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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

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

for the fiscal year ended December 31, 2014

or

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

Commission File Number 001-35280

Vericel Corporation

(Exact name of registrant as specified in its charter)

Michigan	**94-3096597**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

64 Sidney Street
Cambridge, MA 02139
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: **(800) 556-0311**

Securities registered pursuant to Section 12(b) of the Act:

Title of Class	Name of Each Exchange on Which Registered
Common Stock (No par value)	The NASDAQ Stock Market, Inc.

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 Section 15(d) of the Act. Yes o No x

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

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

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

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

The aggregate market value of the registrant's Common Stock, no par value ("Common Stock"), held by non-affiliates of the registrant (based on the closing sales price of the Common Stock as reported on the NASDAQ Capital Market) on June 27, 2014 was approximately $28,488,020. This computation excludes shares of Common Stock held by directors, officers and each person who holds 5% or more of the outstanding shares of Common Stock, since 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.

As of March 19, 2015, 23,785,653 shares of Common Stock, no par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document	Form 10-K Reference
Proxy Statement for the Annual Meeting of Shareholders scheduled for May 12, 2015	Items 10, 11, 12, 13 and 14 of Part III

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VERICEL CORPORATION

ANNUAL REPORT ON FORM 10-K

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Except for the historical information presented, the matters discussed in this Report, including our product development and commercialization goals and expectations, our plans and anticipated timing and results of clinical development activities, potential market opportunities, revenue expectations and the potential advantages and applications of our products and product candidates under development, include forward-looking statements that involve risks and uncertainties. Our actual results may differ significantly from the results discussed in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed under the caption "Risk Factors." Unless the context requires otherwise, references to "we," "us," "our" and "Vericel" refer to Vericel Corporation.

PART I

Item 1. *Business*

General Information

Vericel Corporation is a leader in developing patient-specific expanded cellular therapies for use in the treatment of patients with severe diseases and conditions. We market two autologous cell therapy products in the United States: Carticel® (autologous cultured chondrocytes), an autologous chondrocyte implant for the treatment of cartilage defects in the knee, and Epicel® (cultured epidermal autografts), a permanent skin replacement for the treatment of patients with deep-dermal or full-thickness burns comprising greater than or equal to 30 percent of total body surface area. We are also developing MACI™, a third-generation autologous chondrocyte implant for the treatment of cartilage defects in the knee, and ixmyelocel-T, a patient-specific multicellular therapy for the treatment of advanced heart failure due to ischemic dilated cardiomyopathy.

The following table summarizes our product portfolio and product candidate pipeline:

Acquisition of Sanofi's CTRM Business

On May 30, 2014, we completed the acquisition of the Cell Therapy and Regenerative Medicine (CTRM) business of Sanofi, a French *société anonyme* (Sanofi), certain assets, including all of the outstanding equity interests of Genzyme Biosurgery ApS (now known as Åström BIOSCIENCES DK ApS), a wholly-owned subsidiary of Sanofi and over 250 patents and patent applications of Sanofi and certain of its subsidiaries and assumed certain liabilities for purposes of acquiring the portion of the CTRM business, which researches, develops, manufactures, markets and sells Carticel, MACI and Epicel.

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Our Strategy

Our objective is to become the leading cell therapy and regenerative medicine company by developing, manufacturing and marketing best-in-class therapies for patients with significant unmet medical needs that require the repair and regeneration of damaged tissues and organs.

To achieve this objective, we intend to:

- Fully integrate the acquired commercial stage CTRM business and improve efficiencies to reduce redundancies and related costs, as well as take advantage of complementary technology platforms;
- Increase the operating income from the U.S. Carticel and Epicel business and become profitable without raising additional capital unless required for additional strategic transactions or other events;
- Lower the manufacturing costs for Carticel through an improved ratio of Carticel unit sales to biopsies as well as other efficiencies;
- Assess and capitalize on opportunities to increase revenue from Carticel in the U.S.;
- Develop and execute on a regulatory strategy for the approval of MACI in the U.S.;
- Implement a commercial strategy for a profitable reintroduction of MACI in the European Union (EU);
- Expand Epicel usage in the severely burned patient segment by increasing the level of commercial dedicated to the product and providers;
- Obtain U.S. Food and Drug Administration (FDA) approval to label Epicel for use in pediatric patients and a determination from the FDA that Epicel meets the criteria to be sold for profit; and
- Complete our Phase 2b ixCELL-DCM clinical study for the treatment of advanced heart failure due to ischemic DCM and, if successful, progress ixmyelocel-T into pivotal phase 3 clinical studies for this orphan indication.

Our Marketed Products

We believe that our acquired CTRM business has been a pioneer in the development and commercialization of autologous cell therapies. The CTRM portfolio includes two autologous cell therapy products marketed in the U.S and a third which has been approved in the EU, each of which are further described below: Carticel (autologous cultured chondrocytes), a first-generation product for autologous chondrocyte implantation (ACI) currently marketed in the U.S., MACI (matrix-applied characterized autologous cultured chondrocytes), a third-generation ACI product, and Epicel (cultured epidermal autografts), a permanent skin replacement for full thickness burns greater than or equal to 30% of total body surface area (TBSA), which is currently marketed in the U.S. Our product candidate portfolio also includes ixmyelocel-T, a patient-specific multicellular therapy currently in development for the treatment of advanced heart failure due to ischemic dilated cardiomyopathy (DCM).

Background of Cartilage Defects

Damage to cartilage in the knee can occur from acute trauma or repetitive trauma from playing sports, exercising, working or performing everyday activities. When damaged, cartilage in the knee does not usually heal on its own. If left untreated, cartilage defects can progress and lead to degenerative joint disease, osteoarthritis and potentially require total knee replacement, a poor option for younger and more active patients.

For patients diagnosed with cartilage defects, there are several treatment options, including arthroscopic debridement/chondroplasty, marrow stimulation techniques such as microfracture, a minimally invasive procedure that can be performed during the initial arthroscopic procedure, osteochondral autografts for smaller cartilage injuries, allografts, and autologous chondrocyte implants for larger injuries.

Carticel

Carticel, a first-generation ACI product for the treatment and repair of cartilage defects in the knee, is the first and currently the only FDA-approved autologous cartilage repair product. Carticel is indicated for the repair of symptomatic cartilage defects of the femoral condyle (medial, lateral or trochlea) caused by acute or repetitive trauma, in patients who have had an inadequate response to a prior arthroscopic or other surgical repair procedure such as debridement (the removal of damaged or defective cartilage), microfracture (the creation of tiny fractures in the bone to encourage new cartilage development, drilling/abrasion arthroplasty), or osteochondral allograft/autograft (transferring cartilage from one joint to another). Carticel received a Biologics License Application (BLA) approval in 1997 and is currently marketed in the U.S. It is generally used on patients with larger lesions (greater than 3 cm^2).

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Carticel is implanted by orthopedic surgeons after obtaining a cartilage biopsy during an initial arthroscopic procedure. The patient's chondrocytes, which are the cells that produce cartilage, are isolated and expanded in a manufacturing process compliant with current Good Manufacturing Practices (cGMP). During a second surgical procedure, the cells are implanted in the cartilage defect under a sutured periosteal flap, where they produce new hyaline cartilage. The therapeutic advantage of this approach relative to other approaches, such as microfracture, is that the autologous chondrocytes produce the hyaline cartilage that is naturally present in the knee, rather than fibrous cartilage which lacks durability and the wear characteristics of hyaline cartilage.

The Study of the Treatment of Articular Repair (STAR) was designed to determine the safety and efficacy of Carticel in patients who had an inadequate response to a prior cartilage repair procedure. Completed in 2005, this FDA post-approval commitment was a four-year, prospective, multicenter study of 154 patients at 29 participating sites. In a clinically challenging population comprised of patients who suffered moderate-to-large chondral defects and who failed at least one prior surgical cartilage repair treatment, Carticel demonstrated long-term durability up to four years and statistically significant and clinically meaningful reductions in pain and improvement in function.

Market Opportunity for Carticel

In the U.S. annually, there are approximately 1 million arthroscopic procedures and more than 250,000 cartilage surgical procedures. In addition, approximately 50,000 have full thickness defects greater than 2 cm(2). Patients seek retreatment for the repair of larger, symptomatic femoral condyle cartilage defects caused by acute or repetitive trauma. In our experience, patients are often frustrated by recurring symptoms, as they tend to be young, active and motivated to return to a high level of activity.

Typical initial cartilage surgical procedures include chondroplasty (debridement) and/or microfracture. These two procedures account for 98% of all cartilage surgical procedures. Although initial microfracture results demonstrate pain score improvement, generally, only patients with Class 1, or the smallest, defects do not experience deterioration after 18 months. Patients seeking retreatment account for about 2.5% of the cartilage surgical repair market and often receive either allograft, autograft or ACI. Treatment with Carticel provides an opportunity to replace the damaged cartilage with native hyaline cartilage.

In the U.S., the orthopedic physician target audience is very concentrated, with 60% of the current Carticel business originating from approximately 110 physicians. Our target audience is a group of physicians who self-identify as or have the formal specialty of sports medicine physicians. We believe this target audience is approximately 450 physicians. We currently have a 20 person field force calling on these sports-injury targeted orthopedic physician audience. Most private payers have a medical policy that allows treatment with Carticel. The 15 largest payers have a formal medical policy for Carticel, representing 132 million covered lives.

Including sales both prior to and after the acquisition of the CTRM business, in 2014 approximately 1,100 Carticel implants were performed, which generated net revenues of approximately $34.8 million. Carticel revenue is subject to seasonal fluctuations with stronger sales occurring in the fourth quarter and second quarter due to a number of factors including insurance copay limits and the time of year patients prefer to start rehabilitation. Over the last four years, the percentage of annual sales by quarter has ranged as follows: first quarter, 22% to 24%; second quarter, 24% to 25%; third quarter, 21% to 23%; and fourth quarter, 29% to 33%.

Epicel

Epicel (cultured epidermal autografts) is a permanent skin replacement for full thickness burns greater than or equal to 30% of TBSA. Epicel is currently the only FDA-approved autologous epidermal product available for large total surface area burns. Currently, fewer than 100 patients are treated with Epicel in the U.S. each year. In the year ended December 31, 2014, including sales both pre and post transaction, net revenues were $9.5 million for Epicel.

Epicel is produced by isolating and expanding keratinocytes, which are the predominant cell type in the epidermis or outer layer of the skin, obtained from a small biopsy of a patient's healthy skin. Epicel is an important treatment option for patients with severe burns because these patients are generally understood to need a keratinocyte-based epithelium and there is very little skin, which is the only other source of keratinocyte-based epithelium, available for autografts for these patients.

Epicel is a cell-based product that is regulated by the Center for Biologics Evaluation and Research (CBER) under medical device authorities. Epicel was designated as a Humanitarian Use Device (HUD) in 1998 and a Humanitarian Device Exemption (HDE) application for the product was submitted in 1999. HUDs are devices that are intended for diseases or conditions that affect or are manifested in fewer than 4,000 individuals annually in the United States.

Under the current HDE approval of 2007, Epicel cannot be sold for an amount that exceeds the cost of research and development, fabrication and distribution. However, pursuant to the Pediatric Medical Device Safety and Improvement Act of 2007 and the FDA Safety and Innovation Act of 2012 (FDASIA), a HUD can be sold for profit if certain conditions are met.

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Under current law as recently amended by FDASIA, an HDE holder can make a profit on its HUD after receiving HDE approval if the device is: (a)(i) intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and (ii) is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs, or (b) is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe. If the FDA makes a determination that a HUD meets the eligibility criteria, the HUD is permitted to be sold for profit after receiving HDE approval as long as the number of devices distributed in any calendar year does not exceed the Annual Distribution Number (ADN) for the device. The ADN is determined by the FDA when it approves the original HDE application, or when the agency approves an HDE supplement for an HDE approved before the enactment of FDASIA, if the HDE holder seeks a determination for the HUD in an HDE supplement based upon the profit-making eligibility criteria, and the FDA determines that the HUD meets the eligibility criteria.

We are currently investigating Epicel's eligibility for exemption from the profit prohibition and have requested a pre-submission meeting with the FDA to discuss the process and required data for submitting an HDE supplement for pediatric use and to obtain a determination from FDA that Epicel meets the criteria for an exemption from the profit prohibition. Epicel is currently being sold at a price that reflects the cost of research and development, fabrication and distribution.

Market Opportunity for Epicel

Each year in the U.S., more than 40,000 people are hospitalized for burns. More than 2,000 of these patients are treated for burns covering more than 30% of their TBSA, the labeled indication for Epicel. Of these patients, fewer than 100 each year are treated with Epicel. Currently, the mortality rate for this group is approximately 34%, partially due to the lack of healthy tissue from which to harvest autografts. Although age can vary, the typical Epicel patient is young and has suffered full thickness burns due to occupational, household or auto accidents, trash burning with gasoline, inappropriate use of space heaters or carelessness with flammable materials. Many of the most severely burned patients are medivac transported to one of the 128 specialized burn centers across the U.S. While the average acute care hospital has less than 3 admissions for burns annually, these specialized burn centers average over 200 admissions per year.

Relative to clinical need, we believe Epicel is underutilized due to lack of consistent promotional effort and burn center support. We expect Epicel's utility to grow as commercial and clinical efforts are appropriately dedicated to the product and providers. Currently more than 40% of our Epicel business comes from a single 70 bed burn center. The 127 specialized burn care facilities in the U.S. have a total of approximately 1,700 burn beds as of 2012. Up until September 2014, we only used one sales representative for selling Epicel and two partially dedicated Medical Scientific Liaisons supporting Epicel inquiries. We have recently expanded the Epicel sales force to three representatives and intend to increase the number of burn centers called upon.

Epicel revenue is subject to seasonal fluctuations mostly associated with the use of heating elements during the colder months, with stronger sales occurring in the winter months of the first and fourth quarters, and weaker sales occurring in the hot summer months of the third quarter. However, in any single year, this trend can be absent due to the extreme variability inherent with Epicel's low patient volume of fewer than 100 patients per year. Over the last four years, the percentage of annual sales by quarter has ranged as follows: first quarter, 28%; second quarter, 24%; third quarter, 20%; and fourth quarter, 28%. The variability between the same quarters in consecutive years has been as high as 10% of the annual volume. While the number of patients treated per year remains low, we expect these large swings in revenue in some quarters to continue. In the year ended December 31, 2014, including sales both pre and post transaction net revenues were approximately $9.5 million for Epicel.

MACI

MACI, is a third-generation ACI product for the treatment of focal chondral cartilage defects in the knee. MACI received marketing authorization in Europe in August 2013 by meeting the requirements of the Advanced Therapy and Medicinal Product (ATMP) guidelines based on the results of the SUMMIT trial in which MACI was manufactured at, and supplied from, the Cambridge, Massachusetts site. MACI has been commercially available in the EU since 1998. Aside from a small number of currently pending procedures, as part of the June 2014 restructuring marketing of MACI has been temporarily suspended as of August 2014 primarily due to low utilization and an unfavorable pricing environment. We believe that MACI has strong revenue potential in the U.S. and we are discussing the approval requirements with the FDA. The timing and process to gain approval in the U.S. is the subject of a Type B meeting with the FDA which is scheduled for the middle of the second quarter. The timing and strategy for a possible reintroduction in select EU countries have not yet been determined.

Similar to Carticel, during an initial surgical procedure, a surgeon obtains a biopsy of healthy cartilage and the chondrocytes are isolated, expanded and uniformly seeded onto a bioabsorbable Type I/IIIa collagen membrane to form the implant in a cGMP manufacturing process. Unlike Carticel, MACI is implanted during a mini-arthrotomy in which the implant is trimmed to the size of the defect and fixed in the defect with fibrin glue and without sutures.

The pivotal clinical trial supporting MACI registration in Europe, Superiority of MACI Implant to Microfracture Treatment (SUMMIT), was completed in 2012. Analysis of this 144 patient superiority study demonstrated that there is a statistically significant

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and clinically meaningful improvement in the co-primary endpoint of pain and function for those patients treated with a MACI implant compared to microfracture which was the current standard of care.

MACI was obtained via the acquisition by Genzyme Corporation, a subsidiary of Sanofi, of Verigen AG (Verigen) in 2005. As part of its acquisition of Verigen, Genzyme Corporation agreed to make cash payments to Verigen upon the achievement of developmental milestones relating to regulatory and

commercialization of MACI in the United States. In connection with our acquisition of the CTRM business, we agreed that if we further developed MACI in the U.S., we would be obligated to pay these milestone payments. In the third quarter, at the request of the Company, Sanofi entered into a settlement agreement with the former shareholders of Verigen whereby these shareholders agreed to discharge all obligations related to these MACI milestone payments in exchange for a one-time cash payment of €2.5 million (approximately $3.2 million). We accrued the liability in the third quarter and paid the amount in full in October 2014. This agreement was reached in full settlement of any and all potential obligations to Verigen related to future MACI developmental milestones.

Market Opportunity for MACI

MACI, if introduced in the U.S., should both replace Carticel and expand the market since we believe MACI shares the advantages of Carticel, while being less invasive, shortening procedure time, eliminating the need for a periosteal harvest, having a lower frequency of subsequent surgical interventions and an improved recovery period.

Marrow Donation

Like many companies and academic institutions conducting research on cell therapy, we require consistent access to high quality bone marrow. As part of an effort to lower our costs we have begun collecting bone marrow for research use using our bone marrow collection center located in San Diego, CA and our wholly-owned subsidiary Marrow Donation, LLC. We initiated commercial sales of bone marrow in June 2014. Based on the strong interest that we believe exists across the biopharmaceutical industry in the use of bone marrow and bone marrow-derived cells as drug discovery tools, we believe that this represents an opportunity for our company.

Ixmyelocel-T Technology Platform

Our preapproval stage portfolio also includes ixmyelocel-T, a unique patient-specific multicellular therapy derived from an adult patient's own bone marrow, which utilizes our proprietary, highly automated and scalable manufacturing system. Our proprietary cell manufacturing process significantly expands the mesenchymal stromal cells (MSCs) and M2-like anti-inflammatory macrophages in the patient's bone marrow mononuclear cells while retaining many of the hematopoietic cells. These cell types are known to regulate the immune response and play a key role in tissue repair and regeneration by resolving pathologic inflammation, promoting angiogenesis, and remodeling ischemic tissue. We believe the novelty and advantage of using ixmyelocel-T is the expansion of a unique combination of cell populations, including MSCS and M2-like macrophages, which secrete a distinct combination of angiogenic and regenerative factors, and possess the ability to remain anti-inflammatory in the face of inflammatory challenge.

MSCs and M2-like macrophages have a wide range of biological activities that promote repair and regeneration of damaged tissues through the paracrine effects of their secreted factors, as well as their direct cell activities. These cells produce high levels of potent anti-inflammatory and angiogenic factors, as well as factors involved in extracellular matrix remodeling. These cells also have direct activities such as phagocytosis of cellular debris and apoptotic cells, which control the inflammatory response, uptake of LDL and removal of cholesterol, and remodeling of extracellular matrix.

The following illustration summarizes the multiple biological activities of ixmyelocel-T that promote repair and regeneration of ischemic tissue:

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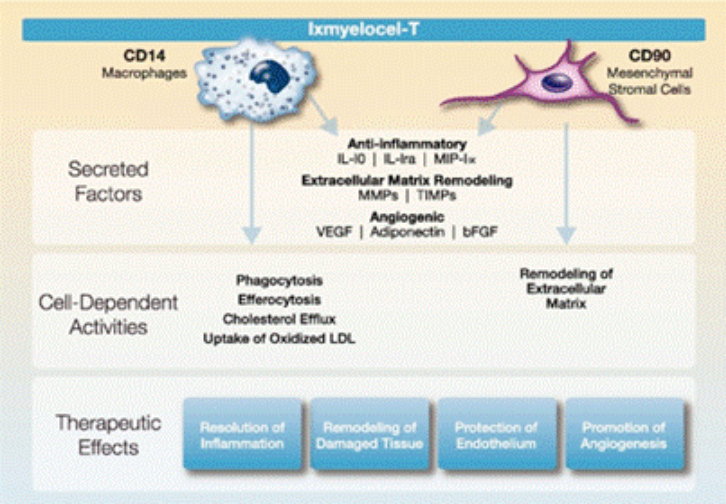

Studies examining the impact of ixmyelocel-T on human umbilical vein endothelial cells *in vitro* demonstrate the secretion of pro-angiogenic factors, enhanced migration of endothelial cells following injury, increased endothelial cell proliferation, and branch formation. Treatment with ixmyelocel-T in a rat model of hind limb ischemia *in vivo* resulted in significantly increased blood flow perfusion and capillary density, gene expression and plasma levels of the anti-inflammatory cytokine. Our studies demonstrate that ixmyelocel-T brings to bear a dynamic combination of angiogenic and anti-inflammatory effects, which facilitate ischemic tissue repair.

Ixmyelocel-T has several features that we believe are primarily responsible for success in treating adult patients with severe ischemic cardiovascular diseases such as advanced heart failure due to ischemic DCM:

- *Patient-specific (autologous)* — We start with the patient's own cells, which are accepted by the patient's immune system, allowing the cells to integrate into existing functional tissues. We believe that this characteristic of our therapy eliminates both the risk of rejection and the need to use immunosuppressive therapy pre- or post-therapy. Our data also suggests that ixmyelocel-T may provide the potential for long-term engraftment and tissue repair.

- *Expanded* — We begin with a small amount of bone marrow from the patient (up to 60 ml) and significantly expand the number of certain cell types, primarily MSCs and M2-like anti-inflammatory macrophages, to a substantially greater number than are present in the patient's own bone marrow (up to 200 times the number of certain cell types compared with the starting bone marrow).

- *Multicellular* — We believe the multiple cell types in ixmyelocel-T, which are normally found in bone marrow but in smaller quantities, possess the key functions required for reducing chronic inflammation and promoting angiogenesis and tissue repair. By reducing inflammation, we believe that ixmyelocel-T provides the ideal conditions to allow for the growth of new tissue and blood vessels.

- Minimally invasive — Our procedure for collecting bone marrow can be performed in an out-patient setting and takes approximately 15 minutes. Administration of ixmyelocel-T for the treatment of advanced heart failure due to ischemic dilated cardiomyopathy is performed in the cardiac catheterization laboratory using a cell injection catheter system in a one-time procedure. Safe — Bone marrow and bone marrow-derived therapies have been used safely and efficaciously in medicine for over three decades. Ixmyelocel-T leverages this body of scientific study and medical experience, and appears well tolerated in over 200 patients treated to date.

Ixmyelocel-T Clinical Development Programs

Our clinical development programs are focused on addressing areas of high unmet medical need in severe, chronic ischemic cardiovascular diseases. We have completed our Phase 1/2 clinical trials in DCM, and we are currently running our Phase 2b ixCELL-DCM study, which is a randomized, double-blind, placebo-controlled clinical trial for patients with advanced heart failure due to ischemic DCM.

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Ixmyelocel-T has been granted a U.S. Orphan Drug designation by the FDA for the treatment of DCM. We also have an ongoing ixmyelocel-T clinical study for the treatment of craniofacial reconstruction, for which we expect results by the first half of 2016, and have conducted clinical studies for the treatment of CLI.

Heart Failure Due to Dilated Cardiomyopathy

Heart failure represents a significant unmet medical need and a growing public health problem. The American Heart Association reports that there are approximately six million patients currently suffering from heart failure in the United States and an estimated 550,000 new cases in the U.S. each year. Current medical costs to treat these patients exceed $25 billion and this is expected to more than triple to nearly $80 billion by 2030 as a result of a growing patient population and the high cost of the limited treatment alternatives for advanced heart failure patients, as described below.

DCM is a leading cause of heart failure and of heart transplantation in the United States. DCM is a disease characterized by weakening of the heart muscle, thinning of the heart walls, enlargement of the heart chambers, and the inability to sufficiently pump blood throughout the body. Patients with DCM typically present with symptoms of congestive heart failure, including limitations in physical activity and shortness of breath. Ischemic DCM is associated with atherosclerotic cardiovascular disease and prior heart attacks and is the most common form of dilated cardiomyopathy. Patient prognosis depends on the stage and cause of the disease, but is typically characterized by a very poor quality of life and a high mortality rate.

Current treatments for ischemic DCM patients that are refractory to further medical therapy such as prescription drugs, devices, and/or further revascularization procedures including bypass surgery and angioplasty, are limited to heart transplantation and placement of left ventricular assist devices (LVADs). There are less than 2,500 heart transplantations in the United States each year. Many refractory DCM patients are not eligible for heart transplantation and transplants are extremely expensive at an estimated cost of approximately $1 million. LVADs are also expensive at an estimated cost of over $175,000 and have a mortality rate of 50% at two years.

We believe that the refractory ischemic DCM market represents a substantial market opportunity for ixmyelocel-T. These refractory ischemic DCM patients are currently the target patient population for our clinical development of ixmyelocel-T. The estimated incidence of DCM is 148 cases per 100,000 persons, or 444,000 patients. The more severe or refractory (NYHA Class III/IV) ischemic DCM patient population is difficult to estimate, but we believe it to be approximately one third of the overall DCM population. Ixmyelocel-T has been granted a U.S. Orphan Drug designation by the FDA for the treatment of DCM, which we believe provides the potential for an efficient and cost-effective path to approval for ixmyelocel-T in this heart failure indication.

We have conducted two phase 2a multicenter, randomized, open-label clinical studies in patients with ischemic DCM and nonischemic DCM investigating surgical (IMPACT-DCM) and catheter-based (Catheter-DCM) delivery of ixmyelocel-T. Sixty-one patients were randomized, and of those, 59 received treatment in the phase 2a studies. We reported 12-month data for the surgical IMPACT-DCM study at the Heart Failure Society of America meeting in September 2011 and final 12-month results from the Catheter-DCM study at the Society for Cardiovascular Angiography and Interventions (SCAI) 2012 Scientific Sessions. The results have also been published in the journal Circulation Research in August of 2014. Results from these studies demonstrated that ixmyelocel-T was well-tolerated in patients with DCM. In the Catheter-DCM study and post-surgery in the IMPACT-DCM study, the incidence of adverse events was comparable between the ixmyelocel-T groups and the control groups.

While these exploratory Phase 2a studies were not powered for determining differences in efficacy between treatment groups, there were consistent trends of clinically meaningful improvement in clinical endpoints observed in the ischemic DCM (IDCM) groups in both studies. In these studies, fewer ischemic patients treated with ixmyelocel-T experienced a major adverse cardiovascular event (MACE) during follow up compared to control patients, representing greater than 50% reduction in the number of patients having a MACE event. A similar benefit was not seen in the non-ischemic patients. Heart failure exacerbation was the most common MACE. In the combined IDCM groups across both studies, major adverse cardiovascular events (MACE) were experienced by a lower percentage of ixmyelocel T-treated patients compared to control patients, representing greater than 50% reduction in the number of patients having a MACE event. Likewise, patients in the combined ischemic DCM groups that were treated with ixmyelocel-T had a reduction in the average number of MACE events per patient. MACE is the recommended endpoint (mortality and cardiovascular hospitalizations) in Phase 3 heart failure studies as stated in the FDA 2009 Somatic Cell Therapy for Cardiac Diseases Draft Guidance. Consistent positive trends also were observed in several secondary efficacy measures in the IDCM groups. The majority of ixmyelocel-T-treated patients with IDCM, but not control patients, had statistically significant improvement in New York Heart Association (NYHA) Class that was sustained over the 12 months following treatment. Improvement in NYHA Class is considered clinically meaningful. Additionally, a higher percentage of ixmyelocel T-treated IDCM patients showed a clinically meaningful improvement in self-reported quality of life and a statistically significant increase in six-minute walk distance compared to the IDCM control patients. Since the initiation of the trial, 28 clinical trial sites have treated 114 patients.

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We completed enrolling and treating patients in our ongoing Phase 2b ixCELL-DCM study in February, 2015. Patients will be followed for 12 months for the primary efficacy endpoint of MACE events, defined as all-cause deaths, all-cause hospitalizations, and unplanned outpatient or emergency department visits for IV treatment of acute worsening heart failure. We expect to have top-line efficacy results around the end of the first quarter of 2016. Secondary endpoints include clinical, functional, structural, symptomatic, quality of life, and biomarker measures at 3, 6 and 9 months. We expect that patients will be followed for an additional 12 months for safety.

Production

Cell Manufacturing and Cell Production Components

We acquired two cell manufacturing facilities as part of the acquired CTRM business in Cambridge, Massachusetts and Copenhagen, Denmark. The Cambridge facility, which is approved by the FDA, is used for U.S. manufacturing and distribution of Carticel, Epicel manufacturing and worldwide distribution and also manufactured MACI for the SUMMIT study conducted for approval in Europe and for a small number of recent MACI implants following suspension of sales in the EU. The Cambridge facility also houses our research and development function, which is responsible for process development, release assay development, and technology transfers between sites and departments. The Copenhagen manufacturing facility, which was approved by the Danish Medicines Agency (DKMA), was responsible for MACI manufacturing and distribution in Europe. As part of the June 2014 restructuring, MACI manufacturing was discontinued. All employees were released via settled severance agreements and the equipment was sold. We have already provided notice that we intend to end the lease at the earliest allowable date, which is October 1, 2015 and are actively marketing the facility for sub-lease. If we can not sub-lease the facility we are obligated to restore the building to its original state prior to occupation by Åström BIOSCIENCES DK ApS. We expect that any future clinical and commercial production of MACI will occur at our Cambridge facility.

We also operate a centralized cell manufacturing facility in Ann Arbor, Michigan. The facility supports the current ixCELL-DCM clinical trial being conducted in the United States and Canada and we believe it has sufficient capacity, with minor modifications, to supply our early commercialization requirements. We may establish and operate larger commercial-scale cell manufacturing facilities for the United States market in the future to accommodate potential market growth. We have reached agreement with the FDA on Chemistry, Manufacturing and Control (CMC) which was completed as part of the Special Protocol Assessment process with the FDA for the Phase 3 REVIVE clinical trial.

Our ixmyelocel-T patient-specific multicellular therapies are manufactured using our proprietary Aastrom Replicell System (ARS) cell manufacturing system. Our manufacturing process is conducted in a highly-automated, fully-closed and rigorously controlled system. Our system is modular and thus both highly scalable and reproducible and is located in a 5,000-square-foot centralized manufacturing facility in Ann Arbor, Michigan. We believe the ARS based production is conducted under cGMP guidelines required by the FDA and has a current annual capacity to treat up to 1,500 patients. Upon approval we can scale-up to meet demand simply by adding additional ARS modules into existing and new clean rooms.

We have established relationships with various third parties who manufacture and/or supply certain components, equipment, disposable devices and other materials used in our cell manufacturing process to develop our cell products, as well as our final assemblies, component parts, subassemblies and associated spare parts used in the instrumentation platform of our cell production system.

In October 2010, we entered into a contract manufacturing and supply agreement (Supply Agreement) with ATEK Medical, LLC (ATEK) for the manufacture of our proprietary cell cassette for use in our manufacturing process. In November 2011, ATEK was purchased by Vention Medical, Inc. (Vention) and currently operates as a division of Vention. There have been no changes to the terms of the Supply Agreement as a result of this purchase.

Pursuant to the terms of the Supply Agreement, we have granted Vention the exclusive right to manufacture our proprietary cell cassette, which includes assembly, labeling, packaging and sterilization. Vention is responsible for obtaining all of our approved components pertaining to the cassettes and we are obligated to order and purchase the cassettes from Vention on an agreed upon schedule and in agreed upon quantities. In addition, we provided Vention with reasonable engineering support to initiate and ramp up manufacturing of the cassettes and expect to supply all manufacturing equipment.

Research & Development

The bulk of our ongoing research and development activities are focused on exploring methods that improve our ability to efficiently manufacture high quality cell therapy products for patients. We have performed an in depth analysis of the cell culture processes used in the manufacture of Epicel, Carticel, and Ixmyelocel-T, and have identified several areas for their potential

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betterment. Therefore, our research and development program is focused on the many facets of process development for all of our products including, but not limited to, tissue procurement and processing, cell culture surface and media modification, and other process efficiencies.

The bulk of our ongoing research is based on ixmyelocel-T, our unique multicellular product produced from a patient's bone marrow using our proprietary manufacturing system. We have demonstrated in the laboratory that the cells in our therapy are capable of multiple biological activities thought to play a critical role in repairing diseased and damaged tissues. These activities include aspects of tissue remodeling, promotion of angiogenesis and resolution of inflammation. In addition to these properties demonstrated *in vitro* , we have also shown that the therapy increases blood perfusion in both rat and mouse models of CLI. We have ongoing preclinical studies designed to further characterize the mechanism of action of our product in the treatment of cardiovascular diseases as well as explore other potential disease states which may benefit from the use of ixmyelocel-T.

In addition, our proprietary cell manufacturing system has demonstrated the capability to produce other types of cells. In the future, we may continue to explore the application of our manufacturing technology for the production of other cell types where there are potential opportunities to collaborate in the development of new cell therapies.

Patents and Proprietary Rights

Our success depends in part on our ability, and the ability of our licensors, to obtain patent protection for our products and processes.

As part of the acquired CTRM business, we acquired a multinational intellectual property estate. The intellectual property estate includes patents and patent applications directed to chondrocyte implants and related technologies. Although we do not own any patents or patent applications relating to Epicel, many of the processes and techniques are trade secrets and would be difficult to replicate without significant investment and time. We do own issued patents directed to the combinations of chondrocytes and collagen membranes used in MACI, which are scheduled to expire in August of 2016 in the U.S. and in August of 2017 abroad. In certain foreign countries, selected patent rights covering Carticel are scheduled to expire in 2022.

We also own a broadly filed trademark portfolio with registrations for Carticel, MACI, and Epicel.

The processes and technologies related to the ixmyelocel-T and ARS system platform include 17 unexpired issued United States patents. Eleven of these patents are material patents that protect our cellular therapy. We own ten of these patents and one has been licensed exclusively from the University of Michigan. These patents present various claims relating to (i) the composition of our ixmyelocel-T cellular therapy, (ii) methods to manufacture or administer the ixmyelocel-T cellular therapy, and (iii) the ARS bioreactor device that is used to make ixmyelocel-T products. The number of United States patents of each type with expiration range is listed in the table below.

Patent Type	Number	Expiry (Years)
Composition of Matter	2	1 and 15
Methods	2	13
Bioreactor Device	7	1 - 2

Certain patent equivalents to the United States patents have also been issued in other jurisdictions including Australia, United Kingdom, and Canada, and under the European Patent Convention. In addition, we have filed applications for patents in the United States and equivalent applications in certain other countries claiming other aspects of our cell products and manufacturing processes. Our most significant patent that protects the composition of the cellular therapy directly, “Mixed cell populations for tissue repair and separation technique for cell processing” (US Patent 7,871,605), was issued in January 2011 and will expire in 2029. A divisional application of 7,871,605 for administration of this composition to patients was allowed by the United States Patent and Trademark Office (USPTO) in January 2012 and was issued in the April 2012 and will expire in 2027. A second divisional application of 7,871,605 directed to the methods of manufacture of our cell compositions was issued in March 2013 and will expire in 2027. Patents that protect our automated bioreactor device and culture system expire in 2015, but we will continue to rely on trade secrets and un-patentable know-how.

In 2007, the use of ixmyelocel-T for the treatment of DCM received an Orphan Drug Designation from the FDA, which provides seven years of market exclusivity, should ixmyelocel-T receive FDA approval for this indication. The validity and breadth of claims in medical technology patents involve complex legal and factual questions and, therefore, may be highly uncertain. No assurance can be given that any patents based on pending patent applications or any future patent applications by us, or our licensors, will be issued,

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that the scope of any patent protection will exclude competitors or provide competitive advantages to us, that any of the patents that have been or may be issued to us or our licensors will be held valid if subsequently challenged or that others will not claim rights in or ownership of the patents and other proprietary rights held or licensed by us. Furthermore, there can be no assurance that others have not developed or will not develop similar products, duplicate any of our products or design around any patents that have been or may be issued to us or our licensors. Since patent applications in the United States are maintained in secrecy until they are published 18 months after filing, we also cannot be certain that others did not first file applications for inventions covered by our and our licensors’ pending patent applications, nor can we be certain that we will not infringe any patents that may be issued to others on such applications.

We rely on certain licenses granted by a number of third parties, including Sanofi and the University of Michigan for certain patent rights. If we breach such agreements or otherwise fail to comply with such agreements, or if such agreements expire or are otherwise terminated, we may lose our rights in such patents.

We also rely on trade secrets and un-patentable know-how that we seek to protect, in part, by confidentiality agreements. It is our policy to require our employees, consultants, contractors, manufacturers, outside scientific collaborators and sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual’s relationship with us is to be kept confidential and not disclosed to third parties except in specific limited circumstances. We also require signed confidentiality or material transfer agreements from any company that is to receive our confidential information. In the case of employees, consultants and contractors, the agreements generally provide that all inventions conceived by the individual while rendering services to us shall be assigned to us as the exclusive property of Vericel. There can be no assurance, however, that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets or un-patentable know-how will not otherwise become known or be independently developed by competitors.

Our success will also depend in part on our ability to develop additional commercially viable products without infringing the proprietary rights of others. We do not believe any of our approved products or our currently contemplated products or processes infringe any existing valid issued patent. However, the results of patent litigation are unpredictable, and no assurance can be given that patents do not exist or could not be filed which would have an adverse effect on our ability to market our products or maintain our competitive position with respect to our products. If our technology components, designs, products, processes or other subject matter are claimed under other existing United States or foreign patents, or are otherwise protected by third-party proprietary rights, we may be subject to infringement actions. In such event, we may challenge the validity of such patents or other proprietary rights or we may be required to obtain licenses from such companies in order to develop, manufacture or market our products. There can be no assurances that we would be able to obtain such licenses or that such licenses, if available, could be obtained on commercially reasonable terms. Furthermore, the failure either to develop a commercially viable alternative or obtain such licenses could result in delays in marketing our proposed products or the inability to proceed with the development, manufacture or sale of products requiring such licenses, which could have a material adverse effect on our business, financial condition and

results of operations. If we are required to defend ourselves against charges of patent infringement or to protect our proprietary rights against third parties, substantial costs will be incurred regardless of whether we are successful. Such proceedings are typically protracted with no certainty of success. An adverse outcome could subject us to significant liabilities to third parties and force us to curtail or cease our development and sale of our products and processes.

Certain of our and our licensors' research has been or is being funded in part by the Department of Commerce and by a Small Business Innovation Research Grant obtained from the Department of Health and Human Services. As a result of such funding, the United States government has certain rights in the technology developed with such funding. These rights include a non-exclusive, fully paid-up, worldwide license under such inventions for any governmental purpose. In addition, the United States government has the right to require us to grant an exclusive license under any of such inventions to a third party if the United States government determines that: (i) adequate steps have not been taken to commercialize such inventions; (ii) such action is necessary to meet public health or safety needs; or (iii) such action is necessary to meet requirements for public use under federal regulations. Additionally, under the federal Bayh-Dole Act, a party which acquires an exclusive license for an invention that was partially funded by a federal research grant is subject to the following government rights: (i) products using the invention which are sold in the United States are to be manufactured substantially in the United States, unless a waiver is obtained; (ii) the government may force the granting of a license to a third party who will make and sell the needed product if the licensee does not pursue reasonable commercialization of a needed product using the invention; and (iii) the United States government may use the invention for its own needs.

Sales and Marketing

Both our marketed and development stage products are specialty products with focused physician and institutional call points. The U.S. Carticel commercial organization is comprised of approximately 27 employees, including Cell Therapy Specialists and Regional

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Sales Directors. The target audience is a small (well under 1,000) set of sports medicine orthopedic surgeons. We expect to utilize the same sales force for MACI.

Reimbursement coverage for Carticel is widespread. The 15 largest payers, representing approximately 98% of commercial lives, have a formal medical policy that allows treatment with Carticel within labeled indications. These 15 plans represent approximately 132 million covered lives and include the top five national plans—WellPoint, United Healthcare, Aetna, CIGNA and Humana.

US Bioservices Corporation (USB) is the exclusive distributor of Carticel in the United States. USB purchases and takes title to Carticel upon shipment of the product. USB works with the payers on behalf of patients and surgeons to ensure medical coverage and to obtain reimbursement for Carticel implantation procedures. We retain all responsibility for shipment of the product to the surgical suite and may have certain indemnification obligations to USB. USB would also be the exclusive distributor of MACI in the United States, if and when it is approved by the FDA.

Sales of Epicel are supported by three Cell Therapy Specialists. This represents an expansion over past support levels. Since there are approximately 128 specialized burn centers in the U.S. increasing coverage to the majority of the target audience should be feasible with only a small number of incremental Cell Therapy Specialists.

If and when ixmyelocel-T is approved, we anticipate augmenting our existing sales and marketing organization to cover the expanded physician audience. The target physician population will likely be heart failure specialists and interventional cardiologists in secondary and tertiary cardiac facilities, a specialty audience which can be covered by a modest sized sales force. However, we intend to explore other options, including partnerships, to help minimize costs and increase penetration if and when the product is commercialized.

Government Regulation

Our research and development activities and the manufacturing and marketing of our products are subject to the laws and regulations of governmental authorities in the United States and other countries in which our products will be marketed. Specifically, in the United States, the FDA regulates drugs, biologics and medical devices and requires new product approvals or clearances to assure safety and effectiveness of these products. Governments in other countries have similar requirements for testing and marketing. In the United States, in addition to meeting FDA regulations, we are also subject to other federal laws, such as the Occupational Safety and Health Act and the Environmental Protection Act, as well as certain state laws.

While some human cell or tissue products that are intended for implantation, transplantation, infusion, or transfer into a human recipient are regulated as human cell, tissue, and cellular and tissue-based products (HCT/Ps) and do not require the FDA's premarket review, if these cell or tissue products do not meet the FDA's requirements for regulation as an HCT/P they require premarket review and a marketing authorization. The type of marketing authorization required depends on how the product is regulated by the FDA. With the exception of Epicel (a medical device), our cell products are regulated as biological products that require an approved BLA to be marketed in the U.S. Commercial production of these products needs to occur in FDA-registered facilities in compliance with cGMP requirements for biologics. Epicel is a humanitarian use medical device that has an approved HDE application.

Regulatory Process

The FDA regulates biologics under the Federal Food, Drug and Cosmetic Act (FFDCA) and the Public Health Service Act, and their implementing regulations. Obtaining approval of a BLA for new biological products is a lengthy process leading from development of a new product through preclinical and clinical testing. This process takes a number of years and the expenditure of significant resources. There can be no assurance that our product candidates will ultimately receive approval.

The FFDCA and other federal and state statutes and regulations govern the research, testing, manufacture, safety, labeling, storage, record-keeping, approval, distribution, use, product reporting, advertising and promotion of our products. Noncompliance with applicable requirements can result in civil penalties, recall, injunction or seizure of products, refusal of the government to approve our product approval applications or to allow us to enter into government supply contracts, withdrawal of previously approved applications and criminal prosecution.

Product Approval

In order to obtain FDA approval of a new biological product, sponsors must submit proof of safety and effectiveness. In most cases, such proof entails extensive nonclinical, also known as preclinical studies and clinical trials. The testing, preparation of necessary applications and processing of those applications by the FDA is expensive, may take several years to complete and is

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uncertain as to outcome. There can be no assurance that the FDA will act favorably or in a timely manner in reviewing submitted applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approvals, in turn, which could delay or preclude us from marketing any products we may develop. The FDA may also require post-marketing testing and surveillance of approved products, or place other conditions on the approvals. These requirements could cause it to be more difficult or expensive to sell the products, and could therefore restrict the commercial applications of such products. Product approvals may be withdrawn if compliance with applicable regulations is not maintained or if problems occur following commercialization. For patented technologies, delays imposed by the governmental approval process may materially reduce the period during which we will have the exclusive right to exploit such technologies.

Clinical data are required by the FDA for approval of a BLA. To conduct a clinical trial the manufacturer or distributor of a biologic will have to submit an Investigational New Drug (IND) application to the FDA prior to commencing human clinical trials. The submission must be supported by data, typically including the results of preclinical and laboratory testing. The conduct of the preclinical tests must comply with federal regulations, including good laboratory practice (GLP), requirements. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. Following submission of the IND, the FDA has 30 days to review the application and raise safety and other clinical trial issues. If we are not notified of objections within that period, clinical trials may be initiated, and human clinical trials may commence at a specified number of investigational sites with the number of patients approved by the FDA. We have submitted several INDs for our cell products, and we have conducted clinical trials under these INDs.

Carticel, MACI and Ixmyelocel-T are regulated by the FDA as biologics, although there can be no assurance that the FDA will not choose to regulate our products in a different manner in the future. For products that are regulated as biologics, the FDA requires: (i) preclinical laboratory and animal testing; (ii) submission to the FDA of an IND application, which must become effective prior to the initiation of human clinical trials; (iii) adequate and well-controlled clinical trials to establish the safety and effectiveness of the product for its intended use; (iv) submission to the FDA of a BLA; and (v) review and approval of the BLA as well as inspections of the manufacturing facility by the FDA prior to commercial marketing of the product.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap:

- Phase 1—The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients. These trials may also provide early evidence on effectiveness.

- Phase 2—These trials are conducted in a limited number of patients in the target population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3—Phase 3 trials are undertaken to provide statistically significant evidence of clinical efficacy and to further evaluate dosage, potency, and safety in an expanded patient population at multiple clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the product has been obtained, and are intended to establish the overall benefit-risk relationship of the investigational product, and to provide an adequate basis for product approval and labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials may be required by the FDA as a condition of approval and are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. The FDA has express statutory authority to require post-market clinical trials to address safety issues. All of these trials must be conducted in accordance with good clinical practice, or GCP, requirements in order protect the health and safety of human subjects and for the data to be considered reliable for regulatory purposes.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events; any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects; or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator

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brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information.

Phase 1, Phase 2, and Phase 3 clinical trials may not be completed successfully or within any specified period, if at all. Regulatory authorities, a data safety monitoring board or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the participants are being exposed to an unacceptable health risk. Similarly, an Institutional Review Board (IRB) can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

Our ongoing and planned clinical trials for our product candidates may not begin or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in:

- Obtaining regulatory approval to commence a trial;
- Reaching agreement with third-party clinical trial sites and their subsequent performance in conducting accurate and reliable trials on a timely basis;
- Obtaining IRB approval to conduct a trial at a prospective site;
- Recruiting patients to participate in a trial; and
- Obtaining supply of the biological product.

Typically, if a biological product is intended to treat a chronic disease, safety and efficacy data must be gathered over an extended period of time, which can range from six months to three years or more. Success in early stage clinical trials does not ensure success in later stage clinical trials. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with GMP requirements. To help reduce the risk of the introduction of adventitious agents with the use of biological products, the PHS Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency, and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

After completion of the required clinical testing, a BLA is prepared and submitted to the FDA. FDA review and approval of the BLA is required before marketing of the product may begin in the United States. The BLA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls and must demonstrate the safety and efficacy of the product based on these results. The BLA must also contain extensive manufacturing information. The cost of preparing and submitting a BLA is substantial. Under federal law, the submission of most BLAs is additionally subject to a substantial application user fee, as well as annual product and establishment user fees, which may total several million dollars and are typically increased annually.

The FDA has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of BLAs. Most such applications for standard review biologics are reviewed within ten months from the date the application is accepted for filing. Although FDA often meets its user fee performance goals, the FDA can extend these timelines if necessary, and FDA review may not occur on a timely basis at all. The FDA usually refers applications for novel biologics, or biologics which present difficult questions of safety or efficacy, to an advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving a BLA, the FDA will typically inspect one, or more, clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the biologic is manufactured. The FDA will not approve the product unless it verifies that compliance with requirements for current good manufacturing practice, or cGMP, is satisfactory and the BLA contains data that provide substantial evidence that the biologic is safe and effective in the indication studied.

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After the FDA evaluates the BLA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter means that the BLA will not be approved in its present form and 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, the FDA will issue an approval letter. The FDA's regulations provide that the agency will review such resubmissions in two or six months depending on the type of information included. The FDA approval is never guaranteed, and the FDA may refuse to approve a BLA if applicable regulatory criteria are not satisfied.

An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. The approval for a biologic may be significantly more limited than requested in the application, including limitations on the specific diseases and dosages or the indications for use, which could restrict the commercial value of the product. The FDA may also require that certain contraindications, warnings, or precautions be included in the product labeling. In addition, as a condition of BLA approval, the FDA may require a risk evaluation and mitigation strategy (REMS) to help ensure that the benefits of the biologic outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use (ETASU). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS or use of a companion diagnostic with a biologic can materially affect the potential market and profitability of the biologic. Moreover, product approval may require, as a condition of approval, substantial post-approval testing and surveillance to monitor the biologic's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Under current requirements, facilities manufacturing biological products for commercial distribution must be registered with the FDA. To accomplish this, an establishment registration must be filed with the FDA. In addition to the preclinical studies and clinical trials, the BLA includes a description of the facilities, equipment and personnel involved in the manufacturing process. An establishment registration/license is granted on the basis of inspections of the applicant's facilities in which the primary focus is on compliance with cGMP and the ability to consistently manufacture the product in the facility in accordance with the BLA. If the FDA finds the results of the inspection unsatisfactory, it may decline to approve the BLA, resulting in a delay in production of products.

Humanitarian Device Exemption

Unless an exemption applies, each medical device commercially distributed in the United States requires either a substantial equivalence determination under a premarket notification submission pursuant to Section 510(k) of the FFDCA, or an approval of a premarket approval application (PMA). The FDA provides an incentive for the development of certain devices intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. These devices receive a HUD designation and may be eligible for marketing approval under an HDE application. An HDE application is a premarket approval application that seeks an HDE from the effectiveness requirement that would otherwise apply to the application. FDA approval of an HDE application authorizes the applicant to market the device.

To obtain approval for a HUD, an HDE application is submitted to the FDA. An HDE application is similar in both form and content to a PMA application in that the applicant must demonstrate a reasonable assurance of safety, but in an HDE application, the applicant seeks an exemption from the PMA requirement of demonstrating a reasonable assurance of effectiveness. An HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. The application, however, must contain sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. Additionally, the applicant must demonstrate that no comparable devices are available to treat or diagnose the disease or condition, and that they could not otherwise bring the device to market.

Except in certain circumstances, HUDs approved under an HDE cannot be sold for an amount that exceeds the costs of research and development, fabrication, and distribution of the device (i.e., for profit). Under the current HDE provision, as amended by FDASIA, a device is eligible to be sold for profit after receiving HDE approval if the device is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe. If the FDA makes a determination that a HUD meets the eligibility criteria, the HUD is permitted to be sold for profit after receiving HDE approval as long as the number of devices distributed in any calendar year does not exceed the ADN for the device. The ADN is determined by the FDA when the agency approves the original HDE application; or when the agency approves an HDE supplement for an HDE approved before the enactment of FDASIA if the HDE holder seeks a determination for the HUD in an HDE supplement based upon the profit-making eligibility criteria, and the FDA determines that the HUD meets the eligibility criteria.

FDA Post-Approval Requirements

Maintaining substantial compliance with applicable federal, state, local, and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Rigorous and extensive FDA regulation of biological products and devices continues after approval, particularly with respect to cGMP. We will rely, and expect to continue to rely, on third parties to manufacture or supply certain components, equipment disposable devices and other materials used in our manufacturing process for any products that we commercialize or may commercialize. Manufacturers of our products are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP and other FDA regulatory requirements. Other post-approval requirements applicable to biological products include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, periodic reporting requirements and complying with electronic record and signature requirements. Similarly, there are a number of post-marketing requirements for devices, including medical device reporting regulations that require manufacturers to report to the FDA if a device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and corrections and removal reporting regulations that require manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FFDCA that may present a risk to health.

After a BLA is approved, the biological product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. After approval of biologics, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements, by us or our suppliers, may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Biological product and medical device manufacturers and other entities involved in the manufacture and distribution of approved biological products and devices are required to register their facilities with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval, with certain exceptions.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration, and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. Patent term restoration can compensate for time lost during product development and the regulatory review process by returning up to five years of patent life for a patent that covers a new product or its use. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The period of patent term restoration is generally one-half the time between the effective date of an IND

(falling after issuance of the patent) and the submission date of a BLA, plus the time between the submission date of the BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The application for patent term extension is subject to approval by the United States Patent and Trademark Office, or PTO, in consultation with the FDA.

A patent term extension is only available when the FDA approves a biological product for the first time. We believe Ixmylocel-T and the manner in which it is manufactured have not been previously approved by the FDA. However, we cannot be certain that the PTO and the FDA will agree with our analysis or will grant a patent term extension.

A biological product can obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Biosimilars

The Patient Protection and Affordable Care Act signed into law on March 23, 2010, includes the Biologics Price Competition and Innovation Act of 2009. That Act created an approval pathway authorizing the FDA to approve biosimilars and interchangeable biosimilars. Biosimilars are biological products which are "highly similar" to a previously approved biologic product or "reference product" and for which there are no clinically meaningful differences between the biosimilar product and the reference product in terms of the safety, purity, and potency as shown through analytical studies, animal studies and a clinical study or studies. For FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the

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biosimilar and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation, which are still being worked out by the FDA.

A reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product. A biosimilar application may be filed four (4) years after the first licensure of the reference biologic. Although the patents for the reference biologic may be challenged by the biosimilar applicant during that time period pursuant to the BPCIA statutory patent challenge framework, no biosimilar or interchangeable product will be licensed by FDA until the end of the exclusivity period. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitting under the abbreviated approval pathway for the lesser of (i) one year after first commercial marketing, (ii) 18 months after the initial application if there is no legal challenge, (iii) 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologics' patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period. At this juncture, it is unclear whether products deemed "interchangeable" by FDA, in fact, will be readily substituted by pharmacies, which are governed by state pharmacy law.

On April 10, 2013, President Obama released his proposed budget for fiscal year 2014 which included cutting this twelve year period of exclusivity down to seven years. The budget also proposed to prohibit additional periods of exclusivity for brand biological products due to minor changes in product formulation, a practice often referred to as "evergreening." The BPCIA is complex and is only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty.

Pediatric Research Equity Act

Under the Pediatric Research Equity Act, or PREA, a BLA or BLA supplement must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The intent of PREA is to compel sponsors whose products have pediatric applicability to study those products in pediatric populations, rather than ignoring pediatric indications for adult indications that could be more economically desirable. FDA may grant deferrals for submission of data or full or partial waivers. By its terms, PREA does not apply to any biological product for an indication for which orphan designation has been granted, unless the FDA issues regulations saying otherwise. Because the FDA has not issued any such regulations, submission of a pediatric assessment is not required for an application to market a product for an orphan-designated indication, and waivers are not needed at this time. However, if only one indication for a product has orphan designation, a pediatric assessment may still be required for any applications to market that same product for the non-orphan indication(s).

Advertising and Promotion

Once an FDA-regulated product is approved, the product will be subject to continuing post-approval regulatory requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of biologics and devices including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Failure to comply with these regulations can result in significant penalties, including the issuance of warning letters directing a company to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and federal and state civil and criminal investigations and prosecutions.

Biologics and devices may be marketed only for the approved or cleared indications and may only make claims for the product that are consistent covered by the approval or clearance. For BLAs, changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new BLA or BLA supplement before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing BLA supplements as it does in reviewing BLAs. Similarly, changes to approved or cleared devices may require FDA's premarket review.

While doctors are free to prescribe any product approved by the FDA for any use, a company can only make claims relating to safety and effectiveness of a biological product that are consistent with the FDA approval or clearance, and the company is allowed to actively market and promote a biological product or device only for the particular use and treatment approved or cleared by the FDA. In addition, any claims we make for our products in advertising or promotion must be appropriately balanced with important safety information and otherwise be adequately substantiated. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising, injunctions and potential civil and criminal penalties.

Orphan Drug

Under the Orphan Drug Act, the FDA may grant orphan drug designation to biologics intended to treat a rare disease or condition—generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation

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must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the biologic and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not necessarily convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first BLA applicant to receive FDA approval for a particular product to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity, which would most likely run concurrently with the exclusivity, if any, received from the time of first licensure of a reference product, does not prevent the FDA from approving a different biologic for the same disease or condition, or the same biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee.

Anti-Kickback and False Claims Laws

In the United States, the research, manufacturing, distribution, sale and promotion of biological products and devices are subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice, state Attorneys General, and other federal, state and local government agencies. For example, sales, marketing and scientific/educational grant programs must comply with the Anti-Kickback Statute, as amended, the False Claims Act, as amended, the privacy regulations promulgated under the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

As noted above, in the United States, we are subject to complex laws and regulations pertaining to healthcare “fraud and abuse,” including, but not limited to, the Anti-Kickback Statute, the federal False Claims Act, and other state and federal laws and regulations. The Anti-Kickback Statute makes it illegal for any person, including a biological product manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase or order of an item for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs. In addition, many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to the referral of patients for healthcare services reimbursed by any insurer, not just federal healthcare programs such as Medicare and Medicaid. Due to the breadth of these federal and state anti-kickback laws and the potential for additional legal or regulatory change in this area, it is possible that our future sales and marketing practices and/or our future relationships with physicians might be challenged under anti-kickback laws, which could harm us. Because we intend to commercialize products that could be reimbursed under a federal healthcare program and other governmental healthcare programs, we plan to develop a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and program requirements to which we will or may become subject.

The federal False Claims Act prohibits anyone from, among other things, knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including biological products, that are false or fraudulent. Although we would not submit claims directly to payers, manufacturers can be held liable under these laws if they are deemed to “cause” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. For example, pharmaceutical companies have been prosecuted under the federal False Claims Act in connection with their off-label promotion of drugs. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between $5,500 and $11,000 for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. If the government were to allege that we were, or convict us of, violating these false claims laws, we could be subject to a substantial fine and may suffer a decline in our stock price. In addition, private individuals have the ability to bring actions under the federal False Claims Act and certain states have enacted laws modeled after the federal False Claims Act.

There are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. In addition, a similar recent federal law, referred to as the Sunshine Act, requires biological product manufacturers to track and report to the federal government certain payments or other transfers of value made to physicians and teaching hospitals made in the previous calendar year. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. In addition,

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given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state, and soon federal, authorities.

International Regulation

In addition to regulations in the United States, a variety of foreign regulations govern clinical trials, commercial sales, and distribution of product candidates. The approval process varies from country to country and the time to approval may be longer or shorter than that required for FDA approval.

Pharmaceutical Coverage, Pricing, and Reimbursement

In the United States and other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payers, including government health administrative authorities, managed care providers, private health insurers, and other organizations. Third-party payers are increasingly examining the medical necessity and cost effectiveness of medical products and services in addition to safety and efficacy and, accordingly, significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Third-party reimbursement adequate to enable us to realize an appropriate return on our investment in research and product development may not be available for our products.

Competitive Environment For Cell Therapy and Regenerative Medicine

The biotechnology and medical device industries are characterized by rapidly evolving technology and intense competition. Our competitors include major multinational medical device companies, pharmaceutical companies, biotechnology companies and stem cell companies operating in the fields of tissue engineering, regenerative medicine, cardiac, vascular, orthopedics and neural medicine. Many of these companies are well-established and possess technical, research and development, financial, and sales and marketing resources significantly greater than ours. In addition, many of our smaller potential competitors have formed strategic collaborations, partnerships and other types of joint ventures with larger, well established industry competitors that afford these companies potential research and development and commercialization advantages in the technology and therapeutic areas currently being pursued by us. Academic institutions, governmental agencies and other public and private research organizations are also conducting and financing research activities which may produce products directly competitive to those being commercialized by us. Moreover, many of these competitors may be able to obtain patent protection, obtain FDA and other regulatory approvals and begin commercial sales of their products before us.

For patients diagnosed with cartilage defects, there are several treatment options, including arthroscopic debridement/chondroplasty, marrow stimulation techniques such as microfracture, osteochondralautografts for smaller cartilage injuries, allografts, and autologous chondrocyte implants for larger, more complex injuries.

The main competitor for Carticel in the U.S. is the microfracture procedure. Microfracture is a minimally invasive procedure that can be performed during the initial arthroscopic procedure. Short term results are generally considered good in smaller cartilage defects. Other competitive treatments in the U.S. include autograft/allograft procedures and a juvenile donor-derived allograft product DeNovo NT from Zimmer Holdings Inc. (Zimmer).

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Carticel is the only FDA-approved ACI product on the market in the United States. We are aware of two ACI products in development. Histogenics Corporation began a Phase 3 study of its Neocart implant in February 2010. Neocart is an autologous chondrocyte tissue implant under development for treatment of symptomatic articular cartilage lesions on the femur. Aesculap Biologics, LLC initiated a Phase 3 study in 2014 of NovoCart 3D®, a matrix induced autologous chondrocyte product designed to repair articular cartilage defects of the knee.

The competitive treatment alternatives to MACI in the EU are the same as those for Carticel in the U.S., including debridement/chondroplasty, microfracture, and osteochondralautografts. Although there is very little use of allografts or allograft-derived products, the competitive product environment is much more robust. Competitors include microfracture augmentation products such as ChondroGide® from Geistlich Pharma AG and direct ACI competitors including ChondroCelect® from TiGenix NV.

Patients suffering catastrophic burns over a significant portion of total body surface area have few options for permanent skin coverage. When undamaged skin is available, a procedure known as meshed split-thickness auto-grafting can be considered. However, this option becomes less viable as the percentage of total body surface area burn increases. Epicel is a lifesaving therapy and represents the only option for patients with TBSA burns greater than 70%.

We are investigating ixmyelocel-T, an autologous cell therapy, in ischemic dilated cardiomyopathy (ischemic heart failure) and is currently in a fully enrolled Phase 2b clinical trial. Competitor cell (autologous and allogeneic) and gene therapies are currently under clinical development in phases 1, 2 and 3 in heart failure patients. Examples are, Mesoblast Ltd., which is conducting a Phase 3 trial with allogeneic cell therapy and Cardio3 Biosciences which completed enrollment in an EU based Phase 3 trial with a bone marrow derived autologous therapy with stated plans to initiate a US Phase 3 trial. Gene therapies are being evaluated in Phase 2 trials by Juventas Therapeutics, Inc. and Celladon Corporation.

Our potential commercial products address a broad range of existing and emerging therapeutic markets, in which cell-based therapy is a new and as of yet, unproven, commercial strategy. In a large part, we face primary competition from existing medical devices and drug products. Some of our competitors have longer operating histories and substantially greater resources. These include companies such as Arthrex Inc. (Arthrex), Zimmer, Baxter International, Inc. (Baxter), Biomet, Inc., Johnson & Johnson, Inc. (Johnson & Johnson), Medtronic, Inc. (Medtronic), and others.

In the general area of cell-based therapies, we potentially compete with a variety of companies, most of whom are specialty medical products or biotechnology companies. Some of these, such as Arthrex and Zimmer, Baxter, Johnson & Johnson, Medtronic and Miltenyi Biotec Inc. are well-established and have substantial technical and financial resources compared to ours. However, as cell-based products are only just emerging as viable medical therapies, many of our most direct competitors are smaller biotechnology and specialty medical products companies. These include Ocata Therapeutics, Inc. (formerly Advanced Cell Technology, Inc.), Cytomedix, Inc. (formerly Aldagen, Inc.), Arteriocyte Medical Systems, Inc., Athersys, Inc., Cytori Therapeutics, Inc., International Stem Cell Corporation, Neostem, Inc., Terumo Medical Corporation (formerly Harvest Technologies Corporation), Mesoblast Ltd., Osiris Therapeutics, Inc., Pluristem, Inc. Stem Cells, Inc., Tengion, Inc., and others.

Employees

As of Decmber 31, 2014, we employed approximately 190 full-time employees. A significant number of our management and professional employees have had prior experience with pharmaceutical, biotechnology or medical product companies. None of our employees are covered by collective bargaining agreements, and management considers relations with our employees to be good.

Executive Officers and Key Employees

The following table presents our executive officers and key employees and their respective ages and positions as of December 31, 2014:

Name	Position	Age	Executive Officer Since
Dominick C. Colangelo(1)	President and Chief Executive Officer	52	2013
Daniel R. Orlando(1)	Chief Operating Officer	49	2012
David Recker, MD	Chief Medical Officer	57	2013
Gerard Michel(1)	Chief Financial Officer & Vice President of Corporate Development	51	2014
Ross Tubo, PhD	Chief Scientific Officer	55	2014

(1) Denotes Executive Officer.

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Dominick C. Colangelo — Mr. Colangelo joined Vericel Corporation in 2013 with more than twenty years of executive management and corporate development experience in the biopharmaceutical industry, including nearly a decade with Eli Lilly and Company. Most recently, he was President and Chief Executive Officer of Promedior, Inc. from 2009 to 2012. During his career, he has held a variety of executive positions of increasing responsibility in product development, pharmaceutical operations, sales and marketing, and corporate development. He has extensive experience in the acquisition, development and commercialization of therapies to treat fibrovascular, metabolic and cardiovascular diseases. During his tenure at Eli Lilly and Company, he held positions as Director of Strategy and Business Development for Lilly's Diabetes Product Group and also served as a founding Managing Director of Lilly Ventures. Mr. Colangelo received his B.S.B.A. in Accounting, Magna Cum Laude, from the State University of New York at Buffalo and a J.D. degree, with Honors, from the Duke University School of Law.

Daniel R. Orlando — Mr. Orlando joined Vericel as Chief Commercial Officer in August of 2012. Mr. Orlando served as interim Chief Executive Officer of Vericel from December 2012 to March 2013. He has more than 20 years of commercial product preparation and launch experience including leadership roles in sales, marketing and most recently as a vice president of business development for North and South America at Takeda Pharmaceuticals. As an early employee at Takeda North America, he served as the original brand director for Actos, which became the #1 branded anti-diabetic agent in the United States. Mr. Orlando's initial pharmaceutical experience came in progressively expanding roles in sales and marketing at Abbott Laboratories. He holds an MBA from Florida Atlantic University and a BA in Economics with Honors from the University of Florida.

David Recker, MD — Dr. Recker joined Vericel in April 2014 and has more than 20 years of experience in drug development most recently at Takeda Global Research & Development, Inc. where he served as Senior Vice President for Clinical Science from 2002 to 2012. Dr. Recker has had responsibility for multiple development programs in a variety of therapeutic areas in his career. He is a Fellow of the American College of Physicians as well as a Fellow of the American College of Rheumatology. He holds an M.D. with Distinction from the University of Michigan where he conducted his internship and residency and was Chief Resident in Internal Medicine. He did his fellowship in training at the National Institutes of Health.

Gerard Michel — Mr. Michel joined Vericel in June of 2014 with over 25 years of experience in the pharmaceutical industry across multiple functional areas. He has considerable experience in business development, raising capital and executing successful financial transactions. Mr. Michel was formerly chief financial officer and vice president, corporate development of Biodel from November 2007 to May 2014, where he oversaw strategic development, fundraising and capital structure management, marketing efforts, investor relations, and financial reporting and internal controls. Prior to his role at Biodel, from August 2002 to November 2007, Mr. Michel served as chief financial officer and vice president of corporate development of NPS Pharmaceuticals, where he led the first syndicated royalty monetization. Prior to that, Mr. Michel was a Principal at Booz Allen Hamilton Inc. and also held a variety of commercial roles at both Lederle Labs and Wyeth Labs. Mr. Michel holds an M.S. in Microbiology from the University of Rochester School of Medicine, an M.B.A. from the Simon School of Business, and a B.S. in both Biology and Geology from the University of Rochester.

Ross Tubo — Dr. Tubo joined Vericel in April 2014 with more than twenty years of experience in cell therapy, regenerative medicine, and stem cell biology. Dr. Tubo was a pioneer in the research, development, and commercialization of the first autologous cell therapy for articular cartilage repair, known as Carticel. As Vice President of Stem Cell and Chemokine Biology for Genzyme Corporation, a position he held from 1998 to 2010, he developed a world-class research organization designed to understand the underlying cell and molecular mechanism(s) of action of mesenchymal stem cells (MSCs) in autoimmune disease and cancer. These efforts led to the identification of specific therapeutic targets for treatment of these diseases. He holds a Ph.D. in Cell and Molecular Biology from the State University of New York at Buffalo and completed post-doctoral studies at Harvard Medical School.

Available Information

Additional information about Vericel is contained at our website, www.vcel.com. Information on our website is not incorporated by reference into this report. We make available on our website free of charge our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K as soon as reasonably practicable after those reports are filed with the Securities and Exchange Commission (SEC). Our reports filed with the SEC are also made available to read and copy at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. You may obtain information about the Public Reference Room by calling the SEC at 1-800-SEC-0330. Reports filed with the SEC are also made available on its website at www.sec.gov. The following Corporate Governance documents are also posted on our website: Code of Business Conduct and Ethics, Code of Ethics for Senior Financial Officers, Board Member Attendance at Annual Meetings Policy, Director Nominations Policy, Shareholder Communications with Directors Policy and the Charters for each of the Committees of the Board of Directors.

Item 1A. ***Risk Factors***

Our operations and financial results are subject to various risks and uncertainties, including those described below, that could adversely affect our business, financial condition, results of operations, cash flows, and trading price of our common stock. The risks and uncertainties described below are not the only ones we face. There may be additional risks and uncertainties that are not known to us or that we do not consider to be material at this time. If the events described in these risks occur, our business, financial condition, and results of operations would likely suffer.

Risks Related to our Business

We have incurred losses, anticipate continuing to incur losses and may not achieve or maintain profitability for some time or at all.

While we are a commercial-stage biopharmaceutical company following our acquisition of the cell therapy and regenerative medicine (CTRM) business of Sanofi, a French *société anonyme* (Sanofi), we have not yet generated significant revenues. We have incurred net losses each year since our inception in 1989, including net losses of $19.9 million and $15.6 million for the years ended December 31, 2014 and 2013, respectively. As of December 31, 2014, we had accumulated a deficit of approximately $308 million and had $30.3 million of cash. On September 17, 2014, we sold 15,784,313 shares of our common stock in a public offering resulting in net proceeds of approximately $37.5 million. Based on our current plan, we expect that this cash will be sufficient to sustain our operations until we achieve profitability.

Although we believe we will achieve profitability without the need to raise additional capital, we may continue to incur significant operating losses over the next several years despite sales increasing and margins improving, due to continuing expenses related to our research and development programs, and the expense associated with continuing the commercialization of our approved products. We cannot predict with any certainty the amount of future losses. Our ability to maintain profitability will depend, among other things, increasing sales of our current products, improving gross margins, successfully commercializing our new products, completing the development of our product candidates, timely initiation and completion of clinical trials, obtaining regulatory approvals, establishing manufacturing, sales and marketing arrangements with third parties, maintaining supplies of key manufacturing components and the possible acquisition and development of complementary products. Therefore, we may not be able to achieve or sustain profitability.

In the longer term, we may need to raise additional funds in order to continue to complete product development programs and complete clinical trials needed to market and commercialize our current product candidates. We cannot be certain that actual results will not differ materially from our current projections and that current capital will be sufficient to achieve profitability nor that funding will be available on favorable terms, if at all. Some of the factors that will impact our ability to raise additional capital and our overall success include:

- Our ability to successfully integrate the acquired business with our existing business and streamline its operations;
- The rate and degree of progress for our product development;
- Our ability to maintain our facility as an U.S. Food and Drug Administration (FDA) compliant and validated product manufacturing facility;
- The rate of regulatory approval to proceed with clinical trial programs;
- The level of success achieved in clinical trials;
- The requirements for marketing authorization from regulatory bodies in the United States and other countries;
- The liquidity and market volatility of our equity securities;
- Regulatory and manufacturing requirements and uncertainties; and
- Technological developments by competitors.

While we have access to certain amounts of financing through an agreement with Lincoln Park Capital Fund, LLC (Lincoln Park) and an at-the-market sales agreement (ATM) with MLV & Co., LLC (MLV) (formerly McNicoll, Lewis & Vlak), there are certain factors, such as volume of trading in our common stock and our stock price and the ability to terminate the agreement with notice, which limit the amount that can be raised in a short period of time through these agreements with Lincoln Park and the ATM. We anticipate that we will incur certain non-recurring charges in connection with the integration of the CTRM business; however, we cannot identify the timing, nature and amount of all such charges. These costs could materially affect our results of operations in the period in which such charges are recorded. If funding is needed and we cannot raise such funds, we will not be able to develop, manufacture or enhance products, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements, which would have a material adverse impact on our business, financial condition and results of operations.

The failure to successfully integrate the acquired business and operations in the expected time frame may adversely affect the combined company's future results.

We believe that the acquisition of the acquired business will result in certain benefits, including certain manufacturing, sales and distribution and operational efficiencies. However, to realize these anticipated benefits, Vericel's existing business and the acquired business must be successfully combined. We may be unable to effectively integrate the acquired business into our organization, make the acquired business profitable, and may not succeed in managing the acquired business or the larger company that results from this acquisition. The process of integration of an acquired business may subject us to a number of risks, including:

- Failure to successfully manage relationships with clients, distributors and suppliers;
- Demands on management related to the increase in size of the company after the acquisition;
- Diversion of management attention;
- Potential difficulties integrating and harmonizing financial reporting systems;
- Difficulties in the assimilation and retention of employees;
- Inability to retain the management, key personnel and other employees of the acquired business;
- Inability to establish uniform standards, controls, systems, procedures and policies;
- Inability to retain the customers of the acquired business;
- Exposure to legal claims for activities of the acquired business prior to acquisition; and

- Incurrence of additional expenses in connection with the integration process.

If the acquired business is not successfully integrated into our company, our business, financial condition and results of operations could be materially adversely affected, as well as our professional reputation. Furthermore, if we are unable to successfully integrate the acquired business and operations, or if there are delays in combining the businesses, the anticipated benefits of the acquisition may not be realized fully or at all or may take longer to realize than expected. Successful integration of the acquired business will depend on our ability to manage these operations, to realize opportunities for revenue growth presented by our products and eliminate certain excess costs of the acquired business.

The acquisition has resulted in the expansion of our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As a result of our acquisition of the CTRM business on May 30, 2014, our employee base increased significantly from 38 employees as of March 31, 2014 to approximately 190 full-time employees as of December 31, 2014. We expect that such growth will impose significant additional responsibilities on our management. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The effective management of the acquired business could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. In connection with the operation of the acquired business we expect to expand our internal sales and marketing capabilities as we build an internal sales and marketing organization and hire additional manufacturing, quality control, pharmacovigilance, regulatory affairs, quality assurance, and management personnel as necessary to maintain or expand our processing operations. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our products and our other product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage our current growth.

We may not be able to raise the required capital to conduct our operations, develop and commercialize our product candidates and otherwise grow and expand our business.

Notwithstanding the net proceeds of approximately $37.5 million we received from our September 2014 public offering and our current projections that we can achieve profitability without raising additional capital, we will require substantial additional capital resources in order to complete the development of ixmyelocel-T for the treatment of advanced heart failure due to ischemic DCM. Further, while we believe we have adequate capital to conduct a confirmatory trial for MACI as well as a pediatric trial for Epicel in pediatric patients, if the trials requested are larger or more costly than anticipated, we may need to raise additional capital.

In order to grow and expand our business, to introduce our new product candidates into the marketplace, we may need to raise additional funds. We may also need significant additional funds or a collaborative partner, or both, to finance the research and development activities of our cell therapy product candidates for additional indications.

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Our future capital requirements will depend upon many factors, including:

- Continued scientific progress in our research, clinical and development programs;
- Costs and timing of conducting clinical trials and seeking regulatory approvals;
- Competing technological and market developments;
- Avoiding infringement and misappropriation of third-party intellectual property;
- Obtaining valid and enforceable patents that give us a competitive advantage;
- Our ability to establish additional collaborative relationships;
- Our ability to scale up our production capabilities for larger quantities of our products;
- The effect of commercialization activities and facility expansions, if and as required; and
- Complementary business acquisitions or development opportunities.

We may direct Lincoln Park to purchase up to $15 million worth of shares of our common stock over a 30-month period generally in amounts up to 50,000 shares of our common stock on certain business days under a Purchase Agreement (the Purchase Agreement) we entered into with Lincoln Park on January 21, 2014 (the Lincoln Park Equity Line). As of December 31, 2014, we had sold $3.7 million worth of shares to Lincoln Park. However, there are certain factors, such as volume of trading in our common stock and our stock price, which limit the amount that can be raised in a short period of time. The extent to which we rely on the Lincoln Park Equity Line as sources of funding will depend on a number of factors, including the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. If obtaining sufficient funding from Lincoln Park were to prove impracticable or prohibitively dilutive, we may need to secure other sources of funding in order to satisfy our working capital needs. Even if we sell the maximum amount we are eligible to sell to Lincoln Park the Purchase Agreement, we may need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive should we require it, the consequences may have a material adverse effect on our business, operating results, financial condition and prospects. Additionally, during the year ended December 31, 2014, the Company raised net proceeds of $7.1 million utilizing our ATM with MLV. The ATM, which as of December 31, 2014 had remaining capacity of approximately $7.8 million, allowed the Company to sell its common stock from time to time under a registration statement on Form S-3 filed in June 2011, pursuant to which the Company registered $100 million of its securities for public sale. The Form S-3 registration statement filed in June 2011 expired in July 2014.

We may try to access the public or private equity markets if conditions are favorable to complete a financing, even if we do not have an immediate need for additional capital at that time, or whenever we require additional operating capital. In addition, we may seek collaborative relationships, incur debt and access other available funding sources. This additional funding may not be available to us on reasonable terms, or at all. Some of the factors that will impact our ability to raise additional capital and our overall success include:

- Our ability to successfully integrate the acquired business and further commercialize our products;
- The rate and degree of progress for our product development;

- The rate of regulatory approval to proceed with clinical trial programs;
- The level of success achieved in clinical trials;
- The requirements for marketing authorization from regulatory bodies in the United States and other countries;
- The liquidity and market volatility of our equity securities; and
- Regulatory and manufacturing requirements and uncertainties, and technological developments by competitors.

If adequate funds are not available in the future, we may not be able to develop or enhance our products, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements and we may be required to delay or terminate research and development programs, curtail capital expenditures, and reduce business development and other operating activities, which would have a material adverse impact on our business, financial condition and results of operations.

Failure to obtain and maintain required regulatory approvals would severely limit our ability to sell our products and product candidates.

We must maintain our domestic and foreign regulatory approvals to continue to commercialize our products. In addition, we must obtain the approval of the FDA before commercial sales of our cell therapy product candidates may commence in the United States, which we believe will ultimately be the largest market for our products. We anticipate that we will also be required to obtain additional approvals from various foreign regulatory authorities to initiate sales activities of cell therapy product candidates in those jurisdictions. If we cannot demonstrate the safety, purity and potency of our product candidates, including our cell therapy product

candidates, produced in our production system, the FDA or other regulatory authorities could delay or withhold regulatory approval of our product candidates.

Even after granting regulatory approval, the FDA and regulatory agencies in other countries continue to review and inspect marketed products, manufacturers and manufacturing facilities, which may create additional regulatory burdens. Later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on the product or manufacturer, including a withdrawal of the product from the market. Further, regulatory agencies may establish additional regulations that could prevent or delay regulatory approval of our product candidates or adversely affect the regulatory approvals of our products.

Any changes in the governmental regulatory classifications of our products and product candidates could prevent, limit or delay our ability to market or develop our products and product candidates.

The FDA establishes regulatory requirements based on the regulatory status of a product. Because our product development programs are designed to satisfy the standards applicable to biological licensure for our cell therapy products, any change in the regulatory classification or designation would affect our ability to obtain FDA approval of our product candidates. As each of our cell therapy product candidates is, under current regulations, regulated as a biologic, a Biologics License Application (BLA) is required to be submitted and approved by the FDA prior to the marketing of any of our product candidates.

Our product candidate, ixmyelocel-T, is still in clinical development. If we do not successfully continue or complete the clinical development of ixmyelocel-T, our ability to finance our operations may be adversely affected.

Our near-term prospects depend in part upon our ability to successfully continue and complete clinical trials of our product candidate, ixmyelocel-T, and to demonstrate its safety and effectiveness, as well as its superiority over existing therapies and standards of care, if any. We are conducting an ongoing Phase 2b ixCELL DCM clinical trial in which we are following patients who have been treated with ixmylocel-T. Our ability to finance our company and to generate revenues will depend in part on our ability to obtain favorable results in the ongoing and planned clinical trials of ixmyelocel-T, including the ongoing ixCELL-DCM Phase 2b clinical trial, and to successfully develop and commercialize ixmyelocel-T. Ixmyelocel-T could be unsuccessful if it:

- Does not demonstrate acceptable safety and efficacy in clinical trials, or otherwise does not meet applicable regulatory standards for approval;
- Does not offer sufficient, clinically meaningful therapeutic or other improvements over existing or future drugs used to treat advanced heart failure due to ischemic DCM;
- Is not capable of being produced in commercial quantities at acceptable costs; or
- Is not accepted as safe, efficacious, cost-effective, less costly and preferable to current therapies in the medical community and by third-party payers.

If we are not successful in developing and commercializing ixmyelocel-T or are significantly delayed in doing so, our financial condition and future prospects may be adversely affected and we may experience difficulties in raising the substantial additional capital required to fund our business.

Our products and product development programs are based on novel technologies and are inherently risky.

We are subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of our therapeutics creates significant challenges in regard to product development and optimization, manufacturing, government regulation, third-party reimbursement and market acceptance. For example, if regulatory agencies have limited experience in approving cellular therapies for commercialization, the development and commercialization pathway for our therapies may be subject to increased uncertainty, as compared to the pathway for new conventional drugs.

Further, when manufacturing autologous cell therapies, the number and the composition of the cell population varies from patient to patient, in part due to the age of the patient, since the therapy is dependent on patient specific physiology. Such variability in the number and composition of these cells could adversely affect our ability to manufacture autologous cell therapies in a cost-effective 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 products represent new classes of therapy that the marketplace may not understand or accept. Furthermore, the success of our products is dependent on wider acceptance by the medical community.

While our acquired products have had some commercial success to date, the broader market may not understand or accept our products. Our products represent new treatments or therapies and compete with a number of more conventional products and

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therapies manufactured and marketed by others. The new nature of our products creates significant challenges in regards to product development and optimization, manufacturing, government regulation, and third-party reimbursement. As a result, the commercialization of our current products and development pathway for our potential products may be subject to increased scrutiny, as compared to the pathway for more conventional products.

The degree of market acceptance of any of our marketed or potential products will depend on a number of factors, including:

- The clinical safety and effectiveness of our products and their perceived advantage over alternative treatment methods;
- Our ability to convince health care providers that the use of our products in a particular procedure is more beneficial than the standard of care or other available methods;
- Our ability to explain clearly and educate others on the autologous use of patient-specific human tissue, to avoid potential confusion with and differentiate ourselves from the ethical controversies associated with human fetal tissue and engineered human tissue;
- Adverse reactions involving our products or the products or product candidates of others that are human tissue based;
- Our ability to supply a sufficient amount of our product to meet regular and repeated demand in order to develop a core group of medical professionals familiar with and committed to the use of our products; and
- The cost of our products and the reimbursement policies of government and third-party payers.

If patients or the medical community do not accept our potential products as safe and effective for any of the foregoing reasons, or for any other reason, it could affect our sales, having a material adverse effect on our business, financial condition and results of operations. While acceptance by the medical community may be fostered by broad evaluation via peer-reviewed literature, we may not have the resources to facilitate sufficient publication.

Our inability to complete our product development activities successfully would materially limit our ability to operate or finance our operations.

In order to commercialize our cell product candidates in the United States, we must complete substantial clinical trials and obtain sufficient safety, purity and potency results to support required regulatory approval and market acceptance of our cell product candidates. We may not be able to successfully complete the development of our product candidates, or successfully market our technologies or product candidates. We, and any of our potential collaborators, may encounter problems and delays relating to research and development, regulatory approval and intellectual property rights of our technologies and product candidates. Our research and development programs may not be successful, and our cell culture technologies and product candidates may not facilitate the production of cells outside the human body with the expected results. Our technologies and cell product candidates may not prove to be safe and effective in clinical trials, and we may not obtain the requisite regulatory approvals for our technologies or product candidates and the cells produced in such products. If any of these events occur, we may not have adequate resources to continue operations for the period required to resolve any issues delaying commercialization and we may not be able to raise capital to finance our continued operations during the period required for resolution of any such issues.

We must successfully complete our clinical trials to be able to market certain of our products and product candidates. Clinical trial failures can occur at any stage of the testing and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent the continued commercialization of our products or future therapeutic product candidates.

To be able to market therapeutic cell products in the United States, we must demonstrate, through extensive preclinical studies and clinical trials, the safety and effectiveness of our processes and product candidates. If our clinical trials are not successful, our products may not be marketable. The results of early stage clinical trials do not ensure success in later clinical trials, and interim results are not necessarily predictive of final results.

With respect to any clinical trials affecting our products or product candidates, failures or delays can occur at any stage of the trials, and may be directly or indirectly caused by a variety of factors, including but not limited to:

- Delays in securing clinical investigators or trial sites for our clinical trials;
- Delays in obtaining Institutional Review Board (IRB) and other regulatory approvals to commence a clinical trial;
- Slower than anticipated rates of patient recruitment and enrollment in our clinical trials, or failing to reach the targeted number of patients due to competition for patients from other trials;
- Limited or no availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third party payers for the use of biological products supplied for use in our clinical trials;
- Negative or inconclusive results from clinical trials;

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- Unforeseen side effects interrupting, delaying, or halting clinical trials of any future therapeutic product candidates, and possibly resulting in the FDA or other regulatory authorities denying approval of any future therapeutic product candidates;
- Unforeseen safety issues;
- Approval and introduction of new therapies or changes in standards of practice or regulatory guidance that render our clinical trial endpoints or the targeting of our proposed indications obsolete;
- Inability to monitor patients adequately during or after treatment or problems with investigator or patient compliance with the trial protocols;
- Inability to replicate in large controlled studies safety and efficacy data obtained from a limited number of patients in uncontrolled trials;
- Inability or unwillingness of medical investigators to follow our clinical protocols; and
- Unavailability of clinical trial supplies.

Moreover, our ability to complete the clinical trials for our product candidates in a timely manner depends on additional factors such as rate of patient enrollment. Patient enrollment can vary with the size of the patient population, the proximity of suitable patients to clinical sites, perceptions of the utility of cell therapy for the treatment of certain diseases, and the eligibility criteria for the study. For example, patients enrolling in future studies of ixmyelocel-T need to provide an adequate amount of bone marrow to process and expand for injection and some patients may not be able to provide sufficient starting material despite our study inclusion and exclusion criteria designed to prevent this. Bone marrow is an inherently variable starting material. We have experienced delays in patient accrual in our previous clinical trials. On March 27, 2013, we announced that we were stopping enrollment in the Phase 3 REVIVE clinical trial due to the slow patient accrual rate for the study and to optimize the use of our financial resources. If we experience similar delays in patient enrollment for other clinical trials, we could experience increased costs and delays associated with these trials, which would impair our product development programs and our ability to market our products.

Furthermore, the FDA monitors the progress of clinical trials and it may suspend or terminate clinical trials at any time due to patient safety or other considerations.

Our research programs are currently directed at improving product functionality for certain clinical indications, improving product shelf life, and decreasing the cost of manufacturing our products. These production process changes may alter the functionality of our cells and require various additional levels of experimental and clinical testing and evaluation. Any such testing could lengthen the time before these products would be commercially available.

Even if successful clinical results are reported for a product from a completed clinical trial, this does not mean that the results will be sustained over time, or will be sufficient for a marketable or regulatory approvable product.

We may rely on third parties to conduct some of our clinical trials, and their failure to perform their obligations in a timely or competent manner may delay development and commercialization of our product candidates.

We may use clinical research organizations (CROs) to assist in conduct of our clinical trials. There are numerous alternative sources to provide these services. However, we may face delays outside of our control if these parties do not perform their obligations in a timely or competent fashion, or if we are forced to change service providers. Any third party that we hire to conduct clinical trials may also provide services to our competitors, which could compromise the performance of their obligations to us. If we experience significant delays in the progress of our clinical trials, the commercial prospects for product candidates could be harmed and our ability to generate product revenue would be delayed or prevented. In addition, we and any provider that we retain will be subject to Good Clinical Practice (GCP) requirements. If GCP and other regulatory requirements are not adhered to by us or our third-party providers, the development and commercialization of our product candidates could be delayed.

Any failure of such CRO to successfully accomplish clinical trial monitoring, data collection, safety monitoring and data management and the other services it provides for us in a timely manner and in compliance with regulatory requirements could have a material adverse effect on our ability to complete clinical development of our products and obtain regulatory approval. Problems with the timeliness or quality of the work of a CRO may lead us to seek to terminate the relationship and use an alternate service provider. However, making such changes may be costly and may delay our trials, and contractual restrictions may make such a change difficult or impossible. Additionally, it may be difficult to find a replacement organization that can conduct our trials in an acceptable manner and at an acceptable cost.

Failure of third parties, including Vention Medical, to manufacture or supply certain components, equipment, disposable devices and other materials used in our ixmyelocel-T cell manufacturing process would impair our cell product development.

We rely on third parties, including Vention Medical, Inc. (Vention), to manufacture and/or supply certain of our devices/manufacturing equipment and to manufacture and/or supply certain components, equipment, disposable devices and other

materials used in our cell manufacturing process to develop our marketed cell therapy products and our product candidates. Vention is our sole supplier of cell cassettes used in the ixmyelocel-T manufacturing process, and it would be difficult to obtain alternate sources of supply on a short-term basis. If any of our manufacturers or suppliers fails to perform its respective obligations, or if our supply of certain components, equipment, disposable devices and other materials is limited or interrupted, it could impair our ability to manufacture our products, which would delay our ability to conduct our clinical trials or market our product candidates on a timely and cost-competitive basis, if at all.

In addition, we may not be able to continue our present arrangements with our suppliers, supplement existing relationships, establish and maintain new relationships or be able to identify and obtain the ancillary materials that are necessary to develop our product candidates in the future. Our dependence upon third parties for the supply and manufacture of these items could adversely affect our ability to develop and deliver commercially feasible products on a timely and competitive basis.

Failure by our third-party manufacturers, including Vention, to comply with the regulatory guidelines set forth by the FDA with respect to our products could delay or prevent the completion of clinical trials, the approval of any product candidates or the commercialization of our products.

Third-party manufacturers, such as Vention, must be inspected by the FDA for current Good Manufacturing Practice, or cGMP, compliance before they can produce commercial product. We may be in competition with other companies for access to these manufacturers' facilities and may be subject to delays in manufacture if the manufacturers give other clients higher priority than they give to us. If we are unable to secure and maintain third-party manufacturing capacity, the development and sales of our products and our financial performance may be materially affected.

Manufacturers are obligated to operate in accordance with FDA-mandated requirements. A failure of any of our third-party manufacturers to establish and follow cGMP requirements and to document their adherence to such practices may lead to significant delays in the availability of material for clinical trials, may delay or prevent filing or approval of marketing applications for our products, and may cause delays or interruptions in the availability of our products for commercial distribution following FDA approval. This could result in higher costs to us or deprive us of potential product revenues.

Complying with cGMP and non-U.S. regulatory requirements will require that we expend time, money, and effort in production, recordkeeping, and quality control to assure that the product meets applicable specifications and other requirements. We, or our contracted manufacturing facility, must also pass a pre-approval inspection prior to FDA approval. Failure to pass a pre-approval inspection may significantly delay FDA approval of our products. If we fail to

comply with these requirements, we would be subject to possible regulatory action and may be limited in the jurisdictions in which we are permitted to sell our products. As a result, our business, financial condition, and results of operations may be materially harmed.

The manufacture of cell therapy products is characterized by inherent risks and challenges and has proven to be a costly endeavor relative to manufacturing other therapeutics products. We have limited experience in manufacturing products for commercial purposes and we cannot assure you that we will be able to successfully and efficiently manage the manufacturing of our products, either ourselves or through third-party contractors with whom we may enter into strategic relationships.

The manufacture of cell therapy products, such as our products and product candidates, is highly complex and is characterized by inherent risks and challenges such as autologous raw material inconsistencies, logistical challenges, significant quality control and assurance requirements, manufacturing complexity, and significant manual processing. Unlike products that rely on chemicals for efficacy, such as most pharmaceuticals, cell therapy products are difficult to characterize due to the inherent variability of biological input materials. Difficulty in characterizing biological materials or their interactions creates greater risk in the manufacturing process. We attempt to mitigate risk associated with the manufacture of biologics by continuing to improve the characterization of all of our input materials, utilizing multiple vendors for supply of qualified biological materials, and manufacturing some of these materials ourselves. However, there can be no assurance that we will be able to maintain adequate sources of biological materials or that biological materials that we maintain in inventory will yield finished products that satisfy applicable product release criteria. Our inability to obtain necessary biological materials or to successfully manufacture cell therapy products that incorporate such materials could have a material adverse effect on our results of operations.

Additionally, we have limited experience in manufacturing products for commercial purposes and could experience difficulties in the continued manufacturing of our products. Because our experience in manufacturing, sales, marketing and distribution is limited, we may encounter unforeseen difficulties in our efforts to efficiently manage the manufacturing, sale and distribution of our products or have to rely on third-party contractors over which we may not have direct control to manufacture our products. Moreover, there can be no assurance that we or any third-party contractors with whom we enter into strategic relationships will be successful in streamlining manufacturing operations and implementing efficient, low-cost manufacturing capabilities and processes that will enable us to meet the quality, price and production standards or production volumes to achieve profitability. Our failure to develop these

manufacturing processes and capabilities in a timely manner could prevent us from achieving our growth and profitability objectives as projected or at all.

We intend to obtain assistance to market our products and some of our future cell products through collaborative relationships with companies with established sales, marketing and distribution capabilities. Our inability to develop and maintain those relationships would limit our ability to market, sell and distribute our products. Our inability to enter into successful, long-term relationships could require us to develop alternate arrangements at a time when we need sales, marketing or distribution capabilities to meet existing demand. We may market one or more of our products through our own sales force. Our inability to develop and retain a qualified sales force could limit our ability to market, sell and distribute our cell products.

We have limited manufacturing capacity and our commercial manufacturing operations in the U.S. depend on one facility. Similarly, manufacturing of our lead product candidate, ixmyelocel-T, is conducted at one facility. If either facility is destroyed or we experience any manufacturing difficulties, disruptions or delays, this could limit supply of our products or adversely affect our ability to conduct our clinical trials and our business would be adversely impacted.

We presently conduct all of our commercial manufacturing operations in the U.S. at one facility located in Cambridge, Massachusetts. As a result, all of the commercial manufacturing of our marketed products, Epicel and Carticel, for the U.S. market takes place at a single U.S. facility. In addition, clinical trials for certain product candidates would primarily depend upon the manufacturing of such product candidates in the same Cambridge facility. Similarly, manufacturing of our product candidate ixmyelocel-T takes place at one facility located in Ann Arbor, Michigan. If regulatory, manufacturing or other problems require us to discontinue production at either facility, we will not be able to supply our products to our patients or have supplies for any clinical trials, which would adversely impact our business. If either facility or the equipment in it is significantly damaged or destroyed by fire, flood, power loss or similar events, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace our facility at all. In the event of a temporary or protracted loss of this facility or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing from one facility to the other or to a third party, the shift would likely be expensive and time-consuming, particularly since an alternative facility would need to comply with the applicable regulatory and quality standard requirements whereby validation and FDA approval would be required before any products manufactured at that facility could be made commercially available.

Currently, we maintain insurance coverage totaling $4.8 million in Denmark and $33.7 million in the U.S. against damage to our property and equipment, an additional $33 million to cover business interruption and extra expenses, and $1.0 million to cover research and development restoration expenses. If we have underestimated our insurance needs, we will not have sufficient insurance to cover losses above and beyond the limits on our policies.

We are subject to significant regulation with respect to the manufacturing of our products.

All of those involved in the preparation of a cellular therapy for clinical trials or commercial sale, including our existing supply contract manufacturers and clinical trial investigators, are subject to extensive and continuing government regulations by the FDA and comparable agencies in other jurisdictions. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Our facilities and quality systems and the facilities and quality systems of some or all of our third party contractors and suppliers must pass inspection for compliance with the applicable regulations as a condition of FDA approval of our products. The FDA also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third party contractors. In addition, the FDA may, at any time, audit or inspect a manufacturing facility involved with the preparation of our products or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted.

Our manufacturing facility in Cambridge, Massachusetts was inspected by the FDA in 2014. On March 19, 2014, the FDA issued a Form 483 List of Inspectional Observations. A Form 483 is issued when, in an investigator’s judgment, the observed conditions or practices observed during an FDA inspection of the manufacturing facility indicate that an FDA-regulated product may be in violation of FDA’s requirements. We have completed remedial measures to improve our manufacturing process and have responded to all FDA observations. Generally, if any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulation occurs independent of such an inspection or audit,

we or the FDA may require remedial measures that may be costly and/or time consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales, recalls, warning letters, market withdrawals, seizures or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

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We could incur significant costs complying with environmental and health and safety requirements, or as a result of liability for contamination or other harm caused by hazardous materials that we use.

Our research and development and manufacturing processes involve the use of hazardous materials. We are subject to federal, state, local and foreign environmental requirements, including regulations governing the use, manufacture, handling, storage and disposal of hazardous materials, discharge to air and water, the cleanup of contamination and occupational health and safety matters. We cannot eliminate the risk of contamination or injury resulting from hazardous materials, and we may incur liability as a result of any contamination or injury. Under some environmental laws and regulations, we could also be held responsible for costs relating to any contamination at our past or present facilities and at third party waste disposal sites where we have sent wastes. These could include costs relating to contamination that did not result from any violation of law, and in some circumstances, contamination that we did not cause. We may incur significant expenses in the future relating to any failure to comply with environmental laws. Any such future expenses or liability could have a significant negative impact on our financial condition. The enactment of stricter laws or regulations, the stricter interpretation of existing laws and regulations or the requirement to undertake the investigation or remediation of currently unknown environmental contamination at our own or third party sites may require us to make additional expenditures, which could be material.

In order to market any of our product candidates, including MACI and ixmyelocel-T, in the United States, the FDA requires us to file a BLA.

The FDA approved Carticel as a biological product, for which we currently hold a biologics license. MACI and ixmyelocel-T are also subject to the FDA's biological product requirements, which will require us to submit a new BLA for each product prior to being granted marketing approval. To the extent the FDA regulates each of MACI and ixmyelocel-T as a biological product and requires us to file a BLA, we would be unable to sell MACI or ixmyelocel-T unless and until we receive BLA approval from the FDA, which requires that we conduct clinical trials in support of approval of a BLA, which would be expensive and time consuming, and uncertain as to outcome. For example, the FDA may require that we conduct one or more clinical trials in support of approval of a BLA, which would result in the expenditure of additional financial resources and extended timelines to commercialization.

Our business, financial condition, results of operation and cash flows could be significantly and negatively affected by substantial governmental regulations.

Our products are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. Overall, there appears to be a trend toward more stringent regulation worldwide, and we do not anticipate this trend to dissipate in the near future.

In general, the development, testing, labeling, manufacturing and marketing of our products are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. The regulatory process requires the expenditure of significant time, effort and expense to bring new products to market. For example, the FDA approved Epicel as a HUD pursuant to an HDE application. A HUD is a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. A HUD with an approved HDE is approved by the FDA for marketing. However, Investigational Review Board (IRB) approval is required before a HUD can be used at a facility, with the exception of emergency use. The HDE holder is responsible for ensuring that a HUD approved under an HDE is administered only in facilities having an IRB constituted and acting in accordance with the agency's regulation governing IRBs, including continuing review of use of the device. HUDs are also subject to additional FDA requirements, such as adverse event reporting and the submission of updated information on a periodic basis to demonstrate that the HUD designation is still valid. Failure to meet FDA requirements pertaining to a HUD could result in the suspension or revocation of the HDE.

If the HDE is suspended or revoked, marketing approval for Epicel would require the submission and approval of a premarket approval application (PMA) in order to be made commercially available. The PMA process is costly, lengthy and uncertain. A PMA must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use. If the HDE approval for Epicel was withdrawn, and we were unable to obtain approval of a PMA, we could not market Epicel for sale in the U.S.

We are also required to implement and maintain stringent reporting, labeling and record keeping procedures. More specifically, in the United States, both before and after a product is commercially released, we have ongoing responsibilities under FDA regulations. Compliance with the FDA's requirements, including the FDA's cGMP recordkeeping regulations, labeling and promotional requirements and adverse event reporting regulations, is subject to continual review and is monitored rigorously through periodic inspections by the FDA. Our failure to comply with U.S. federal, state and foreign governmental regulations could lead to the issuance of warning letters or untitled letters, the imposition of injunctions, suspensions or loss of regulatory clearance or approvals, product

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recalls, termination of distribution, product seizures or civil penalties. In the most extreme cases, criminal sanctions or closure of our manufacturing facility are possible.

In addition, the pharmaceutical, biologic and medical industries also are subject to many complex laws and regulations governing Medicare and Medicaid reimbursement and targeting healthcare fraud and abuse, with these laws and regulations being subject to interpretation. In many instances, the industry does not have the benefit of significant regulatory or judicial interpretation of these laws and regulations. In certain public statements, governmental authorities have taken positions on issues for which little official interpretation was previously available. Some of these positions appear to be inconsistent with common practices within the industry but have not previously been challenged.

Various federal and state agencies have become increasingly vigilant in recent years in their investigation of various business practices, such as the federal Anti-kickback Statute and the federal False Claims Act. Governmental and regulatory actions against us can result in various actions that could adversely impact our operations, including:

- The recall or seizure of products;
- The suspension or revocation of the authority necessary for the production or sale of a product;
- The suspension of shipments from particular manufacturing facilities;
- The imposition of fines and penalties;
- The delay of our ability to introduce new products into the market;
- Our exclusion or the exclusion of our products from being reimbursed by federal and state healthcare programs (such as Medicare, Medicaid, Veterans Administration, or VA, health programs and Civilian Health and Medical Program Uniformed Service, or CHAMPUS); and
- Other civil or criminal prosecution or sanctions against us or our employees, such as fines, penalties or imprisonment.

Any of these actions, in combination or alone, or even a public announcement that we are being investigated for possible violations of these laws, could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In the United States, if the FDA were to conclude that we are not in compliance with applicable laws or regulations or that any of our products are ineffective or pose an unreasonable health risk, the FDA could ban such products, detain or seize adulterated or misbranded products, order a recall, repair, replacement, or refund of payment of certain products, refuse to grant pending approval applications, refuse to provide certificates to foreign governments for exports, and/or require us to notify healthcare professionals and others that the products present unreasonable risks of substantial harm to the public health. The FDA may also impose operating restrictions on a companywide basis, enjoin and restrain certain violations of applicable law pertaining to our products and assess civil or criminal penalties against our officers, employees or us. The FDA may also recommend prosecution to the United States Department of Justice (DOJ). Adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products.

In many of the foreign countries in which our products are marketed, we are subject to regulations affecting, among other things, clinical efficacy, product standards, packaging requirements, labeling requirements, import/export restrictions, tariff regulations, duties and tax requirements. Many of the regulations applicable to our products in these countries, such as the Medicinal Products Directive and the ATMP guidelines, governing products in the EU, are similar to those of the FDA. In addition, in many countries the national health or social security organizations require our products to be qualified before they can be marketed with the benefit of reimbursement eligibility. Failure to receive or delays in the receipt of relevant foreign qualifications also could have a material adverse effect on our business, financial condition, results of operations and cash flows.

As both the U.S. and foreign government regulators have become increasingly stringent, we may be subject to more rigorous regulation by governmental authorities in the future. Our products and our operations are also often subject to the rules of industrial standards bodies, such as the International Standards Organization, or ISO. If we fail to adequately address any of these regulations, our business will be harmed.

Changes to our products or product candidates may require new regulatory approvals or may require us to recall or cease marketing our products until approvals are obtained.

Modifications to our products or product candidates may require new regulatory approvals, including supplements to any of our Investigational New Drug applications (INDs) requesting FDA authorization to administer our investigational biological product to humans or supplements to our BLA or Humanitarian Device Exemption (HDE) application, or require us to recall or cease marketing the modified products until these approvals are obtained. We may not be able to obtain those additional approvals for the changes or additional indications in a timely manner, or at all. Obtaining approvals can be a time consuming process, and delays in obtaining

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required future approvals would adversely affect our ability to introduce new or improved products in a timely manner, which in turn would harm our future growth.

If we or our suppliers fail to comply with ongoing FDA or other foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

The manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for each of our products is subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our suppliers are required to comply with cGMP and Good Tissue Practice (GTP) regulations for the manufacture of our products and other regulations which cover requirements such as the methods and documentation pertaining to production controls, labeling, packaging, storage and shipment of any product for which we obtain clearance or approval. Regulatory bodies, such as the FDA, enforce the cGMP, GTP and other regulations through periodic inspections. For example, the holder of an approved BLA or HUD is obligated to monitor and report adverse events and any failure of a product to meet its specifications. The holder of an approved BLA or HDE device must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP and to confirm that the manufactured products conform with the description in the PMA. If we or a regulatory agency discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

- Untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;

- Unanticipated expenditures to address or defend such actions;
- Client notifications for repair, replacement, refunds;
- Recall, detention or seizure of our products;
- Operating restrictions or partial suspension or total shutdown of production;
- Refusing or delaying our requests for approval of new products or modified products;
- Operating restrictions;
- Withdrawing product approvals that have already been granted;
- Refusal to approve a pending marketing application, such as a BLA or supplements to a BLA submitted by us;
- Refusal to grant export approval for our products; or
- Criminal prosecution.

If any of these actions were to occur it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our products on a timely basis and in the required quantities, if at all. In addition, we may be required to conduct costly post-approval studies, and post-market surveillance to monitor the safety or effectiveness of our products. We also must comply with adverse event reporting requirements, which require that we report certain adverse events involving patient use or treatment with our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as cGMP or GTP, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

Our marketed products may be used by physicians for indications that are not approved by the FDA. If the FDA finds that we marketed our products in a manner that promoted off-label use, we may be subject to civil or criminal penalties.

Under the Federal Food, Drug and Cosmetic Act (FFDCA) and other laws, we are prohibited from promoting our products for off-label uses. This means, for example, that we may not make claims about the use of our marketed products, Carticel or Epicel, outside

of their approved indications, and we may not proactively discuss or provide information on off-label uses of Carticel or Epicel, with very specific and limited exceptions. The FDA does not, however, restrict physicians from prescribing products for off-label uses in the practice of medicine. Should the FDA determine that our activities constitute the promotion of off-label uses, the FDA could bring action to prevent us from distributing Carticel or Epicel for the off-label use and could impose fines and penalties on us and our executives. In addition, failure to follow FDA rules and guidelines relating to promotion and advertising can result in, among other things, the FDA's refusal to approve a product, the suspension or withdrawal of an approved product from the market, product recalls, fines, disgorgement of money, operating restrictions, injunctions or criminal prosecutions.

If the Office of Inspector General within the Department of Health and Human Services, the DOJ, or another federal or state agency determines that we have promoted off-label use of our products, we may be subject to various penalties, including civil or criminal penalties, and the off-label use of our products may result in injuries that lead to product liability suits, which could be costly to our business.

In addition to the FDA restrictions on our marketed products, several other types of state and federal healthcare laws have been applied by DOJ and state attorneys general to restrict certain marketing practices in the pharmaceutical industry. While physicians may prescribe products for off-label uses and indications, if other federal or state regulatory authorities determine that we have engaged in off-label promotion through remuneration, kickbacks or other monetary benefits to prescribers, we may be subject to civil or criminal penalties and could be prohibited from participating in government healthcare programs such as Medicaid and Medicare. In addition, government agencies or departments could conclude that we have engaged in off-label promotion and, potentially, caused the submission of false claims. Even if we are successful in resolving such matters without incurring penalties, responding to investigations or prosecutions will likely result in substantial costs and could significantly and adversely impact our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results, financial condition and ability to finance our operations. In addition, the off-label use of our products may increase the risk of injury to patients, and, in turn, the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention and result in substantial damage awards against us.

The price and sale of any of our products may be limited by health insurance coverage and government regulation.

Maintaining and growing sales of our products will depend in large part on the availability of adequate coverage and the extent to which third-party payers, including health insurance companies, health maintenance organizations (HMOs), and government health administration authorities such as Medicare and Medicaid, private insurance plans and managed care programs will pay for the cost of the products and related treatment. Hospitals and other healthcare provider clients that purchase our products typically bill various third-party payers to cover all or a portion of the costs and fees associated with the procedures in which such products are used, including the cost of the purchase of these products. Third-party payers are also increasingly attempting to contain healthcare costs by demanding price discounts or rebates and limiting both coverage and the amounts that they will pay for certain products, and, as a result, they may not cover or continue to provide adequate payment for our products. We might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of our products and product candidates to such payers' satisfaction. Such studies might require us to commit a significant amount of management time and financial and other resources. Our products and future products might not ultimately be considered cost-effective. Adequate third-party reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in our products and future product development. If coverage and adequate reimbursement are not available, reimbursement is available only to limited levels, or if our costs of production increase faster than increases in reimbursement levels, we may not be able to successfully grow the sales of our products or commercialize any product candidates for which marketing approval is obtained.

Coverage decisions and payment amounts are established at the discretion of the individual third-party payer, and the regulations that govern pricing, coverage and reimbursement vary widely from country to country. Many private payers in the United States, however, use coverage decisions and payment amounts determined by the Centers for Medicare & Medicaid Services (CMS), as guidelines in setting their coverage and reimbursement policies. As the portion of the U.S. population over the age of 65 and eligible for Medicare continues to grow, we may be more vulnerable to coverage and reimbursement limitations imposed by CMS. While certain procedures using our products are currently covered by Medicare and other third-party payers, future action by

CMS or other government agencies may diminish payments to physicians, outpatient centers and/or hospitals for covered services. As a result, we cannot be certain that the procedures performed with our products will be reimbursed at a cost-effective level or reimbursed at all.

Furthermore, the healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with service providers. Therefore, we cannot be certain that the procedures performed with our products will be reimbursed at a cost-effective level. Nor can we be certain that third-party payers using a methodology that sets amounts based on the type of procedure performed, such as those utilized by Medicare and in many privately managed care systems, will view the cost of our products to be justified so as

to incorporate such costs into the overall cost of the procedure. Moreover, we are unable to predict what changes will be made to the reimbursement methodologies used by third-party payers in the future.

There are no assurances that we will be able to submit a Humanitarian Device Exemption supplement for Epicel or obtain FDA approval in order to sell Epicel for profit.

Epicel was designated as a Humanitarian Use Device (HUD) in 1998 and a Humanitarian Device Exemption (HDE) application for the product was submitted in 1999. HUDs are devices that are intended for diseases or conditions that affect or are manifested in fewer than 4,000 individuals annually in the United States. Under the HDE approval of 2007, Epicel cannot not be sold for an amount that exceeds the cost of research and development, fabrication and distribution. However, pursuant to the Pediatric Medical Device Safety and Improvement Act of 2007 and the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), a HUD can be sold for profit if certain conditions are met. Under current law, an HDE holder can make a profit on its HUD after receiving HDE approval if the device is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe. HUD devices are assigned an Annual Distribution Number (ADN) by the FDA that caps the number of devices that can be distributed.

We are currently investigating Epicel's eligibility for exemption from the profit prohibition and have requested a pre-submission meeting with the FDA to discuss the process and required data for submitting an HDE supplement to obtain an exemption from the profit prohibition. Even if we submit an HDE supplement, there can be no assurance that the FDA will approve our application in a timely manner, or at all. If we are unable to submit an HDE supplement, or if the supplement is not approved by the FDA, we will be unable to sell Epicel for profit. The FDA can and does reject requests for an exemption from the profit prohibition if the required eligibility criteria are not met. If we are unable to sell Epicel for profit, we will not be able to attain profitability for Epicel and may be forced to discontinue sales of Epicel, which could have an adverse impact on our business.

We face intense competition in the markets targeted by our products. Many of our competitors have substantially greater resources than we do, and we expect that all of our products will face intense competition from existing or future products.

All of our products face intense competition from existing and future products marketed by large companies. These competitors may successfully market products that compete with our products, successfully identify product candidates or develop products earlier than we do, or develop products that are more effective or cost less than our products. These competitive factors could require us to conduct substantial new research and development activities to establish new product targets, which would be costly and time consuming. These activities would adversely affect our ability to effectively commercialize products and achieve revenue and profits.

If we do not keep pace with our competitors and with technological and market changes, our products will become less attractive or obsolete and our business may suffer.

The markets for our products are highly competitive, subject to rapid technological changes, and vary for different candidates and processes that directly compete with our products. Our competitors in the medical and biotechnology industries may have superior products, research and development, manufacturing, and marketing capabilities, and financial resources or marketing positions. Furthermore, our competitors may have developed, or could in the future develop, new technologies that compete with our products or even render our products obsolete. As an example, in the past, published studies have suggested that hematopoietic stem cell therapy use for bone marrow transplantation, following marrow ablation due to chemotherapy, may have limited clinical benefit in the treatment of breast cancer, which was a significant portion of the overall hematopoietic stem cell transplant market. This resulted in the practical elimination of this market for our cell-based product for this application.

Our cell manufacturing system for ixmyelocel-T is designed to improve and automate the processes for producing cells used in therapeutic procedures. Even if we are able to demonstrate improved or equivalent results, the cost or process of treatment and other factors may cause researchers and practitioners to not use our products and we could suffer a competitive disadvantage. To the extent that others develop new technologies that address the targeted application for our products, our business will suffer. Finally, if we are unable to continue to develop and market new products and technologies in a timely manner, the demand for our products may decrease or our products could become obsolete, and our revenue may decline.

Ethical, legal, social and other concerns surrounding the use of human tissue in synthetic biologically engineered products may negatively affect public perception of us or our products, or may result in increased scrutiny of our products and any future product candidates from a regulatory perspective, thereby reducing demand for our products, restricting our ability to market our products, or adversely affecting the market price for our common stock.

The commercial success of our products depends in part on general public acceptance of the use of human tissue for the treatment of human diseases and other conditions. While not as controversial as the use of embryonic stem cells and fetal tissue, the use of adult tissue has been the subject of substantial debate regarding related ethical, legal and social issues. We do not use embryonic stem cells or fetal tissue, but the public may not be able to, or may fail to, differentiate our autologous use of adult tissue from the use by others of embryonic stem cells or fetal tissue. This could result in a negative perception of our company or our products.

Future adverse events in the field of cellular based therapy or changes in public policy could also result in greater governmental regulation of our products and potential regulatory uncertainty or delay relating to any required testing or approval.

Use of animal-derived materials could harm our product development and commercialization efforts.

Some of the manufacturing materials and/or components that we use in, and which are critical to, implementation of our technology involve the use of animal-derived products, including fetal bovine serum. Supplier changes or regulatory actions may limit or restrict the availability of such materials for clinical and commercial use for a variety of reasons including contamination or perceived risk of contamination with an adventitious agent, such as bovine spongiform encephalopathy (BSE), in one of our suppliers' herds. This may lead to a restricted supply of the serum currently required for our product manufacturing processes. Any restrictions on these materials would impose a potential competitive disadvantage for our products or prevent our ability to manufacture our cell products. The FDA has issued regulations for controls over bovine material in animal feed. These regulations do not appear to affect our ability to purchase the manufacturing materials we currently use. However, the FDA may propose new regulations that could affect our operations. Our inability to develop or obtain alternative compounds would harm our product development and commercialization efforts. There are certain limitations in the supply of certain animal-derived materials, which may lead to delays in our ability to complete clinical trials or eventually to meet the anticipated market demand for our cell products.

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Carticel, MACI or any other product candidate for which we seek approval as a biologic, may face competition sooner than anticipated.

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCI Act, as part of the PPACA, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCI Act, an application for a biosimilar product cannot be approved by the FDA until twelve years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement the BPCI Act 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. While the BCPI Act provides for a twelve-year period of exclusivity, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider any of our future product candidates to be a reference product for competing products, potentially creating the opportunity for competition sooner than anticipated.

Moreover, the extent to which a biosimilar product, 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.

Health care reform measures and changes in policies, funding, staffing and leadership at the FDA and other agencies could hinder or prevent the commercial success of our products.

In the United States, there have been a number of legislative and regulatory changes to the healthcare system in ways that could affect our future results of operations and the future results of operations of our potential customers.

Furthermore, there have been and continue to be a number of initiatives at the federal and state levels that seek to reduce healthcare costs. In March 2010, President Obama signed into law the Patient Protection and Affordable Health Care Act of 2010, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (jointly, the PPACA), which includes measures to significantly change the way health care is financed by both governmental and private insurers. Among the provisions of the PPACA of importance to the pharmaceutical industry are the following:

- An annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- Expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing both the volume of sales and manufacturers' Medicaid rebate liability;
- Expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
  New requirements to report certain financial arrangements with physicians and teaching hospitals, as defined in the PPACA and its implementing regulations, including reporting any "transfer of value" made or distributed to teaching hospitals, prescribers, and other healthcare providers and reporting any ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations during the preceding calendar year, with data collection required and reporting to the Centers for Medicare & Medicaid Services (CMS) required by the 90th day of each calendar year;
- Expansion of health care fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- A licensure framework for follow-on biologic products;
- A new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- Creation of the Independent Payment Advisory Board which, beginning in 2014, has authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription products and those recommendations could have the effect of law even if Congress does not act on the recommendations; and
- Establishment of a Center for Medicare Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

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, among other things, created measures for spending reductions by Congress. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year. On January 2, 2013, President Obama signed into law the

American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

Additionally, individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally-mandated price controls on payment amounts by third-party payers or other restrictions could harm our business, results of operations, financial condition and prospects.

In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products and which suppliers will be included in their healthcare programs. This can reduce demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

Additionally, given recent federal and state government initiatives directed at lowering the total cost of healthcare, Congress and state legislatures will likely continue to focus on healthcare reform and the reform of the Medicare and Medicaid programs. While we cannot predict the full outcome of any such legislation, it may harm our ability to market our products and generate revenues.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and effectiveness can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects.

Tissue-based products are regulated differently in different countries. These requirements may be costly and result in delay or otherwise preclude the distribution of our products in some foreign countries, any of which would adversely affect our ability to generate operating revenues.

Tissue based products are regulated differently in different countries. Many foreign jurisdictions have a different and may have a more difficult regulatory pathway for human tissue based products, which may prohibit the distribution of these products until the applicable regulatory agencies grant marketing approval, or licensure. The process of obtaining regulatory approval is lengthy, expensive and uncertain, and we may never seek such approvals, or if we do, we may never gain those approvals. Any adverse events in our clinical trials for a future product under development could negatively impact our products.

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

The EU medicines rules allow individual member states to permit the supply of a medicinal product without a marketing authorization to fulfill special needs, where the product is supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of a healthcare professional and for use by an individual patient under his direct personal responsibility.

This may, in certain countries, also apply to products manufactured in a country outside the EU and imported to treat specific patients or small groups of patients. In addition, Advanced Therapy Medicinal Products do not need a marketing authorization if they are prepared on a non-routine basis and are used within the same EU member state in a hospital under the exclusive professional responsibility of a medical practitioner and in accordance with a medical prescription for a custom-made product for an individual patient (named-patient basis).

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.

The current credit and financial market conditions may exacerbate certain risks affecting our business.

We rely upon third parties for certain aspects of our business, including collaboration partners, wholesale distributors, contract clinical trial providers, contract manufacturers and third-party suppliers. Because of the recent tightening of global credit and the

volatility in the financial markets, there may be a delay or disruption in the performance or satisfaction of commitments to us by these third parties, which could adversely affect our business.

We are dependent on our key manufacturing, quality and other management personnel and the loss of any of these individuals could harm our business.

Our success depends in large part upon the efforts of our key management and manufacturing and quality staff. The loss of any of these individuals, or our inability to attract and retain highly qualified scientific and management personnel in a timely manner, could materially and adversely affect our business and our future prospects. In the future, we may need to seek additional manufacturing and quality staff members. There is a high demand for highly trained manufacturing and quality personnel in our industry. We face competition for such personnel from other companies, research and academic institutions and other entities. We do not know whether we will be able to attract, train and retain highly qualified manufacturing and quality personnel in the future, which could have a material adverse effect on our business, financial condition and results of operations. A loss of one or more of our key personnel could severely and negatively impact our operations. Our key personnel are employed "at-will," and any of them may elect to pursue other opportunities at any time. We have no present intention of obtaining key man life insurance on any of our key management, manufacturing, quality or other personnel.

Risks Related to Intellectual Property

We have no patent protection for Epicel.

We have no issued patents or pending patent applications relating to Epicel. While we attempt to protect our proprietary information as trade secrets through certain agreements with our employees, consultants, agents and other organizations to which we disclose our proprietary information, we cannot give any assurance that these agreements will provide effective protection for our proprietary information in the event of unauthorized use or disclosure of such information. If other cultured epidermal autografts are approved and marketed, we will be unable to prevent them from competing with Epicel in the marketplace. We expect that the presence of one or more competing products would reduce our market share and could negatively impact price levels and third party reimbursement policies for Epicel, any of which would materially affect our business.

Our issued patents relating to Carticel and MACI will expire soon and may be insufficient to protect our business.

We have issued patents in the United States and in certain foreign countries that relate to the combinations of chondrocytes and collagen membranes used in Carticel and MACI. However, the issued patents relating to Carticel are scheduled to expire by August of 2016 in the U.S. and by 2022 in Europe. Furthermore, the issued patents relating to MACI are scheduled to expire by August of 2016 in the U.S. and by August of 2017 in Europe. When these patents expire we may be subject to increased competition and our opportunity to establish or maintain product revenue could be substantially reduced or eliminated.

The patents we own may not be of sufficient scope or strength to provide us with significant commercial protection or commercial advantage, and competitors may be able to design around our patents or develop products that provide outcomes that are similar to ours without infringing on our intellectual property rights. In addition, we cannot be certain that any of our pending patent applications will be issued or that the scope of the claims in our pending patent applications will not be significantly narrowed or determined to be invalid

If our patents and proprietary rights do not provide substantial protection, then our business and competitive position will suffer.

Our success depends in large part on our ability to develop or license intellectual property rights to protect our proprietary products and technologies. This involves complex legal, scientific, and factual questions and uncertainties. We rely upon patent, trade secret, copyright and contract laws to protect proprietary technology and trademark law to protect brand identities. However, we cannot assure you that any patent applications filed by, assigned to, or licensed to us will be granted, and that the scope of any of our issued or licensed patents will be sufficiently broad to offer meaningful protection. In addition, our issued patents or patents licensed to us could be successfully challenged, invalidated, held to be unenforceable, or circumvented so that our patent rights would not create an effective competitive barrier. We also cannot assure you that the inventors of the patents and applications that we own or license were the first to invent or the first to file on the inventions, or that a third party will not claim ownership in one of our patents or patent applications. We cannot assure you that a third party does not have or will not obtain patents that dominate the patents we own or license now or in the future.

Patent law relating to the scope of claims in the biotechnology field is evolving and our patent rights in this country and abroad are subject to this uncertainty. For example, from time to time, the U.S. Supreme Court (Supreme Court), other federal courts, the U.S. Congress or the United States Patent and Trademark Office (USPTO) may change the standards of patentability and any such changes

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could have a negative impact on our business. There have been several cases involving “gene patents” and diagnostic claims that have been considered by the Supreme Court. A suit brought by multiple plaintiffs, including the American Civil Liberties Union (ACLU) against Myriad Genetics (Myriad) and the USPTO, could impact biotechnology and diagnostic patents. That case involves certain of Myriad’s U.S. patents related to the breast cancer susceptibility genes BRCA1 and BRCA2. The Federal Circuit court issued a written decision on July 29, 2011 that reversed the decision of the U.S. District Court for the Southern District of New York that Myriad’s composition claims to “isolated” DNA molecules cover unpatentable subject matter. The Federal Circuit court instead held that the breast cancer genes are patentable subject matter. Subsequently, on March 20, 2012, the Supreme Court issued a decision in Mayo Collaborative v. Prometheus Laboratories (Prometheus) a case involving patent claims directed to optimizing the amount of drug administered to a specific patient. According to that decision, Prometheus’ claims failed to add enough inventive content to the underlying correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws. The Supreme Court subsequently granted certiorari in the Myriad case, vacated the judgment, and remanded the case back to the Federal Circuit court for further consideration in light of their decision in the Prometheus case. The Federal Circuit court heard oral arguments on July 20, 2012, and issued a decision on August 16, 2012. The Federal Circuit court reaffirmed its earlier decision and held that composition of matter claims directed to isolated nucleic acids are patent-eligible subject matter, but that method claims consisting of only abstract mental processes are not patent-eligible. On September 25, 2012, the ACLU filed a petition for a writ of certiorari asking the Supreme Court to review the Federal Circuit court’s decision with respect to the composition of matter claims. On November 30, 2012, the Supreme Court granted the petition and agreed to review the case. On June 13, 2013, the Supreme Court issued a decision in the Myriad case. According to the decision, claims directed to genomic DNA cover unpatentable subject matter. However, claims directed to cDNA are patent eligible subject matter.

On March 4, 2014, the USPTO issued a memorandum entitled “2014 Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products”. This memorandum provides guidance to patent examiners for examining claims reciting laws of nature/natural principles, natural phenomena, and/or natural products for patent eligibility in view of the Supreme Court decisions in Prometheus and Myriad. The guidance indicates that claims reciting such natural subject matter, read as a whole, that do not significantly differ from such natural subject matter should be rejected as non-statutory subject matter. We cannot assure you that our patent portfolio or our efforts to seek patent protection for our technology and products will not be negatively impacted by the guidance issued by the USPTO, the decisions described above, rulings in other cases, or changes in guidance or procedures issued by the USPTO.

Congress directed the USPTO to study effective ways to provide independent, confirming genetic diagnostic test activity where gene patents and exclusive licensing for primary genetic diagnostic tests exist. This study will examine the impact that independent second opinion testing has on providing medical care to patients; the effect that providing independent second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test; the impact of current practices on testing results and performance; and the role of insurance coverage on the provision of genetic diagnostic tests. The USPTO was directed to report the findings of the study to Congress and provide recommendations for establishing the availability of independent confirming genetic diagnostic test activity by June 16, 2012. On August 28, 2012, the Department of Commerce sent a letter to the House and Senate Judiciary Committee leadership updating them on the status of the genetic testing report. The letter stated in part: “Given the complexity and diversity of the opinions, comments, and suggestions provided by interested parties, and the important policy considerations involved, we believe that further review, discussion, and analysis are required before a final report can be submitted to Congress.” The USPTO issued a Request for Comments and Notice of Public Hearing on Genetic Diagnostic Testing on January 25, 2012, and held additional public hearings in February and March 2013. It is unclear whether the results

of this study will be acted upon by the USPTO or result in Congressional efforts to change the law or process in a manner that could negatively impact our present or future patent portfolio.

There can be no assurance that the Supreme Court's decision in either the Myriad or Prometheus case will not have a negative impact on biotechnology patents generally or the ability of biotechnology companies to obtain or enforce their patents in the future. Such negative decisions by the Supreme Court could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

We also rely on trade secrets and un-patentable know-how that we seek to protect, in part, by confidentiality agreements with our employees, consultants, suppliers and licensees. These agreements may be breached, and we might not have adequate remedies for any breach. Our competitors may also independently develop technologies substantially equivalent or superior to ours. If this were to occur, our business and competitive position would suffer.

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Given our patent position in regard to our products, if we are unable to protect the confidentiality of our proprietary information and know-how related to these products, our competitive position would be impaired and our business, financial condition and results of operations could be adversely affected.

Some of our technology, including our knowledge regarding the processing our products, is unpatented and is maintained by us as trade secrets. In an effort to protect these trade secrets, we require our employees, consultants, collaborators and advisors to execute confidentiality agreements upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. These agreements, however, may not provide us with adequate protection against improper use or disclosure of confidential information, and these agreements may be breached. A breach of confidentiality could affect our competitive position. In addition, in some situations, these agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, collaborators or advisors have previous employment or consulting relationships. Also, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of our trade secrets would impair our competitive position and could have a material adverse effect on our business, financial condition and results of operations.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products or product candidates, our competitive position would be adversely affected.

With respect to MACI and ixmyelocel-T, if we are unable to obtain and enforce patents and to protect our trade secrets, others could use our technology to compete with us, which could limit opportunities for us to generate revenues by licensing our technology and selling products.

Our success will depend in part on our ability to obtain and enforce patents and maintain trade secrets in the United States and in other countries. If we are unsuccessful in obtaining and enforcing patents, our competitors could use our technology and create products that compete with our products, without paying license fees or royalties to us.

The preparation, filing, and prosecution of patent applications can be costly and time consuming. Our limited financial resources may not permit us to pursue patent protection of all of our technology and products throughout the world.

Even if we are able to obtain issued patents covering our technology or products, we may have to incur substantial legal fees and other expenses to enforce our patent rights in order to protect our technology and products from infringing uses. We may not have the financial resources to finance the litigation required to preserve our patent and trade secret rights.

A successful challenge to our trademarks could force us to rebrand Epicel, Carticel, or MACI.

We rely on our trademarks to distinguish our products from the products of our competitors, and have registered or applied to register a number of these trademarks. Third parties may challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing these new brands.

Intellectual property litigation could harm our business. We may be subject to patent infringement claims that could be costly to defend, which may limit our ability to use disputed technologies, and which could prevent us from pursuing research and development or commercialization of some of our products, require us to pay licensing fees to have freedom to operate and/or result in monetary damages or other liability for us.

The success of our business will depend significantly on our ability to operate without infringing patents and other proprietary rights of others. Our cell processing system and cell compositions utilize a wide variety of technologies and we can give no assurance that we have identified or can identify all inventions and patents that may be infringed by development and manufacture of our cell

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compositions. If the technology that we use infringes a patent held by others, we could be sued for monetary damages by the patent holder or its licensee, or we could be prevented from continuing research, development, and commercialization of products that rely on that technology, unless we are able to obtain a license to use the patent. The cost and availability of a license to a patent cannot be predicted, and the likelihood of obtaining a license at an acceptable cost would be lower if the patent holder or any of its licensees is using the patent to develop or market a product with which any of our existing product candidates or our products would compete. If we could not obtain a necessary license, we would need to develop or obtain rights to alternative technologies, which could prove costly and could cause delays in product development, or we could be forced to discontinue the development or marketing of any products that were developed using the technology covered by the patent.

Although we have not been subject to any filed infringement claims, patents could exist or could be filed which would prohibit or limit our ability to market our products or maintain our competitive position. In the event of an intellectual property dispute, we may be forced to litigate. Such litigation is typically protracted and the results are unpredictable. Intellectual property litigation would divert management's attention from developing our products and would force us to incur substantial costs regardless of whether we are successful. An adverse outcome could subject us to significant liabilities to third parties including treble damages and the opposing party's attorney fees, and force us to pay significant license fees and royalties or cease the development and sale of our products and processes.

We have hired and expect to continue to hire individuals who have experience in cell culture and cell based therapeutics and may have confidential trade secret or proprietary information of third parties. We caution these individuals not to use or reveal this third-party information, but we cannot assure you that these individuals will not use or reveal this third-party information. Thus, we could be sued for misappropriation of proprietary information and trade secrets. Such claims are expensive to defend and could divert our attention and could result in substantial damage awards and injunctions that could have a material adverse effect on our business, financial condition or results of operations.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful and have a material adverse effect on the success of our business.

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Also, third parties may initiate legal proceedings against us to challenge the validity or scope of intellectual property rights we own or control. These proceedings can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property.

Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on our business, financial condition or results of operations.

If we infringe the rights of third parties we could be prevented from selling products, forced to pay damages, and defend against litigation.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to: obtain licenses, which may not be available on commercially reasonable terms, if at all; abandon an infringing product; redesign our products or processes to avoid infringement; stop using the subject matter claimed in the patents held by others; pay damages; and/or defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

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Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make products that are the same as or similar to our products or product candidates, but that are not covered by the claims of the patents that we own or have exclusively licensed;
- We or any strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;
- We might not have been the first to file patent applications covering certain of our inventions;
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- It is possible that our pending patent applications will not lead to issued patents;
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- Our competitors might conduct research and development activities in the U.S. and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- We may not develop additional proprietary technologies that are patentable; and
- The patents of others may have an adverse effect on our business.

Others may challenge our patent or other intellectual property rights or sue us for infringement.

The government maintains certain rights in technology that we develop using government grant money and we may lose the revenues from such technology if we do not commercialize and utilize the technology pursuant to established government guidelines.

Certain of our and our licensors' research have been or are being funded in part by government grants. As a result of such funding, the United States government has established guidelines and has certain rights in the technology developed with the grant. These rights include a non-exclusive, fully paid-up, worldwide license under such inventions for any governmental purpose. In addition, the United States government has the right to require us to grant an exclusive license under any of such inventions to a third party if the United States government determines that: (i) adequate steps have not been taken to commercialize such inventions; (ii) such action is necessary to meet public health or safety needs; or (iii) such action is necessary to meet requirements for public use under federal regulations. Additionally, under the federal Bayh Dole Act, a party which acquires an exclusive license for an invention that was partially funded by a federal research grant is subject to the following government rights: (x) products using the invention which are sold in the United States are to be manufactured substantially in the United States, unless a waiver is obtained; (y) the government may force the granting of a license to a third party who will make and sell the needed product if the licensee does not pursue reasonable commercialization of a needed product using the invention; and (z) the United States government may use the invention for its own needs. If we fail to meet these guidelines, we would lose our exclusive rights to these products, and we would lose potential revenue derived from the sale of these products.

The use of our products and product candidates may expose us to product liability claims, and we may not be able to obtain adequate insurance. As a result, such claims could affect our earnings and financial condition.

We face an inherent business risk of exposure to product liability claims in the event that the manufacture and/or use of our products during clinical trials, or after commercialization, results in adverse events. Moreover, we derive the raw materials for our products from patients serving as their own donors, the production process is complex, and the handling requirements are specific, all of which increase the likelihood of quality failures and subsequent product liability claims. We may not be able to obtain or maintain product liability insurance on acceptable terms with adequate coverage or at all. If we are unable to obtain insurance, or if claims against us substantially exceed our coverage, then our business could be adversely impacted. Excessive insurance costs or uninsured claims would increase our operating loss and adversely affect our financial condition. Whether or not we are ultimately successful in any product liability litigation, such litigation could consume substantial amounts of our financial and managerial resources and could result in, among other things:

- Significant awards against us;
- Substantial litigation costs;
- Recall of the product;
- Injury to our reputation;

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- Withdrawal of clinical trial participants; or
- Adverse regulatory action.

Any of these results could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to an Investment in our Common Stock

We have identified a material weakness in our internal control over financial reporting. If we fail to remediate this material weakness and implement and maintain proper and effective internal control over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our common stock.

We identified a material weakness in the operation of our internal controls over financial reporting as of June 30, 2014. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness relates to the evaluation of significant transactions and the financial close process. Specifically, we did not have a sufficient level of accounting and supervisory personnel nor did we have the appropriate level of technical accounting experience and training necessary for our financial reporting requirements during this period. This material weakness contributed to adjustments identified by our independent registered public accounting firm during the quarter ended June 30, 2014 and still existed as of December 31, 2014. We have commenced efforts to remediate this material weakness through process and internal control improvements. However, if we cannot correct the material weakness we have identified, or if we experience other material weaknesses investor confidence and our stock price could be adversely affected. Further, if material weaknesses or deficiencies in our internal controls exist and go undetected, our financial statements could contain material misstatements that, when discovered in the future, could cause us to fail to meet our future reporting obligations and cause the price of our common stock to decline.

The market price of the common stock of the combined company may be affected by factors different from those affecting the market price for our common stock in recent history.

Our business in recent history differs from that of the CTRM business, and our current combined business differs from recent history, and accordingly, the results of operations for the combined company may be affected by factors different from those affecting our results of operation in recent history. As a result, the market price for our stock may be impacted differently in the future by those factors than it is currently.

Our common stock price has been volatile and future sales of shares of common stock could have an adverse effect on the market price of such shares.

The market price of shares of our common stock has been volatile, ranging in closing price between $2.61 and $6.49 during the year ended December 31, 2014. The price of our common stock may continue to fluctuate in response to a number of events and factors, such as:

- Clinical trial results;
- Our inability to successfully integrate the acquired business with our existing business;
- The amount of our cash resources and our ability to obtain additional funding;
- Announcements of research activities, business developments, technological innovations or new products by us or our competitors;

- Entering into or terminating strategic relationships;
- Regulatory developments in both the United States and abroad;
- Disputes concerning patents or proprietary rights;
- Changes in our revenues or expense levels;
- Seasonal or other variations in patient demand for Carticel and Epicel;
- Public concern regarding the safety, efficacy or other aspects of the products or methodologies we are developing;
- News or reports from other stem cell, cell therapy or regenerative medicine companies;
- Reports by securities analysts;
- Status of the investment markets;
- Concerns related to management transitions; and
- Delisting from The NASDAQ Capital Market.

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Any of these events may cause the price of our shares to fall, which may adversely affect our business and financing opportunities. In addition, the stock market in general and the market prices for biotechnology companies in particular have experienced significant volatility recently that often has been unrelated to the operating performance or financial conditions of such companies. These broad market and industry fluctuations may adversely affect the trading price of our common stock, regardless of our operating performance or prospects.

Our failure to meet the continued listing requirements of The NASDAQ Capital Market could result in a de-listing of our common stock.

If we fail to satisfy the continued listing requirements of The NASDAQ Capital Market, such as the corporate governance requirements or the minimum closing bid price requirement, NASDAQ may take steps to de-list our common stock. Such a de-listing would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a de-listing, we would take actions to restore our compliance with NASDAQ's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the NASDAQ minimum bid price requirement or prevent future non-compliance with NASDAQ's listing requirements.

The sale of our common stock through future equity offerings may cause dilution and could cause the price of our common stock to decline.

In the year-ended December 31, 2014, we sold (i) an aggregate gross amount of approximately $7.1 million worth of shares of common stock pursuant to our At-the-Market Sales Agreement (ATM) with MLV (ii) an aggregate of approximately $3.7 million worth of shares of our common stock to Lincoln Park pursuant to the Lincoln Park Equity Line, and (iii) on September 17, 2014, we sold 15.8 million shares of common stock under a Form S-1 registration statement and pursuant to a prospectus first made available on September 11, 2014. During 2013, we sold (i) an aggregate of approximately $5.2 million of shares of common stock pursuant to our ATM through December 31, 2013, and (ii) in August 2013, we sold 1.5 million shares of common stock and warrants to purchase up to 1.5 million shares of common stock under a Form S-1 registration statement and pursuant to a prospectus supplement first made available on August 14, 2013. The ATM, which as of December 31, 2014 had remaining capacity of approximately $7.8 million, allowed us to sell our common stock from time to time under a registration statement on Form S-3 filed in June 2011, pursuant to which we registered $100 million of our securities for public sale. The Form S-3 registration statement filed in June 2011 expired in July 2014. Additionally, pursuant to the Lincoln Park Equity Line we may direct Lincoln Park to purchase up to $15 million worth of shares of our common stock over a 30-month period generally in amounts up to 50 thousand shares of our common stock. As of December 31, 2014, we had remaining capacity of approximately $11.3 million worth of shares under the Lincoln Park Equity Line. However, there are certain factors, such as volume of trading in our common stock, our stock price and the ability to terminate the agreement with notice, which limit the amount that can be raised in a short period of time through the Lincoln Park Equity Line.

Sales of our common stock offered through future equity offerings may result in substantial dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock to investors, 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.

We do not anticipate paying dividends on our common stock, and accordingly, shareholders must rely on stock appreciation for any return on their investment.

We have never declared or paid cash dividends on our common stock and do not expect to do so in the foreseeable future. The declaration of dividends is subject to the discretion of our board of directors and will depend on various factors, including our operating results, financial condition, future prospects and any other factors deemed relevant by our board of directors. You should not rely on an investment in our company if you require dividend income from your investment in our company. The success of your investment will likely depend entirely upon any future appreciation of the market price of our common stock, which is uncertain and unpredictable. There is no guarantee that our common stock will appreciate in value.

We expect that our quarterly results of operations will fluctuate, and this fluctuation could cause our stock price to decline.

Our quarterly operating results are likely to fluctuate in the future. These fluctuations could cause our stock price to decline. The nature of our business involves variable factors, such as the timing of the research, development and regulatory pathways of our product candidates, which could cause our operating results to fluctuate.

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Due to the possibility of fluctuations in our revenues and expenses, we believe that quarter-to-quarter comparisons of our operating results are not a good indication of our future performance.

Efforts to comply with recently enacted changes in securities laws and regulations will increase our costs and require additional management resources, and we still may fail to comply.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the Securities and Exchange Commission (SEC) adopted rules requiring public companies to include a report of management on their internal controls over financial reporting in their annual reports on Form 10-K. In addition, in the event we are no longer a smaller reporting company, the independent registered public accounting firm auditing our financial statements would be required to attest to the effectiveness of our internal controls over financial reporting. If we are unable to conclude that we have effective internal controls over financial reporting or if our independent registered public accounting firm is required to, but is unable to provide us with a report as to the effectiveness of our internal controls over financial reporting, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our securities.

If our common stock becomes subject to the SEC's penny stock rules, broker-dealers may experience difficulty in completing customer transactions and trading activity in our securities may be adversely affected.

If at any time our securities are no longer listed on a national securities exchange, including The NASDAQ Stock Market, or we have net tangible assets of $5.0 million or less and our common stock has a market price per share of less than $5.00, transactions in our common stock will be subject to the SEC's "penny stock" rules. If our common stock becomes subject to the "penny stock" rules promulgated under the Securities Exchange Act of 1934, as amended, broker-dealers may find it difficult to effectuate customer transactions and trading activity in our securities may be adversely affected. For any transaction involving a penny stock, unless exempt, the rules require:

- That a broker or dealer approve a person's account for transactions in penny stocks; and
- The broker or dealer receives from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must:

- Obtain financial information and investment experience objectives of the person; and
- Make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which, in highlight form:

- Sets forth the basis on which the broker or dealer made the suitability determination; and
- That the broker or dealer received a signed, written agreement from the investor prior to the transaction.

Generally, brokers may be less willing to execute transactions in securities subject to the "penny stock" rules. This may make it more difficult for investors to dispose of our common stock and cause a decline in the market value of our stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker-dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

Our corporate documents and Michigan law contain provisions that may make it more difficult for us to be acquired.

Our Board of Directors (Board) has the authority, without shareholder approval, to issue additional shares of preferred stock and to fix the rights, preferences, privileges and restrictions of these shares without any further vote or action by our shareholders. Michigan law contains a provision that makes it more difficult for a 10% shareholder, or its officers, to acquire a company. This authority, together with certain provisions of our charter documents, may have the effect of making it more difficult for a third party to acquire, or of discouraging a third-party from attempting to acquire, control of our company. This effect could occur even if our shareholders consider the change in control to be in their best interest. We have adopted a shareholder rights plan, the purpose of which is, among other things, to enhance our Board's ability to protect shareholder interests and to ensure that shareholders receive fair treatment in the event any coercive takeover attempt of our company is made in the future. The shareholder rights plan could make it more difficult for

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a third party to acquire, or could discourage a third party from acquiring, our company or a large block of our company's common stock.

Item 1B. ***Unresolved Staff Comments***

Not applicable.

Item 2. ***Properties***

We lease approximately 26,000 square feet in Ann Arbor, Michigan and 50,000 square feet in Cambridge, Massachusetts. In conjunction with the acquisition of the CTRM Business, the company also assumed the leases for the facility in Kastrup, Denmark. The Ann Arbor lease agreement expires in April 2018 and the Cambridge and Kastrup leases expire in February 2017. The facilities include clean rooms, laboratories and office space. We believe that our facilities are adequate to meet our current needs. We believe that our facilities are adequate for our current needs. Additional facilities may be required to support expansion for research and development activities or to assume manufacturing operations that are currently fulfilled through contract manufacturing relationships.

Item 3. ***Legal Proceedings***

We are currently not party to any material legal proceedings, although from time to time we may become involved in disputes in connection with the operation of our business.

Item 4. ***Mine Safety Disclosures***

Not applicable.

PART II

Item 5. ***Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchase of Equity Securities***

Our common stock is currently quoted on the NASDAQ Capital Market under the symbol "VCEL". The following table sets forth the high and low closing prices per share of common stock as reported on the NASDAQ Stock Market. Prices per share of our common stock have been adjusted for the twenty-for-one reverse stock split on October 16, 2013 on a retroactive basis.

Price Range of Common Stock

	High	Low
Year ended December 31, 2013		
First Quarter	$ 28.20	$ 14.00
Second Quarter	16.00	8.02
Third Quarter	15.48	5.40
Fourth Quarter	5.80	3.21
Year ended December 31, 2014		
First Quarter	$ 6.49	$ 3.31
Second Quarter	5.05	3.51
Third Quarter	4.08	2.61
Fourth Quarter	3.04	2.68

As of February 28, 2015 there were approximately 426 holders of record of the common stock. We have never paid any cash dividends on our common stock and we do not anticipate paying such cash dividends in the foreseeable future. We currently anticipate that we will retain all future earnings, if any, for use in the development of our business.

Equity Compensation Plan Information as of December 31, 2014

The following table sets forth information as of December 31, 2014 with respect to compensation plans (including individual compensation arrangements) under which equity securities are authorized for issuances:

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	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans
Equity compensation plans approved by security holders (employees and directors)(1)	477,530	$ 21.74	4,011,608

(1) The material features of these securities are described in Note 7 of the Consolidated Financial Statements.

(2) Shares issuable under the 2009 Omnibus Incentive Plan.

Recent Sales of Unregistered Securities

The following is a summary of all securities that we have sold within the past three years without registration under the Securities Act of 1933, as amended.

On March 9, 2012, the Company entered into a Securities Purchase Agreement with Eastern Capital Limited, a Cayman exempted company ("ECL"), to sell 12,308 shares of Series B-1 Non-Voting Preferred Stock in a private placement to ECL, an "accredited investor" (as defined in Regulation D) under the Securities Act, at a price of $3,250.00 per share. The Series B-1 Shares were exchanged on a one-for-one basis for shares of the Series B-2 Voting Preferred Stock of the Company. The sales of the shares of Series B preferred stock were made only to a select number of accredited investors in reliance upon the exemptions from registration afforded by Rule 506 of Regulation D as promulgated by the SEC under the Securities Act and/or Section 4(2) of the Securities Act.

On June 27, 2012, the Company entered into separate warrant exchange agreements with each of certain holders of the Company's outstanding warrants to purchase the Company's common stock, issued in connection with the Company's December 2010 public offering, with an exercise price of $64.40 and an expiration date of December 15, 2015. Pursuant to such warrant exchange agreements, on June 27, 2012, the Company issued an aggregate of 191,667 shares of common stock to Great Point Partners and its affiliated investment funds, Heights Capital Management and its affiliated investment funds, Deerfield Capital and its affiliated investment funds, and Millenium Management and its affiliated investment funds in exchange for the surrender of an aggregate of 383,333 warrants.

On July 30, 2012, the Company announced the results of its previously announced offer to exchange (the "Exchange Offer") any warrant to purchase shares of common stock, no par value per share, of the Company issued in connection with the Company's December 2010 public offering, which was tendered and accepted, for shares of the Company's common stock. Such Exchange Offer was made upon the terms and subject to the conditions set forth in the Company's offer to exchange, dated June 28, 2012, and in the related Exchange Offer materials filed as exhibits to the Tender Offer Statement on

Schedule TO originally filed with the Securities and Exchange Commission on June 28, 2012, as amended. The Exchange Offer expired at 5:00 p.m., Eastern Standard Time, on Friday, July 27, 2012.

The issuance of shares of Common Stock in the warrant exchanges was made pursuant to the exemption from the registration requirements of the Securities Act of 1933, as amended, provided by Section 3(a)(9) of the Securities Act. No proceeds were received and no commissions were paid by the Company in connection with the Exchange Offer.

On January 21, 2014, we completed a private placement to Lincoln Park Capital Fund, LLC pursuant to which we have the right to sell to Lincoln Park up to $15.0 million in shares of common stock, subject to certain limitations, from time to time over the 30-month period commencing on the date that a registration statement covering the resale of the shares is declared effective by the SEC. In connection with the private placement, we issued to Lincoln Park, 48,063 shares of common stock as an initial commitment consideration. The issuance and sale of common shares by us to Lincoln Park was made without registration under the Securities Act in reliance on the exemptions provided by Section 4(2) of the Act and Regulation D promulgated thereunder based on the offering of such securities to one investor, the lack of any general solicitation or advertising in connection with such issuance, the representation of such investor that it was an "accredited investor" (as defined in Regulation D) under the Securities Act and that it was purchasing the shares for its own account and without a view to distribute them.

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Issuer Purchases of Equity Securities

There were no repurchases of shares of common stock made during the year ended December 31, 2014.

Item 6. ***Selected Financial Data***

Not applicable.

Item 7. ***Management's Discussion and Analysis of Financial Condition and Results of Operations***

Overview

Vericel Corporation is a leader in developing patient-specific expanded cellular therapies for use in the treatment of patients with severe diseases and conditions. We market two autologous cell therapy products in the United States: Carticel® (autologous cultured chondrocytes), an autologous chondrocyte implant for the treatment of cartilage defects in the knee, and Epicel® (cultured epidermal autografts), a permanent skin replacement for the treatment of patients with deep-dermal or full-thickness burns comprising greater than or equal to 30 percent of total body surface area. We are also developing MACI™, a third-generation autologous chondrocyte implant for the treatment of cartilage defects in the knee, and ixmyelocel-T, a patient-specific multicellular therapy for the treatment of advanced heart failure due to ischemic dilated cardiomyopathy.

Acquisition of Sanofi's CTRM Business

On May 30, 2014, we completed the acquisition of Sanofi's Cell Therapy and Regenerative Medicine (CTRM) business, certain assets, including all of the outstanding equity interests of Genzyme Biosurgery ApS (now known as Åström BIOSCIENCES DK ApS)(the Danish subsidiary), a wholly-owned subsidiary of Sanofi and over 250 patents and patent applications of the seller and certain of its subsidiaries and assumed certain liabilities for purposes of acquiring a portion of the CTRM business, which researches, develops, manufactures, markets and sells Carticel, MACI and Epicel (the CTRM Transaction). In consideration for the acquisition of the CTRM business, we paid a total purchase price of approximately $6.5 million, as follows: (a) $4 million was paid in cash on the closing date of the CTRM Transaction, and (b) a $2.5 million promissory note which was paid on July 30, 2014.

Concurrent with the closing of the CTRM Transaction, we and Sanofi entered into (i) certain IP assignment and license agreements to effect the transfer and license of the intellectual property related to the CTRM Business assigned and/or licensed to us, (ii) certain assignment and assumption of lease agreements for each of the real property leases being assigned to us, and (iii) transition services and transition supply agreements.

In consideration for the acquisition of the CTRM Business, we paid a total purchase price of approximately $6.5 million, as follows: (a) $4.0 million was paid in cash on the closing date of the CTRM Transaction, and (b) a $2.5 million promissory note which we repaid on July 30, 2014. In accordance with generally accepted accounting principles in the United States of America (U.S. GAAP), we recorded the assets and liabilities of the CTRM Business at fair value. The net assets of the CTRM Business were preliminarily valued at $10.0 million, which is in excess of the $6.5 million purchase price, which resulted in a $3.5 million bargain purchase gain. The primary driving factor for the bargain purchase gain was the structure of the CTRM Transaction. As part of the CTRM Transaction, Sanofi funded the Danish subsidiary with $5.0 million in cash in order to fund the restructuring of the Denmark operations and close the facility. Under U.S. GAAP, no restructuring actions were taken by Sanofi prior to our purchase of the CTRM Business, and accordingly, there were no restructuring related accruals in the opening balance sheet. Additionally, there were no restrictions on the use of the cash in the Danish subsidiary. We implemented our restructuring plans for the Danish subsidiary after the consummation of the CTRM Transaction, and accordingly, have recorded restructuring charges in our current period results of operations. As of December 31, 2014, we have recorded restructuring charges of $3.0 million and do not expect to incur additional costs. See Note 5, "Restructuring" of the Consolidated Financial Statements for additional information.

Manufacturing

We acquired two cell-manufacturing facilities as part of the acquisition of the CTRM Business in Cambridge, Massachusetts and Copenhagen, Denmark. The Cambridge facility, which is approved by the U.S. Food and Drug Administration (FDA), is used for U.S. manufacturing and distribution of Carticel, Epicel manufacturing and also manufactured MACI for the SUMMIT study conducted for approval in Europe. The Copenhagen manufacturing facility, which was approved by the Danish Medicines Agency (DKMA), was responsible for MACI manufacturing and distribution in Europe. As part of the June 2014 restructuring, we discontinued MACI manufacturing at the Copenhagen manufacturing facility. Going forward, we expect that any clinical and commercial production of MACI will occur at our Cambridge facility. We also operate a centralized cell manufacturing facility in Ann Arbor, Michigan. The

facility supports the current ixCELL-DCM clinical trial being conducted in the United States and Canada and we believe we have sufficient capacity, with minor modifications, to supply our early commercialization requirements.

Product Portfolio

Our approved and marketed products were acquired through the CTRM Transaction and include three approved autologous cell therapy products, each of which are further described below: Carticel (autologous cultured chondrocytes), a first-generation product for autologous chondrocyte implantation (ACI) currently marketed in the U.S., MACI (matrix-applied characterized autologous cultured chondrocytes), a third-generation ACI product, and Epicel (cultured epidermal autografts), a permanent skin replacement for full thickness burns greater than or equal to 30% of total body surface area. Our product candidate portfolio also includes ixmyelocel-T, a patient-specific multicellular therapy currently in development for the treatment of advanced heart failure due to ischemic dilated cardiomyopathy (DCM).

Carticel

Carticel, a first-generation ACI product for the treatment and repair of cartilage defects in the knee, is the first and only FDA-approved autologous cartilage repair product. Carticel is indicated for the repair of symptomatic cartilage defects of the femoral condyle (medial, lateral or trochlea) caused by acute or repetitive trauma, in patients who have had an inadequate response to a prior arthroscopic or other surgical repair procedure such as debridement, microfracture, drilling/abrasion arthroplasty, or osteochondral allograft/autograft. Carticel received a Biologics License Application (BLA) approval in 1997 and is currently marketed in the U.S. It is generally used on patients with larger lesions (greater than 3 cm^2).

In the U.S., we focus net sales of Carticel on the sports-injury-targeted orthopedic physician target audience, which is very concentrated, with 60% of the current Carticel business originating from 25% of this audience, or approximately 110 physicians. We currently have a 21-person field force calling on this sports-injury targeted orthopedic physician audience.

Epicel

Epicel is a permanent skin replacement for full thickness burns greater than or equal to 30% of total body surface area (TBSA). Epicel is regulated by the CBER under medical device authorities, and is the only FDA-approved autologous epidermal product available for large total surface area burns. Epicel was designed as a HUD in 1998 and a HDE application for the product was submitted in 1999. HUDs are devices that are intended for diseases or conditions that affect or are manifested in fewer than 4,000 individuals annually in the United States. Currently, approximately less than 100 patients are treated with Epicel in the U.S. each year. In the year ended December 31, 2014, net revenues were $9.5 million for Epicel which represents the entire year net sales pre and post the Transaction.

Under the HDE approval of 2007, Epicel cannot not be sold for an amount that exceeds the cost of research and development, fabrication and distribution. However, pursuant to the Pediatric Medical Device Safety and Improvement Act of 2007 and the FDA Safety and Innovation Act of 2012 (FDASIA), a HUD can be sold for profit if certain conditions are met. Under current law as amended by FDASIA, an HDE holder can make a profit on its HUD after receiving HDE approval if the device is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe. If the FDA makes a determination that a HUD meets the eligibility criteria, the HUD is permitted to be sold for profit after receiving HDE approval as long as the number of devices distributed in any calendar year does not exceed the Annual Distribution Number (ADN) for the device. The ADN is determined by FDA when it approves the original HDE application, or when the agency approves an HDE supplement for an HDE approved before the enactment of FDASIA, if the HDE holder seeks a determination for the HUD in an HDE supplement based upon the profit-making eligibility criteria, and FDA determines that the HUD meets the eligibility criteria.

We are currently investigating Epicel's eligibility for an exemption from the profit prohibition and have requested a pre-submission meeting with the FDA to discuss the process and required data for submitting an HDE supplement to obtain an exemption from the profit prohibition.

Epicel is currently being sold at a price that reflects the cost of research and development, fabrication and distribution.

Also, up until July, 2014, we had one sales representative selling Epicel and two partially dedicated Medical Scientific Liaisons supporting Epicel inquiries.

MACI

MACI is a third-generation ACI product for the treatment of focal chondral cartilage defects in the knee. MACI received marketing authorization in Europe in July 2013 by meeting the requirements of the Advanced Therapy and Medicinal Product (ATMP) guidelines. MACI has been commercially available in the EU since 1998. As part of the June 2014 restructuring we temporarily suspended sales of MACI in August 2014, primarily due to low utilization and an unfavorable pricing environment. We believe that MACI has significant revenue potential in the U.S., and we are planning to discuss approval requirements with the FDA. The timing and process to gain approval in the U.S. is the subject of a Type B meeting with the FDA which is scheduled for the middle of the second quarter. The timing and strategy for and a possible reintroduction in select EU countries have not yet been determined.

MACI was obtained by Sanofi by acquiring Verigen AG (Verigen) in 2005. As part of Sanofi's acquisition of Verigen, Sanofi agreed to make cash payments to Verigen upon the achievement of developmental milestones relating to regulatory and commercialization of MACI in the United States. In connection with our acquisition of the CTRM business from Sanofi, we agreed that if we further developed MACI in the U.S., we would be obligated to pay these milestone payments. During the third quarter of 2014, at the request of the Company, Sanofi entered into a settlement agreement with the former shareholders of Verigen whereby these shareholders agreed to discharge all obligations related to these MACI milestone payments in exchange for a one-time

cash payment of €2.5 million (approximately $3.2 million) due within two months from the date of the settlement agreement. We paid this amount in full on October 17, 2014.

Ixmyelocel-T

Our preapproval stage portfolio also includes ixmyelocel-T, a unique patient-specific multicellular therapy derived from an adult patient's own bone marrow which utilizes our proprietary, highly automated and scalable manufacturing system. Our proprietary cell manufacturing process significantly expands the mesenchymal stromal cells (MSCS) and M2-like anti-inflammatory macrophages in the patient's bone marrow mononuclear cells while retaining many of the hematopoietic cells. These cell types are known to regulate the immune response and play a key role in tissue repair and regeneration by resolving pathologic inflammation, promoting angiogenesis, and remodeling ischemic tissue. The novelty and advantage of using ixmyelocel-T is the expansion of a unique combination of cell populations, including MSCS and M2-like macrophages, which secrete a distinct combination of angiogenic and regenerative factors, and possess the ability to remain anti-inflammatory in the face of inflammatory challenge.

Our lead clinical development program for ixmyelocel-T is focused on severe, chronic ischemic cardiovascular diseases. We are currently conducting the Phase 2b ixCELL-DCM study, which is a randomized, double-blind, placebo-controlled clinical trial for patients with advanced heart failure due to ischemic DCM. Ixmyelocel-T has been granted a U.S. Orphan Drug designation by the FDA for the treatment of DCM. We also have an ongoing ixmyelocel-T clinical program for the treatment of craniofacial reconstruction and have conducted clinical studies for the treatment of critical limb ischemia.

The ongoing Phase 2b ixCELL-DCM clinical study has treated 114 patients at 28 sites in the U.S. and Canada. Patients will be followed for 12 months for the primary efficacy endpoint of MACE events, defined as all-cause deaths, all-cause hospitalizations, and unplanned outpatient or emergency department visits for IV treatment of acute worsening heart failure. Secondary endpoints include clinical, functional, structural, symptomatic, quality of life, and biomarker measures at 3, 6 and 9 months. Patients will be followed for an additional 12 months for safety. We completed enrollment of the ixCELL-DCM study in January 2015, and expect to have top-line efficacy results around the end of the first quarter of 2016.

Results of Operations

We have exited the "Developmental Stage" and are a "Commercial Stage" company following the acquisition of the CTRM Business on May 30, 2014 and the initiation of commercial sales of bone marrow from our wholly owned subsidiary Marrow Donation LLC (Marrow Donation) in June 2014.

Net Loss

Our net loss for the year ended December 31, 2014 totaled $19.9 million or $2.23 per share. Results for the year ended December 31, 2014 include seven months of operating results of the CTRM Business which resulted in net income of $0.4 million. The results below include restructuring charges in the US and Denmark of $3.0 million of which $2.5 million were recorded in cost of product sales and $0.5 million was recorded in selling, general and administrative expenses, other expenses for our discontinued Denmark business of $0.4 million and a bargain purchase gain of approximately $3.5 million.

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(In thousands)	Year Ended December 31, 2014	2013
Total revenues	$ 28,796	$ 19
Cost of product sales	17,293	4
Gross profit (loss)	11,503	15
Total operating expenses	35,037	20,979
Income (loss) from operations	(23,534)	(20,964)
Other income (expense)	141	5,342
Bargain purchase gain	3,473	—
Total other income	3,614	5,342
Net income (loss)	$ (19,920)	$ (15,622)

Net Revenues

Net revenues for the year ended December 31, 2014 and 2013 are shown below.

Revenue by product (In thousands)	Year Ended December 31, 2014	2013
Carticel	$ 22,267	$ —
Epicel	5,989	—
Bone Marrow	354	—
MACI	186	—
Other	—	19
	$ 28,796	$ 19

Net revenues for the year ended December 31, 2014 reflect seven months of results from commercial operations of the CTRM Business. Period comparisons for net revenues are not yet meaningful due to the acquisition of the CTRM Business.

Seasonality. Carticel revenue is subject to seasonal fluctuations with stronger sales occurring in the fourth quarter and second quarter due to a number of factors including insurance copay limits and the time of year patients prefer to start rehabilitation. Over the last four years, the percentage of annual sales by quarter has ranged as follows: first quarter, 22% to 24%; second quarter, 24% to 25%; third quarter, 21% to 23%; and fourth quarter, 29% to 33%. Epicel revenue is also subject to seasonal fluctuations mostly associated with the use of heating elements during the colder months, with stronger sales occurring in the winter months of the first and fourth quarters, and weaker sales occurring in the hot summer months of the third quarter. However, in any single year, this trend can be absent due to the extreme variability inherent with Epicel's low patient volume of fewer than 100 patients per year. Over the last four years, the

percentage of annual sales by quarter has ranged as follows: first quarter, 28%; second quarter, 24%; third quarter, 20%; and fourth quarter, 28%. The variability between the same quarters in consecutive years has been as high as 10% of the annual volume. While the number of patients treated per year remains low, we expect these large swings in revenue in some quarters to continue. These seasonal trends have caused and will likely continue to cause, fluctuations in our quarterly results, including fluctuations in sequential revenue growth rates.

Gross Profit and Gross Profit Ratio

(In thousands)	Year Ended December 31, 2014
Gross profit	$ 11,503
Gross profit %	40%

Period comparisons for gross profit are not yet meaningful due to the acquisition of the CTRM Business. Gross Profit for the year ended December 31, 2014 included $2.5 million of restructuring expenses which reduced the gross profit margin by 10 percentage points for the year ended December 31, 2014.

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Research and Development Costs

(In thousands)	Year Ended December 31, 2014	2013
Research and development costs	$ 21,263	$ 15,104

Research and development expenses for the year ended December 31, 2014 were $21.3 million versus $15.1 million for the same period a year ago. The increase in research and development expenses resulted from $7.2 million in increased expenses for the ixCELL-DCM clinical trial, $4.3 million expenses for MACI (including $3.2 million for the Verigen agreement), $0.6 million of expenses for Epicel, $0.5 million of expenses for Carticel all offset by a $6.4 million reduction in the CLI clinical trial expenses. DCM trial expenses increased in 2014 versus 2013 since most patients were enrolled and treated in 2014. For CLI, we completed the trial in early 2014 trial and as a result, expenses declined.

Our major ongoing research and development program is focused on the clinical development of ixmyelocel-T for treatment of advanced heart failure due to ischemic DCM. The following table summarizes the approximate allocation of cost for our research and development projects:

(In thousands)	Year Ended December 31, 2014	2013
Dilated Cardiomyopathy	$ 15,099	$ 7,881
Critical Limb Ischemia	801	7,223
MACI	3,752	—
Carticel	1,008	—
Epicel	603	—
Total research and development expenses	$ 21,263	$ 15,104

Selling, General and Administrative Costs

(In thousands)	Year Ended December 31, 2014	2013
Selling, general and administrative costs	$ 13,774	$ 5,875

Selling, general and administrative expenses for the years ended December 31, 2014 and 2013 were $13.8 million and $5.9 million, respectively. The increase in expenses is primarily due to approximately $5.4 million in sales and marketing expenses from the CTRM Business, approximately $1.6 million in increased information technology, legal, consulting and personnel costs related to integrating and managing the CTRM Business in the U.S., an increase of approximately $0.5 million in restructuring charges, and $1.4 million in general administrative costs from the Danish subsidiary, which has ceased manufacturing operations net of a reduction of $1.1 million in the acquired leased facility restoration obligation in Denmark. Neither the CTRM Business nor the Danish operations were part of our business in 2013.

Other Income (Expense)

(In thousands)	Year Ended December 31, 2014	2013
(Increase) decrease in fair value of warrants	$ (27)	$ 5,337
Bargain purchase gain	3,473	—
Foreign currency translation gain	152	—
Net interest income	18	5
Other income	(2)	—
Total Other Income (expense)	$ 3,614	$ 5,342

The increase in warrant value for the year ended December 31, 2014 compared to 2013 was primarily due to the reduction of warrants outstanding due to the exercise of warrants in July 2014 partially offset by the reduction in the time to maturity and change in our stock price in the period. Fluctuations in the fair value of the warrants due to the reduction in the time to maturity and change in our stock price in the future periods could result in significant non-cash adjustments to the condensed combined consolidated financial statements, however, any income or expense recorded will not impact our cash, operating expenses, or cash flow.

The bargain purchase gain of $3.5 million for the year ended December 31, 2014 is associated with the acquisition of the CTRM Business on May 30, 2014.

The foreign currency translation gain was the result of the strengthening U.S. dollar and its impact on intercompany balances with the Danish subsidiary.

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Stock Compensation

Non-cash stock-based compensation expense included in research and development expenses and general, selling and administrative expenses is summarized in the following table:

(in thousands)	Years Ended December 31, 2014	2013
Research and development	$ 197	$ 75
General, selling and administrative	642	851
Total non-cash stock-based compensation expense	$ 839	$ 926

Non-cash stock-based compensation expense for the years ended December 31, 2014 and 2013 were consistent.

Liquidity and Capital Resources

We are currently focused on utilizing our technology to identify, develop and commercialize innovative therapies that enable the body to repair and regenerate damaged tissues and organs to restore normal structure and function. Until such time as we satisfy, if at all, applicable regulatory approval requirements for ixmyelocel-T and MACI, we expect the sales of Carticel and Epicel therapies to constitute nearly all of our product sales revenues. Additionally, we are focusing significant resources to successfully integrate and grow our CTRM Business.

While we believe we will achieve positive cash flow without needing to raise additional capital, we do not expect to generate positive cash flows from our consolidated operations for at least a year and then only if we achieve some combination of significant product sales growth, improved product margins, and lower selling, general and administrative expenses and research and development expenses.

We have raised significant funds in order to complete our product development programs, and complete clinical trials needed to market and commercialize our products. To date, we have financed our operations primarily through public and private sales of our equity securities. On September 17, 2014, we completed the sale of 15,784,313 shares of common stock at an offering price of $2.55 per share, and received net proceeds of $37.5 million. While we believe this amount of cash will be sufficient to sustain operations until we become cash flow positive, if actual results differ from our projections, we may need to access additional capital. We have access to certain amounts of financing through an agreement with Lincoln Park Capital Fund, LLC (Lincoln Park). We may direct Lincoln Park to purchase up to $15.0 million worth of shares of our common stock over a 30-month period generally in amounts up to 50,000 shares of our common stock on certain business days under a Purchase Agreement (the Purchase Agreement) we entered into with Lincoln Park on January 21, 2014 (the Lincoln Park Equity Line). As of December 31, 2014, we had issued to Lincoln Park 935,499 shares of common stock and raised $3.7 million. However, there are certain factors, such as volume of trading in our common stock and our stock price, which limit the amount that can be raised in a short period of time. The extent to which we rely on the Lincoln Park Equity Line as a source of funding will depend on a number of factors, including the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. Additionally, during the year ended December 31, 2014, we raised net proceeds of $7.1 million utilizing our at the market sales agreement (ATM) with MLV & Co., LLC. The ATM, which as of December 31, 2014 had remaining capacity of approximately $7.8 million, allowed us to sell our common stock from time to time under a registration statement on Form S-3 filed in June 2011, pursuant to which we registered $100 million of our securities for public sale. The Form S-3 registration statement filed in June 2011 expired in July 2014.

Our cash totaled $30.3 million at December 31, 2014, an increase of $22.3 million from December 31, 2013. During the year ended December 31, 2014, the primary uses of cash included $25.4 million for our operations and working capital requirements. This use of funds was fueled largely by our operating loss. Cash used in investing activities is the result of the acquisition of the CTRM Business. Cash provided by investing activities is the result of our September 2014 public offering as well as our Lincoln Park Equity Line and ATM activity.

As of December 31, 2014 we had $28.5 million of cash deposited into an Insured Cash Sweep (ICS) program which is administered by Bank of New York Mellon. This program maximizes our Federal Deposit Insurance Company (FDIC) coverage by dividing our ICS funds into amounts under the standard FDIC maximum and places these amounts with other ICS Network member banks (each an FDIC-insured institute). These funds are placed in savings accounts at the member banks earning interest while still maintaining insurance coverage.

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While the Company believes that our current cash will be sufficient to sustain operations until the business becomes cash flow positive, actual cash requirements may differ from projections and will depend on many factors, including continued scientific progress in our research and development programs, the scope and results of clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting and enforcing patents, competing technological and market developments, costs of possible acquisition or development of complementary business activities the cost of successfully integrating the CTRM Business and the cost of product commercialization. We do not expect to generate positive cash flows from operations for at least a year due to the expected spending for research and development programs and the cost of marketing and commercializing our products and product candidates.

Critical Accounting Estimates

The preparation of our consolidated financial statements in accordance with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that could materially impact the consolidated financial statements and disclosures based on varying assumptions. We believe our estimates and assumptions are reasonable; however, actual results and the timing of the recognition of such amounts could differ from these estimates.

The following is a list of accounting policies that are most significant to the portrayal of our financial condition and results of operations and/or that require management's most difficult, subjective or complex judgments.

Stock-Based Compensation — Our accounting for stock-based compensation requires us to determine the fair value of common stock issued in the form of stock option awards. We use the value of our common stock at the date of the grant in the calculation of the fair value of our share-based awards. The fair value of stock options held by our employees is determined using a Black-Scholes option valuation method, which is a valuation technique that is acceptable for share-based payment accounting. Key assumptions in determining fair value include volatility, risk-free interest rate, dividend yield and expected term. The assumptions used in calculating the fair value of stock options represent our best estimates, however; these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the stock-based compensation expense could be materially different in the future. In addition, we are required to estimate the expected forfeiture rate and only recognize expense for those stock options expected to vest over the service period. We estimate the forfeiture rate considering the historical experience of our stock-based awards. If the actual forfeiture rate is different from the estimate, we adjust the expense accordingly.

Warrants — Warrants that could require cash settlement or have anti-dilution price protection provisions are recorded as liabilities at their estimated fair value at the date of issuance, with subsequent changes in estimated fair value recorded in other income (expense) in our statement of operations in each subsequent period. In general, warrants are measured using the Black-Scholes valuation model. The Black-Scholes model is based, in part, upon inputs for which there is little observable market data, requiring us to develop our own assumptions. Inherent in the model are assumptions related to expected stock-price volatility, expected life, risk-free interest rate and dividend yield. The assumptions used in calculating the estimated fair value of the warrants represent our best estimates; however, these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the warrant liability and the change in estimated fair value could be materially different.

Research and Development Expenses — Research and development costs, including internal and contract research costs, are expensed as incurred. Research and development expenses consist mainly of clinical trial costs, manufacturing of clinical material, process development costs, other preclinical studies, pharmacoeconomic research, grants to outside investigators including medical education and personnel costs.

Tax Valuation Allowance — A valuation allowance is recorded if it is more likely than not that a deferred tax asset will not be realized. We provided a full valuation allowance on our deferred tax assets that primarily consist of cumulative federal net operating losses. Due to our three year cumulative loss position, history of operating losses and losses expected to be incurred in the foreseeable future, a full valuation allowance against our net deferred tax assets was considered necessary.

The summary of significant accounting policies should be read in conjunction with our consolidated financial statements and related notes and this discussion of our results of operations.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that have or are reasonably likely to have a material effect on our financial condition.

Recent Accounting Pronouncements

See Note 3 to the consolidated financial statements.

Item 7A. *Quantitative and Qualitative Disclosures About Market Risk*

As of December 31, 2014, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates or credit conditions on our securities portfolio.

We believe that the interest rate risk related to our accounts receivable is not significant. We manage the risk associated with these accounts through periodic reviews of the carrying value for non-collectability and establishment of appropriate allowances. We do not enter into hedging transactions and do not purchase derivative instruments.

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We operate in the United States and in Denmark and are exposed to the risk that our earnings, cash flows and equity could be adversely impacted by fluctuations in foreign exchange. We are primarily exposed to foreign exchange risk with respect to recognized assets and liabilities. Our vendors in countries outside the United States are typically paid in Euro and/or Danish Krone. We do not enter into hedging transactions and do not purchase derivative instruments.

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Item 8. *Financial Statements and Supplementary Data*

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders
of Vericel Corporation:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of shareholders' equity (deficit), of comprehensive loss and of cash flows present fairly, in all material respects, the financial position of Vericel Corporation and its subsidiaries at December 31, 2014 and December 31, 2013, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2014 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Detroit, Michigan
March 25, 2015

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VERICEL CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(amounts in thousands)

	December 31, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash	$ 30,343	$ 8,059
Accounts receivable (net of $40 allowance for doubtful accounts as of December 31, 2014)	8,191	8
Inventory	1,920	—
Other current assets	1,036	409
Total current assets	41,490	8,476
Property and equipment, net	2,892	739
Intangible assets	3,197	—
Total assets	$ 47,579	$ 9,215
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,824	$ 2,676
Accrued expenses	4,714	620
Warrant liabilities	1,081	2,019
Other	210	6
Total current liabilities	11,829	5,321
Long term liabilities	109	—
COMMITMENTS AND CONTINGENCIES (Note 14)		
Shareholders' equity:		
Series B-2 voting convertible preferred stock, no par value: shares authorized and reserved — 39, shares issued and outstanding — 12	38,389	38,389
Common stock, no par value; shares authorized — 75,000 and 15,000; shares issued and outstanding — 23,786 and 4,723, respectively	305,008	253,270
Other comprehensive loss	(71)	—
Accumulated deficit	(307,685)	(287,765)
Total shareholders' equity	35,641	3,894
Total liabilities and shareholders' equity	$ 47,579	$ 9,215

The accompanying Notes to Consolidated Financial Statements are an integral part of these statements.

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VERICEL CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)

	Year Ended December 31,		
	2014	2013	2012
Revenues:			
Product sales	$ 28,796	$ 19	$ 21
Total revenues	28,796	19	21
Costs and expenses:			
Cost of product sales	17,293	4	6
Gross profit	11,503	15	15
Research and development	21,263	15,104	26,025
Selling, general and administrative	13,774	5,875	7,750
Total operating expenses	35,037	20,979	33,775
Loss from operations	(23,534)	(20,964)	(33,760)
Other income (expense):			
(Increase) decrease in fair value of warrants	(27)	5,337	4,248
Bargain purchase gain	3,473	—	—
Foreign currency translation gain	152	—	—
Interest income	24	16	50
Other expense	(2)	—	—
Interest expense	(6)	(11)	(12)
Total other income (expense)	3,614	5,342	4,286
Net loss	$ (19,920)	$ (15,622)	$ (29,474)
Net loss per share attributable to common shareholders (Basic and Diluted) (see note 9)	$ (2.23)	$ (6.95)	$ (16.25)
Weighted average number of common shares outstanding (Basic and Diluted)	11,642	3,016	2,060

The accompanying Notes to Consolidated Financial Statements are an integral part of these statements.

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VERICEL CORPORATION
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)
(In thousands)

	Preferred Stock		Common Stock		Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
BALANCE, DECEMBER 31, 2012	—	$ —	2,189	$ 243,215	$ —	$ (275,315)	$ (32,100)
Net loss						(15,622)	(15,622)
Compensation expense related to stock options granted				926			926
Reclassification of Series B-2 Preferred Stock to equity	12	38,389				3,224	41,613
Reverse stock split, common stock in lieu of fractional shares			14	52		(52)	—
Exercise of stock purchase warrants			367	1,983			1,983
Issuance of common stock, net of issuance costs of $980			2,153	7,094			7,094
BALANCE, DECEMBER 31, 2013	12	38,389	4,723	253,270		(287,765)	3,894
Net loss						(19,920)	(19,920)
Compensation expense related to stock options granted				839			839
Exercise of stock purchase warrants			408	2,490			2,490
Issuance of common stock, net of issuance costs of $3,167			18,655	48,409			48,409
Foreign currency translation adjustment					(71)		(71)
BALANCE, DECEMBER 31, 2014	12	$ 38,389	23,786	$ 305,008	$ (71)	$ (307,685)	$ 35,641

The accompanying Notes to Consolidated Financial Statements are an integral part of these statements.

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VERICEL CORPORATION
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)

	Year Ended December 31,		
	2014	2013	2012
Net loss	$ (19,920)	$ (15,622)	$ (29,474)
Other comprehensive loss			
Foreign currency translation	(71)	—	—
Comprehensive loss	$ (19,991)	$ (15,622)	$ (29,474)

The accompanying Notes to Consolidated Financial Statements are an integral part of these statements.

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VERICEL CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,		
	2014	2013	2012
Operating activities:			
Net loss	$ (19,920)	$ (15,622)	$ (29,474)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	752	489	649
Stock compensation expense	839	926	3,610
Change in fair value of warrants	27	(5,337)	(4,248)
Bargain purchase gain	(3,473)	—	—
Foreign currency translation gain	(152)	—	—
Loss on sale of fixed assets	139	—	—
Write down of retirement asset obligation	(1,102)	—	—
Changes in operating assets and liabilities:			
Inventory	119	—	—
Accounts receivable	(8,139)	—	—
Other current assets	(455)	(65)	293
Accounts payable	2,773	(571)	284
Accrued expenses	3,007	237	(659)
Other liabilities	175	—	—
Net cash used for operating activities	(25,410)	(19,943)	(29,545)
Investing activities:			
Acquisition of CTRM business, net of cash acquired	(1,450)	—	—
Property and equipment purchases	(829)	(40)	(273)
Other	101	—	—
Net cash used for investing activities	(2,178)	(40)	(273)
Financing activities:			
Net proceeds from issuance of common stock and warrants	49,934	14,438	346
Net proceeds from issuance of preferred stock	—	—	37,620
Payments on long-term debt	(8)	(34)	(40)
Net cash provided by financing activities	49,926	14,404	37,926
Effect of exchange rate changes on cash	(54)	—	—
Net increase (decrease) in cash	22,284	(5,579)	8,108
Cash at beginning of period	8,059	13,638	5,530
Cash at end of period	$ 30,343	$ 8,059	$ 13,638
Supplemental cash flow information (non-cash):			
Accretion of convertible preferred stock	$ —	$ 1,263	$ 3,993
Warrants exchanged for common stock	$ 965	$ —	$ 10,382
Additions to equipment in process included in accounts payable	$ 199	$ —	$ —
Equipment acquired under capital lease	$ 153	$ —	$ —

The accompanying Notes to Consolidated Financial Statements are an integral part of these statements.

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VERICEL CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization

Vericel Corporation (the Company or Vericel, which was formerly known as Aastrom Biosciences, Inc.) was incorporated in March 1989 and began employee-based operations in 1991. On May 30, 2014, Vericel completed the acquisition of certain assets of Sanofi, a French société anonyme (Sanofi), including all of the outstanding equity interests of Genzyme Biosurgery ApS (Genzyme Denmark), a wholly-owned subsidiary of Sanofi, and over 250 patents and patent applications of Sanofi and certain of its subsidiaries and assumed certain liabilities for purposes of acquiring the portion of the cell therapy and regenerative medicine business (the CTRM Business), which researches, develops, manufactures, markets and sells Carticel®, MACI™ and Epicel® (the CTRM Transaction). The CTRM Business researches, develops, manufactures, markets and sells the Carticel, MACI and Epicel products. As a result, the Company exited the development stage, and is now a fully integrated, commercial-stage biopharmaceutical company dedicated to the identification, development and commercialization of innovative therapies that enable the body to repair and regenerate damaged tissues and organs to restore normal structure and function. Vericel has marketed products as well as developmental stage product candidates and the Company's goal is to become the leader in cell therapy and regenerative medicine by developing, manufacturing and marketing best-in-class therapies for patients with significant unmet medical needs.

The Company operates its business primarily in the U.S. in one reportable segment — the research, product development, manufacture and distribution of patient-specific, expanded cellular therapies for use in the treatment of specific diseases.

Successful future operations are subject to several technical hurdles and risk factors, including satisfactory product development, timely initiation and completion of clinical trials, regulatory approval and market acceptance of the Company's products, and the successful integration and profitability of the CTRM Business.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of Vericel and its wholly-owned subsidiaries, Aastrom Biosciences GmbH, located in Berlin, Germany, Marrow Donation, LLC, located in San Diego, California, and Åström BIOSCIENCES DK ApS, in Kastrup, Demark (collectively, the Company). All inter-company transactions and accounts have been eliminated in consolidation. Aastrom Biosciences GmbH ceased operations in 2014.

Use of Estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reported period. Actual results could differ from those estimates.

Inventory

Inventories are measured at the lower of cost or market value. Cost is calculated based upon standard-cost which approximates costs determined on the first-in, first-out method. Utilization reserves are established for estimated obsolescence or un-marketable inventory in an amount equal to the cost of inventory.

Accounts Receivable

Accounts receivable is initially recorded at the contractual amount owed by the customer. Allowances for doubtful accounts are established when the facts and circumstances indicate that a receivable may not be collectible.

Property, Plant and Equipment

Property, plant and equipment are initially measured and recognized at acquisition cost, including any directly attributable cost of preparing the asset for its intended use or, in the case of assets acquired in a business combination, at fair value as at the date of the combination. After initial measurement, property, plant and equipment are carried at cost less accumulated depreciation and impairment. Repair and maintenance costs of property, plant and equipment are expensed as incurred.

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The depreciable value of property, plant and equipment, net of any residual value, is depreciated on a straight line basis over the useful life of the asset. The useful life of an asset is usually equivalent to its economic life. The useful lives of property, plant and equipment are as follows:

- Equipment and computers: 3 to 5 years
- Furniture and fixtures: 5 years
- Building improvements and leasehold improvements: Shorter of the remaining life of the lease or 7 years

The costs of assets retired or otherwise disposed of and the accumulated depreciation thereon are removed from the accounts, with any gain or loss realized upon sale or disposal credited or charged to operations.

Intangible Assets and Other Long Lived Assets

Intangible assets are initially measured at acquisition cost, including any directly attributable costs of preparing the asset for its intended use or, in the case of assets acquired in a business combination at fair value as at the date of the combination. Identifiable intangible assets related to commercial rights are amortized on a straight line basis over their expected useful lives. Amortization of intangible assets is recognized in these financial statements under Costs of product sales.

Intangible assets and long-lived assets are assessed for potential impairment when there is evidence that events or changes in circumstances indicate that the carrying amount of an asset may not be recovered. An impairment loss would be recognized when an asset's fair value, determined based on undiscounted

cash flows expected to be generated by the asset, is less than its carrying amount. The impairment loss would be measured as the amount by which the asset's carrying value exceeds its fair value and recognized in these financial statements. Intangible assets are carried at cost less accumulated amortization and impairment.

Foreign Currency Translation

Assets and liabilities of Genzyme Denmark are translated from Danish Krone into U.S. dollars using the applicable exchange rates in effect at the period end. Expenses of the operations in Denmark are translated from the applicable currencies into U.S. dollars using average exchange rates for the reported period.

Revenue Recognition

Total revenues are comprised of product sales of Carticel, Epicel, MACI, bone marrow and surgical kits. Revenue is recognized when persuasive evidence of an arrangement exists, the goods are shipped or delivered, depending on shipping terms, title and risk of loss pass to the customer and collectability is reasonably assured. Shipping and handling costs are included as a component of revenue.

Revenue is recorded net of a provision for rebates and cash discounts. These rebates and cash discounts are established by the Company at the time of sale, based on historical experience adjusted to reflect known changes in the factors that impact such reserves. For instance, distributors are entitled to chargeback incentives for services that are provided for based on the selling price to the end customer, under specific contractual arrangements. Cash discounts may also be granted for prompt payment.

Research and Development Expense

Research and development activities represent a significant part of the Company's business. These expenditures relate to the development of new products, improvement of existing products, technical support of products and compliance with governmental regulations for the protection of consumers and patients. Research and development expenses are expensed as incurred.

Diversity of Credit Risk

The Company has established guidelines relative to diversification in an effort to limit risk. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates.

Stock-Based Compensation

The Company's accounting for stock-based compensation requires it to determine the fair value of common stock issued in the form of stock option awards. The Company uses the value of its common stock at the date of the grant in the calculation of the fair value of its share-based awards. The fair value of stock options held by the employees is determined using a Black-Scholes option valuation method, which is a valuation technique that is acceptable for share-based payment accounting. Key assumptions in determining fair value include volatility, risk-free interest rate, dividend yield and expected term. The assumptions used in calculating

the fair value of stock options represent the Company's best estimates, however; these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the stock-based compensation expense could be materially different in the future. In addition, the Company is required to estimate the expected forfeiture rate and only recognize expense for those stock options expected to vest over the service period. The estimated forfeiture rate considers the historical experience of the Company's stock-based awards. If the actual forfeiture rate is different from the estimate, expense is adjusted accordingly.

Income Taxes

Deferred tax assets are recognized for deductible temporary differences and tax credit carryforwards and deferred tax liabilities are recognized for taxable temporary differences. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized.

Net Loss Per Share Attributable to Common Shareholders

Basic earnings (loss) per share is calculated using the two-class method, which is an earnings allocation formula that determines earnings (loss) per share for the holders of the Company's common shares and holders of the Series B preferred stock. The Series B preferred stock shares contain participation rights in undistributed earnings, but do not share in the losses of the Company. The accumulated but undeclared dividends on the Series B preferred stock of $6.0 million are treated as a reduction of earnings attributable to common shareholders.

Financial Instruments

The Company's financial instruments include receivables for which the current carrying amounts approximate market value based upon their short-term nature.

Warrants

Warrants that could be cash settled or have anti-dilution price protection provisions are recorded as liabilities at their estimated fair value at the date of issuance, with subsequent changes in estimated fair value recorded in other income (expense) in our statement of operations in each subsequent period. In general, warrants are measured using the Black-Scholes valuation model. The methodology is based, in part, upon inputs for which there is little or no observable market data, requiring the Company to develop its own assumptions. The assumptions used in calculating the estimated fair value of the warrants

represent our best estimates; however, these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the warrant liability and the change in estimated fair value could be materially different.

3. Recent Accounting Pronouncements

Revenue Recognition

In May 2014, the Financial Accounting Standards Board (FASB) issued authoritative guidance requiring entities to apply a new model for recognizing revenue from contracts with customers. The guidance will supersede the current revenue recognition guidance and require entities to evaluate their revenue recognition arrangements using a five step model to determine when a customer obtains control of a transferred good or service. The guidance is effective for annual reporting periods beginning after December 15, 2016 and may be adopted using a full or modified retrospective application. The Company is currently in the process of evaluating its revenue arrangements under the issued guidance and has not yet determined the impact to its consolidated financial statements.

Going Concern Assessment

The FASB has issued authoritative guidance for management on how to assess whether substantial doubt exists regarding an entity's ability to continue as a going concern and guidance on how to prepare related footnote disclosures. The guidance will require management to evaluate whether there are conditions or events that raise substantial doubt about an entity's ability to continue as a going concern for one year from the date the financial statements are issued. The guidance is effective for annual reporting periods beginning after December 15, 2016. As of December 31, 2014, the Company does not expect the guidance to impact future disclosures.

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4. Acquisitions

CTRM Business acquisition

On May 30, 2014, Vericel completed its acquisition of certain assets of Sanofi, including all of the outstanding equity interests of Genzyme Denmark, a wholly-owned subsidiary of Sanofi, and over 250 patents and patent applications and assumed certain liabilities for purposes of acquiring portions of the CTRM Business. Vericel Corporation is a leader in developing patient-specific expanded cellular therapies for use in the treatment of patients with severe diseases and conditions. The CTRM Business, also a leading developer of patient-specific expanded cellular therapies, expands the Company's portfolio of cellular therapies to include products which treat severe burns and as well as cartilage defects. The CTRM Business is a commercial business, with manufacturing, marketing and sales capabilities. Pursuant to the terms of the asset purchase agreement, the Company paid a total purchase price of $6.5 million, including $4.0 million in cash and a $2.5 million promissory note which was repaid on July 30, 2014.

The total purchase price consideration is as follows:

Acquisition consideration (In thousands):	Fair Value
Cash payment	$ 4,000
Promissory note	2,500
Total acquisition consideration	$ 6,500

The Company recognized tangible and intangible assets and liabilities acquired based upon their respective estimated fair values as of the acquisition date. The table below shows the fair values assigned to the assets acquired and liabilities assumed. Based on this analysis, the transaction resulted in a bargain purchase gain.

The final purchase price allocation is as follows:

Purchase price allocation (In thousands):	Fair Value
Cash	$ 5,050
Accounts receivable	53
Inventory	2,039
Other current assets	192
Accounts payable and accrued expenses	(939)
Asset retirement obligation	(1,600)
Property and equipment	1,818
Intangible assets	3,360
Bargain purchase gain	(3,473)
Total consideration	$ 6,500

As part of the acquisition, the Company received $5.0 million in cash from Sanofi in order to fund a restructuring of the Denmark operations and close the facility. As of December 31, 2014, the Company has recorded restructuring charges of $3.0 million. See Note 5 "Restructuring" below for additional information.

The intangible assets acquired represent commercial use rights for certain products acquired in the transaction. This fair value of $3.4 million was determined using the income approach based on projected cash flows attributed to the commercial rights. The calculated value of the commercial rights intangible assets are amortized using the straight line method over an estimated useful life of twelve years.

Revenue and net income included in the condensed consolidated financial statements include seven months of operations related to the CTRM Business since the May 30, 2014 acquisition and are $28.4 million and $0.4 million, respectively. The net income related to the CTRM Business includes the restructuring costs of $3.0 million described in Note 5 as well as $0.4 million of other expenses from the Danish subsidiary that the Company is in the process of shutting down.

The following pro forma condensed combined information for the year ended December 31, 2014, and 2013, respectively are presented as if the acquisition of the CTRM Business had occurred on January 1, 2013.

In management's opinion, all adjustments necessary to reflect the significant effects of this transaction have been made. These statements are based on assumptions and estimates considered appropriate by management; however, they are not necessarily, and should not be assumed to be, an indication of Vericel's financial position or results of operations that would have been achieved had the acquisitions been completed as of the dates indicated or that may be achieved in the future.

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(in thousands)	Year Ended December 31, 2014	2013
Pro forma revenue	$ 44,794	$ 43,863
Pro forma net loss	(26,106)	(49,124)
Pro forma net loss per share — basic and diluted	$ (2.77)	$ (18.06)

5. Restructuring

Acquisition Restructuring

In June 2014, the Company announced a strategic plan to maximize the profitability and growth potential of the CTRM Business (the Plan). Under the Plan, the Company discontinued manufacturing MACI in Denmark, temporarily suspended sales of MACI in Europe, and significantly reduced research and development expenses associated with MACI. Furthermore, the Company eliminated approximately 80 full time employee positions, which represented approximately 30% of the Company's current total workforce. Employees terminated as part the Plan were provided with severance payments and outplacement assistance.

As a result of the Plan, the Company recorded a restructuring charge of $3.0 million for the year ended December 31, 2014, related to the operations in the United States and Denmark, primarily representing cash payments for severance and other personnel-related expenses. Of the total restructuring charge, $2.5 million was recorded in cost of product sales, and $0.5 million was recorded in selling, general and administrative expenses. There was no restructuring reserve as of December 31, 2014 as a result of cash payments made for severance and other personnel-related expenses. In addition to restructuring charges recorded thus far, the Company may incur additional lease and other contract termination costs associated with current contracts associated with the Danish operations.

R&D Restructuring

In March, 2013, the Company announced a strategic change in its research and development programs to focus on the clinical development of ixmyelocel-T for the treatment of advanced heart failure due to ischemic dilated cardiomyopathy (DCM). The Company previously received a U.S. orphan drug designation for the use of ixmyelocel-T in the treatment of DCM. As a result of the strategic change, the Company stopped enrollment of the Phase 3 REVIVE clinical trial in patients with critical limb ischemia (CLI). In addition, the Company executed a corporate restructuring that reduced staff and operating expenses. Employees directly affected by the restructuring plan were provided with severance payments and outplacement assistance. As a result of the ceasing of enrollment in the Phase 3 REVIVE clinical trial, the Company recorded a one-time restructuring charge of $0.4 million in the first quarter of 2013 in research and development expenses. The restructuring accrual for the strategic changes decreased to less than $0.1 million as of December 31, 2013 as a result of cash payments made for severance and other personnel-related expenses. There was no restructuring reserve related to the strategic change as of December 31, 2014.

6. Selected Balance Sheet Components

Inventory as of December 31, 2014:

(In thousands)	2014
Raw materials	$ 1,078
Work-in-process	458
Finished goods	384
Inventory	$ 1,920

Property and Equipment, net as of December 31, 2014 and 2013:

(In thousands)	2014	2013
Machinery and equipment	$ 3,135	$ 2,547
Furniture, fixtures and office equipment	777	761
Computer equipment and software	667	500
Leasehold improvements	1,691	1,018
Construction in process	1,019	—
	7,289	4,826
Less accumulated depreciation	(4,397)	(4,087)
	$ 2,892	$ 739

Depreciation expense for the years ended December 31, 2014, 2013 and 2012 were $0.8 million, $0.5 million and $0.6 million, respectively.

Intangible assets, net as of December 31, 2014:

(In thousands)	2014
Commercial rights	$ 3,360
Less accumulated amortization	(163)
	$ 3,197

Amortization expense was $0.2 million for the year ended December 31, 2014. There was no amortization expense in 2013. The increase in intangible assets from December 31, 2013 to December 31, 2014 is due to the acquisition of the CTRM Business.

Estimated future amortization expense is as follows:

Calendar Years Ending December 31, (In thousands)	
2015	$ 280
2016	280
2017	280
2018	280
2019	280
Thereafter	1,797
Total	$ 3,197

Accrued Expenses as of December 31, 2014 and 2013:

(In thousands)	2014	2013
Bonus	$ 2,044	$ 387
Employee related accruals	1,281	233
Accrued expenses	605	—
Asset retirement obligation	348	—
Other	436	—
	$ 4,714	$ 620

The Company acquired an asset retirement obligation of $1.6 million related to the obligation to restore the Denmark facility to its original state which was reduced to $0.3 million during the fourth quarter of 2014 due to a change in estimate.

7. Stock-Based Compensation

Stock Option and Equity Incentive Plans

The Company has historically had various stock incentive plans and agreements that provide for the issuance of nonqualified and incentive stock options as well as other equity awards. Such awards may be granted by the Company's Board of Directors to certain of the Company's employees, directors and consultants. Options granted under these plans expire no later than ten years from the date of grant, and other than those granted to non-employee directors, generally become exercisable over a four-year period, under a graded-vesting methodology, following the date of grant. The Company generally issues new shares upon the exercise of stock options.

The 2009 Omnibus Incentive Plan (2009 Plan) provides incentives through the grant of stock options, stock appreciation rights, restricted stock awards and restricted stock units. The exercise price of stock options granted under the 2009 Plan shall not be less than the fair market value of the Company's common stock on the date of grant. The 2009 Plan replaced the 1992 Stock Option Plan, the 2001 Stock Option Plan and the Amended and Restated 2004 Equity Incentive Plan (Prior Plans), and no new awards will be granted under the Prior Plans. However, the expiration or forfeiture of options previously granted under the Prior Plans will increase the awards available for issuance under the 2009 Plan.

As of December 31, 2014, there were 4,011,608 shares available for future grant under the 2009 Plan.

Service-Based Stock Options

During the period ended December 31, 2014, the Company granted 242,025 service-based options to purchase common stock. The exercise price of the options is the fair market value per share of common stock on the grant date, generally vest over four years (other than 12,000 non-employee options which generally vest over one year) and have a term of ten years. The weighted average grant-date fair value of service-based options granted during the years ended December 31, 2014, 2013 and 2012 was $2.85, $14.07 and $24.00, respectively.

The net compensation costs recorded for the service-based stock options related to employees and directors (including the impact of the forfeitures) for the years ended December 31, 2014, 2013 and 2012 were $0.8 million, $0.9 million and $3.6 million, respectively.

The fair value of each service-based stock option grant for the reported periods is estimated on the date of the grant using the Black-Scholes option-pricing model using the weighted average assumptions noted in the following table.

	Year Ended December 31,		
Service-Based Stock Options	2014	2013	2012
Expected dividend rate	0%	0%	0%
Expected stock price volatility	82.4% - 88.2%	74.0% – 87.9%	73.9% – 79.1%
Risk-free interest rate	1.66% - 2.2%	0.1% – 2.1%	0.9% – 1.5%

Expected life (years)	5.5 – 6.3	5.0 – 6.3	5.5 – 6.3

The following table summarizes the activity for service-based stock options for the indicated periods:

Service-Based Stock Options	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2011	403,984	$ 47.60	8.4	$ 674,000
Granted	273,372	$ 44.20		
Exercised	(7,208)	$ 29.60		$ 52,000
Cancelled	(52,885)	$ 40.60		
Forfeited or expired	(117,889)	$ 43.60		
Outstanding at December 31, 2012	499,374	$ 47.60	7.5	$ —
Granted	75,751	$ 21.32		
Exercised	—	$ —		$ —
Expired	(164,189)	$ 51.76		
Forfeited	(113,076)	$ 45.38		
Outstanding at December 31, 2013	297,860	$ 39.53	7.9	$ —
Granted	242,025	$ 3.91		
Exercised	—	$ —		$ —
Expired	(32,012)	$ 42.63		
Forfeited	(30,347)	$ 32.13		
Outstanding at December 31, 2014	477,530	$ 21.74	8.0	$ —
Exercisable at December 31, 2014	209,375	$ 36.43	6.9	$ —

As of December 31, 2014, there was approximately $0.8 million, of total unrecognized compensation cost related to non-vested service-based stock options granted under the 2009 Plan and the Prior Plans. That cost is expected to be recognized over a weighted-average period of 2.82 years.

The total fair value of stock options vested for the years ended December 31, 2014, 2013 and 2012 was $1.5 million, $2.3 million $3.0 million, respectively.

8. Shareholders' Equity

2013 Stock and Warrant Sale

On August 16, 2013, the Company completed the sale of 1.5 million shares of common stock and warrants to purchase up to an aggregate of 1.5 million shares of common stock (including 50,000 shares of common stock and warrants sold to the underwriter pursuant to the exercise of its over-allotment option). Each share of common stock and its associated warrant was sold at a public offering price of $6.00 per share. The Company received $8.2 million in net proceeds from the sale of the shares of common stock and warrants (including the partial exercise of the over-allotment option), after underwriting discounts, commissions and other offering expenses. The total fair market value of the warrants at the date of issuance was $5.9 million. The sales proceeds were first allocated to the warrants based on the total fair market value and the residual amount of the sales proceeds were allocated to common stock.

2014 Warrant Exercises

On July 9, 2014, the Company entered into a Warrant Exercise Agreement with one holder of warrants issued by the Company on August 16, 2013 (the 2013 Warrants) to purchase an aggregate of 362,500 shares of the Company's common stock, no par value. Pursuant to the Warrant Exercise Agreement, the holder agreed to exercise the 2013 Warrants at the existing exercise price of $4.80.

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The net proceeds to the Company in connection with the exercise of the 2013 Warrants, after deducting a warrant inducement payment and expenses, were approximately $1.5 million.

2014 Stock Purchase Agreement

On January 21, 2014, the Company entered into a purchase agreement (Purchase Agreement), together with a registration rights agreement, for the sale of up to $15.0 million of shares of its common stock to Lincoln Park, subject to certain limitations, from time to time over a 30-month period, which began on April 3, 2014 and ends on October 3, 2016. The Company may direct Lincoln Park, at its sole discretion, to purchase up to 50,000 shares of common stock in regular purchases, increasing to amounts of up to 100,000 shares depending upon the closing sale price of the common stock. In addition, the Company may direct Lincoln Park to purchase additional amounts as accelerated purchases if on the date of a regular purchase the closing sale price of the common stock equals or exceeds $3.00 per share. The purchase price of shares of common stock related to the future funding will be based on the prevailing market prices of such shares at the time of sales (or over a period of up to 10 business days leading up to such time), but in no event will shares be sold to Lincoln Park on a day the common stock closing price is less than the floor price of $2.50, subject to adjustment. The Company controls the timing and amount of any sales of common stock to Lincoln Park. The Company's sales of shares of common stock to Lincoln Park under the Purchase Agreement are limited to no more than the number of shares that would result in the beneficial ownership by Lincoln Park and its affiliates, at any single point in time, of more than 9.99% of the then outstanding shares of the common stock. For the year ended December 31, 2014, the Company issued 935,499 shares of common stock to Lincoln Park and raised gross proceeds of $3.7 million (with the ability to sell up to an additional $11.3 million more in common stock).

At-the-Market Sales Agreement

During the years ended December 31, 2014 and 2013, the Company raised net proceeds of $7.1 million and $4.8 million utilizing the At-the-Market Sales Agreement (ATM) with MLV & Co. LLC (formerly McNicoll, Lewis & Vlak) (MLV). The Company originally entered into the ATM with MLV in June 2011 in which the Company may sell shares of its common stock through MLV, as sales agent, in registered transactions from its shelf registration statement filed

in July 2011, for aggregate proceeds of up to $20.3 million. Shares of common stock sold under the ATM are to be sold at market prices. The Company will pay up to 3% of the gross proceeds to MLV as a commission. At December 31, 2014 there was approximately $7.8 million of net capacity remaining on the ATM.

2014 Public Equity Offering

On September 17, 2014, the Company closed on a public equity offering whereby it sold 15,784,313 shares of common stock at an offering price of $2.55 per share (the 2014 offering). The proceeds of $37.5 million, net of $2.4 million of underwriters' discount and $0.3 million of issuance costs consisting primarily of legal and accounting fees, were recorded as a common stock issuance.

Dividends

No cash dividends have been declared or paid by the Company since its inception.

9. Net Loss Per Common Share

The following reflects the net loss attributable to common shareholders and share data used in the basic and diluted earnings per share computations using the two class method:

(Amounts in thousands, except per share amounts)	Year Ended December 31, 2014	2013	2012
Numerator:			
Net loss	$ (19,920)	$ (15,622)	$ (29,474)
Less: earnings attributable to convertible preferred stock	6,005	5,352	3,993
Numerator of basic and diluted EPS	$ (25,925)	$ (20,974)	$ (33,467)
Denominator:			
Denominator for basic and diluted EPS: weighted- average common shares outstanding	11,642	3,016	2,060
Net loss per share attributable to common shareholders (basic and diluted)	$ (2.23)	$ (6.95)	$ (16.25)

Common equivalent shares are not included in the diluted per share calculation where the effect of their inclusion would be anti-dilutive. The aggregate number of common equivalent shares (related to options, warrants and preferred stock) that have been

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excluded from the computations of diluted net loss per common share for the years ended December 31, 2014, 2013 and 2012 was 2.3 million, 2.4 million and 1.4 million, respectively.

10. Stock Purchase Warrants

The Company has historically issued warrants to purchase shares of the Company's common stock in connection with certain common stock offerings. The following warrants were outstanding during the years ended December 31, 2014, 2013 and 2012, and include provisions that could require cash settlement of the warrants or have anti-dilution price protection provisions requiring each to be recorded as liabilities of the Company at the estimated fair value at the date of issuance, with changes in estimated fair value recorded as non-cash income or expense in the Company's statement of operations in each subsequent period:

	January 2010 Class A Warrants	December 2010 Warrants	August 2013 Warrants
Exercise price	$ 7.86	$ 2.55	$ 4.80
Expiration date	July 21, 2015	December 15, 2015	August 16, 2018
Total shares issuable on exercise	226,299	15,405	724,950

The fair values of the warrants are measured using the Black-Scholes valuation model. The methodology is based, in part, upon inputs for which there is little market data, requiring the Company to develop its own assumptions. The assumptions used in calculating the estimated fair value of the warrants represent the Company's best estimates, however; these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the warrant liabilities and the change in estimated fair value of the warrants could be materially different.

Inherent in the Black-Scholes valuation model are assumptions related to expected stock-price volatility, expected life, risk-free interest rate and dividend yield. The Company estimates the volatility of its common stock based on historical volatility that matches the expected remaining life of the warrants. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected remaining life of the warrants. The expected life of the warrants is assumed to be equivalent to their remaining contractual term. The dividend rate is based on the historical rate, which the Company anticipates to remain at zero.

The assumptions used by the Company are summarized in the following tables:

January 2010 Class A Warrants	December 31, 2014	December 31, 2013
Closing stock price	$ 3.04	$ 3.23
Expected dividend rate	0%	0%
Expected stock price volatility	45.1%	84.6%
Risk-free interest rate	0.1%	0.3%
Expected life (years)	0.55	1.50

December 2010 Warrants	December 31, 2014	December 31, 2013
Closing stock price	$ 3.04	$ 3.23
Expected dividend rate	0%	0%
Expected stock price volatility	99.7%	80.4%
Risk-free interest rate	0.2%	0.4%
Expected life (years)	0.96	1.96

August 2013 Warrants	December 31, 2014	December 31, 2013
Closing stock price	$ 3.04	$ 3.23
Expected dividend rate	0%	0%
Expected stock price volatility	83.2%	77.5%
Risk-free interest rate	1.2%	1.6%
Expected life (years)	3.63	4.63

11. Fair Value Measurements

The Company's fair value measurements are classified and disclosed in one of the following three categories:

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
- Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability;

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- Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

The following table summarizes the valuation of the Company's investments and financial instruments that are measured at fair value on a recurring basis:

	December 31, 2014				December 31, 2013			
	Fair value measurement category				Fair value measurement category			
(In thousands)	Total	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3
Liabilities:								
Warrant liabilities	$ 1,081	$ —	$ 1,061	$ 20	$ 2,019	$ —	$ 1,934	$ 85

The fair values of the warrants are measured using the Black-Scholes valuation model. See Note 10 for further discussion of the significant observable inputs use to measure the warrant liabilities.

The following table summarizes the change in the estimated fair value of the Company's warrant liabilities:

Warrant Liabilities (In thousands)	
Balance at December 31, 2012	$ 1,995
Warrant issuance	5,874
Warrant exercises	(513)
Decrease in fair value	(5,337)
Balance at December 31, 2013	2,019
Warrant issuance	—
Warrant exercises	(965)
Increase in fair value	27
Balance at December 31, 2014	$ 1,081

A reconciliation of beginning and ending balances for the Company's fair value measurements using Level 3 inputs is as follows:

Warrants:

	Year Ended	
(In thousands)	December 31, 2014	December 31, 2013
Beginning balance	$ 85	$ 1,995
Decrease in fair value	(65)	(1,910)
Ending balance	$ 20	$ 85

12. Income Taxes

Income (loss) before income taxes for U.S and non-U.S operations was as follows:

	Year Ended December 31,		
	2014	2013	2012
U.S. loss	$ (18,078)	$ (15,622)	$ (29,474)
Non U.S. loss	(1,842)	—	—
	$ (19,920)	$ (15,622)	$ (29,474)

A reconciliation of income taxes computed using the federal statutory rate to the taxes reported in the consolidated statements of operations is as follows:

	Year Ended December 31,		
(In thousands)	2014	2013	2012

Loss before income taxes	$ 19,920	$ 15,622	$ 29,474
Federal statutory rate	34%	34%	34%
Taxes computed at federal statutory rate	(6,773)	(5,311)	(10,021)
State taxes (net of federal benefit)	(463)	—	—
Warrants	(10)	(1,815)	(1,445)
Nondeductible stock compensation	48	81	872
Michigan NOL benefit	—	(791)	(1,229)
Net operating loss expirations	655	612	612
Write-off of Section 382 limited NOL's	67,781	—	—
Write-off of Section 383 limited R&D credits	1,600	—	—
Other	352	(27)	300
Change in valuation allowance	(63,190)	7,251	10,911
Reported income taxes	$ —	$ —	$ —

Deferred tax assets consist of the following:

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(In thousands)	Year Ended December 31, 2014	2013
Net operating loss carryforwards	$ 7,092	$ 70,738
Research and development credit carryforwards	—	1,600
Employee benefits and stock compensation	1,897	1,655
Research and development costs	2,184	—
Fixed assets	254	—
Intangible assets	(510)	—
Asset Retirement obligation	127	—
Other, net	301	524
Total deferred tax assets	11,345	74,517
Valuation allowance	(11,345)	(74,517)
Net deferred tax assets	$ —	$ —

On September 17, 2014, the Company underwent a change in control as defined by Section 382 of the Internal Revenue Code. A change in control is generally defined as a cumulative change of 50% or more in the ownership positions of certain stockholders during a rolling three year period. This change in control resulted in substantial limitations being placed on certain tax attributes including net operating losses and tax credit carryforwards. The limitations are computed based upon several variable factors including the value of the Company on the date of the change in control. The projected annual limitation on the use of the net operating losses that existed prior to September 17, 2014 is $0.8 million. As a result, a significant portion of the net operating losses and tax credit carryforwards will expire prior to their utilization, regardless of the level of future profitability. Accordingly, the Company reduced our net operating losses and tax credit carryforwards (with a corresponding adjustment to our valuation allowance) to reflect the amount available to offset future profits.

As of December 31, 2014, the Company's U.S. federal, and state tax net operating loss carryforwards available to offset future profits, after considering the aforementioned annual Section 382 limit, are $19.3 million and $7.8 million, respectively. These net operating loss carryforwards will expire between 2015 and 2034.

In accordance with the accounting guidance for income taxes, the Company estimated whether recoverability of its deferred tax assets is "more likely than not," based on forecasts of taxable income in the related tax jurisdictions. In this estimate, the Company uses historical results, projected future operating results based upon approved business plans, eligible carry forward periods, tax planning opportunities and other relevant considerations. Based on these factors, including historical losses incurred by the Company, a full valuation allowance for the deferred tax assets, including the deferred tax assets for the aforementioned net operating losses and credits, has been provided since they are not more likely than not to be realized. If the Company achieves profitability, these deferred tax assets may be available to offset future income taxes. The decrease in the valuation allowance was $63.2 million for the year ended December 31, 2014 and a $7.3 million increase for the year ended December 31, 2013.

The Company assesses uncertain tax positions in accordance with the guidance for accounting for uncertain tax positions. This pronouncement prescribes a recognition threshold and measurement methodology for recording within the financial statements uncertain tax positions taken, or expected to be taken, in the Company's income tax returns. To the extent the uncertain tax positions do not meet the "more likely than not" threshold, the Company has derecognized such positions. To the extent the uncertain tax positions meet the "more likely than not" threshold, the Company has measured and recorded the highest probable benefit, and have established appropriate reserves for benefits that exceed the amount likely to be sustained upon examination.

A reconciliation of the beginning and ending amounts of uncertain tax provision is as follows:

(In thousands)	Unrecognized Income Tax Benefits
Balance at December 31, 2012	$ 2,100
Decrease in prior year tax positions	(1,200)
Balance at December 31, 2013	900
Decrease in prior year tax positions	(900)
Balance at December 31, 2014	$ —

It is not anticipated that the unrecognized tax benefits will significantly increase or decrease within the next twelve months.

The Company files U.S. federal, Michigan and California income tax returns. Due to the Company's net operating loss carryforwards, Federal income tax returns from incorporation are still subject to examination. Michigan tax returns for the year ended December 31, 2012 and forward are subject to

examination. California tax returns for the year ended December 31, 2012 and forward are subject to examination.

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13. Concentration of Credit

Revenue from one customer, a distributor in the U.S., represented approximately 76% of total revenue during the year ended December 31, 2014. Excluding that distributor, the largest customer represented approximately 10% of revenue for the year ended December 31, 2014 and no other customer accounted for more than 10% of revenue reported. Revenue primarily reflects sales related to the acquisition of the CTRM Business from Sanofi since May 30, 2014.

14. Commitments and Contingencies

Licenses, Royalties and Collaborative Agreements

University of Michigan — In 1989, the Company entered into a research agreement with the University of Michigan (the University) and in 1992, as provided for under the research agreement, the Company also entered into a license agreement for the technology developed under the research agreement. The license agreement, as amended, provides for a royalty to be paid to the University equal to 2% of net sales of products containing the licensed technology sold by the Company. Such royalties have been nominal since Inception. This license agreement expired in 2014.

Corning Incorporated — In December 2002, the Company entered into an agreement with Corning Incorporated (Corning) that granted Corning an exclusive sublicense relating to the Company's cell transfection technology. Under the terms of the agreement, the Company retains exclusive rights to the applications of the technologies involving cells for therapeutic applications. In addition, the agreement provides for future royalty payments on net sales of licensed products sold under the sublicense amounting to 5% of such sales up to $50,000,000. However, the Company does not expect to receive material revenue from this source for several years, if ever.

RealBio Technologies — In May 2009, the Company entered into an agreement with RealBio Technologies, Inc. (RealBio) that granted RealBio an exclusive license to utilize our technology outside of the Company's core area of focus - human regenerative medicine. In return for this license, the Company received a minority equity interest in RealBio, which was not material as of December 31, 20142013.

Manufacture, Supply and Other Agreements — The Company has entered into various agreements relating to the manufacture of its products and the supply of certain components. If the manufacturing or supply agreements expire or are otherwise terminated, the Company may not be able to identify and obtain ancillary materials that are necessary to develop its product and such expiration and termination could have a material effect on the Company's business.

Operating Leases

The Company renewed their operating lease in Ann Arbor, Michigan to extend the term of the lease for an additional five years, which began on May 1, 2013. The Company has a right to terminate on the third anniversary of the renewal, and has two five-year market value renewal options. In March 2015, the Company subleased a portion of the property in Ann Arbor which is reflected in the future minimum payments below. The Company also leases property in Cambridge, Massachusetts and Kastrup, Denmark which expire in February 2017. The Company has a right to extend the Cambridge operating lease for two three-year market value renewal options. In addition to the property leases, the Company also leases various vehicles and computer equipment.

As of December 31, 2014, future minimum payments related to Vericel's operating and capital leases are as follows:

		Payments Due by Period				
Contractual Obligations	Total	2015	2016	2017	2018	More than 5 Years
Operating leases	$ 9,809	$ 4,215	$ 4,023	$ 1,323	$ 248	$ —
Capital leases	152	43	43	43	23	—
Total	$ 9,961	$ 4,258	$ 4,066	$ 1,366	$ 271	$ —

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Rent expense for the years ended December 31, 2014, 2013 and 2012, was $2.5 million, $1.0 million and $1.1 million, respectively.

15. Employee Savings Plan

The Company has a 401(k) savings plan that allows participating employees to contribute a portion of their salary, subject to annual limits and minimum qualifications. The Board may, at its sole discretion, approve Company matching contributions to the plan. The Company made contributions of $0.3 million, $0.1 million and $0.2 million for the years ended December 31, 2014, 2013 and 2012, respectively.

16. Preferred Stock

Shareholder Rights Plan

In August 2011, the Board of Directors of the Company adopted a Shareholder Rights Plan, as set forth in the Shareholder Rights Agreement between the Company and the rights agent, the purpose of which is, among other things, to enhance the Board's ability to protect shareholder interests and to ensure that shareholders receive fair treatment in the event any coercive takeover attempt of the Company is made in the future. The Shareholder Rights Plan could make it more difficult for a third party to acquire, or could discourage a third party from acquiring, the Company or a large block of the Company's common stock.

In March 2012, the Board approved an amendment to the Shareholder Rights Plan to enable Eastern Capital Limited and its affiliates to purchase up to 49.9% of the shares of common stock of the Company without becoming an "acquiring person" and thereby triggering the stockholder rights, with the limitations under the Shareholder Rights Plan remaining in effect for all other stockholders of the Company.

In connection with the adoption of the Shareholder Rights Plan, the Board of Directors of the Company declared a dividend distribution of one preferred stock purchase right (Right) for each outstanding share of common stock to stockholders of record as of the close of business on August 15, 2011. In addition, one Right will automatically attach to each share of common stock issued between August 15, 2011 and the distribution date. As a result of the October 2013 reverse stock split, the number of Rights associated with each share of common stock was automatically proportionately adjusted so that (i) twenty rights were then associated with each outstanding share of common stock and (ii) so long as the Rights are attached to the common stock, twenty rights shall be deemed to be delivered for each share of common stock issued or transferred by the Company in the future. The Rights currently are not exercisable and are attached to and trade with the outstanding shares of common stock. Each Right entitles the registered holder of common stock to purchase from the Company a unit consisting of one ten-thousandth of a share (Unit) of Series A Junior Participating Preferred Stock, no par value per share, at a cash exercise prices of $30.00 per Unit. There are currently 45,000 shares authorized and zero issued and outstanding. Under the Shareholder Rights Plan, the Rights become exercisable if a person or group becomes an "acquiring person" by acquiring 15% or more of the outstanding shares of common stock or if a person or group commences a tender offer that would result in that person owning 15% or more of the common stock. If a person or group becomes an "acquiring person," each holder of a Right (other than the acquiring person and its affiliates, associates and transferees) would be entitled to purchase, at the then-current exercise price, such number of shares of the Company's preferred stock which are equivalent to shares of common stock having a value of twice the exercise price of the Right. If the Company is acquired in a merger or other business combination transaction after any such event, each holder of a Right would then be entitled to purchase, at the then-current exercise price, shares of the acquiring company's common stock having a value of twice the exercise price of the Right.

The Rights may be redeemed in whole, but not in part, at a price of $0.001 per Right (payable in cash, common stock or other consideration deemed appropriate by the Board of Directors) by the Board of Directors only until the earlier of (i) the time at which any person becomes an "acquiring person" or (ii) the expiration date of the Rights Agreement. Immediately upon the action of the Board of Directors ordering redemption of the Rights, the Right will terminate and thereafter the only right of the holders of Rights will be to receive the redemption price. The Rights will expire at the close of business on August 15, 2021, unless previously redeemed or exchanged by the Company as described above.

Series B Convertible Preferred Stock

On March 9, 2012, the Company completed the sale of 12,308 shares of Series B-1 Non-Voting Convertible Preferred Stock (Series B-1 preferred stock) at an offering price of $3,250 per share. In addition to the Series B-1 preferred stock, which was issued at the closing, the Company also authorized Series B-2 Voting Convertible preferred Stock (Series B-2 preferred stock). The Series B-1 preferred stock and Series B-2 preferred stock collectively are referred to as the Series B preferred stock. The Series B preferred stock is convertible, at the option of the holder thereof at any time after the five year anniversary of the closing of the offering, into shares of common stock at a conversion price of $3.25 per share of common stock, at a conversion ratio of one share of preferred stock for fifty shares of common stock. At any time after the five year anniversary of issuance, the Company may elect to convert any or all outstanding shares of Series B preferred stock into shares of common stock, subject to certain limitations. Dividends on the Series B

preferred stock will be cumulative and compound daily, at a rate of 11.5% per annum, payable upon conversion, liquidation, redemption or other similar events, and payable in cash or Series B-1 preferred stock until the five year anniversary of issuance. As of December 31, 2014, there are 235,077 accumulated but undeclared Series B-1 dividends. Unless prohibited by Michigan law governing distributions to shareholders, the Series B-1 preferred stock shall be redeemable at the option of holder of the Series B-1 preferred stock commencing at any time after the five year anniversary of issuance, liquidation, winding up, dissolution or other similar events, subject to certain terms and limitations.

The Series B preferred stock does not, in its entirety, require liability classification and was evaluated for embedded features to determine if those features require bifurcation and separate classification as derivative liabilities. The Series B preferred stock host contract was evaluated for equity or mezzanine classification based upon the nature of the redemption and conversion features. Generally, any feature that could require cash redemption for matters not within the Company's control, irrespective of probability of the event occurring, requires classification outside of shareholders' equity. The Series B preferred stock was initially recorded as mezzanine in the Consolidated Balance Sheets and was accreted to its redemption value through charges to accumulated deficit using the effective interest method.

On August 12, 2013, the Company amended the Series B preferred stock agreement to remove the cash redemption provision, modify the liquidation preferences for the Series B-2 preferred stock and to increase the redemption price for the Series B-1 preferred stock. The redemption price, prior to the five year anniversary, is now equal to $7,430 multiplied by the number of Series B-1 preferred shares redeemed minus the Company's closing stock price multiplied by the number of common shares into which the outstanding Series B-2 preferred stock are convertible. The redemption price, after the five year anniversary, is the amount equal to the greater of the Series B offering price plus accrued dividends or the conversion value in common stock. As a result of the amendment to the agreement, the total amount of $38.4 million Series B preferred stock was reclassified from mezzanine into shareholders' equity.

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

There are none to report.

Item 9A. ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

The Company has established disclosure controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and that such information is accumulated and communicated to management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer (its "Certifying Officers"), as appropriate, to allow timely decisions regarding required disclosure.

Management of the Company, with the participation of its certifying officers, evaluated the effectiveness of the Company's disclosure controls and procedures as defined in Rules l3a-15(e) and l5d-15(e) under the Exchange Act. Based on the evaluation as of December 31, 2014, our Certifying Officers concluded that the Company's disclosure controls and procedures were not effective because of the material weakness in our internal control over financial reporting described below.

Management's 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 l3a-l5(f) under the Exchange Act). Our internal control over financial reporting is a process designed under the supervision of our CEO and CFO to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external purposes in accordance with generally accepted accounting principles. Management evaluated the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control — Integrated Framework* (2013). Management, under the supervision and with the participation of the CEO and CFO, assessed the effectiveness of our internal control over financial reporting as of December 31, 2014 and concluded that it was not effective because of a material weakness in our internal control over financial reporting as described below.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness relates to the evaluation of significant transactions and the financial close process. Specifically, we did not have a sufficient level of accounting and supervisory personnel nor did we have the appropriate level of technical accounting experience and training necessary for our financial reporting requirements. This material weakness contributed to adjustments identified by our independent registered public accounting firm during the quarter ended June 30, 2014. This control deficiency could result in a material misstatement in the consolidated financial statements that would not be prevented or detected.

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Notwithstanding the material weakness described above, we believe the Company's financial statements included in this Quarterly Report on Form l0-K present fairly, in all material respects, the Company's financial position, results of operations, shareholders' equity (deficit), statements of comprehensive loss and cash flows for the periods presented.

Plan for Remediation of Material Weakness

With the oversight of senior management and our audit committee, we have taken steps to remediate the material weakness noted above. We initiated a plan to remediate the weakness, but have not yet fully eliminated this weakness. During the second quarter, we hired a Chief Financial Officer (CFO), who has extensive finance experience. In addition, in Q4 we have hired a Director of Finance with extensive control and system implementation knowledge and a qualified Controller with substantial SEC reporting expertise to augment our accounting staff and to provide more resources to support effective internal controls. The CFO hired in June remains with the organization and is leading our financial reporting activities with the assistance from the Controller. Management believes that hiring qualified accounting personnel increased the level of technical accounting knowledge and improved the overall system of internal controls and which will fully remediate this material weakness.

Changes in Internal Control over Financial Reporting

During the quarter ended December 31, 2014, there were changes made in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and l5d-15(f) of the Exchange Act), described in the "Plan for Remediation of Material Weakness," that have materially affected, or are reasonable likely to material affect, our internal control over financial reporting, related to the remediation of the material weakness.

Item 9B. ***Other Information***

Not applicable.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K, and is incorporated by reference to our definitive Proxy Statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with our 2014 Annual Meeting of Shareholders scheduled for May 12, 2015.

Item 10. ***Directors, Executive Officers and Corporate Governance***

The information relating to our directors is incorporated by reference to the Proxy Statement as set forth under the caption "Election of Directors." Information relating to our executive officers is set forth in Part I of this Report under the caption "Executive Officers."

Information with respect to delinquent filings pursuant to Item 405 of Regulation S-K is incorporated by reference to the Proxy Statement as set forth under the caption "Section 16(a) Beneficial Ownership Reporting Compliance."

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Item 11. ***Executive Compensation***

The information relating to executive compensation is incorporated by reference to the Proxy Statement under the caption "Executive Compensation and Related Information."

Item 12. ***Security Ownership of Certain Beneficial Owners and Management, and Related Shareholder Matters***

The information relating to ownership of our equity securities by certain beneficial owners and management is incorporated by reference to the Proxy Statement as set forth under the caption "Stock Ownership of Certain Beneficial Owners and Management."

Item 13. ***Certain Relationships and Related Transactions, and Director Independence***

The information relating to certain relationships and related person transactions is incorporated by reference to the Proxy Statement under the caption "Certain Relationships and Related Party Transactions."

Item 14. ***Principal Accountant Fees and Services***

The information relating to principal accountant fees and services is incorporated by reference to the Proxy Statement under the caption "Ratification of Appointment of Independent Registered Public Accounting Firm."

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

(a) The following documents are filed as part of this Annual Report on Form 10-K:

1. Financial Statements (see Item 8).

2. All information is included in the Financial Statements or Notes thereto.

3. Exhibits:

See Exhibit Index.

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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.

Date: March 25, 2015

Vericel Corporation

/s/ DOMINICK C. COLANGELO
Dominick C. Colangelo
President and Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed on behalf of the registrant on March 25, 2015 by the following persons in the capacities indicated.

Signature	Title
/s/ DOMINICK C. COLANGELO Dominick C. Colangelo	*President and Chief Executive Officer, Director* *(Principal Executive Officer)*
/s/ GERARD J. MICHEL Gerard J. Michel	*Chief Financial Officer and Vice President of Corporate Development* *(Principal Financial and Accounting Officer)*
/s/ ROBERT L. ZERBE, M.D. Robert L. Zerbe, M.D.	*Chairman of the Board of Directors*
/s/ NELSON M. SIMS Nelson M. Sims	*Director*
/s/ ALAN L. RUBINO Alan L. Rubino	*Director*
/s/ HEIDI M. HAGEN Heidi M. Hagen	*Director*
/s/ STEVEN C. GILMAN Steven C. Gilman	*Director*
/s/ KEVIN F. MCLAUGHLIN Kevin F. McLaughlin	*Director*

/s/ PAUL K. WOTTON — *Director*

Paul K. Wotton

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EXHIBIT INDEX

Exhibit No.	Description
3.1	Restated Articles of Incorporation of the Company, filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on December 17, 2009, incorporated herein by reference.
3.2	Certificate of Amendment to Restated Articles of Incorporation of the Company dated February 9, 2010, filed as Exhibit 3.2 to the Company's Post Effective Amendment No. 1 to Form S-1 filed on March 31, 2010, incorporated herein by reference.
3.3	Certificate of Amendment to Restated Articles of Incorporation of the Company dated March 22, 2011, attached as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on March 25, 2011, incorporated herein by reference.
3.4	Certificate of Amendment to the Restated Articles of Incorporation of the Company, dated November 21, 2014, attached as Exhibit 3.1 to Vericel's Current Report on Form 8-K filed on November 24, 2014, incorporated herein by reference.
3.5	Certificate of Designation, Preferences and Rights, of the Company classifying and designating the Series A Junior Participating Cumulative Preferred Stock, attached as Exhibit 3.1 to the Company's Current Report on Form 8-A filed on August 12, 2011, incorporated herein by reference.
3.6	Amended and Restated Certificate of Designations, Preferences and Rights, of the Company classifying and designating the Series B-1 Non-Voting Convertible Preferred Stock and the Series B-2 Voting Convertible Preferred Stock, attached as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on August 12, 2013, incorporated herein by reference.
3.7	Bylaws, as amended, attached as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on November 12, 2010, incorporated herein by reference.
4.1	Form of Senior Indenture for Senior Debt Securities, filed as Exhibit 4.1 to the Company's Registration Statement on Form S-3 filed on June 16, 2011 and incorporated herein by reference.
4.2	Form of Indenture for Subordinated Debt Securities, filed as Exhibit 4.3 to the Company's Registration Statement on Form S-3 filed on June 16, 2011 and incorporated herein by reference.
4.3	Shareholder Rights Agreement, dated as of August 11, 2011, between the Company and Continental Stock Transfer & Trust Company, as Rights Agent, attached as Exhibit 4.3 to the Company's Current Report on Form 8-A filed on August 12, 2011, incorporated herein by reference.
4.4	Amendment to Shareholder Rights Agreement, dated as of March 9, 2012, between the Company and Continental Stock Transfer & Trust Company, as Rights Agent, attached as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on March 9, 2012, incorporated herein by reference.
10.1 #	Form of Indemnification Agreement, attached as Exhibit 10.1 to the Company's Registration Statement on Form S-1 (No. 333-15415), filed on November 1, 1996, incorporated herein by reference.
10.2 #	Amended and Restated 1992 Incentive and Non-Qualified Stock Option Plan and forms of agreements thereunder, attached as Exhibit 10.5 to the Company's Registration Statement on Form S-1 (No. 333-15415), filed on November 1, 1996, incorporated herein by reference.
10.3 #	Form of Employment Agreement, attached as Exhibit 10.8 to the Company's Registration Statement on Form S-1 (No. 333-15415), filed on November 1, 1996, incorporated herein by reference.
10.4	License Agreement, dated March 13, 1992, between the Company and the University of Michigan and

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	amendments thereto dated March 13, 1992, October 8, 1993 and June 21, 1995, attached as Exhibit 10.17 to the Company's Registration Statement on Form S-1 (No. 333-15415), filed on November 1, 1996, incorporated herein by reference.
10.5 #	2001 Stock Option Plan, attached as Exhibit 10.72 to the Company's Annual Report on Form 10-K for the year ended June 30, 2002, incorporated herein by reference.
10.6 #	2004 Equity Incentive Plan, attached as Exhibit 10.82 to Amendment No. 1 to the Company's Quarterly Report on Form 10-Q/A for the quarter ended September 30, 2004, incorporated herein by reference.
10.7 #	Form of Option and Restricted Stock Award Agreements for Grants under 2004 Equity Incentive Plan, attached as Exhibit 10.84 to the

	Company's Annual Report on Form 10-K for the year ended June 30, 2005, incorporated herein by reference.
10.8	Amendment dated December 5, 2002 to License Agreement with the University of Michigan, attached as Exhibit 10.87 to the Company's Annual Report on Form 10-K for the year ended June 30, 2005, incorporated herein by reference.
10.9 #	2004 Equity Incentive Plan, as amended, attached as Exhibit 99.1 to the Company's Current Report on Form 8-K filed on November 8, 2006, incorporated herein by reference.
10.10 #	Forms of Grant Notice and Stock Option Agreement for Grants under 2004 Equity Incentive Plan, as amended, attached as Exhibit 99.2 to the Company's Current Report on Form 8-K filed on November 8, 2006, incorporated herein by reference.
10.11	Form of Purchase Agreement, attached as Exhibit 10.3 to the Company's Current Report on Form 8-K filed on October 16, 2007, incorporated herein by reference.
10.12	Form of Warrant, attached as Exhibit 10.4 to the Company's Current Report on Form 8-K filed on October 16, 2007, incorporated herein by reference.
10.13	Standard Lease between the Company and Domino's Farms Office Park, L.L.C. dated January 31, 2007., attached as Exhibit 10.96 to Amendment No. 1 to the Company's Annual Report on Form 10-K for the year ended June 30, 2007, incorporated herein by reference.
10.14 #	2009 Omnibus Incentive Plan, attached as Appendix II to the Company's Proxy Statement filed on October 9, 2009, incorporated herein by reference.
10.15	Class A Warrant Agreement, dated as of January 21, 2010, by and between the Registrant and Continental Stock Transfer & Trust Company (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on January 27, 2010).
10.16	Class B Warrant Agreement, dated as of January 21, 2010, by and between the Registrant and Continental Stock Transfer & Trust Company (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on January 27, 2010).
10.17	Underwriting Agreement, dated as of January 15, 2010, and between the Registrant and Oppenheimer & Co. Inc. (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on January 15, 2010).
10.18 #	Form of indemnification agreement entered into between the Company and each of its directors, attached as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 31, 2010, incorporated herein by reference.
10.19	Amended Code of Business Conduct and Ethics, attached as Exhibit 14.1 to the Company's Current

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	Report on Form 8-K filed on August 31, 2010, incorporated herein by reference.
10.20*	Contract Manufacturing and Supply Agreement, dated as of November 8, 2010, by and between Vention Medical (formerly ATEK Medical, LLC) and the Company (incorporated herein by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K for the year ended December 31, 2010).
10.21	Warrant agreement, dated as of December 15, 2010, by and between the Registrant and Continental Stock Transfer & Trust Company (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on December 16, 2010).
10.22	Underwriting Agreement, dated as of December 10, 2010, and between the Registrant and Stifel, Nicolaus & Company, Incorporated, Needham & Company, LLC and Roth Capital Partners (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on December 10, 2010).
10.23#	Amendment to the 2009 Omnibus Incentive Plan, dated March 21, 2011 (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K, filed on March 25, 2011).
10.24#	Employment Agreement with Ronnda L. Bartel, PhD, dated March 22, 2011 (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on March 25, 2011).
10.25#	Employment Agreement with Sharon Watling, PharmD, dated March 22, 2011 (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on March 25, 2011).
10.26#	Senior Executive Incentive Bonus Plan (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed on March 25, 2011).
10.27	At Market Issuance Sales Agreement, dated June 16, 2011, by and among the Company and MLV & Co. LLC ("MLV") (formerly McNicoll, Lewis & Vlak LLC),(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 16, 2011).
10.28	Master Services Agreement by and between the Company and PPD, made and entered into as of September 23, 2011 (the "Master Services Agreement") (incorporated herein by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K for the year ended December 31, 2012).
10.29	Project Addendum to the Master Services Agreement, dated as of November 16, 2011 (incorporated herein by reference to Exhibit 10.2 to

the Company's Current Report on Form 8-K filed with the SEC November 22, 2011).

10.30 Registration Rights Agreement, dated March 9, 2012, between the Company and Eastern Capital Limited, attached as Exhibit 10.2 to the Company's Current Report on Form 8-K filed on March 9, 2012, incorporated herein by reference.

10.31 Securities Purchase Agreement, dated as of March 9, 2012, by and between the Company and Eastern Capital Limited (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on March 9, 2012).

10.32# Employment Agreement, dated as of April 3, 2013, by and between the Company and Daniel R. Orlando (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on April 9, 2013).

10.33# Employment Agreement, dated as of October 26, 2012, by and between the Company and Brian Gibson (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on October 26, 2012).

10.34# Amendment to the 2009 Omnibus Incentive Plan, dated May 3, 2012 (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed on August 7, 2012).

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10.35 Form of Warrant Exchange Agreement, dated June 27, 2012 (incorporated herein by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed on June 27, 2012).

10.36# Executive Resignation Agreement, executed on December 14, 2012, by and between the Company and Tim M. Mayleben (incorporated herein by reference to Exhibit 10.36 to the Company's Annual Report on Form 10-K for the year ended December 31, 2012, filed on March 18, 2013).

10.37# Executive Employment Agreement, executed March 4, 2013 and effective March 1, 2013, by and between the Company and Dominick C. Colangelo (incorporated herein by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed on March 9, 2013).

10.38 Form of Warrant Exercise Agreement, dated September 24, 2013 (incorporated herein by reference to Exhibit 10 to the Company's Report on Form 8-K, filed on September 27, 2013).

10.39 Consulting Services Agreement, executed January 9, 2014 and effective January 1, 2014, by and between the Company and Ronnda L. Bartel (incorporated herein by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed on January 14, 2014).

10.40 Underwriting Agreement, dated as of August 13, 2013, by and between the Company and Aegis Capital Corp. (incorporated herein by reference to Exhibit 1.1 to the Company's Registration Statement on Form S-1 (File No. 333-188186) filed on August 13, 2013).

10.41 Amendment No.1 to At Market Issuance Sales Agreement, dated November 29, 2013, by and between the Company and MLV (incorporated herein by reference to Exhibit 1.1 to the Company's Report on Form 8-K, filed on November 29, 2013).

10.42 Purchase Agreement, dated as of January 21, 2014, by and between the Company and Lincoln Park Capital Fund, LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 27, 2014).

10.43 Registration Rights Agreement, dated as of January 21, 2014, by and between the Company and Lincoln Park Capital Fund, LLC (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on January 27, 2014).

10.44 Asset Purchase Agreement, dated as of April 19, 2014, by and between the Company and Sanofi (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on June 2, 2014).

10.45# Employment Agreement, dated May 13, 2014, by and between the Company and Gerard Michel (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 4, 2014).

10.46 Transition Services Agreement, dated as of May 30, 2014, by and between the Company and Genzyme Corporation (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 2, 2014).

10.47 Transition Supply Agreement, dated as of May 30, 2014, by and between the Company and Genzyme Corporation (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on June 2, 2014).

10.48 Form of Warrant Exercise Agreement, dated July 9, 2014 (incorporated herein by reference to Exhibit 10 to the Company's Report on Form 8-K, filed on July 11, 2014).

10.49# Employment Agreement, dated as of March 27, 2014, by and between the Company and Ross Tubo (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 1, 2014).

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10.50# Employment Agreement, dated as of March 27, 2014, by and between the Company and David Recker (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on April 1, 2014).

10.51#	Employment Agreement, dated September 25, 2014, by and between the Company and Ross Tubo (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 25, 2014).
10.52#	Employment Agreement, dated September 25, 2014, by and between the Company and David Recker (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on September 25, 2014).
10.53#	Second Amended and Restated 2009 Omnibus Incentive Plan (previously filed as Appendix II to the Company's definitive proxy statement on Schedule 14A, filed on October 21, 2014 and incorporated herein by reference).
10.54#	Employment Agreement, dated November 6, 2014, by and between the Company and Gerard Michael (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 12, 2014).
10.55#	Amended and Restated Non employee Director Compensation Guidelines.
21.1	Subsidiaries of Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

Management contract or compensatory plan or arrangement covering executive officers or directors of Vericel.
* Confidential treatment status has been requested as to certain portions thereto, which portions are omitted and filed with Securities and Exchange Commission.

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GLOSSARY

TERM	DEFINITION
Adverse Event	Any adverse change in health or "side-effect" that occurs in a person participating in a clinical trial, from the time they consent to joining the trial until a pre-specified period of time after their treatment has been completed.
Autologous (Patient Specific)	Originating from the patient receiving treatment. (Vericel uses only autologous cells)
BLA — Biologics License Application	An application containing product safety, efficacy and manufacturing information required by the FDA to market biologics products in the U.S.
CLI — Critical Limb Ischemia	A vascular disease characterized by insufficient blood flow in the lower extremities that causes severe pain, tissue loss or both.
CMC — Chemistry, Manufacturing, and Control	The composition, manufacture, and control of the drug substance and the drug product. It is information on the identification, quality, purity, and strength of the investigational product.
Controlled Clinical Trial	A clinical study that compares patients receiving a specific treatment to patients receiving an alternate treatment for the condition of interest. The alternate treatment may be another active treatment, standard of care for the condition and/or a placebo (inactive) treatment.
DCM — Dilated Cardiomyopathy	A chronic cardiac disease where expansion of the patient's heart reduces the pumping function to a point that the normal circulation of blood cannot be maintained.
Double-Blind Clinical Trial	Clinical trials in which neither the patient nor the physician know if the patient received the experimental treatment or a control/placebo.
FDA — Food & Drug Administration	The U.S. FDA ensures that medicines, medical devices, and radiation-emitting consumer products are safe and effective. Authorized by Congress to enforce the Federal Food, Drug, and Cosmetic Act and several other public health laws, the agency monitors the manufacture, import, transport, storage, and sale of $1 trillion worth of goods annually.
GMP — Good Manufacturing Practice	GMP regulations require that manufacturers, processors, and packagers of drugs, medical devices, some food, and blood take proactive steps to ensure that their products are safe, pure, and effective. GMP regulations require a quality approach to manufacturing, enabling companies to minimize or eliminate instances of contamination, mix-ups, and errors.
Hematopoietic Stem Cells	Stem cells that give rise to all the blood cell types including myeloid (monocytes and macrophages, neutrophils, basophils, eosinophils, erythrocytes, megakaryocytes/platelets,

	dendritic cells), and lymphoid lineages (T-cells, B-cells, NK-cells).
IMPACT-DCM	Vericel's U.S. Phase 2 dilated cardiomyopathy clinical trial.
IND — Investigational New Drug	An application submitted to the FDA for a new drug or biologic that, if allowed, will be used in a clinical trial.
Ischemia	A shortage or inadequate flow of blood to a body part (commonly an organ or tissue) caused by a constriction or obstruction of the blood vessels supplying it.
LVEF — Left Ventricular Ejection Fraction	The fraction of blood pumped out of the left ventricle with each heartbeat.
Mesenchymal stromal cells	Connective tissue cells that, in the case of bone marrow derived MSC, function to support blood forming cells and secrete anti-inflammatory factors.
M2 anti-inflammatory macrophages	Specialized blood cells that remove damaged tissue and bacteria and secrete anti-inflammatory factors.
Open-label Clinical Trial	A trial in which both the treating physician and the patient know whether they are receiving the experimental treatment or control/placebo treatment.
Orphan Drug Designation	"Orphan drug" refers to a drug or biologic that is intended for use in the treatment of a rare disease or condition. Orphan drug designation from the U.S. Food and Drug Association (FDA) qualifies the sponsor to receive certain benefits from the Government in exchange for developing the drug for a rare disease or condition. The drug must then go through the FDA marketing approval process like any other drug or biologic which evaluates for safety and efficacy. Usually a sponsor receives a quicker review time and lower application fees for an orphan product.

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TERM	DEFINITION
Phase 1 Clinical Trial	A Phase 1 trial represents an initial study in a small group of patients to test for safety and other relevant factors.
Phase 2 Clinical Trial	A Phase 2 trial represents a study in a moderate number of patients to assess the safety and efficacy of a product.
Phase 2b Clinical Trial	A Phase 2b trial is a moderately-sized Phase 2 trial that is more specifically designed assess the efficacy of a product than a Phase 2a trial.
Phase 3 Clinical Trial	Phase 3 studies are initiated to establish safety and efficacy in an expanded patient population at multiple clinical trial sites and are generally larger than trials in earlier phases of development.
Prospective Clinical Trial	A clinical trial in which participants are identified and then followed throughout the study going forward in time.
Randomized Clinical Trial	A clinical trial in which the participants are assigned randomly to different treatment groups.
Somatic Cell	Any of the cells responsible for forming the body of an organism such as internal organs, bones, skin, connective tissues and blood.
Stem Cell	Unspecialized (undifferentiated) cells that retain the ability to divide throughout a lifetime and give rise to more specialized (differentiated) cells which take the place of cells that die or are lost. In culture, these undifferentiated cells possess the ability to divide for indefinite periods in culture and may give rise to highly specialized cells.

Exhibit 10.55

Nonemployee Director Compensation Guidelines

Following a review conducted by the Compensation Committee (the "Compensation Committee") of the Board of Directors (the "Board") of the Company of changing practices for compensating outside directors, on March 20, 2015, the Board approved a new compensation arrangement for recognizing the service of outside directors and more closely aligning their overall compensation with the interests of other shareholders. The Chairman of the Board will continue to receive an annual fee of $80,000 paid in equal quarterly increments. Each nonemployee director will receive an annual fee of $40,000 paid in equal quarterly increments. The chairperson of the Audit Committee of the Board (the "Audit Committee") will receive an annual fee of $18,000, and each non-chair member of the Audit Committee will receive an annual fee of $8,000, payable quarterly. The Chairperson of the Compensation Committee will receive an annual fee of $12,500, and each non-chair member of the Compensation Committee will continue to receive an annual fee of $5,000, payable quarterly. The Chairperson of the Governance and Nominating Committee of the Board (the "Governance Committee") will receive an annual fee of $10,000, and each non-chair member of the Governance Committee will continue to receive an annual fee of $5,000, payable quarterly. Directors will not be paid a separate amount for each board or committee meeting attended. Each nonemployee director who continues to serve beyond an Annual Shareholder Meeting will also receive a stock option to purchase 15,000 shares granted on January 1st of each fiscal year, with an exercise price equal to the fair market value of the common stock on the date of grant, and will vest in equal quarterly increments over a period of one year. Any nonemployee director joining the Board mid-year will be provided a pro-rata annual grant for service until the next Annual Meeting. In addition, each current nonemployee director received a one-time stock option to purchase 15,000 shares on March 20, 2015, and any future nonemployee director who joins the Board will also receive a one-time stock option to purchase 15,000 shares on the date of such director's appointment, with an exercise price equal to the fair market value of the common stock on the date of such grant, and to vest in equal monthly installments over a period of three years. These equity grants will be made under the terms of the existing equity compensation plans. These new arrangements replaced the previous nonemployee director compensation program.

EXHIBIT 21.1

SUBSIDIARIES OF REGISTRANT

Aastrom Biosciences GmbH, Germany
Marrow Donation, LLC
Åström BIOSCIENCES DK ApS

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (Nos. 333-187346, 333-174758, 333-163832, 333-140624, 333-121006, 333-115505, 333-81340, 333-51556, 333-38886 and 333-25021) of Vericel Corporation. of our report dated March 25, 2015 relating to the consolidated financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Detroit, Michigan
March 25, 2015

EXHIBIT 31.1

CERTIFICATION

I, Dominick C. Colangelo, certify that:

1. I have reviewed this Annual Report on Form 10-K of Vericel Corporation for the year ended December 31, 2014;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

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

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

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

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

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

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

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

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

/s/ DOMINICK C. COLANGELO
Dominick C. Colangelo
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 25, 2015

EXHIBIT 31.2

CERTIFICATION

I, Gerard J. Michel, certify that:

1. I have reviewed this Annual Report on Form 10-K of Vericel Corporation for the year ended December 31, 2014;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

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

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

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

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

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

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

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

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

/s/ GERARD J. MICHEL

Gerard J. Michel
Chief Financial Officer and Vice President
of Corporate Development
(Principal Financial and Accounting Officer)

Date: March 25, 2015

EXHIBIT 32.1

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

In connection with the Annual Report of Vericel Corporation (Company) on Form 10-K for the year ended December 31, 2014, as filed with the Securities and Exchange Commission on the date hereof (Report), each of the undersigned officers of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Section 906), the following:

(1) The Report fully complies with the requirements of section 13(a) and 15(d) of the Securities Exchange Act of 1934; and

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

/s/ DOMINICK C. COLANGELO
Dominick C. Colangelo
President and Chief Executive Officer
(Principal Executive Officer)

/s/ GERARD J. MICHEL
Gerard J. Michel
Chief Financial Officer and Vice President
of Corporate Development
(Principal Financial and Accounting Officer)

Date: March 25, 2015

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