqualified report regarding the effectiveness of our internal control over financial reporting and it is unable to do so, investors could lose confidence in the reliability of our financial statements. This could result in a decrease in the value of our common stock.

RISKS RELATED TO OUR CELL THERAPY PRODUCT DEVELOPMENT EFFORTS

Our future success may be dependent on the timely and successful continued development and commercialization of CLBS12, our experimental product candidate for CLI that is in clinical development in Japan, CLBS16 for CMD and CLBS14 for NORDA, and if we encounter delays or further difficulties in the development of these product candidates, 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. We have never taken a product through the regulatory approval process or successfully to U.S. or international commercialization.

In early 2018, we treated the first patient in a clinical trial in Japan for CLBS12 for use in CLI taking advantage of the paradigm of potential conditional approval for regenerative medicine products established by new regulations in Japan for products that show sufficient safety evidence and some evidence of efficacy. We also recently reported preliminary top-line data from the 6-month follow-up of patients in a clinical trial using CD34+ cells to treat CMD (CLBS16). Additionally, we currently have an open IND for CLBS14, a program that is now poised to commence a single Phase 3 confirmatory trial for registration in the U.S. in patients with NORDA. Actual initiation of that trial is contingent upon the acquisition of sufficient funding to give us confidence that we could complete the trial uninterrupted.

Clinical testing is expensive, difficult to design and implement, and can take many years to complete. Importantly, a failure of one or more of these or any other clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of clinical trials that could delay or prevent our ability to complete our clinical trials, receive regulatory approval or commercialize our cell therapy product candidates, including the following:

- suspensions, delays or changes in the design, initiation, enrollment, implementation or completion of required clinical trials;
- adverse changes in our financial position or significant and unexpected increases in the cost of our clinical development program;
- changes or uncertainties in, or additions to, the regulatory approval process that require us to alter our current development strategy;
- clinical trial results that are negative, inconclusive or even less than desired as to safety and/or efficacy, which could result in the need for additional clinical trials or the termination of the product's development;
- delays in our ability to manufacture the product in quantities or in a form that is suitable for any required clinical trials;
- intellectual property constraints that prevent us from making, using, or commercializing any of our cell therapy product candidates;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of these product candidates may be insufficient or inadequate;
- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation of clinical trials;
- delays in reaching agreement on acceptable terms with prospective contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, CMOs and clinical trial sites;

- delays in obtaining required IRB approval at each clinical trial site;
- inability to file INDs with the FDA for our development candidates or comparable clinical trial applications with other regulatory authorities outside of the U.S.;
- 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 the FDA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, CMOs other third parties, or us to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA or international GCP requirements;
- failure to reach agreement with the FDA on a satisfactory development path of our development candidates;
- delays in having patients qualify for or complete participation in a trial or return for post-treatment follow-up;
- patients dropping out of a clinical trial;
- occurrence of adverse events associated with the product candidate;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials or abandoning existing trials;
- transfer of manufacturing processes from our academic collaborators to larger-scale facilities operated by either a contract manufacturing organization, or CMO, or by us, and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process;
- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing; and
- the 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.

Pandemics such as the corona virus could have an adverse impact on our developmental programs and our financial condition.

In December 2019, a novel strain of coronavirus was first identified in Wuhan, Hubei Province, China. Any outbreak of contagious diseases, or other adverse public health developments, could have a material and adverse effect on our business operations. These could include disruptions or restrictions on our ability to travel, pursue partnerships and other business transactions, conduct clinical trials, make shipments of biologic materials, as well as be impacted by the temporary closure of the facilities of suppliers and clinical trial sites. Any disruption of suppliers, clinical trial sites or access to patients would likely impact our clinical trial enrollment progress and rates as well as our ability to access capital through the financial markets. The extent to which the coronavirus may impact our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus.

Even if we are able to successfully complete our clinical development programs for our product candidates and receive regulatory approval to market one or more of the products, if the commercial opportunities are smaller than we anticipate, our future revenues may be adversely affected, and our business may suffer.

If the size of the commercial opportunities in any of our target indications is smaller than we anticipate, or if the FDA grants our candidates approval to treat only specific subpopulations or otherwise approves the products for more narrow indications for use than we are seeking, we may not be able to achieve profitability and growth.

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

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

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

We may not be able to initiate or complete as planned any clinical trials if we are unable to identify and enroll a sufficient number of eligible patients to participate in the clinical trials required by the FDA or other regulatory authorities. We also may be unable to engage a sufficient number of clinical trial sites to conduct our trials. Moreover, our ability to conduct trials outside of the United States may be constrained by our inability 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. Moreover, changes to enrollment criteria may be prohibited by regulating agencies, may have no impact on enrollment rates and may change or harm the outcome of the study. In addition, some patients may have concerns or negative perceptions regarding cell therapy that may affect 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.

Outside of the unique aspects of conducting a clinical trial for a cell therapy candidate, patient enrollment in general is affected by many factors, including:

- size of the target patient population;
- severity of the disease or disorder under investigation;
- eligibility criteria for the clinical trial in question;
- other clinical trials being conducted at the same time involving patients who have the disease or disorder under investigation;
- perceived risks and benefits of the product candidate under study;
- approval and availability of other therapies to treat the disease or disorder that is being investigated in the clinical trial;
- willingness or unwillingness to participate in a placebo controlled clinical trial;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients in any of our planned clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

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 CLBS12, CLBS14 or CLBS16 or any of our other product candidates in development. Our management lacks significant experience in completing Phase 3 pivotal clinical trials and bringing a drug or biological product through commercialization. Clinical trials for 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, IRBs, or independent ethics committees to authorize us or our investigators at individual sites 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 applicable cGMP/cGTP requirements for the clinical supplies of the cell therapy candidate;
- 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;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- treatment candidates demonstrating a lack of efficacy during clinical trials;
- inability to continue to fund clinical trials or to find a partner to fund the clinical trials;
- competition with ongoing clinical trials and scheduling conflicts with participating clinicians; and
- delays in completing data collection and analysis for clinical trials.

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

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

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

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

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

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, 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 product development timelines.

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 any Phase 2 clinical trial we may conduct supports 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 control CMC issues raised by the FDA prior to initiating such trials. We may not be successful in our efforts to address any CMC issues raised by the FDA. If we cannot initiate, or if we are delayed in initiating, a pivotal Phase 3 clinical program as a result of our failure to satisfy the FDA's CMC concerns or otherwise, the timing of regulatory submission for commercialization of our product candidates would be delayed, or we may be unable to seek regulatory approval to commercialize our products at all.

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

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

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 pre-specified, 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.

If serious or unacceptable side effects are identified during the development of any of our product candidate, we may need to abandon or limit our development of that product candidate.

All of our product candidates are in clinical development and their risk of failure is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive marketing approval. If our product candidates are associated with undesirable side effects or have other unexpected, unacceptable characteristics, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many investigational products that initially showed promise in clinical or earlier stage testing have later been found to cause side effects or other safety issues that prevented further development. Even if we receive regulatory approval for a candidate with a known safety risk, such an approved product may not achieve market acceptance by physicians, patients, third-party payors or others in the medical community, which would materially and adversely affect our business.

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

We were granted SAKIGAKE designation in Japan and Advanced Therapeutic Medicinal Product ("ATMP") designation in Europe for CLBS12 for the treatment of CLI, and RMAT designation for CLBS14 for the treatment of no-option refractory disabling angina. However, SAKIGAKE, ATMP and RMAT designations do not ensure that we will experience a faster development, regulatory review or approval process compared to conventional FDA or Japan PMDA procedures. Additionally, a regulatory authority may withdraw a designation if it believes that the designation is no longer supported by data from the clinical development program. Moreover, award of a particular designation does not imply a higher probability of success of a product in the approval process.

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 cell therapy 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.

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 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 rely on contract manufacturing organizations to produce our product candidates at development and commercial scale quantities and have not yet qualified an alternate manufacturing supply, which could negatively impact our ability to meet any future demand for the products.

We currently rely on contract manufacturers to provide the cell processing services necessary for clinical production for our various CD34+ cell therapy product candidates. The Foundation for Biomedical Research and Innovation, a Japanese corporation with its principal place of business in Kobe, Japan ("FBRI") will provide all cell processing services for the CLBS12 CLI trial in Japan. Hitachi Chemical Advanced Therapeutics Systems ("HCATS") and FBRI also provide services and produce materials for clinical trials on behalf of unaffiliated third parties. To date, neither has produced any products at commercial scale quantities. We expect that HCATS and FBRI would need to expand significantly their manufacturing capabilities to meet potential commercial demand for CLBS12, CLBS14 and CLBS16 and any other of our product candidates, if approved, as well as any of our other product candidates that might attain regulatory approval. Such expansion would require additional regulatory approvals. Even if they increase their manufacturing capabilities, it is possible that they may still lack sufficient capacity to meet demand. Ultimately, if we are unable to supply our products to meet commercial demand, whether because of processing constraints or other disruptions, delays or difficulties that we experience, sales of the products and their long-term commercial prospects could be significantly damaged.

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

Ultimately, if we are unable to supply our cell therapy product candidates to meet commercial demand, were commercial approval to be obtained, whether because of processing constraints or other disruptions, delays or difficulties that we experience, our production costs could increase dramatically, 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:

- the efficacy and potential advantages compared to alternative treatments or competitive products;

- the prevalence and severity of any side effects;
- physician acceptance of our cell therapy approach to our target disease indications, include the ease or difficulty of administering the future products;
- restrictions on how the product is distributed or used;
- the strength of our marketing and distribution support, including whether we receive support from any patient advocacy groups;
- the adequacy of product supply in light of complex manufacturing and distribution processes;
- 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. Thus, we may need to conduct additional nonclinical studies and clinical trials to support approval of any such changes. Furthermore, this review process could be costly and time-consuming and could delay or prevent the commercialization of product candidates.

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

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

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

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

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

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

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

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

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

The clinical development, commercialization and marketing of cell and tissue-based therapies are at an early stage, substantially research-oriented and financially speculative. To date, very few companies have been successful in their efforts to develop and commercialize a cell therapy product. In general, cell-based or tissue-based products may be susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy, or other characteristics that may prevent or limit their approval or commercial use. Regulatory approval of novel product candidates such as CLBS12, CLBS14 and CLBS16, which are each 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 five autologous cell therapy products 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.

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 FDA-approved products in highly regulated commercial health care markets. 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.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated pathway for licensure of so-called biosimilar and interchangeable biological products, both of which have specific defined meanings under the law. 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 reference product is approved for marketing in the U.S. a stand-alone BLA. The law is complex and is still being interpreted and implemented by the FDA. 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, as well as unique state laws and government/private policies.

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. None of our product candidates have been widely used over an extended period of time, and therefore relevant safety data are limited. Cell therapy companies also derive the raw materials for manufacturing of product candidates from human cell sources, and therefore the manufacturing process and handling requirements, including ensuring compliance with cGTPs, 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, decrease 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.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate information about our products and the diseases that our therapies are designed to treat. Social media practices in our industry continue to evolve and regulations related to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients and others may use social media channels to comment on the effectiveness of a product or to report an alleged adverse event. When such disclosures occur, we may fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend against political and market pressures generated by social media due to restrictions on what we may say about our products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face overly restrictive regulatory actions or incur other harm to our business.

RISKS RELATED TO MANUFACTURING OUR DEVELOPMENT PRODUCT CANDIDATES

We have no internal capacity to manufacture our development product candidates and have no assurance that we will continue to have access to manufacturers in our industry that can effectively make our development products or make them at an affordable, salable or otherwise commercially reasonable price or quantity.

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

We currently have no manufacturing contracts to produce materials for our clinical trials in the United States. It is possible that the demand for our products could exceed existing manufacturing capacity. We expect that, as our own cell therapy development programs progress and demand for cell therapy services in the industry expand, it may become necessary or desirable for us to expand our manufacturing vendors for cell therapy services and products in the future, which may require us to invest significant amounts of capital and to obtain regulatory approvals. If manufacturers are unable to meet our rising demand for products and services on a timely basis or unable to maintain cGMP/cGTP compliance standards, then it is likely that the progress of our own programs will be impaired which could materially and adversely affect the overall success of our development programs.

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

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

CMOs cannot provide assurances that they will be able to develop process enhancements that are acceptable to regulators or other comparable regulatory authorities, on a timely basis, on commercially reasonable terms, or at all, or that any expected improvement in profitability will be realized. If they are unsuccessful in their efforts to develop necessary improvements, we may be unable to develop commercially viable products, which would impair our ability to continue our operations.

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

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

RISKS RELATED TO GOVERNMENT REGULATION

The development and commercialization of our product candidates are 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.

Government authorities in the United States, at the federal, state and local level, and in other countries, extensively regulate, among other things, the research, development, testing, manufacture, including any manufacturing changes, packaging, storage, recordkeeping, labeling, advertising and promotion, distribution, marketing, import and export of pharmaceutical and biological products, such as CLBS12, CLBS14 and CLBS16. 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 CLBS12, CLBS14 or CLBS16 or any future product candidates. There also are extensive and ongoing post-marketing compliance obligations to which we would be subject following FDA approval of any of our product candidates. In addition, these federal regulations may change, and our product candidates may be subject to new laws or regulations due to the rapid advancement of the regenerative medicine field and legislators'/regulators' interest in it.

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 Japanese and potentially other regulatory authorities extensive preclinical and clinical data supporting the safety and efficacy of such products, as well as information about the manufacturing process and to undergo inspection of manufacturing facilities, among other things. The process of obtaining FDA and other regulatory approvals is expensive, typically takes many years and is subject to numerous risks and uncertainties, particularly with complex and/or novel product candidates such as our cell-based product candidates. Changes in regulatory approval policies during the clinical research and 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/licensure process and may refuse to accept any application or may decide that our product candidate data are insufficient for approval without the submission of additional preclinical, clinical or other time-consuming studies. In addition, varying agency interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

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

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

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

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

Although we seek to conduct our business in compliance with applicable laws and regulations, these laws and regulations are exceedingly complex and often subject to varying interpretations. The cell therapy industry is the topic of significant government interest, and thus the laws and regulations applicable to our business are subject to frequent change and/or reinterpretation. As such, there can be no assurance that we will be able, or will have the resources, to maintain compliance with all applicable biopharmaceutical and health care laws and regulations. Failure to comply with such biopharmaceutical and health care laws and regulations could result in significant enforcement actions, civil or criminal penalties, which along with the costs associated with such compliance or with enforcement of such biopharmaceutical and health care 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 human cells, tissues or cellular- and tissue-based products, or the screening or testing of a donor, are required to register with the applicable regulatory agencies. Any third party retained by us to process our samples must be similarly registered with regulators and comply with applicable regulations as well as applicable cGTP regulations and any failure to comply with these requirements could adversely affect our business.

In addition to cGTPs, cGMP regulations govern the manufacture, processing, packaging and holding of cell therapy products that are regulated as drugs. Any third-party manufacturers that prepare our products must comply with cGMP requirements including quality control, quality assurance and the maintenance of records and documentation for certain products. They may be unable to comply with these cGMP requirements and with other national regulators and state and local regulatory requirements. These requirements may change over time and we or third-party manufacturers may be unable to comply with the revised requirements.

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

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

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

- third-party clinical investigators do not perform the clinical trials on the anticipated schedule or consistent with the clinical trial protocol, GCPs 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 may be subject to numerous and varying privacy and security laws, and our failure to comply could result in penalties and reputational damage.

We are subject to laws and regulations covering data privacy and the protection of personal information including health information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. In the U.S., we may be subject to state security breach notification laws, state health information privacy laws and federal and state consumer protections laws which impose requirements for the collection, use, disclosure and transmission of personal information. Each of these laws are subject to varying interpretations by courts and government agencies, creating complex compliance issues for us. If we

fail to comply with applicable laws and regulations we could be subject to penalties or sanctions, including criminal penalties if we knowingly obtain individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting the violation of HIPAA.

Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. In May 2016, the European Union formally adopted the General Data Protection Regulation (GDPR), which applies to all EU member states from May 25, 2018 and replaced the EU Data Protection Directive The regulation introduces stringent new data protection requirements in the European Union and substantial fines for breaches of the data protection rules. It has increased our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new EU data protection rules. The GDPR is a complex law and the regulatory guidance is still evolving, including with respect to how the GDPR should be applied in the context of clinical studies. Furthermore, many of the countries within the European Union are still in the process of drafting supplementary data protection legislation in key fields where the GDPR allows for national variation, including the fields of clinical study and other health-related information. These variations in the law may raise our costs of compliance and result in greater legal risks.

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

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

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

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

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

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

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

Both federal and state government agencies have heightened civil and criminal enforcement efforts. There are numerous ongoing investigations of health care companies, including drug, biologic and medical device companies, as well as their executives and managers. In addition, amendments to the Federal False Claims Act, including under health care 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 health care-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 health care 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 government, private health insurers and third-party payors will approve coverage or provide reimbursement for the therapies and products to which our research and development 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 health care 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 health care 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 health care reform legislation in the U.S. may adversely affect our business.

The health care 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 health care for the uninsured and control the escalation of health care expenditures within the economy. In March 2010, the Patient Protection and Affordable Care Act ("PPACA"), as amended by the Health Care and Education Reconciliation Act, or the Affordable Care Act, was passed, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. While we do not believe this legislation will have a direct impact on our business, the legislation requires the adoption of implementing regulations, which may have unintended consequences or indirectly impact our business. For instance, the scope and implications of the amendments pursuant to the

Fraud Enforcement and Recovery Act of 2009 ("FERA"), have yet to be fully determined or adjudicated and as a result it is difficult to predict how future enforcement initiatives may impact our business. Also, in some instances our clients may be health insurers that will be subject to limitations on their administrative expenses and federal review of "unreasonable" rate increases that could impact the prices they pay for our services. If the legislation causes such unintended consequences or indirect impact, it could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, particularly the member states of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various E.U. member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries where we may seek to market our product candidates in the future, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidate to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, upon completion of this offering and in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our 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 health care 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, designated 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;
- differing coverage and reimbursement 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, such as the U.K. Anti-Bribery Act;
- 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 human cells as well as compositions and methods relating to hematopoietic stem cells. These patent applications may never result in the issuance of patents.

The patent positions of biotechnology companies can be highly uncertain and involve complex legal, scientific and factual questions and recent court decisions have introduced significant uncertainty regarding the strength of patents in the industry. Moreover, the legal systems of some foreign countries do not favor the aggressive enforcement of patents and may not protect our intellectual property rights to the same extent as the laws of the United States. Any of the issued patents we own or license may be challenged by third parties and held to be invalid, unenforceable or with a narrower or different scope of coverage than 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 agreements. Even so, improper use or disclosure of our

confidential information could occur, and in such case, adequate remedies may not exist. The disclosure of trade secrets and know-how could impair our competitive position.

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

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

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

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

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

Our commercial success depends in part on our avoiding infringement of the patents, trademarks and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, and reexamination proceedings before the U.S. Patent and Trade Office (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 upon.

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, 2019 through March 5, 2020 our common stock traded as low as $2.00 per share and as high as $5.44 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 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 product candidates;
- positive developments concerning our cell therapy product candidates that lead to the need for additional capital to complete the development process; 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, 2019, there were 10,528,689 shares of our common stock outstanding. In addition, there were outstanding stock options, restricted stock units and warrants representing the potential issuance of an additional 1,192,539 shares of our common stock. The issuance of these shares in the future would result in significant dilution to our current stockholders and could adversely affect the price of our common stock and the terms on which we could raise additional capital. In addition, the issuance and subsequent trading of shares could cause the supply of our common stock available for purchase in the market to exceed the purchase demand for our common stock. Such supply in excess of demand could cause the market price of our common stock to decline.

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

We entered into a Common Stock Sales Agreement with H.C. Wainwright & Co. in February 2018, which was subsequently amended on August 2, 2018, pursuant to which we may sell up to $25 million of shares of our common stock over the term of that agreement, subject to certain terms and conditions. In March 2019, subsequent to the filing of our 2018 Form 10-K, the aggregate market value of our outstanding common stock held by non-affiliates was approximately $52.8 million. Pursuant to General Instruction I.B.6 of Form S-3, since the aggregate market value of our outstanding common stock held by non-affiliates was below $75.0 million at the time of our 2018 Form 10-K filing, the aggregate amount of securities that we were

permitted to offer and sell at such time was reduced to $17.6 million (or a maximum of 4.8 million shares), which was equal to one-third of the aggregate market value of our common stock held by non-affiliates at such time.

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

Provisions in our amended and restated certificate of incorporation and by-laws 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 by-laws 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 may 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.

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

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

Our corporate headquarters are in Basking Ridge, New Jersey. The space is approximately 11,600 rentable square feet. The base monthly rent is approximately $24,000 and the lease term ends May 31, 2022. In addition, there are two five-year renewal options. In July 2019, we executed a three-year lease extension for the approximately 3,400 rentable square feet in our Rye Brook, New York office, which extension expires in March 2023. The base monthly rent for our Rye Brook office is approximately $8,900. We believe the total leased space is sufficient for the near future.

ITEM 3. LEGAL PROCEEDINGS.

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

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

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

Market for Our Common Equity

Our common stock trades on The Nasdaq Capital Market under the symbol “CLBS.”

Holders

As of March 5, 2020, there were approximately 693 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. 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, 2019 regarding shares of our common stock that may be issued under our existing equity compensation plans, including our 2018 Equity Incentive Compensation Plan (the "2018 Plan"), our 2015 Equity Compensation Plan (the "2015 Plan"), our 2009 Stock Option and Incentive Plan (the “2009 Plan”), our 2003 Stock Option and Incentive Plan (the “2003 Plan”), and our amended 2017 Employee Stock Purchase Plan (the "Amended 2017 ESPP").

	Equity Compensation Plan Information			
	Number of securities to be issued upon exercise of outstanding options (1)	**Weighted Average exercise price of outstanding options and rights**	**Number of securities remaining available for future issuance under equity compensation plan (excluding securities referenced in column (a))**	
Equity compensation plans approved by security holders (2)	1,044,417	$18.31	1,080,812	(3)
Equity compensation plans not approved by security holders	0	—	0	

(1) Includes stock options only; does not include purchase rights accruing under the Amended 2017 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 2018 Plan, the 2015 Plan, the 2009 Plan, the 2003 Plan, and the Amended 2017 ESPP.

(3) Includes shares available for future issuance under the 2018 Plan and the Amended 2017 ESPP.

Recent Sales of Unregistered Securities

None.

ITEM 6. SELECTED FINANCIAL DATA.

Not applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Cautionary Note Regarding Forward-Looking Statements" and under "Risk Factors" herein.

OVERVIEW

Caladrius Biosciences, Inc. ("we," "us," "our," "Caladrius" or the "Company") is a clinical-stage biopharmaceutical company dedicated to the development of cellular therapies designed to reverse cardiovascular disease. We are developing first-in-class therapy products that are based on the notion that our body contains finely tuned mechanisms for self-repair. Our technology leverages and enables these mechanisms in the form of specific, naturally-occurring minimally manipulated cells, using formulations unique to each indication.

Our leadership team collectively has decades of biopharmaceutical development experience and world-recognized scientific achievement in the field of cardiovascular disease, among other fields. Our goal is to build a broad portfolio of novel and versatile products that address important unmet medical needs. Our current product candidates include three developmental treatments for ischemic diseases based on our CD34+ cell therapy platform: CLBS12, recipient of SAKIGAKE designation and eligible for early conditional approval in Japan for the treatment of critical limb ischemia ("CLI") based on the results of an ongoing clinical trial; CLBS16, in a Phase 2 clinical trial in the U.S. for the treatment of coronary microvascular dysfunction ("CMD"); and CLBS14, a Regenerative Medicine Advanced Therapy ("RMAT") designated therapy for which we have finalized with the U.S. Food and Drug Administration (the "FDA") a protocol for a Phase 3 confirmatory trial in subjects with no-option refractory disabling angina ("NORDA").

Additional Out-licensing Opportunities

Our broad intellectual property portfolio of cell therapy assets includes notable programs available for out-licensing in order to continue their clinical development. Our current long-term strategy focuses on advancing our therapies through development with the ultimate objective of obtaining market authorizations and entering commercialization, either alone or with partners, to provide treatment options to patients suffering from life-threatening medical conditions. We believe that we are well-positioned to realize potentially meaningful value increases within our own proprietary pipeline if we are successful in advancing our product candidates to their next significant development milestones.

Results of Operations

Year Ended December 31, 2019 Compared to Year Ended December 31, 2018

Overall, net losses were $19.4 million and $16.2 million for the years ended December 31, 2019 and 2018, respectively.

Operating Expenses

For the year ended December 31, 2019, operating expenses totaled $20.1 million compared to $17.0 million for the year ended December 31, 2018, representing an increase of $3.1 million or 18%. Operating expenses comprise the following:

- Research and development expenses were approximately $10.8 million for the year ended December 31, 2019 compared to $7.6 million for the year ended December 31, 2018, representing an increase of approximately $3.2 million, or 42%. Research and development in both periods focused on the advancement of our ischemic repair platform and related to:
    - ongoing registration-eligible study expenses for CLBS12 in critical limb ischemia in Japan, whereby we continue to focus spending on our patient enrollment, and anticipate completing enrollment in the first half of 2020;
    - ongoing Phase proof-of-concept study expenses for CLBS16 in coronary microvascular dysfunction, whereby study enrollment was completed in the second quarter of 2019, preliminary top-line results were reported in November 2019 and full results expected in the first half of 2020; and
    - expenses associated with preparation our confirmatory Phase 3 study of CLBS14 in NORDA. In late 2019, we projected that the Phase 3 study would cost approximately $70 million in external expenses over the next several years to complete, and as a result, we elected to postpone the initiation of the study until we have confidence that we can access sufficient capital to allow us to complete the study uninterrupted.
- General and administrative expenses were approximately $9.3 million for the year ended December 31, 2019, compared to $9.4 million for the year ended December 31, 2018, representing a decrease of approximately $0.1 million, or 1%. Our general and administrative expenses focus on general corporate-related 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)

Total other income (expense) is primarily comprised of investment income on cash and marketable securities.

Analysis of Liquidity and Capital Resources

At December 31, 2019, we had cash, cash equivalents, and marketable securities of approximately $25.2 million, working capital of approximately $20.0 million, and stockholders' equity of approximately $20.8 million. During the year ended December 31, 2019, we met our immediate cash requirements through existing cash balances.

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

	Year Ended December 31,	
	2019	2018
Net cash used in operating activities	$ (18,882)	$ (19,986)
Net cash provided by (used in) investing activities	21,432	(4,707)
Net cash provided by financing activities	1,183	824

Operating Activities

Our cash used in operating activities during the year ended December 31, 2019 totaled approximately $18.9 million, which is the sum of (i) our net loss of $19.4 million, and adjusted for non-cash income and expenses totaling $1.6 million (which includes adjustments for equity-based compensation, depreciation and amortization, and amortization/accretion of marketable securities), and (ii) changes in operating assets and liabilities of approximately $1.1 million.

Our cash used in operating activities during the year ended December 31, 2018 totaled approximately $20.0 million, which is the sum of (i) our net loss of $16.2 million, and adjusted for non-cash income and expenses totaling $1.5 million (which includes adjustments for equity-based compensation, depreciation and amortization, gain on disposal of assets, deferred income taxes, and amortization/accretion of marketable securities), and (ii) changes in operating assets and liabilities of approximately $5.3 million.

Investing Activities

Our cash provided by investing activities during the year ended December 31, 2019 totaled approximately $21.4 million and was entirely due to net proceeds from the sale of marketable securities investments (net of purchases of marketable securities).

Our cash used in investing activities during the year ended December 31, 2018 totaled approximately $4.7 million and was primarily due to net purchases of marketable securities (net of sales of marketable securities), and partially offset by $2.5 million in proceeds from the sale of our Counterflow Centrifuge System device.

Financing Activities

Our cash provided by financing activities during the year ended December 31, 2019 consisted of proceeds of $1.0 million through the issuance of shares of our common stock under the provisions of our common stock purchase agreement with Lincoln Park Capital, and proceeds of $0.3 million through the issuance of shares of our common stock under the provisions of our Common Stock Sales Agreement with H.C. Wainwright, which was partially offset by tax withholding-related payments on net share settlement equity awards to employees.

Our cash provided by financing activities during the year ended December 31, 2018 consisted of proceeds of approximately $1.0 million through the issuance of shares of our common stock under the provisions of our Common Stock Sales Agreement with H.C. Wainwright and $0.4 million of option exercise proceeds, which was partially offset by payment obligations under equipment finance leases and tax withholding-related payments on net share settlement equity awards to employees.

Liquidity and Capital Requirements Outlook

To meet our short and long-term liquidity needs, we expect to use existing cash balances and a variety of other means. Other sources of liquidity could include additional potential issuances of debt or equity securities in public or private financings, partnerships and/or collaborations and/or sale of assets. Our history of operating losses and liquidity challenges may make it difficult for us to raise capital on acceptable terms or at all. The demand for the equity and debt of biopharmaceutical companies like ours is dependent upon many factors, including the general state of the financial markets. During times of extreme market

volatility, capital may not be available on favorable terms, if at all. Our inability to obtain such additional capital could materially and adversely affect our business operations. We will also continue to seek, as appropriate, grants for scientific and clinical studies from various governmental agencies and foundations, and other sources of non-dilutive funding. For example, in December 2019, we received preliminary approval from the New Jersey Economic Development Authority to participate in the Technology Business Tax Certificate Transfer (NOL) Program. That program permits qualified companies to sell a percentage of their New Jersey net operating losses to unrelated profitable corporations. While we expect to receive final approval for our New Jersey net operating losses sale in the first quarter of 2020, there can be no assurance that such approval will be received at that time, if ever. We believe that our cash on hand will enable us to fund operating expenses for at least the next 12 months following the issuance of our financial statements considering the assumption that any initiation of a CLBS14 Phase 3 study is contingent on our acquisition of additional capital to fund such a study.

In March 2019, we and Lincoln Park Capital Fund, LLC (“Lincoln Park”) entered into a purchase agreement (the “Purchase Agreement”) and a registration rights agreement (the “Registration Rights Agreement”), pursuant to which we have the right to sell to Lincoln Park shares of our common stock having an aggregate value of up to $26 million, subject to certain limitations and conditions set forth in the Purchase Agreement (the “Offering”). As consideration for entering into the Purchase Agreement, we issued to Lincoln Park an additional 181,510 shares of common stock as commitment shares. Pursuant to the Purchase Agreement, Lincoln Park purchased 250,000 shares of common stock, at a price of $4.00 per share, for a total gross purchase price of $1.0 million (the “Initial Purchase”) upon commencement. Thereafter, as often as every business day from and after one business day following the date of the Initial Purchase and over the 36-month term of the Purchase Agreement, we have the right, from time to time, at its sole discretion and subject to certain conditions, to direct Lincoln Park to purchase up to 100,000 shares of common stock, with such amount increasing as the closing sale price of the common stock increases; provided Lincoln Park’s obligation under any single such purchase will not exceed $2,500,000, unless we and Lincoln Park mutually agree to increase the maximum amount of such single purchase (each, a “Regular Purchase”). If we direct Lincoln Park to purchase the maximum number of shares of common stock it then may sell in a Regular Purchase, then in addition to such Regular Purchase, and subject to certain conditions and limitations in the Purchase Agreement, we may direct Lincoln Park in an “accelerated purchase” to purchase an additional amount of common stock that may not exceed the lesser of (i) 300% the number of shares purchased pursuant to the corresponding Regular Purchase or (ii) 30% of the total number of shares of our common stock traded during a specified period on the applicable purchase date as set forth in the Purchase Agreement. Under certain circumstances and in accordance with the Purchase Agreement, we may direct Lincoln Park to purchase shares in multiple accelerated purchases on the same trading day. As of December 31, 2019, the Company had not made any sales of common stock to Lincoln Park under the Purchase Agreement other than the Initial Purchase.

In February 2018, we entered into a common stock sales agreement (the "Sales Agreement") with H.C. Wainwright & Co., LLC ("HCW"), as sales agent, in connection with an “at the market offering” under which we from time to time may offer and sell shares of our common stock, which was further amended in August 2018, having an aggregate offering price of up to $25 million. In March 2019, subsequent to the filing of our 2018 Form 10-K, the aggregate market value of our outstanding common stock held by non-affiliates was approximately $52.8 million. Pursuant to General Instruction I.B.6 of Form S-3, since the aggregate market value of our outstanding common stock held by non-affiliates was below $75.0 million at the time of our 2018 Form 10-K filing, the aggregate amount of securities that we were permitted to offer and sell at such time was reduced to $17.6 million (or a maximum of 4.8 million shares), which was equal to one-third of the aggregate market value of our common stock held by non-affiliates at such time. Subject to the terms and conditions of the Sales Agreement, HCW will use its commercially reasonable efforts consistent with its normal trading and sales practices to sell the shares from time to time, based upon our instructions, including any price, time or size limits specified by us. We have provided HCW with customary indemnification rights, and HCW will be entitled to a commission at a fixed commission rate equal to 3.0% of the gross proceeds per share sold. We have no obligation to sell any of the shares and may at any time suspend sales under the Sales Agreement or terminate the Sales Agreement. The Sales Agreement will terminate upon the sale of all of the shares under the Sales Agreement unless terminated earlier by either party as permitted under the Sales Agreement. As of December 31, 2019, we issued 260,349 shares of common stock under the Sales Agreement for net proceeds of $1.3 million.

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

SEASONALITY

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

OFF-BALANCE SHEET ARRANGEMENTS

We do not have any off-balance sheet arrangements.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and judgments that affect the amounts reported in the financial statements. On an ongoing basis, we evaluate our estimates and assumptions. We base our estimates on historical experience and other assumptions believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could differ from these estimates.

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

Share-Based Compensation

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

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

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The financial statements and notes thereto required to be filed under this Item are presented commencing on page 50 of this Annual Report on Form 10-K.

Caladrius Biosciences, Inc. and Subsidiaries

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders

Caladrius Biosciences, Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of Caladrius Biosciences, Inc., (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, equity, and cash flows for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Basis for opinion

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

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

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

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

New York, New York
March 5, 2020

CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)

	December 31, 2019	December 31, 2018
ASSETS		
Current Assets		
Cash and cash equivalents	$ 14,032	$ 10,299
Marketable securities	11,125	32,754
Prepaid and other current assets	815	1,053
Total current assets	25,972	44,106
Property and equipment, net	100	165
Other assets	1,081	309
Total assets	$ 27,153	$ 44,580
LIABILITIES, NON-CONTROLLING INTERESTS AND EQUITY		
Liabilities		
Accounts payable	$ 1,490	$ 762
Accrued liabilities	4,486	4,857
Total current liabilities	5,976	5,619
Other long-term liabilities	624	1,507
Total liabilities	6,600	7,126
Commitments and Contingencies		
Stockholders' Equity		
Preferred stock; authorized, 20,000,000 shares Series B convertible redeemable preferred stock liquidation value, 0.001 share of common stock, $.01 par value; 825,000 shares designated; issued and outstanding, 10,000 shares at December 31, 2019 and December 31, 2018, respectively	—	—
Common stock, $.001 par value, authorized 500,000,000 shares; issued and outstanding, 10,528,689 and 9,865,735 shares, at December 31, 2019 and December 31, 2018, respectively	11	10
Additional paid-in capital	438,911	436,433
Treasury stock, at cost; 11,080 shares at December 31, 2019 and December 31, 2018 respectively	(708)	(708)
Accumulated deficit	(417,400)	(397,977)
Accumulated other comprehensive income (loss)	2	(32)
Total Caladrius Biosciences, Inc. stockholders' equity	20,816	37,726
Noncontrolling interests	(263)	(272)
Total equity	20,553	37,454
Total liabilities, non-controlling interests and equity	$ 27,153	$ 44,580

See accompanying notes to consolidated financial statements.

CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)

	Year Ended December 31,	
	2019	**2018**
Operating Expenses:		
Research and development	$ 10,797	$ 7,594
General, and administrative	9,295	9,393
Operating expenses	20,092	16,987
Operating loss	(20,092)	(16,987)
Other income (expense):		
Other income, net	740	824
Interest expense	—	(5)
Total other income (expense), net	740	819
Net loss	(19,352)	(16,168)
Less - net income (loss) attributable to noncontrolling interests	9	(1)
Net loss attributable to Caladrius Biosciences, Inc. common shareholders	$ (19,361)	$ (16,167)
Basic and diluted loss per share:		
Caladrius Biosciences, Inc. common shareholders	$ (1.88)	$ (1.67)
Weighted average common shares outstanding:		
Basic and diluted shares	10,325	9,689

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,	
	2019	**2018**
Net loss	$ (19,352)	$ (16,168)
Other comprehensive loss:		
Available for sale securities - net unrealized income (loss)	34	(4)
Total other comprehensive income (loss)	34	(4)
Comprehensive loss	(19,318)	(16,172)
Comprehensive income (loss) attributable to noncontrolling interests	9	(1)
Comprehensive loss attributable to Caladrius Biosciences, Inc. common stockholders	$ (19,327)	$ (16,171)

See accompanying notes to consolidated financial statements.

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

	Series B Convertible Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Treasury Stock	Total Caladrius Biosciences, Inc. Stockholders' Equity	Non-Controlling Interest in Subsidiary	Total Equity
	Shares	Amount	Shares	Amount							
Balance at December 31, 2017	10	$ —	9,484	$ 9	$ 433,044	$ (28)	$ (381,810)	$ (708)	$ 50,507	$ (318)	$ 50,189
Net loss	—	—	—	—	—	—	(16,167)	—	(16,167)	(1)	(16,168)
Unrealized loss on marketable securities	—	—	—	—	—	(4)	—	—	(4)	—	(4)
Share-based compensation	—	—	129	—	2,053	—	—	—	2,053	—	2,053
Net proceeds from issuance of common stock	—	—	176	1	1,028	—	—	—	1,029	—	1,029
Proceeds from option exercises	—	—	77	—	355	—	—	—	355	—	355
Change in ownership in subsidiary	—	—	—	—	(47)	—	—	—	(47)	47	—
Balance at December 31, 2018	10	$ —	9,866	$ 10	$ 436,433	$ (32)	$ (397,977)	$ (708)	$ 37,726	$ (272)	$ 37,454
Adoption of accounting standard	—	—	—	—	—	—	(62)	—	(62)	—	(62)
Net loss	—	—	—	—	—	—	(19,361)	—	(19,361)	9	(19,352)
Unrealized loss on marketable securities	—	—	—	—	—	34	—	—	34	—	34
Share-based compensation	—	—	94	—	1,165	—	—	—	1,165	—	1,165
Net proceeds from issuance of common stock	—	—	569	1	1,313	—	—	—	1,314	—	1,314
Balance at December 31, 2019	10	$ —	10,529	$ 11	$ 438,911	$ 2	$ (417,400)	$ (708)	$ 20,816	$ (263)	$ 20,553

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,	
	2019	2018
Cash flows from operating activities:		
Net loss	$ (19,352)	$ (16,168)
Adjustments to reconcile net loss to net cash used in operating activities:		
Equity-based compensation expense	1,295	2,453
Depreciation and amortization	65	225
Gain on disposal of assets	—	(1,429)
Amortization/accretion on marketable securities	232	282
Changes in operating assets and liabilities:		
Prepaid and other current assets	238	261
Other assets	504	291
Accounts payable, accrued liabilities and other liabilities	(1,864)	(5,901)
Net cash used in operating activities	(18,882)	(19,986)
Cash flows from investing activities:		
Purchase of marketable securities	(32,938)	(69,690)
Sales of marketable securities	54,370	62,567
Proceeds from CFC device sale	—	2,550
Acquisition of property and equipment	—	(134)
Net cash provided by (used in) investing activities	21,432	(4,707)
Cash flows from financing activities:		
Proceeds from exercise of options	—	355
Tax withholding payments on net share settlement equity awards	(130)	(403)
Net proceeds from issuance of capital stock	1,313	1,031
Repayment of notes payable	—	(159)
Net cash provided by financing activities	1,183	824
Net increase (decrease) in cash and cash equivalents	3,733	(23,869)
Cash and cash equivalents at beginning of year	10,299	34,168
Cash and cash equivalents at end of year	$ 14,032	$ 10,299
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the period for:		
Interest	$ —	$ 5
Taxes	—	—

See accompanying notes to consolidated financial statements.

CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 – The Business

OVERVIEW

Caladrius Biosciences, Inc. (“we,” “us,” "our," “Caladrius” or the “Company”) is a clinical-stage biopharmaceutical company dedicated to the development of cellular therapies designed to reverse cardiovascular disease. The Company is developing first-in-class therapy products that are based on the notion that our body contains finely tuned mechanisms for self-repair. The Company's technology leverages and enables these mechanisms in the form of specific, naturally-occurring, minimally manipulated cells, using formulations unique to each indication.

The Company's leadership team collectively has decades of biopharmaceutical development experience and world-recognized scientific achievement in the field of cardiovascular disease, among other fields. Its goal is to build a broad portfolio of novel and versatile products that address important unmet medical needs. The Company's current product candidates include three developmental treatments for ischemic diseases based on its CD34+ cell therapy platform: CLBS12, recipient of SAKIGAKE designation and eligible for early conditional approval in Japan for the treatment of critical limb ischemia ("CLI") based on the results of an ongoing clinical trial; CLBS16, in a Phase 2 clinical trial in the U.S. for the treatment of coronary microvascular dysfunction ("CMD"); and CLBS14, a Regenerative Medicine Advanced Therapy ("RMAT") designated therapy for which the Company has finalized with the U.S. Food and Drug Administration (the "FDA") a protocol for a Phase 3 confirmatory trial in subjects with no-option refractory disabling angina ("NORDA").

Additional Out-licensing Opportunities

The Company's broad intellectual property portfolio of cell therapy assets includes notable programs available for out-licensing in order to continue their clinical development. Its current long-term strategy focuses on advancing its therapies through development with the ultimate objective of obtaining market authorizations and entering commercialization, either alone or with partners, to provide treatment options to patients suffering from life-threatening medical conditions. The Company believes that it is well-positioned to realize potentially meaningful value increases within its own proprietary pipeline if the Company is successful in advancing its product candidates to their next significant development milestones.

Basis of Presentation

The accompanying Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”).

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements. Estimates also affect the reported amounts of expenses during the reporting period. The Company bases its estimates on historical experience and other assumptions believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. The Company makes critical estimates and assumptions in determining stock-based awards values. 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 majority owned subsidiaries and affiliates. All intercompany activities have been eliminated in consolidation.

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

The Company is subject to credit risk from its portfolio of cash, cash equivalents and marketable securities. Under its investment policy, the Company limits 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 the Company's

investment policy, in order of priority, are as follows: safety and preservation of principal and diversification of risk, liquidity of investments sufficient to meet cash flow requirements, and a competitive after-tax rate of return.

Marketable Securities

The Company determines the appropriate classification of its marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. All of the Company's marketable securities are considered as available-for-sale and carried at estimated fair values and reported in cash equivalents. Unrealized gains and losses on available-for-sale securities are excluded from net income and reported in accumulated other comprehensive income (loss) as a separate component of stockholders' equity. Other income (expense), net, includes interest, dividends, amortization of purchase premiums and discounts, realized gains and losses on sales of securities and other-than-temporary declines in the fair value of securities, if any. The cost of securities sold is based on the specific identification method. The Company regularly reviews all of its investments for other-than-temporary declines in fair value. The Company's 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 the Company has the intent to sell the securities and whether it is more likely than not that it will be required to sell the securities before the recovery of their amortized cost basis. When the Company determines that the decline in fair value of an investment is below its accounting basis and this decline is other-than-temporary, it reduces the carrying value of the security it holds and records a loss for the amount of such decline.

Property and Equipment

The cost of property 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 and equipment are as follows:

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

Long-lived Assets

Long-lived assets consist of property and equipment. The assets are amortized on a straight line basis over their respective useful lives. The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset exceeds the fair value of the asset. If other events or changes in circumstances indicate that the carrying amount of an asset that the Company expects to hold and use may not be recoverable, the Company will estimate the undiscounted future cash flows expected to result from the use of the asset and/or its eventual disposition, and recognize an impairment loss, if any. The impairment loss, if determined to be necessary, would be measured as the amount by which the carrying amount of the assets exceeds the fair value of the assets.

Share-Based Compensation

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

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 to losses incurred in all periods presented.

Treasury Stock

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

Research and Development Costs

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

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

New Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). ASU 2016-02 requires that a lessee recognize lease assets and lease liabilities for those leases classified as operating leases. The guidance was effective for interim and annual periods beginning after December 15, 2018 and was adopted as of January 1, 2019. The Company adopted the standard using the optional transition method, with an immaterial adjustment to accumulated deficit upon adoption. The comparative information has not been restated and continues to be reported under the accounting standards that were in effect for those periods. The Company concluded that the adoption of ASU 2016-02 was non-cash in nature, did not affect the Company's cash position, and did not have a material impact on the Company's financial statements.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments—Credit Losses, which will require companies to present assets held at amortized cost and available for sale debt securities net of the amount expected to be collected. The guidance requires the measurement of expected credit losses to be based on relevant information from past events, including historical experiences, current conditions and reasonable and supportable forecasts that affect collectibility. The guidance will be effective for fiscal years and interim periods beginning after December 15, 2019 and early adoption is permitted. The adoption of this guidance is not expected to have a material impact on our consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, "Improvements to Nonemployee Share-Based Payment Accounting," which supersedes ASC 505-50 and expands the scope of ASC 718 to include all share-based payments arrangements related to the acquisition of goods and services from both employees and nonemployees. For public companies, the amendments are effective for annual reporting periods beginning after December 15, 2018, including interim periods within those annual periods. Early adoption is permitted, but no earlier than a company's adoption date of ASC 606. The Company determined that the adoption of this new accounting guidance did not have a material impact on its financial statements and footnote disclosures.

In July 2019, the FASB issued ASU 2019-07, "Codification Updates to SEC Sections", to codify the SEC releases that clarify and improve the disclosure and presentation requirements of a variety of codification topics, thereby eliminating certain disclosure requirements that were redundant, duplicative, overlapping, outdated, or superseded. The Company determined that the adoption of this new accounting guidance did not have a material impact on its financial statements and footnote disclosures.

In October 2019, the FASB issued ASU 2019-12, which affects general principles within Topic 740, Income Taxes. The amendments of ASU 2019-12 are meant to simplify and reduce the cost of accounting for income taxes. For public business entities, the amendments in this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The Company believes that the adoption of this new accounting guidance will not have a material impact on its financial statements and footnote disclosures.

Note 3 – Available-for-Sale-Securities

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

	December 31, 2019				December 31, 2018			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities	$ 11,673	$ 3	$ (1)	$ 11,675	$ 33,536	$ —	$ (32)	$ 33,504
Money market funds	11,093	—	—	11,093	4,314	—	—	4,314
Total	$ 22,766	$ 3	$ (1)	$ 22,768	$ 37,850	$ —	$ (32)	$ 37,818

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 the Company's Consolidated Balance Sheets (in thousands):

	December 31, 2019	December 31, 2018
Cash and cash equivalents	$ 11,643	$ 5,064
Marketable securities	11,125	32,754
Total	$ 22,768	$ 37,818

The following table summarizes the Company's portfolio of available-for-sale securities by contractual maturity (in thousands):

	December 31, 2019		December 31, 2018	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Less than one year	$ 22,766	$ 22,768	$ 37,850	$ 37,818
Greater than one year	—	—	—	—
Total	$ 22,766	$ 22,768	$ 37,850	$ 37,818

Note 4 – Property and Equipment

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

	December 31,	
	2019	2018
Furniture and fixtures	$ 26	$ 26
Computer equipment	247	247
Leasehold improvements	76	76
Property and equipment, gross	349	349
Accumulated depreciation	(249)	(184)
Property and equipment, net	$ 100	$ 165

The Company’s results included depreciation expense of approximately $0.1 million and $0.2 million for the years ended December 31, 2019 and 2018, respectively.

Note 5 – Loss Per Share

For the years ended December 31, 2019 and 2018, 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, 2019 and 2018, the Company excluded the following potentially dilutive securities (in thousands):

	December 31,	
	2019	2018
Stock Options	1,044	1,019
Warrants	30	30
Restricted Stock Units	118	58

Note 6 – Fair Value Measurements

Fair value of financial assets and liabilities that are being measured and reported are defined as the exchange price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the principal market at the measurement date (exit price). The Company is required to classify fair value measurements in one of the following categories:

Level 1 inputs are defined as quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2 inputs are defined as inputs other than quoted prices included within Level 1 that are observable for the assets or liabilities, either directly or indirectly.

Level 3 inputs are defined as unobservable inputs for the assets or liabilities. Financial assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of the fair value of assets and liabilities and their placement within the fair value hierarchy levels.

The Company's financial assets and liabilities that were accounted for at fair value on a recurring basis as of December 31, 2019 and December 31, 2018 were as follows (in thousands):

	December 31, 2019				December 31, 2018			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Marketable securities - available for sale	$ —	$ 11,125	$ —	$ 11,125	$ —	$ 32,754	$ —	$ 32,754
	$ —	$ 11,125	$ —	$ 11,125	$ —	$ 32,754	$ —	$ 32,754

Note 7 – Accrued Liabilities

Accrued liabilities were as follow (in thousands):

	December 31,	
	2019	2018
Salaries, employee benefits and related taxes	$ 1,834	$ 1,758
Operating lease liabilities - current	354	—
CIRM upfront funding - current	1,600	2,583
Other	698	516
	$ 4,486	$ 4,857

Note 8 – Operating Leases

The Company has operating leases for two offices with terms that expire in 2022 and 2023. In addition, the Company pays for facility space through a third-party manufacturing contract that contains an embedded operating lease, with an estimated expiration in 2020. The Company estimates its incremental borrowing rate, at lease commencement, to determine the present value of lease payments, since most of the Company's leases do not provide an implicit rate of return. The Company recognizes lease expense on a straight-line basis over the lease term. For lease agreements entered into or reassessed after the adoption of Topic 842, the Company elected to account for non-lease components associated with its leases and lease components as a single lease component. Upon adoption of Topic 842 on January 1, 2019, the Company recognized $1.4 million of operating lease liabilities and $1.3 million of operating lease right-of-use assets for its existing operating leases in its balance sheet. As of December 31, 2019, the Company's operating lease liabilities and right-of-use assets were $1.0 million and $0.9 million, respectively. Each of the Company's leases includes options for the Company to extend the lease term and/or sub-lease space in whole or in part.

Operating lease liabilities and right-of-use assets were recorded in the following captions of our balance sheet were as follows (in thousands):

	December 31, 2019
Right-of Use Assets:	
Other assets	$ 906
Total Right-of-Use Asset	$ 906
Operating Lease Liabilities:	
Accrued liabilities	$ 353
Other long-term liabilities	624
Total Operating Lease Liabilities	$ 977

As of December 31, 2019, the weighted average remaining lease term for our operating leases was 1.97 years, and the weighted average discount rate for our operating leases was 9.625%. Future minimum lease payments under the lease agreements as of December 31, 2019 were as follows (in thousands):

Years ended	Operating Leases
2020	$ 431
2021	414
2022	239
2023	27
Total lease payments	1,111
Less: Amounts representing interest	(134)
Present value of lease liabilities	$ 977

Note 9 – Stockholders' Equity

Equity Plans

The Company has used long-term incentive plans for the purpose of granting equity awards to employees of the Company, including officers, and nonemployees, including consultants and nonemployee members of the Company's board of directors (collectively, "Participants"). The Participants may receive awards as determined by a committee of independent members of the Company's board of directors or, to the extent authorized by such committee with respect to certain Participants, a duly authorized employee (collectively, the "Committee"). The incentive plan currently used by the Company is the 2018 Equity Incentive Compensation Plan (the "2018 Plan"), which was adopted by the stockholders of the Company in June 2018, with 1,500,000 shares authorized for issuance thereunder, plus any shares awarded under the 2015 Equity Compensation Plan (the "2015 Plan") or the Amended and Restated 2009 Equity Compensation Plan (the "2009 Plan") that are not issued due to their subsequent forfeiture, cancellation, or other settlement thereof. Concurrent with the adoption of the 2018 Plan, no future awards will occur under the 2015 Plan or the 2009 Plan. The awards that may be made under the 2018 Plan include: (a) incentive stock options and nonqualified stock options, (b) shares of restricted stock, (c) restricted stock units, and (d) other kinds of equity-based compensation awards. All stock options under the 2015 Plan and 2009 Plan were granted and the 2018 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 nonemployee, employee or director of the Company. As of December 31, 2019, there were 700,966 shares available for future grants under the 2018 Plan. No additional awards may be made under the 2015 Plan or the 2009 Plan.

The Company adopted an employee stock purchase plan effective January 1, 2013 and authorized 50,000 shares under the plan (the "2012 ESPP"). The plan has two six-month offering periods per year under which eligible employees may contribute up to 15% of their compensation toward the purchase of the Company's common stock per offering period (with a $25,000 cap per calendar year). The employee's purchase price is equal to (i) 85% of the closing price of a share of the Company's common stock on the enrollment date of such offering period or (ii) 85% of the closing price of a share of the Company's common stock on the Exercise Date of such Offering Period, whichever is lower. In May 2017, the Company's stockholders approved an amendment and restatement to the 2012 ESPP (the "2017 ESPP") in order to effect an increase of authorized shares from 50,000 to 100,000. In June 2018, the Company's stockholders approved an amendment to the 2017 ESPP (the " Amended 2017 ESPP") in order to effect an increase of authorized shares from 100,000 to 500,000. During the year ended December 31, 2019, 25,809 shares were issued under the Amended 2017 ESPP. At December 31, 2019, the Company had 379,846 shares of the Company's common stock available for future grant in connection with this plan.

Equity Issuances

Purchase Agreement

In March 2019, the Company and Lincoln Park Capital Fund, LLC (“Lincoln Park”) entered into a purchase agreement (the “Purchase Agreement”) and a registration rights agreement (the “Registration Rights Agreement”), pursuant to which the Company has the right to sell to Lincoln Park shares of the Company’s common stock having an aggregate value of up to $26.0 million, subject to certain limitations and conditions set forth in the Purchase Agreement (the “Offering”). As consideration for entering into the Purchase Agreement, the Company issued to Lincoln Park an additional 181,510 shares of common stock as commitment shares.

Pursuant to the Purchase Agreement, Lincoln Park purchased 250,000 shares of common stock, at a price of $4.00 per share, for a total gross purchase price of $1,000,000 (the “Initial Purchase”) upon commencement. Thereafter, as often as every business day from and after one business day following the date of the Initial Purchase and over the 36-month term of the Purchase Agreement the Company has the right, from time to time, at its sole discretion and subject to certain conditions, to direct Lincoln Park to purchase up to 100,000 shares of common stock, with such amount increasing as the closing sale price of the common stock increases; provided Lincoln Park’s obligation under any single such purchase will not exceed $2,500,000, unless the Company and Lincoln Park mutually agree to increase the maximum amount of such single purchase (each, a “Regular Purchase”). If the Company directs Lincoln Park to purchase the maximum number of shares of common stock it then may sell in a Regular Purchase, then in addition to such Regular Purchase, and subject to certain conditions and limitations in the Purchase Agreement, the Company may direct Lincoln Park in an “accelerated purchase” to purchase an additional amount of common stock that may not exceed the lesser of (i) 300% the number of shares purchased pursuant to the corresponding Regular Purchase or (ii) 30% of the total number of shares of the Company’s common stock traded during a specified period on the applicable purchase date as set forth in the Purchase Agreement. Under certain circumstances and in accordance with the Purchase Agreement, the Company may direct Lincoln Park to purchase shares in multiple accelerated purchases on the same trading day.

The Company controls the timing and amount of any sales of its common stock to Lincoln Park. There is no upper limit on the price per share that Lincoln Park must pay for its common stock under the Purchase Agreement, but in no event will shares be sold to Lincoln Park on a day the closing price is less than the floor price specified in the Purchase Agreement. In all instances, the Company may not sell shares of its common stock to Lincoln Park under the purchase agreement if it would result in Lincoln Park beneficially owning more than 9.99% of its common stock.

The Purchase Agreement does not limit the Company’s ability to raise capital from other sources at the Company’s sole discretion, except that (subject to certain exceptions) the Company may not enter into any Variable Rate Transaction (as defined in the Purchase Agreement, including the issuance of any floating conversion rate or variable priced equity-like securities) during the 36 months after the date of the Purchase Agreement. The Company has the right to terminate the Purchase Agreement at any time, at no cost to the Company.

As of December 31, 2019, the Company had not made any sales of common stock to Lincoln Park under the Purchase Agreement other than the Initial Purchase.

Common Stock Sales Agreement

In February 2018, the Company entered into a common stock sales agreement with H.C. Wainwright & Co., LLC ("HCW") as sales agent, which was subsequently amended in August 2018 (the "Sales Agreement"), in connection with an “at the market offering” under which the Company from time to time may offer and sell shares of its common stock, having an aggregate offering price of not more than $25.0 million. In March 2019, subsequent to the filing of the Company's 2018 Form 10-K, the aggregate market value of its outstanding common stock held by non-affiliates was approximately $52.8 million. Pursuant to General Instruction I.B.6 of Form S-3, since the aggregate market value of the Company's outstanding common stock held by non-affiliates was below $75.0 million at the time of its 2018 Form 10-K filing, the aggregate amount of securities that the Company was permitted to offer and sell at such time was reduced to $17.6 million (or a maximum of 4.8 million shares), which was equal to one-third of the aggregate market value of the Company's common stock held by non-affiliates at such time.

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

During the year ended December 31, 2019, the Company issued 260,349 shares of common stock under the Sales Agreement for net proceeds of $1.3 million.

Stock Options and Warrants

The following table summarizes the activity for stock options and warrants for the year ended December 31, 2019:

	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, 2018	1,018,530	$ 30.50	5.30	$ 3.3	30,000	$ 5.90	4.19	$ —
Changes during the Year:								
Granted	209,346	$ 4.86			—	$ —		
Exercised	(240)	$ 3.54			—	$ —		
Forfeited	(2,625)	$ 4.63			—	$ —		
Expired	(180,594)	$ 71.92			—	$ —		
Outstanding at December 31, 2019	1,044,417	$ 18.31	6.06	$ —	30,000	$ 5.89	3.19	$ —
Vested at December 31, 2019 or expected to vest in the future	1,028,387	$ 18.52	6.01	$ —	30,000	$ 5.89	3.19	$ —
Exercisable at December 31, 2019	804,407	$ 22.41	5.26	$ —	30,000	$ 5.89	3.19	$ —

Restricted Stock

During the years ended December 31, 2019 and 2018, the Company issued restricted stock for services as follows ($ in thousands, except share data):

	2019	2018
Number of Restricted Stock Issued	123,564	91,740
Value of Restricted Stock Issued	$ 611.6	$ 347.7

The weighted average estimated fair value of restricted stock issued for services in the years ended December 31, 2019 and 2018 was $4.95 and $3.79 per share, respectively. The fair value of the restricted stock was determined using the Company's closing stock price on the date of issuance. The vesting terms of restricted stock issuances are generally between one to four years.

Restricted Stock Units

During the years ended December 31, 2019 and 2018, the Company issued restricted stock units for services as follows ($ in thousands, except share data):

	2019	2018
Number of Restricted Stock Units Issued	184,454	139,497
Value of Restricted Stock Units Issued	$ 908.6	$ 711.9

The weighted average estimated fair value of restricted stock issued for services in the years ended December 31, 2019 and 2018 was $4.93 and $5.10 per share, respectively. The fair value of the restricted stock units was determined using the Company's closing stock price on the date of issuance. The vesting terms of restricted stock unit issuances are generally one year, or upon the achievement of performance-based milestones.

Note 10 – Share-Based Compensation

Share-based Compensation

The Company utilizes share-based compensation in the form of stock options and restricted stock. The following table summarizes the components of share-based compensation expense for the years ended December 31, 2019 and 2018 ($ in thousands):

	Year Ended December 31,	
	2019	2018
Research and development	$ 274	$ 446
General and administrative	1,021	2,007
Total share-based compensation expense	$ 1,295	$ 2,453

Total compensation cost related to unvested awards not yet recognized and the weighted-average periods over which the awards are expected to be recognized at December 31, 2019 were as follows ($ in thousands):

	Stock Options	Restricted Stock Units	Restricted Stock
Unrecognized compensation cost	$ 646	$ 49	$ 403
Expected weighted-average period in years of compensation cost to be recognized	1.57	1.43	1.82

Total fair value of shares vested and the weighted average estimated fair values of shares granted for the years ended December 31, 2019 and 2018 were as follows ($ in thousands):

	Stock Options	
	Year Ended December 31,	
	2019	2018
Total fair value of shares vested	$ 399	$ 218
Weighted average estimated fair value of shares granted	3.18	2.61

Valuation Assumptions

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

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

	Stock Options	
	Year Ended December 31,	
	2019	2018
Expected term - minimum (in years)	6	5.5
Expected term - maximum (in years)	6	6
Expected volatility - minimum	74%	68%
Expected volatility - maximum	74%	73%
Weighted Average volatility	74%	72%
Expected dividend yield	—	—
Risk-free interest rate - minimum	2.35%	2.35%
Risk-free interest rate - maximum	2.62%	2.96%

Note 11 – Research Funding

California Institute of Regenerative Medicine Grant Award

In February 2017, the California Institute for Regenerative Medicine ("CIRM") awarded the Company funds of up to $12.2 million to support the T-Rex Study. The funding will be based upon the achievement of certain milestones related to the proportion of subjects enrolled in California, as well as manufacturing and development costs incurred in California. In March 2018, CIRM calculated the precise amount of the funding award as $8.1 million, based on the actual number of subjects enrolled in California. The Company received $5.7 million in initial funding in May 2017, and a $1.9 million milestone payment in December 2017,

$0.3 million progress payment in March 2018, and $200,000 progress payment in May 2019, of which the total will be amortized over the estimated award period through July 2020 as a reduction to the related research and development expenses. As of December 31, 2019, $1.6 million of the funding received is recorded in accrued liabilities, representing the amount expected to be recognized over the next 12 months. During the years ended December 31, 2019 and December 31, 2018, the Company amortized and recognized a $2.7 million and $2.6 million credit to research and development related to CIRM funds received.

Note 12 – Income Taxes

The provision 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,	
Pre-tax book income	2019	2018
United States	$ (19,352)	$ (16,168)
	$ (19,352)	$ (16,168)

The provision for income taxes is determined by applying the U.S. Federal statutory rate of 21% to income before income taxes as a result of the following ($ in thousands):

	Years Ended December 31,	
	2019	2018
U.S. Federal benefit at statutory rate	$ (4,064)	$ (3,395)
State and local (benefit) / expense net of U.S. federal tax	—	—
Permanent non deductible expenses for U.S. taxes	14	11
AMT credit benefit	—	—
Change in state deferred	(4,720)	2,799
Return to actual	(17)	(177)
Other true ups	1,941	(1,949)
Effect of change in deferred tax rate	—	—
Valuation allowance for deferred tax assets	6,846	2,711
Tax provision	$ —	$ —

Deferred income taxes at December 31, 2019 and 2018 consist of the following ($ in thousands):

	December 31,	
	2019	2018
Deferred Tax Assets:		
Accumulated net operating losses (tax effected)	$ 70,747	$ 60,544
CIRM funding	336	1,033
Right of use liability	205	5
Share-based compensation	3,584	6,390
Intangibles	141	199
Charitable contributions	—	9
Accumulated depreciation	9	9
Accrued payroll	121	117
Other	737	525
Deferred tax assets	75,880	68,831
Deferred Tax Liabilities:		
Right of use asset	$ (190)	$ —
Deferred tax liabilities	(190)	—
	75,690	68,831
Valuation allowance	(75,690)	(68,831)
Net deferred tax asset	$ —	$ —

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, 2019 and 2018, the Company had approximately $246 million and $225 million, respectively of Federal NOLs available to offset future taxable income expiring from 2030 through 2036. In accordance with Section 382 of the Internal Revenue code, the usage of the Company's NOLs could be limited in the event of a change in ownership. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period when those temporary differences become deductible.

The Company performed an analysis and determined that they have had ownership change of greater than 50% over a 3-year testing period. The last ownership change was determined to be on June 3, 2015. Based on a market capitalization of $125 million and using an applicable federal rate of 2.5% the annual limitation would be approximately $3.0 million. Post change losses from June 3, 2015 would not be subject to 382 limitations.

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, 2019, 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.

For years prior to 2016 the federal statute of limitations is closed for assessing tax. The Company's state tax returns remain open to examination for a period of three to four years from date of filing.

Note 13 – Contingencies

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

ITEM 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, 2019, 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, 2019. 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, 2019, 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, 2019 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Management and Corporate and Governance Matters," "Section 16(a) Beneficial Ownership Reporting Compliance," and "Code of Conduct and Ethics" in the Company's Proxy Statement for the 2020 Annual Meeting of Stockholders.

ITEM 11. EXECUTIVE COMPENSATION

The response to this item is incorporated by reference from the discussion responsive thereto under the caption “Executive Officer and Director Compensation,” in the Company’s Proxy Statement for the 2020 Annual Meeting of Stockholders.

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

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” in the Company’s Proxy Statement for the 2020 Annual Meeting of Stockholders.

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

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Certain Relationships and Related Transactions” and “Management and Corporate Governance Matters” in the Company’s Proxy Statement for the 2020 Annual Meeting of Stockholders.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The response to this item is incorporated by reference from the discussion responsive thereto under the caption “Independent Public Accountants” in the Company’s Proxy Statement for the 2020 Annual Meeting of Stockholders.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

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

(a)(1) FINANCIAL STATEMENTS:

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

(a)(2) FINANCIAL STATEMENT SCHEDULE:

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

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

(a)(3) EXHIBITS:

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

Exhibit	Description
3.1	Amended and Restated Certificate of Incorporation of Caladrius Biosciences, Inc., as amended, effective July 27, 2016 (filed as Exhibit 3.1 to the Company's on Form 10-Q for the quarter ended June 30, 2016, filed with the SEC on August 9, 2016).
3.2	Amended and Restated By-Laws of the Caladrius Biosciences, Inc. as amended, effective as of July 27, 2016 (filed as Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, filed with the SEC on August 9, 2016).
3.3	Amendments to Amended and Restated Bylaws of Caladrius Biosciences, Inc., effective as of September 18, 2017 (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on September 21, 2017).
4.1	Form of Trust Indenture (filed as Exhibit 4.5 to the Company's Registration Statement on Form S-3, File No. 333-206175, filed with the SEC on August 6, 2015).
4.2	Form of Warrant (filed as Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 5, 2016).
4.3	Description of Capital Stock.
10.1	Director Compensation Policy (filed as Exhibit 10.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on March 22, 2018 and amended on April 2, 2018).
10.2	2015 Equity Compensation Plan (filed as Annex A to the Company's Definitive Proxy Statement filed on Schedule 14A, filed with the SEC on June 8, 2015).
10.3 +	2017 Employee Stock Purchase Plan (filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 10, 2017).
10.4	Form of Indemnification Agreement for executive officers (filed as Exhibit 10.44 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2014 as filed with the SEC on March 2, 2015).
10.5	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).
10.6	Consent and Third Amendment to Loan and Security Agreement, dated March 11, 2016, by and between Caladrius Biosciences, Inc., and Oxford Finance LLC (filed as Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q. for the quarter ended March 31, 2016, filed with the SEC on May 5, 2016).
10.7	Unit Purchase Agreement, dated March 11, 2016, by and among Caladrius Biosciences, Inc., PCT, LLC, a Caladrius Company and Hitachi Chemical Co. America, LTD (filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, filed with the SEC on May 5, 2016).

10.8	Amended and Restated Operating Agreement of PCT, LLC, a Caladrius Company, dated March 11, 2016, by and among PCT, LLC, a Caladrius Company, Caladrius Biosciences, Inc. and Hitachi Chemical Co. America, LTD (filed as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, filed with the SEC on May 5, 2016).
10.9	Technology License Agreement, dated March 11, 2016, by and between PCT, LLC, a Caladrius Company and Hitachi Chemical Co. LTD (filed as Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q. for the quarter ended March 31, 2016, filed with the SEC on May 5, 2016).

10.10	Interest Purchase Agreement, by and among Hitachi Chemical Co. America, Ltd., PCT LLC, a Caladrius Company and Caladrius Biosciences, Inc., dated as of March 16, 2017 (filed as Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the SEC on March 17, 2017).
10.11	Warrant for the Purchase of Units of PCT, LLC, a Caladrius Company, effective as of March 16, 2017 (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on March 17, 2017).
10.12	Common Stock Sales Agreement, dated February 8, 2018, by and between Caladrius Biosciences, Inc. and H.C. Wainwright & Co., LLC (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on February 8, 2018).
10.13	First Amendment to the Common Stock Sales Agreement, dated August 2, 2018, by and between Caladrius Biosciences, Inc. and H.C. Wainwright & Co., LLC (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on August 2, 2018).
10.14 +	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).
10.15 +	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).
10.16 +	Amendment to Employment Agreement, dated as of July 25, 2016, by and between the Company and David J. Mazzo, PhD (filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q. for the quarter ended June 30, 2016, filed with the SEC on August 9, 2016).
10.17 +	Amendment to Employment Agreement with David J. Mazzo, effective September 18, 2017 (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on September 21, 2017).
10.18 +	Amendment to Employment Agreement with David J. Mazzo, dated December 6, 2018 (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on December 7, 2018).
10.19 +	Employment Agreement, dated as of August 9, 2016, by and between Caladrius Biosciences, Inc. and Douglas W. Losordo, MD (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on August 9, 2016).
10.20 +	Amendment to Employment Letter with Doug Losordo, effective November 1, 2017 (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on November 1, 2017).
10.21 +	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).
10.22 +	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.
10.23 +	Amendment to Letter Agreement, dated as of July 25, 2016, by and between the Company and Joseph Talamo (filed as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, filed with the SEC on August 9, 2016).

10.24 +	Purchase Agreement, dated March 13, 2019 by and between Caladrius Biosciences, Inc. and Lincoln Park Capital Fund, L.L.C. (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on March 14, 2019).
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 year ended December 31, 2018 filed with the SEC on March 14, 2019).
21.1 †	Subsidiaries of Caladrius Biosciences, Inc.
23.1 †	Consent of Grant Thornton LLP
31.1 †	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

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

+	Management contract or compensatory plan, contract or arrangement required to be filed as an exhibit to this Form 10-K pursuant to Item 15(b) of Form 10-K.
†	Filed herewith.
††	Furnished herewith.
(1)	Certain portions of this exhibit were omitted based upon a request for confidential treatment, and the omitted portions were filed separately with the SEC on a confidential basis.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in Basking Ridge (Bernards Township), State of New Jersey, on March 5, 2020.

CALADRIUS BIOSCIENCES, INC.

By:
/s/ David J. Mazzo, PhD

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

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

Signature	Title	Date
/s/ David J. Mazzo David J. Mazzo, PhD	Director, and President and Chief Executive Officer (Principal Executive Officer)	March 5, 2020
/s/ Joseph Talamo Joseph Talamo	Senior Vice President, and Chief Financial Officer (Principal Financial and Accounting Officer)	March 5, 2020
/s/ Gregory B. Brown Gregory B. Brown, MD	Chairman of the Board of Directors	March 5, 2020
/s/ Steven S. Myers Steven S. Myers	Director	March 5, 2020
/s/ Steven M. Klosk Steven M. Klosk	Director	March 5, 2020
/s/ Peter G. Traber Peter G. Traber, MD	Director	March 5, 2020
/s/ Cynthia Schwalm Cynthia Schwalm	Director	March 5, 2020