Fibrocell Science, Inc.
Form 10-K
March 13, 2015

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

ý 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
¨ Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Fibrocell Science, Inc.
(Exact name of registrant as specified in its Charter.)

Delaware	001-31564	87-0458888
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

405 Eagleview Boulevard
Exton, Pennsylvania 19341
(Address of principal executive offices, including zip code)
(484) 713-6000
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of each exchange on which registered
Common Stock, $.001 par value	The NASDAQ Stock Market LLC

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

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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 ý
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 ý
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, as amended, 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 ý 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 ý 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, 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. ý
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or 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 x	Non-accelerated filer ¨	Smaller reporting company ¨

(Do not check if a smaller reporting company)

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

The approximate aggregate market value of common stock held by non-affiliates of the registrant was $64.1 million as of June 30, 2014, the last business day of the registrant's most recently completed second fiscal quarter. Such aggregate market value was computed by reference to the closing price of the common stock as reported on the NYSE MKT on June 30, 2014.

As of March 6, 2015, registrant had 40,856,815 shares issued and outstanding of common stock, par value $0.001.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2015 Annual Meeting of Stockholders (hereinafter referred to as the "Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K.

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Forward-Looking Statements

This Annual Report on Form 10-K (including the section regarding Management's Discussion and Analysis of Financial Condition and Results of Operations) contains certain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as well as information relating to Fibrocell Science, Inc. and its subsidiaries (collectively referred to as "Fibrocell," "Company," "we," "us,"or "our") that is based on management's exercise of business judgment and assumptions made by and information currently available to management. Although forward-looking statements in this Annual Report on Form 10-K reflect the good faith judgment of our management, such statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in or anticipated by the forward-looking statements. When used in this document and other documents, releases and reports released by us, the words "anticipate," "believe," "estimate," "expect," "intend," "the facts suggest" and words of similar import, are intended to identify any forward-looking statements. You should not place undue reliance on these forward-looking statements. These statements reflect our current view of future events and are subject to certain risks and uncertainties as noted below. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, our actual results could differ materially from those anticipated in these forward-looking statements. Actual events, transactions and results may materially differ from the anticipated events, transactions or results described in such statements. Although we believe that our expectations are based on reasonable assumptions, we can give no assurance that our expectations will materialize. Many factors could cause actual results to differ materially from our forward looking statements including those set forth in Item 1A of this report. Other unknown, unidentified or unpredictable factors could materially and adversely impact our future results. We undertake no obligation and do not intend to update, revise or otherwise publicly release any revisions to our forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of any unanticipated events. Several of these factors include, without limitation:

- the progress and results of our pre-clinical studies and clinical trials of our cell therapy applications, including whether our clinical human trials relating to the use of autologous cell and gene therapy applications, in particular, for vocal cord scars and gene therapy orphan indications, and such other target indications as we may identify and pursue can be conducted within the timeframe that we expect, whether such studies and trials will yield positive results, or whether additional applications for the commercialization of autologous cell therapy can be identified by us and advanced into human clinical trials;
- the cost of manufacturing related to our pre-clinical studies and clinical trials;
- our ability to meet requisite regulations or receive regulatory approvals in the United States and in Europe, our ability to retain any regulatory approvals that we may obtain and the absence of adverse regulatory developments in the United States and Europe;
- the costs, timing and outcome of regulatory review of our product candidates;
- the dependence on our facility in Exton, Pennsylvania for our research, development and manufacturing operations, and the potential that such facility is damaged or if we are otherwise required to discontinue research, development and production at such facility;
- whether our collaboration with Intrexon can be advanced with positive results within the timeframe and budget that we expect;
- our dependence on suppliers for gene therapy products which are critical to the completion of our gene therapy applications;
- the scope, progress, results and costs of pre-clinical development, laboratory testing and clinical trials for our cell therapy applications;
- the number and development requirements of other product candidates that we pursue;
- the emergence of competing technologies and other adverse market developments;
- the extent to which we acquire or invest in businesses, products and technologies;

- our ability to establish collaborations and obtain milestone, royalty or other payments from any such collaborators;
- any adverse claims relating to our intellectual property and the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property related claims; and
- our dependence on physicians to correctly follow our established protocols for the safe and optimal administration of our product.

Our corporate headquarters is located at 405 Eagleview Boulevard, Exton, Pennsylvania 19341. Our phone number is (484) 713-6000. Our fiscal year begins on January 1, and ends on December 31, and any references herein to "Fiscal 2014"

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mean the fiscal year ended December 31, 2014, and references to other “Fiscal” years mean the fiscal year ending December 31, of the year indicated.

We own or have rights to various copyrights, trademarks and trade names used in our business including but not limited to the following: Fibrocell Science, Fibrocell Therapy, Fibrocell Process and LAVIV®. This report also includes other trademarks, service marks and trade names of other companies. Other trademarks and trade names appearing in this report are the property of the holder of such trademarks and trade names.

We obtained the industry, market and competitive position data in this annual report from our own internal estimates and research as well as from industry and general publications and research surveys and studies conducted by third parties. Industry publications and surveys generally state that the information contained therein has been obtained from sources believed to be reliable. We believe this data is accurate in all material respects as of the date of this annual report.

Part I

Item 1. Business

Overview

We are an autologous cell therapy company primarily focused on developing first-in-class treatments for rare and serious skin and connective tissue diseases with high unmet medical needs. Our lead orphan gene therapy program is in late stage pre-clinical development for the treatment of recessive dystrophic epidermolysis bullosa ("RDEB"). In addition to our gene therapy program, we are pursuing the medical application of azficel-T for vocal cord scarring using our proprietary autologous fibroblast technology. We are also in pre-clinical development for our second gene therapy program for linear scleroderma.

Fibroblasts are the most common cell located in skin and connective tissue and are responsible for synthesizing extracellular matrix proteins that provide cellular structure and support. Fibroblasts are targeted to the localized environment of skin and connective tissue. Rare and serious skin and connective tissue diseases represent an ideal therapeutic focus for our autologous fibroblast technology. Such diseases are typically difficult to treat with systemic drug therapies because blood flow is limited in skin and connective tissue. Therefore, we believe that a localized approach is an optimum choice for treating these debilitating conditions.

Working in collaboration with Intrexon Corporation (NYSE:XON) ("Intrexon"), a leader in synthetic biology, we are pursuing genetic modification of autologous fibroblast cells to express collagen VII that is missing or inactive from patients with RDEB. Collagen VII is responsible for forming fibrils which attach the epidermis and the dermis layers of the skin. RDEB is a rare congenital orphan skin disease that ultimately leads to premature death. The lack of collagen VII is the underlying cause of this disease. We expect to file our investigational new drug ("IND") application for RDEB with the U. S. Food and Drug Administration ("FDA") by mid-2015 and initiate our Phase I clinical trials in the second half of Fiscal 2015.

Vocal cord scarring is caused by damage to the fibroblast layer of the vocal cords causing scarring and edema. This scarring limits airflow and results in severe and significant limitations in voice quality, including, in some cases, the loss of voice, altogether. Our clinical focus is patients with age-related dysphonia or idiopathic causes. We currently have a Phase II vocal cord clinical trial in progress.

Linear scleroderma is an excess production of extracellular matrix characterized by skin fibrosis and linear scars. The linear areas of skin thickening may extend to underlying tissue and muscle in children which may impair growth in affected legs and arms or forehead. Lesions appearing across joints can impair motion and may be permanent.

Our ongoing scientific research collaboration with the Regents of the University of California, Los Angeles (“UCLA”) focuses on discoveries and technologies related to regenerative medicine. The technologies from this collaboration and our exclusive license agreements with UCLA may enable us to expand our biologics platform which uses human fibroblasts to create localized therapies that are compatible with the unique biology of each patient.

Our Strategy

Currently, our personalized biologics platform embodies two separate product engines, each of which uses our proprietary fibroblast technology.

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Our Proprietary Personalized Biologics Approach:
Harnessing Autologous Fibroblast Cells to Deliver Localized Therapies That Are Compatible with Each Patient's Unique Biology:

Our Gene Therapy Product Engine combines our autologous fibroblast technology with the synthetic biology technology of our collaborator, Intrexon, to develop personalized biologic gene therapies to address the fundamental source of serious and rare skin and connective tissue diseases that have unmet medical needs.
Our Gene Therapy Product Engine utilizes several proprietary technologies in our pursuit of gene therapies for our lead orphan gene therapy program, RDEB, and our second gene therapy program, linear scleroderma.

- Intrexon's UltraVector® technology is designed to facilitate the assembly and delivery of the necessary target gene constructs for delivery to autologous fibroblasts. Access to this platform allows us a rapid method to screen and construct gene therapy solutions for rare and serious skin and connective tissue diseases.
- In certain therapeutic applications with our Gene Therapy Product Engine, we will also deploy Intrexon's proprietary RheoSwitch Therapeutic System® technology, which is a biologic switch activated by a small molecule ligand that provides the ability to control level and timing of protein expression in those diseases where such control is critical.

Our Autologous Fibroblast Product Engine utilizes autologous fibroblast cells to treat vocal cord scarring leveraging its FDA-approved biologics license application ("BLA") for aesthetics with azficel-T, the USAN name for our commercial product LAVIV®. We are expanding the medical application of azficel-T to create a therapeutic comprised of fibroblast cells in the treatment of vocal cord scarring. Vocal cord scarring results in severe and significant limitations in voice quality and often loss of voice.

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Clinical and Pre-Clinical Development Programs

Our development programs are focused on the serious skin and connective tissue disease market where there are unmet needs. Our clinical and pre-clinical development programs consist of the following:

Program	Indication	Status
azficel-T sBLA	Vocal Cord Scarring	Phase II Clinical Trial
GM-HDF	RDEB	Pre-clinical
GM-HDF	Linear Scleroderma	Pre-clinical

Vocal Cord Scarring – Phase II Trial: The exact incidence of vocal cord scaring is difficult to determine. However, various third party studies indicate that the incidence of vocal cord scarring is in the range of 200,000 to 700,000 patients in the United States. For patients with vocal cord scarring that results in severe or chronic dysphonia, we estimate the prevalence as 146,000. Our Phase II clinical trial for vocal cord scarring currently in progress is designed to test the safety and efficacy of azficel-T in patients with dsyphonia caused by idiopathic vocal cord scarring or age-related dysphonia. We have currently enrolled 22 patients and we will continue to recruit to allow for any potential discontinuations that may occur during the course of this clinical trial. The goal is to achieve 20 patients treated. Our first patient in this Phase II clinical trial was enrolled in April 2014 and we are targeting the last patient to be treated by the end of 2015.

In a Phase I clinical trial IT-V-001, which was a feasibility study to determine the safety and efficacy of injections for the treatment of vocal fold scarring, 5 patients received 3 doses (1-2 x 10^7 cells/mL per treatment) of azficel-T per vocal fold in the lamina propia compartment, where each treatment was approximately 1 month apart. In this clinical trial, we evaluated the efficacy and safety of azficel-T for the treatment of vocal cord scarring in patients who had failed to improve following anti-reflux regimen, speech therapy, or vocal fold injections with collagen. Starting in Month 3, a sustained improvement was noted in a majority of patients through Month 12 in the mucosal wave grade assessment, voice handicap index, and patient-assessed voice quality.

Three of the 5 patients reported a total of 16 adverse events (“AEs”). All reported AEs other than ear pain (12 events in 3 patients) were considered by the investigator to be unrelated to treatment. A majority of the cases (10) were mild or moderate in severity. All AEs were non-serious and no deaths were reported. There were no laboratory abnormalities or other untoward events that were considered related to the study treatment. Based on these results, azficel-T was well tolerated in this patient population.

Recessive Dystrophic Epidermolysis Bullosa ("RDEB") – Pre-clinical: Our product candidate is utilized to transduce the fibroblasts with the COL7A gene in order to treat patients with RDEB. This concept utilizes gene therapy applied to autologous fibroblasts to up-regulate and produce collagen VII in a controlled manner for localized treatment of RDEB. We are collaborating with Intrexon to employ Intrexon’s synthetic biology platforms to optimize gene expression in our genetically-modified fibroblasts. RDEB is the most severe form of dystrophic epidermolysis bullosa (“DEB”), a genetic disorder that causes severe blistering and areas of missing skin, which is a response to any kind of friction, including normal daily occurrences like rubbing or scratching. The blistering occurs because of the lack of anchoring fibrils that were not produced due to the lack of collagen VII.

We have estimated, based on the epidemiology from various published studies, that the prevalence of DEB is 5,500 to 12,500 U.S. patients, 1,100 to 2,500 of whom have RDEB, the most severe form of DEB. RDEB is caused by a recessively inherited COL7A1 mutation while dominant dystrophic epidermolysis bullosa ("DDEB") is caused by a dominant gene. Although less severe than RDEB, DDEB is a significant disease with approximately 4,400 to 10,000 U.S. patients.

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To date, our pre-clinical work has consisted of selecting our gene target, gene construct and successfully transducing the gene for collagen VII into the autologous fibroblast cell. We have optimized cell culture conditions, selected a contract manufacturing organization and have successfully completed multiple runs. We have also developed assays for potency and safety. We have been granted orphan drug status, and held a pre-IND meeting with the FDA. We have also completed clinical trial protocol review by the National Institutes of Health ("NIH") Recombinant DNA Advisory Committee (RAC), with no questions posed from the RAC and no request to attend the quarterly public meeting. Pre-clinical mouse studies are currently underway at Stanford University. We expect to file our IND application in mid-2015.

Linear Scleroderma – Pre-clinical: We expanded our agreement with Intrexon to broaden our existing collaboration to include potential treatments based on engineered autologous fibroblast cells for the localized treatment of autoimmune and inflammatory disorders, including linear scleroderma. Intrexon plans to engineer transgenes to optimize the functionality of our autologous fibroblast cells in order to produce factors under the control of its proprietary RheoSwitch Therapeutic System® (“RTS®”) that will modulate immune and inflammatory pathways. It is estimated that 200,000 people suffer from localized scleroderma, which is comprised of many subtypes. Linear scleroderma is an autoimmune disease that primarily affects skin and connective tissues causing hardened plaques and joint contractures. The total prevalence of linear scleroderma in the United States is estimated to be approximately 40,000 patients with scleroderma over a major joint and exhibit severe joint pain. Children and young adults represent the most problematic cases.

Product development is underway and has included gene selection and design, transduction efficiency and protein expression analysis, RTS® ligand development and analytical assay design. Research is ongoing to select the optimal gene configuration, optimize RTS® control, develop animal models to establish proof of concept and progress the regulatory path for the product candidate.

Other development programs consist of the following:

Restrictive Burn Scarring ("RBS") – Phase II Trial: According to the American Burn Association, 40,000 people are hospitalized each year with severe burns in the United States. These patients are often left with restrictive burn scars that decrease mobility and cause continuous pain. Our Phase II trial of azficel-T for the treatment of restrictive burn scarring was designed to evaluate the use of azficel-T to improve range of motion, function and flexibility, among other parameters. Patient enrollment has been challenging; therefore, we have closed enrollment and will evaluate the current population through the current study design, then convert to an open label trial to allow those patients who were treated with placebo to be treated with azficel-T. Additional patients will not be enrolled in this trial and we will reassess our clinical development plan after data has been compiled.

Intrexon Collaboration

On October 5, 2012, we entered into an Exclusive Channel Collaboration Agreement, as amended, (the “Channel Agreement”) with Intrexon that originally granted us an exclusive license to use proprietary technologies and other intellectual property of Intrexon to research, develop, use, import, export, make, have made, sell, and offer for sale certain products in the "Field" in the United States. The “Field” in the Channel Agreement originally included: (a) the enhanced production and purification of autologous fibroblasts, without gene therapy, for all aesthetic and therapeutic indications; (b) the enhanced production and purification of autologous dermal cells, without gene therapy, for aesthetic and therapeutic treatment of dermal, vocal cord, and periodontal indications; (c) the development of our gene therapies applied to autologous fibroblasts for all aesthetic and therapeutic indications; and (d) the development of our gene therapies applied to autologous dermal cells for aesthetic and therapeutic treatment of dermal, vocal cord, and periodontal indications. On June 28, 2013, we amended the Channel Agreement. Pursuant to the first amendment, the “Field” was modified to add autologous human fibroblasts with gene therapy to express a therapeutic protein and/or bioactive ribonucleic acid for the treatment of autoimmune and non-infectious inflammatory disorders that manifest in cutaneous tissues, fascia and/or muscle. Pursuant to the second amendment to the Channel Agreement executed on January 10, 2014, the “Field” in the Channel Agreement was further modified to add autologous human fibroblasts with gene therapy to express bioactive Tenascin-X locally to correct connective tissue disorders.

Pursuant to the Channel Agreement, we engage Intrexon for support services for the development of new products covered under the Channel Agreement, and reimburse Intrexon for its fully-loaded cost for time and materials for transgenes, cell processing, or other work performed by Intrexon for such research and development. We will pay quarterly cash royalties on improved products equal to one third of the cost of goods sold savings less any such savings developed by us outside of the Channel Agreement. On all other developed products, we will pay Intrexon quarterly cash royalties of 7% on aggregate annualized net sales up to $100 million, and 14% on aggregate annualized net sales greater than $100 million. Sales from our products (including new indications) that we are marketing at the time of the Channel Agreement are not subject to royalty payments unless they are improved upon through the Channel Agreement, as amended.

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License Agreements

On May 3, 2012, we entered into an exclusive license agreement with The Regents of the University of California, under which we acquired the rights to commercially apply discoveries resulting from the scientific collaboration between us and UCLA. Under the terms of the license agreement, we agreed to pay UCLA a non-refundable initial license fee, and to pay UCLA an annual license maintenance fee of a percentage of product royalties, and milestone payments based on our achievement of certain clinical and regulatory related milestones for these rights. Our ability to meet the milestones is dependent on a number of factors including final approvals by regulatory agencies and the continued enforceability of patent claims.

On June 13, 2014 we entered into two exclusive license agreements with The Regents of the University of California. Pursuant to the first exclusive license agreement (the “BMP2 Agreement”), UCLA granted us an exclusive, sublicensable right and license to use certain patent rights developed in collaboration with UCLA relating to the use of human skin cells to produce Bone Morphogenetic Protein ("BMP"2) for use in osteogenic therapies. In consideration of the license granted under the BMP2 Agreement, we will pay to UCLA a license issue fee, certain one-time milestone payments, a license maintenance fee, earned royalties on net sales of all licensed products (including sales by sublicensees and affiliates) and a percentage of amounts received from sublicensing activities. We are subject to minimum annual royalty payments to UCLA beginning after the first commercial sale of a licensed product.

Under the terms of the second exclusive license agreement (the “Genomic Stability Agreement”), UCLA granted us an exclusive, sublicensable right and license to use certain patent rights developed in collaboration with UCLA relating to media that promotes genomic stability in induced pluripotent stem cell cultures for all research and commercialization purposes. In consideration of the license granted under the Genomic Stability Agreement, we will pay to UCLA a license issue fee, certain one-time milestone payments, a license maintenance fee, earned royalties on net sales of all licensed products (including sales by affiliates) and a percentage of amounts received from sublicensing activities. We are subject to minimum annual royalty payments to UCLA beginning after first commercial sale of a licensed product.

On May 3, 2012, we also entered into a sponsored research agreement with MIT. Research is currently focused on mesenchymal stem cells derived from adult human skin. The agreement is currently scheduled to terminated in June 2015.

Manufacturing

We currently outsource the manufacturing for our gene therapy product to a manufacturing facility located in Mountainview, California. We currently have one manufacturing facility located in Exton, Pennsylvania, for our cell therapy products. All component parts used in either manufacturing process are readily available, and all machinery is maintained and calibrated. We believe we currently have adequate manufacturing capacity to satisfy our clinical demands, as well as the limited commercial demand we expect during Fiscal 2015.

The fibroblast cells that are the foundation of our product platforms are grown by our patented manufacturing process which begins with the collection of three small (3 mm) skin samples from behind the ear on the patient’s skin. The biopsies are then sent to us for processing according to cGMP. The skin samples are treated with an enzymatic process designed to separate the tissue into its individual component cells by breaking down the extracellular matrix holding the cells in place. The cells are also treated with antibiotics to prevent extraneous infection by microorganisms. The cells are then expanded using classical tissue culture techniques until the numbers are adequate for repeated injection. The patient’s cells are frozen and stored until the time of injection. When an injection is needed, the cells are thawed and washed to prepare them for patient injection. Within 24 hours of this preparation and shipment, vials containing a suspension consisting of 10 million to 20 million cells per milliliter arrives at the doctor’s office, ready for intradermal injection of the patient.

Intellectual Property

We believe that patents, trademarks, copyrights and other proprietary rights are important to our business. We also rely on trade secrets, know-how and continuing technological innovations to develop and maintain our competitive position. We seek to protect our intellectual property rights by a variety of means, including obtaining patents, maintaining trade secrets and proprietary know-how, and technological innovation to operate, without infringing on the proprietary rights of others and to prevent others from infringing on our proprietary rights. Our policy is to seek to

protect our proprietary position by, among other methods, actively seeking patent protection in the United States and certain foreign countries.

As of December 31, 2014, we had been assigned or licensed 13 issued U.S. patents, 11 pending U.S. patent applications, 3 pending international patents, 9 granted foreign patents and 23 pending foreign patent applications. Our issued patents and patent applications primarily cover the method of using autologous cell fibroblasts for the repair of skin and soft tissue defects and the use of autologous fibroblast cells for tissue regeneration. In particular, we own issued patents in the U.S. and other countries that are directed to methods of long-term augmentation of subcutaneous or dermal tissue by injecting an effective amount of a suspension of autologous passaged dermal fibroblasts into subadjacent tissue, which covers the approved

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use of LAVIV®, as well as azficel-T for the treatment of restrictive burn scars and vocal cord scars, and which was set to expire in July 2015. We have been awarded the maximum 5 year extension of this patent term in the U.S that with a new expiration of July 2020. In addition, we own an issued U.S. patent and pending applications in Australia, Canada, China, Europe, India, Japan, South Korea, Hong Kong and the U.S. directed to dosage formulations for injection containing particular amounts of autologous human fibroblasts and uses thereof, which also covers LAVIV® as well as azficel-T for the treatment of vocal cord scars and restrictive burn scars, and which naturally expire in 2030 and 2031. We also own pending applications in the U.S. and several foreign countries related to topical formulations of autologous dermal fibroblasts and uses thereof, which, if issued would naturally expire in 2031.

Competition

There are many companies currently competing in drug development for rare diseases, including Shire PLC (for the treatment of RDEB), Cytori Therapuetics (for the treatment of scleroderma of the hands) and Merz, Inc. (for the treatment of vocal cord scarring).

We believe that our cell and gene therapy product and product candidates provide an advantage over our competitors due to their autologous nature as well as to our localized treatment approach. However, some of our competitors have substantially greater financial resources and larger research and development organizations. In addition, our experience in clinical trials, obtaining FDA and other regulatory approvals, manufacturing and commercialization of products may be more limited. We also compete in recruiting and retaining highly qualified scientific and regulatory personnel.

Research and Development

We expense research and development costs as they are incurred. For the years ended December 31, 2014, 2013 and 2012, we incurred research and development expenses of $16.2 million, $13.8 million and $10.2 million, respectively.

Government Regulation

We are subject to extensive government regulation, principally by the FDA and state and local authorities in the United States and by comparable agencies in foreign countries. Governmental authorities in the United States extensively regulate the pre-clinical and clinical testing, safety, efficacy, research, development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution, among other things, of pharmaceutical products under various federal laws including the Federal Food, Drug and Cosmetic Act, or FFDCA, the Public Health Service Act, or PHSA, and under comparable laws by the states and in most foreign countries.

Domestic Regulation

In the United States, the FDA, under the FFDCA, the PHSA, and other federal statutes and regulations, subjects pharmaceutical and biologic products to rigorous review. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or allow us to manufacture or market our products or product candidates, and we may be criminally prosecuted. The FDA also has the authority to discontinue or suspend manufacture or distribution, require a product withdrawal or recall or revoke previously granted marketing authorizations if we fail to comply with regulatory standards or if we encounter problems during commercial operations.

FDA Approval Process

To obtain approval of a new product from the FDA, we must, among other requirements, submit data demonstrating the product's safety and efficacy as well as detailed information on the manufacture and composition of the product candidate. In most cases, this entails extensive laboratory tests and pre-clinical and clinical trials. This testing and the preparation of necessary applications and processing of those applications by the FDA are expensive and typically take many years to complete. The FDA may deny our applications or may not act quickly or favorably in reviewing these applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approvals that could delay or preclude us from marketing any products we may develop. The FDA also may require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approvals that could restrict the commercial applications of these products. Regulatory authorities may withdraw product approvals if we fail to comply with regulatory standards or if we encounter problems following initial marketing. With respect to patented products or technologies, delays imposed by the governmental approval process may materially reduce the

period during which we may have the exclusive right to exploit the products or technologies.

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The FDA does not apply a single regulatory scheme to human tissues and the products derived from human tissue. On a product-by-product basis, the FDA may regulate products such as drugs, biologics, or medical devices, in addition to regulating them as human cells, tissues, or cellular or tissue-based products ("HCT/P"), depending on whether or not the particular product triggers any of an enumerated list of regulatory factors. A fundamental difference in the treatment of products under these classifications is that the FDA generally permits HCT/Ps that do not trigger any of those regulatory factors to be commercially distributed without marketing approval. In contrast, products that trigger those factors, such as if they are more than minimally manipulated when processed or manufactured, are regulated as drugs, biologics, or medical devices and require FDA approval. We have determined that our Fibrocell Therapy (TM) triggers regulatory factors that make it a biologic, in addition to an HCT/P, and consequently, we must obtain approval from FDA before marketing Fibrocell Therapy (TM) and must also satisfy all regulatory requirements for HCT/Ps.

The process required by the FDA before a new drug or biologic may be marketed in the United States generally involves the following:

- completion of pre-clinical laboratory tests or trials and formulation studies;
- submission to the FDA of an Investigational New Drug ("IND") application for a new drug or biologic, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug or biologic for its intended use;
- detailed information on product characterization and manufacturing process; and
- submission and approval of a New Drug Application ("NDA") for a drug, or a BLA for a biologic.

Pre-clinical tests include laboratory evaluation of product chemistry formulation and stability, as well as animal and other studies to evaluate toxicity. In view of the autologous nature of our product candidates and our prior clinical experience with our product candidates, the FDA concluded that it was reasonably safe to initiate clinical trials in vocal cord scarring and restrictive burn scarring without pre-clinical studies and that the clinical trials would be adequate to further assess both the safety and efficacy of our product candidates. Under FDA regulations, the results of any pre-clinical testing, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application. The FDA requires a 30-day waiting period after the filing of each IND application before clinical trials may begin, in order to ensure that human research patients will not be exposed to unreasonable health risks. At any time during this 30-day period or at any time thereafter, the FDA may halt proposed or ongoing clinical trials, may authorize trials only on specified terms, or may require additional trials. The IND application process may become extremely costly and substantially delay development of our products. Moreover, positive results of pre-clinical tests will not necessarily indicate positive results in clinical trials.

The sponsor typically conducts human clinical trials in three sequential phases, which may overlap. These phases generally include the following:

- Phase I: The product is usually first introduced into healthy humans or, on occasion, into patients, and is tested for safety, dosage tolerance, absorption, distribution, excretion and metabolism;
- Phase II: The product is introduced into a limited patient population to:
  - assess its efficacy in specific, targeted indications;
  - assess dosage tolerance and optimal dosage; and
  - identify possible adverse effects and safety risks.
- Phase III: These are commonly referred to as pivotal studies. If a product is found to have an acceptable safety profile and to be potentially effective in Phase II clinical trials, clinical trials in Phase III will be initiated to further demonstrate clinical efficacy, optimal dosage and safety within an expanded and diverse patient population at geographically dispersed clinical study sites; and
- Phase IV: If the FDA does ultimately approve the product, it may require post-marketing testing, including potentially expensive Phase IV studies, to confirm or further evaluate its safety and effectiveness. Continued ability to commercialize the product may be based on the successful completion of these additional studies.

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Before proceeding with a study, sponsors may seek a written agreement from the FDA regarding the design, size, and conduct of a clinical trial. This is known as a Special Protocol Assessment ("SPA"). Among other things, SPAs can cover clinical studies for pivotal trials whose data will form the primary basis to establish a product's efficacy. SPAs thus help establish up-front agreement with the FDA about the adequacy of a clinical trial design to support a regulatory approval, but the agreement is not binding if new circumstances arise. Even if the FDA agrees to an SPA, the agreement may be changed by the sponsor or the FDA on written agreement by either parties, or if a senior FDA official determines that a substantial scientific issue essential to determining the safety or effectiveness of the product was identified after the testing began. There is no guarantee that a study will ultimately be adequate to support an approval, even if the study is subject to an SPA. The FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement.

Clinical trials must meet requirements for Institutional Review Board ("IRB") oversight, patient informed consent and the FDA's Good Clinical Practice ("GCP"). Prior to commencement of each clinical trial, the sponsor must submit to the FDA a clinical plan, or protocol, accompanied by the approval of the committee responsible for overseeing clinical trials at the clinical trial sites. The FDA or the IRB at each institution at which a clinical trial is being performed may order the temporary or permanent discontinuation of a clinical trial at any time if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. Data safety monitoring committees, which monitor certain studies to protect the welfare of study patients, may also require that a clinical study be discontinued or modified.

The sponsor must submit to the FDA the results of the pre-clinical and clinical trials, together with, among other things, detailed information on the manufacturing and composition of the product, and proposed labeling, in the form of an NDA, or, in the case of a biologic, a BLA. The applicant must also submit with the NDA or BLA a substantial user fee payment, unless a waiver or reduction applies. The FDA has advised us that it would regulate our Fibrocell Therapy as a biologic. Therefore, we expect to submit BLAs to seek approval of our product candidates. In some cases, we may be able to expand the indications in an approved BLA through a submission of a Prior Approval Supplement. Each NDA or BLA submitted for FDA approval is usually reviewed for administrative completeness and reviewability within 60 days following submission of the application. If deemed complete, the FDA will "file" the NDA or BLA, thereby triggering substantive review of the application. The FDA can refuse to file any NDA or BLA that it deems incomplete or not properly reviewable. Once the submission has been accepted for filing, the FDA will review the application and will usually respond to the applicant in accordance with performance goals the FDA has established for the review of NDAs and BLAs - six months from the receipt of the application for priority applications and ten to twelve months for regular applications. The review process is often significantly extended by FDA requests for additional information, pre-clinical or clinical studies, clarification, or a risk evaluation and mitigation strategy ("REMS") or by changes to the application submitted by the applicant in the form of amendments. The FDA may refer applications for novel product candidates 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 and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. It is possible that our product candidates will not successfully proceed through this approval process or that the FDA will not approve them in any specific period of time, or at all. The FDA may deny or delay approval of applications that do not meet applicable regulatory criteria, or if the FDA determines that the clinical data does not adequately establish the safety and efficacy of the product. Satisfaction of FDA pre-market approval requirements for a new biologic is a process that may take a number of years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. The FDA reviews these applications and, when and if it decides that adequate data is available to show that the product is both safe and effective and that other applicable requirements have been met, approves the drug or biologic for marketing. Government regulation may delay or prevent marketing of potential products for a considerable period of time and imposes costly procedures upon our activities. Success in early stage clinical trials does not assure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Upon approval, a product candidate may be marketed only for those indications

approved in the BLA or NDA and will be subject to labeling and promotional requirements or limitations, including warnings, precautions, contraindications and use limitations, which could materially impact profitability. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-market regulatory standards and requirements are not maintained or if safety, efficacy or other problems occur after the product reaches the marketplace.

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The FDA may, during its review of an NDA or BLA, ask for additional study data. If the FDA does ultimately approve the product, it may require post-marketing testing, including potentially expensive Phase IV studies, to confirm or otherwise further evaluate the safety and effectiveness of the product. The FDA also may require, as a condition to approval or continued marketing of a drug, a REMS to ensure that the benefits of a drug or biologic product outweigh its risks. REMS can include additional educational materials for healthcare professionals and patients such as Medication Guides and Patient Package Inserts, a plan for communicating information to healthcare professionals, and restricted distribution of the product. In addition, the FDA may, in some circumstances, impose restrictions on the use of the product, which may be difficult and expensive to administer and may require prior approval of promotional materials. Following approval, FDA may require labeling changes or impose new post-approval study, risk management, or distribution restriction requirements.

Ongoing FDA Requirements

Before approving an NDA or BLA, the FDA usually will inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facilities are in compliance with the FDA's cGMP requirements which govern the manufacture, holding and distribution of a product. Manufacturers of human cellular or tissue-based biologics also must comply with the FDA's Good Tissue Practices, as applicable, and the general biological product standards. Following approval, the FDA periodically inspects drug and biologic manufacturing facilities to ensure continued compliance with the cGMP requirements. Manufacturers must continue to expend time, money and effort in the areas of production, quality control, record keeping and reporting to ensure compliance with those requirements. Failure to comply with these requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, voluntary recall of product, withdrawal of marketing approval or civil or criminal penalties. Adverse experiences with the product must be reported to the FDA and could result in the imposition of marketing restrictions through labeling changes or market removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

The labeling, advertising, promotion, marketing and distribution of a drug or biologic product also must be in compliance with FDA and Federal Trade Commission ("FTC") requirements which include, among others, promotional activities, standards and regulations for direct-to-consumer advertising, promotional activities involving the internet, and industry sponsored scientific and educational activities. In general, all product promotion must be consistent with the labeling approved by the FDA for such product, contain a balanced presentation of information on the product's uses, benefits, risks, and important safety information and limitations on use, and otherwise not be false or misleading. The FDA, as well as the FTC, have very broad enforcement authority, and failure to abide by these regulations can result in penalties, including the issuance of a warning letter directing a company to correct deviations from regulatory standards and enforcement actions that can include seizures, injunctions and criminal prosecution. Failure to comply with applicable FDA requirements and restrictions also may subject a company to adverse publicity and enforcement action by the FDA, the U.S. Department of Justice, or DOJ, or the Office of the Inspector General of the U.S. Department of Health and Human services, or HHS, as well as state authorities. This could subject the company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes its products. Manufacturers are also subject to various laws and regulations governing laboratory practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances in connection with their research. In each of the above areas, the FDA has broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products and deny or withdraw approvals.

Post-Marketing Obligations

The Food and Drug Administration Amendments Act of 2007 expanded FDA authority over drug products after approval. All approved drug products are subject to continuing regulation by the FDA, including record-keeping requirements, reporting of adverse experiences with the product, sampling and distribution requirements, notifying the FDA and gaining its approval of certain manufacturing or labeling changes, complying with certain electronic records and signature requirements, submitting periodic reports to the FDA, maintaining and providing updated safety and efficacy information to the FDA, and complying with FDA promotion and advertising requirements. Failure to

comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, seizure of product, injunctive action, criminal prosecution, or civil penalties.

The FDA may require post-marketing studies or clinical trials to develop additional information regarding the safety of a product. These studies or trials may involve continued testing of a product and development of data, including clinical data, about the product's effects in various populations and any side effects associated with long-term use. The FDA may require post-marketing studies or trials to investigate possible or known serious risks or signals of serious risks, or to identify unexpected serious risks, and may require periodic status reports if new safety information develops. Failure to conduct these studies in a timely manner may result in substantial civil fines, or withdrawal of product approval.

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Drug and biologics manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and to list their products with the FDA. The FDA periodically inspects manufacturing facilities in the United States and abroad in order to assure compliance with the applicable cGMP regulations and other requirements. Facilities also are subject to inspections by other federal, foreign, state or local agencies. In complying with the cGMP regulations, manufacturers must continue to assure that the product meets applicable specifications, regulations and other post-marketing requirements. We must ensure that any third-party manufacturers continue to ensure full compliance with all applicable regulations and requirements. Failure to comply with these requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing or recall or seizure of product.

Also, newly discovered or developed safety or efficacy data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, additional pre-clinical or clinical studies, or even in some instances, withdrawal of the approval. Violations of regulatory requirements at any stage, including after approval, may result in various adverse consequences, including the FDA's withdrawal of an approved product from the market, other voluntary or FDA-initiated action that could delay or restrict further marketing, and the imposition of civil fines and criminal penalties against the manufacturer and BLA holder. In addition, later discovery of previously unknown problems may result in restrictions on the product, manufacturer or BLA holder, including withdrawal of the product from the market. Furthermore, new government requirements may be established that could delay or prevent regulatory approval of our products under development, or affect the conditions under which approved products are marketed.

With respect to our LAVIV® product, which was approved in June 2011, as part of our label the FDA required us, based on clinical study data, to conduct a post-marketing study of approximately 2,700 patients (to assess the risk of skin cancer such as basal cell cancer in the area of LAVIV® injections and the risk of immune-mediated hypersensitivity reactions such as leukocytoclastic vasculitis), which must be completed by 2016. The FDA concluded that analysis of spontaneous post-marketing AEs would not be sufficient to evaluate potential risk of such events with use of LAVIV® and they required performance of a formal post-marketing study involving 2,700 patients. We have been engaged in discussions with the FDA on the design of the post-marketing study, as we believe the original study design, especially the sample size, is no longer consistent with our current emphasis on development of LAVIV® for critical medical applications and our decreased involvement with cosmetic applications. The FDA acknowledged that commercial volume since the marketing of LAVIV® is inadequate to meet the original enrollment rate proposed but has required submission of actual enrollment data before considering a revision. We have initiated enrollment in the post-marketing study and submitted the second biannual interim report to the FDA containing this enrollment data. We plan to submit a formal request for adjustment to the post marketing requirements in the second half of 2015.

HIPAA Requirements

Other federal legislation may affect our ability to obtain certain health information in conjunction with our research activities. We may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by HITECH, and its implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates"— independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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Other U.S. Regulatory Requirements

In the United States, the research, manufacturing, distribution, sale, and promotion of drug and biological products are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), other divisions of the HHS (e.g., the Office of Inspector General), the DOJ and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, and similar state laws, each as amended.

If a drug product is reimbursed by Medicare or Medicaid, pricing and rebate programs must comply with, as applicable, the Medicare Modernization Act as well as the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, or the OBRA, and the Veterans Health Care Act of 1992, or the VHCA, each as amended. Among other things, the OBRA requires drug manufacturers to pay rebates on prescription drugs to state Medicaid programs and empowers states to negotiate rebates on pharmaceutical prices, which may result in prices for our future products that will likely be lower than the prices we might otherwise obtain. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Under the VHCA, drug companies are required to offer some drugs at a reduced price to a number of federal agencies including the U.S. Department of Veterans Affairs and the U.S. Department of Defense, the Public Health Service and some private Public Health Service designated entities in order to participate in other federal funding programs including Medicaid. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulation. All of these activities are also potentially subject to federal and state consumer protection, unfair competition, and other laws.

In March 2010, President Obama signed one of the most significant healthcare reform measures in decades. The Affordable Care Act, substantially changes the way healthcare will be financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Affordable Care Act was a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The Affordable Care Act will impact existing government healthcare programs and will result in the development of new programs. While the Affordable Care Act could result in additional downward pressure on coverage and the price that we could receive for any approved product, we do not believe it to be applicable to our business at this time. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. In addition, it is possible that there will be further legislation or regulation that could harm our business, financial condition and results of operations.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting some business arrangements from prosecution, the exemptions and safe harbors are drawn narrowly and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from federal Anti-Kickback Statute liability. The reach of the Anti-Kickback Statute was broadened by the Affordable Care Act, which, among other things, amends the intent requirement of the federal Anti-Kickback Statute. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a

false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

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The federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses. HIPAA created new federal criminal statutes that prohibit knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

International Regulation

The regulation of our product candidates outside of the United States varies by country. Certain countries regulate human tissue products as a pharmaceutical product, which would require us to make extensive filings and obtain regulatory approvals before selling our product candidates. Certain other countries classify our product candidates as human tissue for transplantation but may restrict its import or sale. Other countries may have no application regulations regarding the import or sale of products similar to our product candidates, creating uncertainty as to what standards we may be required to meet.

Employees

As of March 6, 2015, we employed 50 people on a full-time basis, all located in the United States. We also have 6 people working on a contract basis or part-time basis. None of our employees are covered by a collective bargaining agreement, and we consider our relationship with our employees to be good. We also employ consultants and temporary labor on an as needed basis to supplement existing staff.

Corporate Information

On August 10, 2001, American Financial Holding, Inc. acquired Isolagen Technologies through the merger of a wholly owned subsidiary, Isolagen Acquisition Corp., and an affiliated entity, Gemini IX, Inc., with and into Isolagen Technologies. As a result of the merger, Isolagen Technologies became a wholly owned subsidiary of American Financial Holding, Inc. On November 13, 2001, the name was changed to Isolagen, Inc. On August 27, 2009, the United States Bankruptcy Court for the District of Delaware in Wilmington entered an order confirming the Joint First Amended Plan of Reorganization dated July 30, 2009, as supplemented by the Plan Supplement dated August 21, 2009, or the Plan, of Isolagen, Inc. and Isolagen's wholly owned subsidiary, Isolagen Technologies, Inc. The effective date of the Plan was September 3, 2009. Isolagen, Inc. and Isolagen Technologies, Inc. were subsequently renamed Fibrocell Science, Inc. and Fibrocell Technologies, Inc., respectively.

Our mailing address and executive offices are located at 405 Eagleview Boulevard, Exton, Pennsylvania and our telephone number at that address is (484) 713-6000. We maintain an Internet website at the following address: www.fibrocellscience.com. The information on our website is not incorporated by reference in this annual report on Form 10-K or in any other filings we make with the Securities and Exchange Commission, or SEC.

We make available on or through our website certain reports and amendments to those reports that we file with or furnish to the SEC in accordance with the Exchange Act. These include our annual reports on Form 10-K, our quarterly reports on Form 10-Q, and our current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. We make this information available on or through our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC.

The public may read and copy any materials the Company files with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330.

Item 1A. Risk Factors

The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment. You should understand that it is not possible to predict or identify all such risks. Consequently, you should not consider the following to be a complete discussion of all potential risks or uncertainties.'

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Risks Related to Our Business, Financial Position and Need for Additional Capital

We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future.

We have incurred losses since our inception, have not generated significant revenue from commercial sales of our products since emerging from bankruptcy, and have never been profitable. Since 2013, which is when we decided to change our business strategy to focus on label-expansion medical indications for azficel-T and on rare skin and connective tissue diseases in collaboration with our partner Intrexon, we have reduced sales and marketing efforts of our LAVIV® aesthetic product line. We performed a nominal amount of LAVIV® aesthetic procedures in Fiscal 2013 and Fiscal 2014 and will continue to do so in Fiscal 2015. Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. We continue to incur significant research, development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since we emerged from bankruptcy in September 2009. For the year ended December 31, 2014, we reported a net loss of $25.7 million, and we had an accumulated deficit of $112.7 million at December 31, 2014.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- continue our research and pre-clinical and clinical development of our product candidates;
- initiate additional pre-clinical, clinical or other studies or trials for our product candidates, including under our collaboration agreement with Intrexon;
- continue or expand our collaboration with Intrexon and our other collaborators;
- further develop the manufacturing process for our product candidates;
- change or add additional manufacturers or suppliers;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel;
- create additional infrastructure to support our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with any of the above.

The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

We do not generate significant revenues from product sales and may never be profitable.

Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory approvals necessary for, the manufacture and commercialization of our product candidates. Other than from the sale of LAVIV®, we do not anticipate generating revenues from product sales for the foreseeable future, if ever. Our ability to generate future revenues from product sales depends heavily on our success in:

- completing research and pre-clinical and clinical development of our product candidates;
- seeking and obtaining regulatory and marketing approvals for product candidates for which we complete clinical trials;
- developing a sustainable, scalable, reproducible, and transferable manufacturing process for our product candidates;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate (in amount and quality) products and services to support clinical development and the market demand for our product candidates, if approved;
- launching and commercializing product candidates for which we obtain regulatory and marketing approval, either by collaborating with a partner or, if launched independently, by establishing a sales force, marketing and distribution infrastructure;
- obtaining market acceptance of our product candidates and cell therapy as a viable treatment option;

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- addressing any competing technological and market developments;
- implementing additional internal systems and infrastructure, as needed;
- identifying and validating new cell therapy product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies, domestic or foreign, to perform clinical trials or other studies in addition to those that we currently anticipate. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

We will require additional capital to fund our operations and if we fail to obtain necessary financing, we may be unable to complete the development and commercialization of our product candidates.

Our operations have consumed substantial amounts of cash. We expect to continue to spend substantial amounts to advance the clinical development of our product candidates and launch and commercialize any product candidates for which we may receive regulatory approval, including potentially building our own commercial organization to address selected markets. We may require additional capital for the further development and commercialization of our product candidates and may also need to raise additional funds sooner in order to accelerate development of our product candidates.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or one or more of our other research and development initiatives. If we are unable to raise additional capital when required or on acceptable terms, we also could be required to:

- significantly delay, scale back or discontinue the development or, if/when applicable, the commercialization, of our product candidates;
- seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves; or
- significantly curtail operations.

We will seek to raise additional funds in the future, which may be dilutive to stockholders or impose operational restrictions.

We expect to seek to raise additional capital in the future to help fund our clinical trials, our collaboration efforts with Intrexon and for the development of our proposed products. If we raise additional capital through the issuance of equity or of debt securities, the percentage ownership of our current stockholders will be reduced. We may also enter into strategic transactions, issue equity as part of license issue fees to our licensors, compensate consultants or settle outstanding payables using equity that may be dilutive. Our stockholders may experience additional dilution in net book value per share and any additional equity securities may have rights, preferences and privileges senior to those of

the holders of our common stock. If we cannot raise additional funds, we will have to delay our development activities.

We have a limited operating history, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We have a limited operating history and our primary business activities consist of conducting clinical trials and pre-clinical development, pursuing our collaboration with Intrexon and commercializing our LAVIV® product. As such, our historical financial data is of limited value in estimating future operating expenses. Our budgeted expense levels are based in part on our expectations concerning the costs of our clinical trials, pre-clinical development and our collaboration with Intrexon, which depend on the success of such trials and our ability to effectively and efficiently conduct such trials, pre-clinical development and expectations related to our efforts to achieve FDA approval with respect to our product candidates. Our limited operating history and clinical trial experience make these costs difficult to forecast accurately. We may be unable to adjust our operations in a timely manner to compensate for any unexpected increase in costs. Further, our fixed manufacturing costs and business development and marketing expenses will increase significantly as we expand our operations. Accordingly, a significant increase in costs could have an immediate and material adverse effect on our business, results of operations and financial condition.

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We may acquire other assets or businesses, or form collaborations or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of assets or businesses, or strategic alliances and collaborations, to expand our existing technologies and operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any such transaction, any of which could have a detrimental effect on our financial condition, results of operations and cash flows. We may not be able to find suitable acquisition candidates, and if we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business and we may incur additional debt or assume unknown or contingent liabilities in connection therewith. Integration of an acquired company or assets may also disrupt ongoing operations, require the hiring of additional personnel and the implementation of additional internal systems and infrastructure, especially the acquisition of commercial assets, and require management resources that would otherwise focus on developing our existing business. We may not be able to find suitable collaboration partners or identify other investment opportunities, and we may experience losses related to any such investments.

To finance any acquisitions or collaborations, we may choose to issue debt or shares of our common stock as consideration. Any such issuance of shares would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other assets or companies or fund a transaction using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

Our business and operations would suffer in the event of computer system failures.

Despite the implementation of security measures, our internal computer systems, and those of our contract research organizations, contract manufacturing organization, and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations or the unauthorized transfer of our proprietary information, and could result in a material disruption of our clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

Risks Related to Clinical Development and Regulatory Approval of Our Product Candidates

Our cell therapy product candidates are based on a novel technology, which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval.

We have concentrated our therapeutic product research and development efforts on our autologous cell therapy platform, and our future success depends on the successful development of this therapeutic approach. There can be no assurance that any development problems we experience in the future related to our cell therapy platform will not cause significant delays or unanticipated costs, or that such development problems can be solved. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical trials or commercializing our products on a timely or profitable basis, if at all.

In addition, the clinical trial requirements of the FDA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied

pharmaceutical or other product candidates.

Regulatory requirements governing cell therapy products have evolved and may continue to change in the future. For example, the FDA has established the Office of Cellular, Tissue and Gene Therapies within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of cell therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. Cell therapy clinical trials conducted at institutions that receive funding for recombinant DNA research from the U.S. National Institutes of Health, or the NIH, are also subject to review by the NIH Office of Biotechnology Activities' Recombinant DNA Advisory Committee, or the RAC. Although the FDA decides

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whether individual cell therapy protocols may proceed, the RAC review process can impede the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation. Conversely, the FDA can put an IND on clinical hold even if the RAC has provided a favorable review. Also, before a clinical trial can begin at an NIH-funded institution, that institutional review board, or IRB, and its Institutional Biosafety Committee will have to review the proposed clinical trial to assess the safety of the trial. In addition, adverse developments in clinical trials of cell therapy products conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of our product candidates.

These regulatory review agencies, committees and advisory groups and the new requirements and guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory and advisory groups and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of our product candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue to maintain our business.

We may find it difficult to enroll patients in our clinical trials, which could delay or prevent clinical trials of our product candidates.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates. We have experienced delays in some of our clinical trials, and we may experience similar delays in the future. If patients are unwilling to participate in our cell therapy clinical trials because of negative publicity from adverse events in the biotechnology or cell therapy industries or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting patients, conducting clinical trials and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether.

We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a clinical trial, to complete our clinical trials in a timely manner. Patient enrollment is affected by factors including:

- severity of the disease under investigation;
- design of the study protocol;
- size of the patient population;
- eligibility criteria for the clinical trial in question;
- perceived risks and benefits of the product candidate under study;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

In particular, each of the conditions for which we plan to evaluate our current gene therapy product candidates are rare genetic diseases with limited patient pools from which to draw for clinical trials. Additionally, the process of finding and diagnosing patients may prove costly. We have estimated that there are approximately 1,100 to 2,500 U.S.

patients with RDEB and approximately 40,000 U.S. patients with linear scleroderma over a major joint who exhibit severe joint pain.

Our current gene therapy product candidates are being developed to treat rare conditions. We plan to seek initial marketing approval in the United States. We may not be able to initiate or continue clinical trials if we cannot enroll a sufficient number of eligible patients to participate in the clinical trials required by the FDA or other regulatory agencies. If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business.

Clinical trials may fail to demonstrate the safety or efficacy of our product candidates, which could prevent or significantly delay regulatory approval and prevent us from raising additional financing.
Prior to receiving approval to commercialize any of our product candidates, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA and other regulatory authorities in the United States and abroad, that our product candidates are both safe and effective. We will need to demonstrate our product candidates'

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efficacy and monitor their safety throughout the process. We previously completed a pivotal Phase III clinical trial related to LAVIV®. However, the success of prior pre-clinical or clinical trials does not ensure the success of these trials, which are being conducted in populations with different racial and ethnic demographics than our previous trials. If our current trials or any future clinical trials are unsuccessful, our business and reputation would be harmed and the price at which our stock trades could be adversely affected.

All of our product candidates are subject to the risks of failure inherent in the development of biotherapeutic products. The results of early-stage clinical trials of our product candidates do not necessarily predict the results of later-stage clinical trials. Product candidates in later-stage clinical trials may fail to demonstrate desired safety and efficacy traits despite having successfully progressed through initial clinical testing. Even if we believe the data collected from clinical trials of our product candidates is promising, this data may not be sufficient to support approval by the FDA or any other U.S. or foreign regulatory approval. The FDA may also reject any of our completed clinical trials as inadequate to support approval if the study design does not include specific safety monitoring measures. Pre-clinical and clinical data can be interpreted in different ways. Accordingly, FDA officials could reach different conclusions in assessing such data than we do which could delay, limit or prevent regulatory approval. In addition, the FDA, other regulatory authorities, our IRB or we may suspend or terminate clinical trials at any time.

Obtaining FDA and other regulatory approvals is complex, time consuming and expensive, and the outcomes are uncertain.

The process of obtaining FDA and other regulatory approvals is time consuming, expensive and difficult. Clinical trials are required to establish the safety and efficacy of product candidates. Applications to market product candidates must be submitted to the FDA which must be reviewed for approval and approved by the FDA before product candidates may be marketed and clinical trials, manufacturing, and the marketing of products, if approved, are subject to strict regulatory compliance. The commencement and completion of clinical trials for any of our product candidates could be delayed or prevented by a variety of factors, including:

- delays in obtaining regulatory approvals to commence a study or trial;
- delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;
- delays or failures in obtaining approval of our clinical trial protocol from an IRB to conduct a clinical trial at a prospective study site;
- delays in the enrollment of patients;
- manufacturing difficulties;
- failure of our clinical trials and clinical investigators to be in compliance with the FDA's GCP;
- failure of our third-party contract research organizations, clinical site organizations or other clinical trial managers, to satisfy their contractual duties, comply with regulations or meet expected deadlines;
- lack of efficacy during clinical trials; or
- unforeseen safety issues.

We do not know whether our clinical trials will need to be restructured or will be completed on schedule, if at all, or whether they will provide data necessary to support necessary regulatory approval. Significant delays in clinical trials will impede our ability to commercialize our product candidates and generate revenue, and could significantly increase our development costs.

In addition, we utilize bovine-sourced materials to manufacture our product candidates. It is possible that future FDA regulations may require us to change the source of the bovine-sourced materials we use in our products or to cease using bovine-sourced materials. If we are required to use alternative materials in our products, and in the event that such alternative materials are available to us, or if we choose to change the materials used in our products in the future, we would need to validate the new manufacturing process and run comparability trials with the reformulated product, which could delay our submission for regulatory approval of our product candidates and negatively impact

the development and potential commercialization of our product candidates.

If we fail to obtain the necessary regulatory approvals, or if such approvals are limited, we will not be able to commercialize our product candidates, and we will not generate product revenues.

Even if we comply with all FDA pre-approval regulatory requirements, the FDA may determine that our product candidates are not safe or effective, and we may never obtain regulatory approval for such product candidates. If we fail to obtain regulatory approval for some or all of our product candidates, we will have fewer commercial products, if any, and correspondingly lower product revenues, if any. Even if our product candidates receive regulatory approval, such approval may involve limitations on the indications and conditions of use or marketing claims for our products. Further, later discovery of previously unknown problems or AEs could result in additional regulatory restrictions, including withdrawal of products and addition of warnings or other statements on the product label.

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With respect to our LAVIV® product, which was approved in June 2011, as part of our label the FDA required us, based on clinical study data, to conduct a post-marketing study of approximately 2,700 patients, which must be completed by 2016. The FDA concluded that analysis of spontaneous post-marketing AEs would not be sufficient to evaluate potential risk of such events with use of LAVIV® and they required performance of a formal post-marketing study involving 2,700 patients.

We have been engaged in discussions with the FDA on the design of the post-marketing study, as we believe the original study design, especially the sample size, is no longer consistent with our current emphasis on development of LAVIV® for critical medical applications and our decreased involvement with cosmetic applications. The FDA acknowledged that commercial volume since the marketing of LAVIV® is inadequate to meet the original enrollment rate proposed but has required submission of actual enrollment data before considering a revision. We have initiated enrollment in the post-marketing study and submitted the second biannual interim report to the FDA containing this enrollment data. We plan to submit a formal request for adjustment to the post marketing requirements in the second half of 2015. Although we believe we will be able to reach an agreement with the FDA on this post-marketing study, to the extent we are unable to complete an acceptable post-marketing study, the FDA may determine to take action against us, including the withdrawal of its approval of LAVIV®.

In jurisdictions outside the United States, we must receive marketing authorizations from the appropriate regulatory authorities before commercializing our product candidates. Regulatory approval processes outside the United States generally include requirements and risks similar to, and in many cases in excess of, the risks associated with FDA approval.

Our failure to comply with extensive governmental regulation may significantly affect our operating results.

Even if we obtain regulatory approval for some or all of our product candidates, we will continue to be subject to extensive ongoing requirements by the FDA, as well as by a number of foreign, national, state and local agencies. These regulations will impact many aspects of our operations, including testing, research and development, manufacturing, safety, efficacy, labeling, storage, quality control, AE reporting, import and export, record keeping, approval, distribution, advertising and promotion of our future products. We must also submit new or supplemental applications and obtain FDA approval for certain changes to an approved product, product labeling or manufacturing process. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical trials. The FDA enforces post-marketing regulatory requirements, including the cGMP requirements, through periodic unannounced inspections. We have recently
received a Form 483 Letter from the FDA identifying issues with its inspection of our autologous fibroblast manufacturing facility. We do not know whether the FDA will accept our proposals for addressing the issues noted in its letter or if similar or additional issues will be identified in subsequent inspections. We do not know whether we will pass any future FDA inspections. Failure to pass an inspection could disrupt, delay or shut down our manufacturing operations. Failure to comply with applicable regulatory requirements could, among other things, result in:

- administrative or judicial enforcement actions;
- changes to advertising;
- failure to obtain marketing approvals for our product candidates;
- revocation or suspension of regulatory approvals of products;
- product seizures or recalls;
- court-ordered injunctions;
- import detentions;
- delay, interruption or suspension of product manufacturing, distribution, marketing and sales; or
- civil or criminal sanctions.

The discovery of previously unknown problems with our products may result in restrictions of the products, including withdrawal from the market. In addition, the FDA may revisit and change its prior determinations with regard to the safety or efficacy of our future products. If the FDA's position changes, we may be required to change our labeling or cease to manufacture and market our future products. Even prior to any formal regulatory action, we could voluntarily decide to cease the distribution and sale or recall any of our future products if concerns about their safety or efficacy develop.

In their regulation of advertising and other promotion, the FDA and the FTC may issue correspondence alleging that some advertising or promotional practices are false, misleading or deceptive. The FDA and FTC are authorized to impose a wide array of sanctions on companies for such advertising and promotion practices, which could result in any of the following:

- incurring substantial expenses, including fines, penalties, legal fees and costs to comply with the FDA's requirements;
- changes in the methods of marketing and selling products;
- taking FDA mandated corrective action, which may include placing advertisements or sending letters to physicians rescinding previous advertisements or promotions; or

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- disruption in the distribution of products and loss of sales until compliance with the FDA's position is obtained.

Improper promotional activities may also lead to investigations by federal or state prosecutors, and result in criminal and civil penalties. If we become subject to any of the above requirements, it could be damaging to our reputation and restrict our ability to sell or market our future products, and our business condition could be adversely affected. We may also incur significant expenses in defending ourselves.

Physicians may prescribe pharmaceutical or biologic products for uses that are not described in a product's labeling or differ from those tested by us and approved by the FDA. While such "off-label" uses are common and the FDA does not regulate physicians' choice of treatments, the FDA does restrict a manufacturer's communications on the subject of off-label use. Companies cannot promote FDA-approved pharmaceutical or biologic products for off-label uses, but under certain limited circumstances they may disseminate to practitioners' articles published in peer-reviewed journals. To the extent allowed by the FDA, we may disseminate peer-reviewed articles on our future products, if approved, to practitioners. If, however, our activities fail to comply with the FDA's regulations or guidelines, we may be subject to warnings from, or enforcement action by, the FDA or other regulatory or law enforcement authorities.

Our sales, marketing, and scientific/educational grant programs, if any in the future, must also comply with applicable requirements of the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, the federal anti-kickback law, and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veteran's Health Care Act of 1992, each as amended. 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. The distribution of product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act.

Depending on the circumstances, failure to meet post-approval requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, or refusal to allow us to enter into supply contracts, including government contracts. Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity.

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

All of those involved in the marketing of our product candidates for clinical trials or commercial sale, including us and our existing supply contract manufacturers and clinical trial investigators, are subject to extensive regulation by the FDA. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with current Good Manufacturing Practices. 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. In addition, the FDA may, at any time, audit or inspect a manufacturing facility, including our manufacturing facility, involved with the preparation of LAVIV® or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. 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. 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, 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.

Risks Related to Our Intellectual Property

If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate for our technology and products and product candidates, our competitive position could be harmed.

Our commercial success will depend in large part on our ability to obtain and maintain patent and other intellectual property protection in the U.S. and other countries with respect to our proprietary technology and products. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third

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parties, all of which offer only limited protection. We seek to protect our proprietary position by filing and prosecuting patent applications in the U.S. and abroad related to our novel technologies and products that are important to our business.

The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patents, including those patent rights licensed to us by third parties, are highly uncertain. The steps we or our licensors have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the U.S. Further, the examination process may require us or our licensors to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The rights already granted under any of our currently issued patents or those licensed to us and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we or our licensors are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be adversely affected. It is also possible that we or our licensors will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them.

With respect to patent rights, we do not know whether any of the pending patent applications for any of our therapies will result in the issuance of patents that protect our technology or products, or if any of our or our licensors' issued patents will effectively prevent others from commercializing competitive technologies and products. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing or in some cases not at all, until they are issued as a patent. Therefore we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

Our issued patents, those that may be issued in the future or those licensed or acquired by us, may be challenged, invalidated or circumvented, and the rights granted under any issued patent may not provide us with proprietary protection or competitive advantages against competitors with similar technology. In particular, we do not know if competitors will be able to design variations on our treatment methods to circumvent our current and anticipated patent claims. Furthermore, competitors may independently develop similar technologies or duplicate any technology developed by us.

Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or have licensed from third parties may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our or our licensor's patented technology, trademarks and other intellectual property rights is expensive, difficult and may in some cases not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could harm our business.

Our commercial success depends upon our ability to develop, manufacture, and if approved, market and sell our product candidates and to use our related proprietary technologies. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products or product candidates, including interference or derivation proceedings before the U.S. Patent and Trademark Office, or USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our products. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Under certain circumstances, we could be forced, including by court order, to cease commercializing our products and then expend time and funding to redesign our product and/or product candidates so that it does not infringe others' patents while still allowing us to compete in the market with a substantially similar product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our products or force us to cease some of our business operations, which could materially harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business. In addition, our involvement in any of these proceedings may cause us to incur substantial costs and result in diversion of management and technical personnel. Furthermore, parties making claims against us may be able to obtain

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injunctive or other equitable relief that could effectively block our ability to develop, commercialize and sell products, and could result in the award of substantial damages against us.

While azficel-T is in pre-clinical studies and clinical trials for additional indications, we believe that the use of azficel-T in these pre-clinical studies and clinical trials falls within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the United States, which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. As azficel-T progresses toward commercialization in the additional indications, the possibility of a patent infringement claim against us increases. We attempt to ensure that azficel-T and the methods we employ to manufacture it, as well as the methods for its use we intend to promote, do not infringe other parties' patents and other proprietary rights. There can be no assurance they do not, however, and competitors or other parties may assert that we infringe their proprietary rights in any event.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive, and our or our licensors' intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws and practices of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S. Consequently, we and our licensors may not be able to prevent third parties from practicing our and our licensors' inventions in all countries outside the U.S., or from selling or importing products made using our and our licensors' inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and may export otherwise infringing products to territories where we or our licensors have patent protection, but where enforcement is not as strong as that in the U.S. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our or our licensor's patents or marketing of competing products in violation of our proprietary rights generally in those countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put our and our licensors' patents at risk of being invalidated or interpreted narrowly and our and our licensors' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors. We or our licensors may not prevail in any lawsuits that we or our licensors initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

The laws of certain foreign countries may not protect our rights to the same extent as the laws of the U.S., and these foreign laws may also be subject to change. For example, methods of treatment and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries, particularly developing countries. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for, and launch generic versions of our products. Many countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under certain circumstances to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time.

Given the amount of time required for the development, testing and regulatory review of products, such as LAVIV®, and our other products candidates, such as azficel-T, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the U.S. and, if available, in other countries where we are prosecuting patents. In the U.S., the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO in the U.S., and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and pre-clinical data and launch their product earlier than might otherwise be the case.

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Changes in patent law, including recent patent reform legislation, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve technological and legal complexity, and obtaining and enforcing pharmaceutical patents is costly, time-consuming, and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection. For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensors' ability to obtain new patents or to enforce existing patents and patents we and our licensors may obtain in the future. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents.

In September 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the U.S. transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO and may become involved in opposition, derivation, reexamination, inter-partes review or interference proceedings challenging our patent rights or the patent rights of our licensors. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our or our licensors' patent rights, which could adversely affect our competitive position.

The USPTO is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, did not become effective until March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents and those licensed to us.

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 or our licensors fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

If we are unable to protect the confidentiality of our proprietary information and know-how, our competitive position would be impaired.

Some of our technology 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. Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. 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

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may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets. The disclosure of our trade secrets would impair our competitive position and may materially harm
our business, financial condition and 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 or our licensors 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 the price of shares of our common stock.

We may be subject to claims by third parties asserting that our licensors, employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees and our licensors' employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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 compounds that are the same as or similar to our product candidates, but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors 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 or our licensors 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;

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- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Risks Related to the Commercialization of Our Product Candidates

If physicians do not follow our established protocols, the efficacy and safety of our product candidates may be adversely affected.

We are dependent on physicians to follow our established protocols both as to the administration and the handling of our product candidates in connection with our clinical trials, and we continue to be dependent on physicians to follow such protocols after our product candidates are commercialized. The treatment protocol requires each physician to verify the patient's name and date of birth with the patient and the patient records immediately prior to injection. In the event more than one patient's cells are delivered to a physician or we deliver the wrong patient's cells to the physician, which has occurred in the past, it is the physician's obligation to follow the treatment protocol and assure that the patient is treated with the correct cells. If the physicians do not follow our protocol, the efficacy and safety of our product candidates may be adversely affected.

Ethical, legal and social concerns about synthetic biologically engineered products could limit or prevent the use of the product candidates we may develop in the future with Intrexon.

The products candidates we are developing with Intrexon use a synthetic biology platform. Public perception about the safety of products with cell therapy applied, as well as ethical concerns over these products, could influence public acceptance of these product candidates. If we are not able to overcome the ethical, legal and social concerns relating to synthetic biological engineering, these product candidates may not be accepted. These concerns could result in increased expenses, regulatory scrutiny, delays or other impediments to the public acceptance and commercialization of these product candidates. Our ability to develop and commercialize these product candidates could be limited by public attitudes and governmental regulation.

The subject organisms with cell therapy applied has received negative publicity. This adverse publicity could lead to greater regulation of products altered with gene therapy. Further, there is a risk that our product candidates could cause adverse health effects or other AEs, which could also lead to negative publicity.

The synthetic biological technologies that are being utilized for the product candidates we are developing with Intrexon may have significantly enhanced characteristics compared to those found in naturally occurring organisms, enzymes or microbes. While these synthetic biological technologies are being produced only for use in a controlled laboratory and industrial environment, the release of such synthetic biological technologies into uncontrolled environments could have unintended consequences. Any adverse effect resulting from such a release could have a material adverse effect on our business and financial condition, and we may have exposure to liability for any resulting harm.

Our competitors in the pharmaceutical, medical device and biotechnology industries may have superior products, manufacturing capabilities, financial resources or marketing position.

The human healthcare products and services industry is extremely competitive. Our competitors include major pharmaceutical, medical device and biotechnology companies. Most of these competitors have more extensive research and development and marketing and production capabilities than we do, as well as greater financial resources. Our future success will depend on our ability to develop and market effectively our products against those of our competitors. If our products cannot compete effectively in the marketplace, our results of operations and financial position will suffer.

If any of our approved products were to become the subject of problems related to their efficacy, safety, or otherwise, our business would be seriously harmed.

LAVIV®, in addition to any other of our product candidates that may be approved by the FDA, will be subject to continual review by the FDA, and we cannot assure you that newly discovered or developed safety issues will not arise. For all of our product candidates, the FDA has required us to pay special attention to potential skin cancer and hypersensitivity reactions at the site of injection and, while we have seen no issues to date, we cannot rule out that issues may arise in the future. With the use of any newly marketed drug by a wider patient population, serious adverse events ("AE's") may occur from time to time that initially do not appear to relate to the drug itself. Any safety issues could cause us to suspend or cease marketing of our approved products, cause us to modify how we market our

approved products, subject us to substantial liabilities, and adversely affect our revenues and financial condition. Due to the novel nature of our technology, we face uncertainty related to pricing and reimbursement for these product candidates.

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Our target patient populations are relatively small, as a result of which the pricing and reimbursement of our product candidates, if approved, must be adequate to support commercial infrastructure. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell our product candidates will be adversely affected. The manner and level at which reimbursement is provided for services related to our product candidates (e.g., for administration of our product to patients) is also important. Inadequate reimbursement for such services may lead to physician resistance and adversely affect our ability to market or sell our products.

If the market opportunities for our product candidates are smaller than we believe they are, our revenues may be adversely affected and our business may suffer. Because the target patient populations of our product candidates are small, we must be able to successfully identify patients and achieve a significant market share to maintain profitability and growth.

We focus our research and product development on treatments for severe skin and connective tissue diseases. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates. These estimates may prove to be incorrect and new studies or clinical trials may change the estimated incidence or prevalence of these diseases. The number of patients in the United States and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

In order to commercialize any future product candidates, we will need to increase our manufacturing capacity and improve our manufacturing capabilities, which will require significant expenditures and regulatory approval.

We currently have limited manufacturing capacity and we have had limited manufacturing experience. In addition, our current manufacturing process is primarily a manual process. In order to commercialize any future product candidates, we will need to add manufacturing capacity. We also are developing enhancements and alternatives to our current manual manufacturing process. If we have difficulties in increasing our manufacturing capacity and improving our capabilities, we will be limited in our ability to manufacture and commercialize our product candidates, if they are approved for marketing; and we may not be able to decrease our manufacturing costs. These difficulties could adversely affect our financial performance and damage our reputation. Even if we are successful in developing such enhancements or finding alternatives to our current process, such manufacturing changes will require additional expenditures, for which we may be required to seek external financing. In addition, our ability to increase our manufacturing capacity or modify our manufacturing processes will be subject to additional FDA review and approval.

We may be liable for product liability claims not covered by insurance.

Physicians who used our facial aesthetic product in the past, or who may use any of our future products, and patients who have been treated by our facial aesthetic product in the past, or who may use any of our future products, may bring product liability claims against us. While we have taken, and continue to take, what we believe are appropriate precautions, we may be unable to avoid significant liability exposure. We currently keep in force product liability insurance, although such insurance may not be adequate to fully cover any potential claims or may lapse in accordance with its terms prior to the assertion of claims. We may be unable to obtain product liability insurance in the future, or we may be unable to do so on acceptable terms. Any insurance we obtain or have obtained in the past may not provide adequate coverage against any asserted claims. In addition, regardless of merit or eventual outcome, product liability claims may result in:

•diversion of management’s time and attention;
•expenditure of large amounts of cash on legal fees, expenses and payment of damages;
•decreased demand for our products or any of our future products and services; or
•injury to our reputation.

If we are the subject of any future product liability claims, our business could be adversely affected, and if these claims are in excess of insurance coverage, if any, that we may possess, our financial position will suffer.

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We face risks in connection with doing business in China.

In April 2010, we entered into a letter of intent with Chinese company Heifei Meifu Bio-Tech Limited Co. to form a joint venture to commercialize autologous fibroblast therapies in Asia (excluding Japan) and to produce and develop such therapies in China. This letter of intent was intended to serve as the template for a joint venture agreement between us and Heifei Meifu, which would expand the scope of our operations to China and Asia more broadly. However, to date we and Heifei Meifu have not received Chinese governmental approval to form the proposed joint venture and we are considering alternative business structures in Asia (excluding Japan). If we are able to consummate alternative business structures in Asia (excluding Japan), we expect to generally no longer have an independent right to make or sell autologous fibroblast therapies in Asia (excluding Japan). If, however, we are unable to finalize alternative business structures in Asia (excluding Japan), our business could be harmed.

Risks Related to Our Dependence on Third Parties

We and our collaborators depend on third parties to conduct our pre-clinical studies and clinical trials, which may result in costs and delays that prevent us from obtaining regulatory approval or successfully commercializing our product candidates.

We and our collaborators engage third parties to perform various aspects of our pre-clinical studies and clinical trials. For instance, one of our collaborators obtains genetically-modified material from a sole source supplier in connection with the pre-clinical development of RDEB. We and our collaborators depend on these third parties to perform these activities on a timely basis in accordance with the protocol, good laboratory practices, good clinical practices, and other regulatory requirements. Our reliance on these third parties for pre-clinical and clinical development activities reduces our control over these activities. Accordingly, if these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, our pre-clinical studies and clinical trials may be extended, delayed, terminated or our data may be rejected by the FDA. For example, if our collaborator's sole source supplier of genetically-modified material in connection with the pre-clinical development of RDEB were to cease to be able to supply genetically-modified material to our collaborator, or decline to supply genetically-modified material to our collaborator, our RDEB program would be delayed until our collaborator obtained an alternative source, which could take a considerable length of time. If it became necessary to replace a third party that was assisting with one of our pre-clinical studies or clinical trials, we believe that there are a number of other third-party contractors that could be engaged to continue these activities, although it may result in a delay of the applicable pre-clinical study or clinical trial. If there are delays in testing or obtaining regulatory approvals as a result of a third party's failure to perform, our drug discovery and development costs will likely increase, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

We will incur additional expenses in connection with our exclusive channel collaboration arrangement with Intrexon.

Pursuant to our exclusive channel collaboration with Intrexon, we are responsible for future research and development expenses of product candidates developed under such collaboration, the effect of which we expect will increase the level of our overall research and development expenses going forward. Although all manufacturing, pre-clinical studies and human clinical trials are expensive and difficult to design and implement, costs associated with the manufacturing, research and development of biologic product candidates are generally greater in comparison to small molecule product candidates. We have added personnel and expect to add additional personnel, either directly or through consulting arrangements, to support our exclusive channel collaboration with Intrexon.

Because development activities are determined pursuant to a joint steering committee comprised of Intrexon and ourselves and we have limited experience, future development costs associated with this program may be difficult to anticipate and exceed our expectations. Our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, unanticipated technical challenges, changes in the focus and direction of our development activities or adjustments necessitated by changes in the competitive landscape in which we operate. If we are unable to continue to financially support such collaboration due to our own working capital constraints, we may be forced to discontinue the collaboration or delay our activities.

We may not be able to retain the exclusive rights licensed to us by Intrexon.

Under the Channel Agreement, we are using Intrexon's technology in connection with various of our product candidates. The Channel Agreement grants us a worldwide license to use patents and other intellectual property of

Intrexon in connection with the research, development, use, importing, manufacture, sale, and offer for sale of products within a pre-defined "field" that we set forth above in the "Item 1. Business - Intrexon Collaboration". The Channel Agreement may be terminated by Intrexon if we fail to exercise diligent efforts in developing products through the collaboration or if we elect not to pursue the development of a therapy in the "Field" identified by Intrexon that is a

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"Superior Therapy" as defined in the Channel Agreement. Upon such termination, the products covered by the Channel Agreement in active and ongoing Phase II or III clinical trials or later stage development through the Channel Agreement shall be entitled to be continued by us with a continuation of the related royalties for such products, and all rights to products covered by the Channel Agreement still in an earlier stage of development shall revert to Intrexon. There can be no assurance that we will be able to successfully perform under the Channel Agreement and if the Channel Agreement is terminated it may prevent us from achieving our business objectives.

If we breach our license agreement or collaboration agreement, it could have a material adverse effect on our commercialization efforts.

We have collaborated and may collaborate in the future with other entities on research, development and commercialization activities. Disputes may arise about inventorship and corresponding rights in know-how and inventions resulting from the joint creation or use of intellectual property by us and our subsidiaries, collaborators, partners, licensors and consultants. As a result, we may not be able to maintain our proprietary position.

We have limited manufacturing capacity and any manufacturing difficulties, disruptions or delays could limit supply of our products and or adversely affect our ability to conduct our clinical trials.

Manufacturing biologic human therapeutic products is difficult, complex and highly regulated. We currently manufacture LAVIV® and our cell therapy product candidates at one facility and outsource the manufacturing of our gene therapy product candidates to a separate facility, both located in the United States. Our ability to adequately and timely manufacture and supply our products is dependent on the uninterrupted and efficient operation of our sole facility and those of our third-party suppliers, which may be impacted by:

- availability or contamination of raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier;
- capacity of our facility and those of our suppliers;
- the performance of our information technology systems;
- compliance with regulatory requirements;
- inclement weather and natural disasters;
- changes in forecasts of future demand for product components;
- timing and actual number of production runs for product components;
- potential facility contamination by microorganisms or viruses;
- updating of manufacturing specifications; and
- product quality success rates and yields.

If the efficient manufacture and supply of our products is interrupted, we may experience delayed shipments or supply constraints. If we are at any time unable to provide an uninterrupted supply of our products to patients, we may lose patients and physicians may elect to prescribe competing therapeutics instead of our products, which could materially and adversely affect our product sales and results of operations. In addition, if we are unable to supply our clinical trials due to manufacturing limitations, our trials may be delayed or compromised.

Our manufacturing processes and those of our suppliers must undergo a potentially lengthy FDA approval process, as well as other regulatory approval processes, and are subject to continued review by the FDA and other regulatory authorities. It is a multi-year process to build and license a new manufacturing facility and it can take significant time to qualify and license a new supplier.

If regulatory authorities determine that we or our suppliers or certain of our third-party service providers have violated regulations or if they restrict, suspend or revoke our prior approvals, they could prohibit us from manufacturing our products or conducting clinical trials or selling our marketed products until we or the affected third-party service providers comply, or indefinitely. Because our third-party service providers are subject to FDA and, potentially, in the future, foreign regulatory authorities, alternative qualified third-party service providers may not be available on a timely basis or at all. If we or our third-party service providers cease or interrupt production or if our third-party service providers fail to supply materials, products or services to us, we may experience delayed shipments, and supply constraints for our products.

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Our research, development and manufacturing operations depend on one facility each for both our cell therapy and gene therapy product candidates. If such facility is destroyed or is out of operation for a substantial period of time, our business will be adversely impacted.

We currently conduct our research, development and manufacturing operations related to our cell therapy product in one facility located in Exton, Pennsylvania. As a result, all of the commercial manufacturing of LAVIV® takes place at a single U.S. facility. In addition, most of our clinical trials for our cell therapy product candidates primarily depend upon the manufacturing of such product candidates in the same facility. We currently outsource our research, development and manufacturing operations related to our gene therapy product candidates to one facility located in Mountainview, California.

If regulatory, manufacturing or other problems require us to discontinue production at either facility, we will not be able to supply our product to our customers or have supplies for our 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 either facility or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need FDA approval before any products manufactured at that facility could be sold or used.

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

We are dependent on the efforts of our key management and manufacturing and quality staff. The loss of any of these individuals, or our inability to recruit and train additional key personnel in a timely manner, could materially and adversely affect our business and our future prospects. A loss of one or more of our current officers or key personnel could severely and negatively impact our operations. We have an employment agreement with our chief executive officer, but the remainder of 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 executive officers or key management personnel.

We may need to attract, train and retain additional highly qualified senior executives and manufacturing and quality personnel in the future.

In the future, we may need to seek additional senior executives, as well as manufacturing and quality staff members. There is a high demand for highly trained executive, manufacturing and quality personnel in our industry. 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.

Risks Related to Ownership of our Common Stock

The trading price of the shares of our common stock has been highly volatile, and purchasers of our common stock could incur substantial losses.

Our stock began trading on NYSE MKT on May 17, 2013 and then on NASDAQ on August 29, 2014. Between May 17, 2013 and December 31, 2014, our common stock has traded between $2.28 and $7.20. Our stock price could be subject to wide fluctuations in response to a variety of factors, which include:

- whether our clinical human trials relating to the use of autologous cell therapy applications, in particular, for vocal cord scars, and such other indications as we may identify and pursue can be conducted within the timeframe that we expect, whether such trials will yield positive results, or whether additional applications for the commercialization of autologous cell therapy can be identified by us and advanced into human clinical trials;
- whether our collaboration with Intrexon can be advanced with positive results within the timeframe and budget that we expect;
- changes in laws or regulations applicable to our products or product candidates, including but not limited to clinical trial requirements for approvals;
- unanticipated serious safety concerns related to the use of our products or product candidates;
- a decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;

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- our ability to increase our manufacturing capacity and reduce our manufacturing costs through the improvement of our manufacturing process, our ability to validate any such improvements with the relevant regulatory agencies and our ability to accomplish the foregoing on a timely basis, if at all;
- adverse regulatory decisions;
- the introduction of new products or technologies offered by us or our competitors;
- the inability to effectively manage our growth;
- actual or anticipated variations in quarterly operating results;
- the failure to meet or exceed the estimates and projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- the overall performance of the U.S. equity markets and general political and economic conditions;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- the trading volume of our common stock; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the stock of biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

Our operating results may fluctuate significantly in the future, which may cause our results to fall below the expectations of securities analysts, stockholders and investors.

Our operating results may fluctuate significantly in the future as a result of a variety of factors, many of which are outside of our control. These factors include, but are not limited to:

- the timing, implementation and cost of our clinical trials;
- expenses in connection with our exclusive channel collaboration arrangement with Intrexon;
- the level of demand and profitability of LAVIV®;
- the timely and successful implementation of improved manufacturing processes;
- our ability to attract and retain personnel with the necessary strategic, technical and creative skills required for effective operations;
- the amount and timing of expenditures by practitioners and their patients;
- introduction of new technologies;
- product liability litigation, class action and derivative action litigation, or other litigation;
- the amount and timing of capital expenditures and other costs relating to the expansion of our operations;
- the state of the debt and/or equity markets at the time of any proposed offering we choose to initiate;
- our ability to successfully integrate new acquisitions into our operations;
- government regulation and legal developments regarding LAVIV® and our product candidates in the United States and in the foreign countries in which we may operate in the future; and
- general economic conditions.

As a strategic response to changes in the competitive environment, we may from time to time make pricing, service, technology or marketing decisions or business or technology acquisitions that could have a material adverse effect on our

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operating results. Due to any of these factors, our operating results may fall below the expectations of securities analysts, stockholders and investors in any future period, which may cause our stock price to decline.

We are substantially controlled by our current officers, directors, and principal stockholders.

Currently, our directors, executive officers, and principal stockholder beneficially own approximately 15.2 million shares, or 37%, of our common stock as of March 6, 2015. In addition, two of our seven directors are affiliates of our principal stockholder. As a result, our directors, officers and principal stockholders will be able to exert substantial influence over the election of our Board of Directors and the vote on issues submitted to our stockholders.

Future sales of our common stock may depress our stock price.

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market, or as a result of the perception that these sales could occur, which could occur if we issue a large number of shares of common stock (or securities convertible into our common stock) in connection with a future financing, as our common stock is trading at low levels. These factors could make it more difficult for us to raise funds through future offerings of common stock or other equity securities. As of the date of this report, all of our outstanding shares held by non-affiliates are freely transferable without restriction or further registration under the Securities Act. In addition to our common stock outstanding, as of December 31, 2014, we had warrants and options outstanding that were exercisable for a total of 7,133,300 shares of common stock.

We have identified a material weakness in our internal control over financial reporting. This material weakness could continue to adversely affect our ability to report our results of operations and financial condition accurately and in a timely manner.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with U.S. generally accepted accounting principles (“GAAP”). Our management is likewise required, on a quarterly basis, to evaluate the effectiveness of our internal control and to disclose any changes and material weaknesses in that internal control. 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.

As described elsewhere in this Annual Report on Form 10-K, we identified a material weakness in our internal control over financial reporting related to management's review of the assumptions used in the valuation modeling of our warrants classified as a liability. As a result of this material weakness, our management concluded that our internal control over financial reporting was not effective as of December 31, 2014.

To respond to this material weakness, we have devoted, and plan to continue to devote, significant effort and resources to the remediation and improvement of our internal control over financial reporting. We will require additional information in the valuation report provided by any third parties to which we outsource financial modeling to verify that management's assumptions were used as expected during the valuation process. In the past, management has utilized such third parties to assist us and will reconsider the appropriate selection of its external advisors that it will utilize in the future. The elements of management's remediation plan can only be accomplished over time and Management can offer no assurance that these initiatives will ultimately have the intended effects. For a discussion of management’s consideration of the material weakness identified, related to our warrant accounting, see Part II, Item 9A, “Controls and Procedures” included in this Annual Report on Form 10-K.

Any failure to maintain such internal control could adversely impact our ability to report our financial results on a timely and accurate basis. If our financial statements are not accurate, investors may not have a complete understanding of our operations. Likewise, if our financial statements are not filed on a timely basis as required by the SEC and NASDAQ, we could face severe consequences from those authorities. In either case, there could result a material adverse effect on our business. Inferior internal control could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock. We can give no assurance that the measures we have taken and plan to take in the future will remediate the material weaknesses identified or that any additional material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or circumvention of these

controls. In addition, even if we are successful in strengthening our controls and procedures, in the future those controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our consolidated financial statements.

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We have not declared any dividends on our common stock to date, and we have no intention of declaring dividends in the foreseeable future.

The decision to pay cash dividends on our common stock rests with our Board of Directors and will depend on our earnings, unencumbered cash, capital requirements and financial condition. We do not anticipate declaring any dividends in the foreseeable future, as we intend to use any excess cash to fund our operations. Investors in our common stock should not expect to receive dividend income on their investment, and investors will be dependent on the appreciation of our common stock to earn a return on their investment.

Provisions in our charter documents could prevent or delay stockholders' attempts to replace or remove current management.

Our charter documents provide for staggered terms for the members of our Board of Directors. Our Board of Directors is divided into three staggered classes, and each director serves a term of three years. At stockholders' meetings, only those directors comprising one of the three classes will have completed their term and be subject to re-election or replacement.

In addition, our Board of Directors is authorized to issue "blank check" preferred stock, with designations, rights and preferences as they may determine. Accordingly, our Board of Directors has in the past and may in the future, without stockholder approval, issue shares of preferred stock with dividend, liquidation, conversion, voting or other rights that could adversely affect the voting power or other rights of the holders of our common stock. This type of preferred stock could also be issued to discourage, delay or prevent a change in our control.

The use of a staggered Board of Directors and the ability to issue "blank check" preferred stock are traditional anti-takeover measures. These provisions in our charter documents make it difficult for a majority stockholder to gain control of the Board of Directors and of our company. These provisions may be beneficial to our management and our Board of Directors in a hostile tender offer and may have an adverse impact on stockholders who may want to participate in such a tender offer, or who may want to replace some or all of the members of our Board of Directors.

Provisions in our bylaws provide for indemnification of officers and directors, which could require us to direct funds away from our business and future products.

Our bylaws provide for the indemnification of our officers and directors. We have in the past and may in the future be required to advance costs incurred by an officer or director and to pay judgments, fines and expenses incurred by an officer or director, including reasonable attorneys' fees, as a result of actions or proceedings in which our officers and directors are involved by reason of being or having been an officer or director of our company. Funds paid in satisfaction of judgments, fines and expenses may be funds we need for the operation of our business and the development of our product candidates, thereby affecting our ability to attain profitability.

The public trading market for our common stock may not be sustained.

In the past, we have had a limited, volatile and sporadic public trading market for our common stock. Although our common stock is listed on NASDAQ, an active trading market for our common stock may not be sustained, especially given the large percentage of our common stock held by our affiliates. If an active market for our common stock is not sustained, it may be difficult for our stockholders to sell shares without depressing the market price for our common stock.

Provisions of the warrants issued in connection with certain of our prior financings provide for preferential treatment to the holders of the warrants and could impede a sale of the Company.

The warrants we issued in connection with certain of our prior financings gives each holder the option to receive a cash payment based on a Black-Scholes valuation upon our change of control or upon our failure to be listed on any trading market. We are required, at the warrant holder's option, exercisable at any time concurrently with, or within 30 days after, the announcement of a fundamental transaction, to redeem all or any portion of these warrants from the warrant holder by paying to the holder an amount of cash equal to the Black-Scholes value of the remaining unexercised portion of the warrant on or prior to the date of the consummation of such fundamental transaction.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. Securities and industry

analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our

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company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our corporate headquarters and manufacturing operations are located in one location, Exton, Pennsylvania. The Exton, Pennsylvania location is leased and consists of approximately 86,500 square feet. The lease ends March 31, 2023.

Item 3. Legal Proceedings

Shandong Fabosaier Bio-Tech Co., Ltd. and Ran Liu v. Fibrocell Science, Inc., Civil Action No. 14-7180 (U.S. Dist. Ct. for the E.D. of PA)

On or about December 19, 2014, Shandong Fabosaier Bio-Tech Co., Ltd. of China ("Shandong") and Ran Liu of Vancouver, Canada, who is allegedly a director of Shandong, commenced a lawsuit against us in the United States District Court for the Eastern District of Pennsylvania, Case No. 2:14-cv-07180-CMR. The Complaint asserts claims for breach of contract, promissory estoppel, and unjust enrichment against us. The Complaint alleges that we agreed to appoint Shandong and Ran Liu as the exclusive marketers of our product "LAVIV®," in China and Vancouver, respectively, for certain periods of time. Shandong alleges that we approved Shandong's promotion of LAVIV®, however we subsequently and without justification terminated these relationships and agreements, causing plaintiffs to suffer various damages.

We vigorously deny and dispute the factual allegations contained in the Complaint and, on February 12, 2015, we filed an amended answer, additional defenses and counterclaims against Shandong and Ms. Liu. Our counterclaims include counts for trademark infringement, violations of the Lanham Act and the Anticybersquatting Consumer Protection Act, unfair competition, and tortious interference with contractual relations resulting from Shandong's unauthorized use of our marks on Shandong's website and in other marketing materials, which included inaccurate and misleading representations about the LAVIV® product. We have added our wholly-owned subsidiary, Fibrocell Technologies, Inc., as an additional counterclaim plaintiff against Shandong because that entity owns the trademarks that are the subject of the counterclaims. At this time, we are unable to state whether an outcome unfavorable to us is either probably or remote within the meaning of the Statement of Policy nor are we able to estimate the amount or range of loss in the event of an unfavorable outcome.

Item 4. Mine Safety Disclosure

Not applicable.

Part II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock trades under the symbol "FCSC." Our stock traded on the Over the Counter Bulletin Board ("OTCBB") from October 21, 2009 until May 16, 2013. On May 17, 2013 our stock began trading on the NYSE MKT. On August 28, 2014, the Company delisted its common stock from the NYSE MKT and began trading on NASDAQ. The following table provides, for the periods during which we traded on the OTCBB, the high and low bid prices for our common stock. These quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions. The following table also provides, for the periods during we traded on the NYSE MKT and NASDAQ, the high and low sales prices for our common stock. The share prices have been adjusted to give effect to the 1-for-25 reverse stock split effective April 30, 2013.

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	High	Low
Year Ended December 31, 2014		
First Quarter	$6.30	$4.00
Second Quarter	$5.23	$2.70
Third Quarter prior to August 29, 2014 (the date we began trading on the NASDAQ)	$4.31	$2.88
Third Quarter (from August 29, 2014 to September 30, 2014))	$3.40	$2.60
Fourth Quarter	$3.25	$2.28
Year Ended December 31, 2013		
First Quarter	$4.25	$3.25
Second Quarter prior to May 17, 2013 (the date we began trading on the NYSE MKT)	$5.05	$3.00
Second Quarter (from May 17, 2013 to June 30, 2013)	$7.20	$4.50
Third Quarter	$6.23	$4.10
Fourth Quarter	$4.44	$3.28

The closing price of our common stock on March 6, 2015 was $5.82 as reported on NASDAQ.

Holders of Record

As of March 6, 2015, there were 40,856,815 shares of our common stock outstanding. There were approximately 174 stockholders of record at March 6, 2015. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividends

We have never paid any cash dividends on our common stock and our board of directors does not intend to do so in the foreseeable future. The declaration and payment of dividends in the future, of which there can be no assurance, will be determined by the board of directors in light of conditions then existing, including earnings, financial condition, capital requirements and other factors.

During 2012, we had outstanding shares of our Series D and Series E preferred stock. All of these shares were converted into common stock on October 9, 2012. Prior to such conversion, these preferred shares were entitled to certain dividends. There were no cash payments for Series D and Series E preferred stock dividends for 2014 or 2013 and approximately $0.5 million for 2012.

Recent Sales of Unregistered Securities

All information regarding our issuance of unregistered securities during Fiscal 2014 have been previously disclosed in current reports we have filed on Form 8-K or in quarterly reports we have filed on Form 10-Q.

Stock Performance Graph

The following graph compares the cumulative total return on our common stock relative to the cumulative total returns of the NASDAQ composite index and the NASDAQ Biotechnology index for the period from October 21, 2009 (date of inception) through December 31, 2014. An investment of $100 (with reinvestment of all dividends) is assumed to have been made in our common stock and in each of the indexes on October 21, 2009 (our date of inception) and its relative performance is tracked through December 31, 2014.

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	As of 12/31/2009	12/31/2010	12/31/2011	12/31/2012	12/31/2013	12/31/2014
Fibrocell Science, Inc.	62.16	27.57	21.62	8.11	8.78	5.60
NASDAQ Composite Index	105.51	123.35	121.13	140.39	194.19	220.21
NASDAQ Biotechnology Index	104.89	120.63	134.88	177.91	294.64	395.11

The stock price performance included in this graph is not necessarily indicative of future stock price performance.

Purchases of Equity Securities

We did not repurchase any of our equity securities during any month within the fourth quarter of the fiscal year ended December 31, 2014.

Item 6. Selected Financial Data

The selected financial data presented below was derived from our audited consolidated financial statements and related notes. The per share data has been retroactively adjusted to reflect the April 30, 2013 reverse stock split.

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	$ in thousands, except share data Twelve Months Ended 12/31/2014	12/31/2013	12/31/2012	12/31/2011	12/31/2010
Income Statement					
Total revenue	$180	$200	$153	$—	$936
Cost of sales	2,312	7,501	7,804	13	503
Gross loss	(2,132)	(7,301)	(7,651)	(13)	433
Selling, general and administrative expenses	11,623	9,440	11,546	12,795	6,516
Research and development expenses	16,199	13,762	10,193	7,171	5,486
Warrant revaluation and other finance income (expense)	3,930	(1,053)	20,404	2,562	(465)
Derivative revaluation income	—	—	(23)	(5,452)	—
Interest expense	6	2	(1,017)	(1,062)	(1,045)
Loss on extinguishment of debt	—	—	(5,617)	—	—
Other income	368	—	—	—	248
Loss from continuing operations before income tax	(25,650)	(31,554)	(15,643)	(23,931)	(12,831)
Income taxes	—	—	2,500	—	—
Loss from continuing operations	(25,650)	(31,554)	(13,143)	(23,931)	(12,831)
Loss from discontinued operations, net of tax	—	—	(11)	(94)	(49)
Gain on sale of discontinued operations, net of tax	—	—	467	—	—
Net loss	(25,650)	(31,554)	(12,687)	(24,025)	(12,880)
Net loss attributable to noncontrolling interest	—	—	(24)	(18)	(52)
Net loss attributable to common shareholders	(25,650)	(31,554)	(12,711)	(24,043)	(12,932)
Loss from continuing operations per common share - basic	$(0.63)	$(1.06)	$(1.47)	$(10.91)	$(17.10)
Loss from continuing operations per common share - diluted	$(0.70)	$(1.12)	$(2.65)	$(10.99)	$(17.10)
Net loss per common share - basic	$(0.63)	$(1.06)	$(1.42)	$(10.96)	$(17.23)
Net loss per common share - diluted	$(0.70)	$(1.12)	$(2.60)	$(11.04)	$(17.23)
Balance Sheet					
Cash and cash equivalents	$37,495	$60,033	$31,346	$10,799	$868
Total current assets	39,348	61,860	33,156	12,499	1,916
Total assets	45,634	69,014	40,603	20,274	8,278
Total current liabilities	3,493	3,593	1,554	9,612	1,943
Warrant liability	11,286	15,216	14,515	23,754	8,172
Total liabilities	15,225	19,348	16,413	36,542	22,281
Mezzanine preferred stock	—	—	—	—	1,070
Total equity/(deficit) and noncontrolling interest	30,409	49,666	24,190	(16,268)	(15,073)

We have never paid dividends on our common stock.

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

The following discussion of our consolidated financial condition and results of operations should be read in conjunction with the consolidated financial statements and the related notes thereto included elsewhere in this Form 10-K. The matters discussed herein contain forward-looking statements within the meaning of Section 21E of the Exchange Act, and Section 27A of the Securities Act, which involve risks and uncertainties. All statements other than statements of historical information provided herein may be deemed to be forward-looking statements. Without limiting the foregoing, the words "believes", "anticipates", "plans", "expects" and similar expressions are intended to identify forward-looking statements. Factors that could cause actual results to differ materially from those reflected in the forward-looking statements include, but are not limited to, those discussed in "Item 1A. Risk Factors" and elsewhere in this report and the risks discussed in our other filings with the SEC. Readers are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis, judgment, belief or expectation only as of the date hereof. Although we believe that our expectations

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are based on reasonable assumptions, we can give no assurance that our expectations will materialize. We undertake no obligation to publicly revise these forward-looking statements to reflect events or circumstances that arise after the date hereof.

General

We are an autologous cell therapy company primarily focused on developing first-in-class treatments for rare and serious skin and connective tissue diseases with high unmet medical needs. Our lead orphan gene therapy program is in late stage pre-clinical development for the treatment of recessive dystrophic epidermolysis bullosa ("RDEB"). In addition to our gene therapy program, we are pursuing the medical application of azficel-T for vocal cord scarring using our proprietary autologous fibroblast technology. We are also in pre-clinical development for our second gene therapy program for linear scleroderma.

Working in collaboration with Intrexon Corporation (NYSE:XON), a leader in synthetic biology, we are genetically modifying autologous fibroblast cells to express collagen VII which is missing or inactive from patients with RDEB. Collagen VII is responsible for forming fibrils which attach the epidermis and the dermis layers of the skin. RDEB is a rare congenital orphan skin disease is a devastating, progressive, painful blistering disease that ultimately leads to premature death. The lack of collagen VII is the underlying cause of this disease. We expect to file our investigational new drug ("IND") application with the Food and Drug Administration ("FDA") by mid-2015 and to initiate our Phase I clinical trials in the second half of 2015.

Our ongoing scientific research collaboration with the Regents of the University of California, Los Angeles (“UCLA”) focuses on discoveries and technologies related to regenerative medicine. The technologies from this collaboration and our exclusive license agreements with UCLA may enable us to expand our biologics platform which uses human fibroblasts to create localized therapies that are compatible with the unique biology of each patient.

Critical Accounting Policies

The following discussion and analysis of financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in conformity with U.S. generally accepted accounting principles (“GAAP”). However, certain accounting policies and estimates are particularly important to the understanding of our financial position and results of operations and require the application of significant judgment by our management or can be materially affected by changes from period to period in economic factors or conditions that are outside of the control of management. As a result they are subject to an inherent degree of uncertainty. In applying these policies, our management uses their judgment to determine the appropriate assumptions to be used in the determination of certain estimates. Those estimates are based on our historical operations, our future business plans and projected financial results, the terms of existing contracts, our observance of trends in the industry, information provided by our customers and information available from other outside sources, as appropriate. The following discusses our critical accounting policies and estimates.

Intangible Assets: Intangible assets are research and development assets related to our primary study that was recognized upon emergence from bankruptcy. Amortization commenced in the first quarter of 2012 with the recognition of revenue from the sale of LAVIV®.

Intangibles are tested for recoverability whenever events or changes in circumstances indicate the carrying amount may not be recoverable. The impairment test consists of a comparison of the fair value of the intangible asset to its carrying amount. If the carrying amount exceeds the fair value, an impairment loss is recognized equal in amount to that excess.

Warrant Liability: The Company accounts for stock warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreement. Stock warrants are accounted for as a derivative in accordance with Accounting Standards Codification 815, Derivatives and Hedging (“ASC 815”) if the stock warrants contain “down-round protection” or other terms that could potentially require “net cash settlement” and therefore, do not meet the scope exception for treatment as a derivative. Since “down-round protection” is not an input into the calculation of the fair value of the warrants, the warrants cannot be considered indexed to our stock which is a requirement for the scope exception as outlined under ASC 815. Warrant instruments that could potentially require “net cash settlement” in the absence of express language precluding such settlement and those which include

“down-round provisions” are initially classified as derivative liabilities at their estimated fair values, regardless of the likelihood that such instruments will ever be settled in cash. We will continue to classify the fair value of the warrants that contain “down-round protection” and “net cash settlement” as a liability until the warrants are exercised, expire or are amended in a way that would no longer require these warrants to be classified as a liability.

Cost of Sales: Cost of sales includes the costs related to the processing of cells for LAVIV®, including direct and indirect costs. Beginning in Fiscal 2014, cost of sales is accounted for using a standard cost system for direct and indirect costs. Direct costs include the majority of costs incurred in our manufacturing, facility, quality control, and quality assurance operations along with an allocation of overhead and indirect costs.

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Research and Development Expenses: Research and development costs are expensed as incurred and include salaries and benefits, costs paid to third-party contractors to perform research, conduct clinical trials, develop and manufacture drug materials and delivery devices, and a portion of facilities cost. Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. Invoicing from third-party contractors for services performed can lag several months. We accrue the costs of services rendered in connection with third-party contractor activities based on our estimate of management fees, site management and monitoring costs and data management costs. Actual clinical trial costs may differ from estimated clinical trial costs and are adjusted for in the period in which they become known.

Stock Based Compensation: We account for stock-based awards to employees using the fair value based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. In addition, we account for stock-based compensation to nonemployees in accordance with the accounting guidance for equity instruments that are issued to other than employees. We use a Black-Scholes option-pricing model to determine the fair value of each option grant as of the date of grant for expense incurred. The Black-Scholes model requires inputs for risk-free interest rate, dividend yield, volatility and expected lives of the options. Expected volatility is based on historical volatility of our common stock and our peer companies. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of the grant. The expected lives for options granted represents the period of time that options granted are expected to be outstanding and is derived from the contractual terms of the options granted. We estimate future forfeitures of options based upon historical forfeiture rates.

Income Taxes: An asset and liability approach is used for financial accounting and reporting for income taxes. Deferred income taxes arise from temporary differences between income tax and financial reporting and principally relate to recognition of revenue and expenses in different periods for financial and tax accounting purposes and are measured using currently enacted tax rates and laws. In addition, a deferred tax asset can be generated by net operating loss (“NOL”) carryover. If it is more likely than not that some portion or all of a deferred tax asset will not be realized, a valuation allowance is recognized.

Basis of Presentation

The following discussion should be read in conjunction with the Consolidated Financial Statements and the accompanying Notes to the Consolidated Financial Statements included in this Form 10-K.

Results of Operations

Comparison of Years Ending December 31, 2014 and 2013

Revenue and Cost of Sales. Revenue and cost of sales were comprised of the following:

	Year Ended December 31,		Increase (Decrease)	
($ in thousands)	2014	2013	$	%
Total revenue	$180	$200	$(20)	(10.0)%
Cost of sales	2,312	7,501	(5,189)	(69.2)%
Gross loss	$(2,132)	$(7,301)	$5,169	70.8 %

Revenue was approximately $0.2 million for each of the years ended December 31, 2014 and 2013. Revenue is booked based on the shipment of cells to the patients for injection of LAVIV®.

Cost of sales was $2.3 million and $7.5 million for the years ended December 31, 2014 and 2013, respectively. Cost of sales includes the costs related to the processing of cells for LAVIV®, including direct and indirect costs. Beginning in Fiscal 2014, cost of sales is accounted for using a standard cost system which allocates the costs associated with our manufacturing, facility, quality control, and quality assurance operations as well as overhead costs. The decrease of $5.2 million is primarily due to a reallocation of manufacturing costs related to research and development expense, increased production efficiency and yield as well as a de-emphasis on commercial sales in the aesthetic market (LAVIV®).

The principal reasons for the relatively small level of revenue as compared to the cost of sales are: (1) We changed corporate strategy in Fiscal 2013 to de-emphasize sales of azficel-T into the aesthetic markets, and strategically transition to focus on high-value therapeutic applications for treatment of unmet medical conditions of the skin and

connective tissue (2) Manufacturing capacity — our current manufacturing capacity is limited to no more than twenty biopsies a week as assessed by the FDA in connection with the approval of our BLA; (3) Charging for biopsies and injections — we offered complimentary and reduced price biopsies and injections throughout Fiscal 2012 and Fiscal 2013; and (4) Manufacturing complexity and quality control and assurance criteria. We currently have adequate manufacturing capacity to meet clinical demand and the limited commercial demand we expect for Fiscal 2015. We believe that cost of sales will remain at or above

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product revenue for the foreseeable future and, thus, we anticipate that we will continue to report gross losses from sales of LAVIV® for the aesthetic indication for the foreseeable future.

Selling, General and Administrative Expense. Selling, general and administrative expense was comprised of the following:

	Year Ended December 31,		Increase (Decrease)		
($ in thousands)	2014	2013	$	%	
Compensation and related expense	$4,727	$3,841	$886	23.1	%
Professional fees	1,713	964	749	77.7	%
Marketing expense	57	295	(238)	(80.7)	%
Legal fees	1,056	697	359	51.5	%
Facilities and related expense and other	4,070	3,643	427	11.7	%
Total selling, general and administrative expense	$11,623	$9,440	$2,183	23.1	%

Selling, general and administrative expense increased by approximately $2.2 million, or 23%, to $11.6 million for the year ended December 31, 2014 as compared to $9.4 million for the year ended December 31, 2013. Compensation and related expense increased approximately $0.9 million due to $0.5 million in employee bonuses, $0.2 million in severance costs, increased salaries of $0.1 million and increased stock compensation expense of $0.1 million. Professional fees increased approximately $0.7 million, primarily due to the $0.4 million in accounting and audit related costs for our warrant restatement project in the second quarter of Fiscal 2014 and an increase of $0.3 million in temporary staffing costs. Marketing expense decreased approximately $0.2 million due to the de-emphasis on sales of our commercial product, LAVIV®. Legal fees increased approximately $0.4 million due to negotiations with respect to our corporate contracts as well as the warrant restatement project. Facilities and related expense and other increased approximately $0.4 million due to a $0.3 million increase in repairs and maintenance costs and a $0.1 million increase in office and other general expenses.

Research and Development Expense.

For each of our research and development programs, we incur both direct and indirect expenses. Direct expenses include third party costs related to these programs such as contract research, consulting, pre-clinical and clinical development costs. Indirect expenses include regulatory, lab costs, personnel, facility, stock compensation and other overhead costs that are not attributable to any one program. We expect research and development costs to continue to be significant for the foreseeable future as a result of our clinical trials and our collaboration with Intrexon.

Research and development expense was comprised of the following:

	Year Ended December 31,		Increase (Decrease)		
($ in thousands)	2014	2013	$	%	
Direct costs:					
Vocal Cord Scarring	$778	$322	$456	141.6	%
RDEB	3,800	1,773	2,027	114.3	%
Restrictive Burn Scarring	645	344	301	87.5	%
Autoimmune diseases	558	7,140	(6,582)	(92.2)	%
azficel-T	549	1,555	(1,006)	(64.7)	%
Ehlers-Danlos Syndrome hypermobility type	5,171	—	5,171	100.0	%
Other	460	631	(171)	(27.1)	%
Total direct costs	11,961	11,765	196	1.7	%
Indirect costs:					
Regulatory costs	1,012	923	89	9.6	%
Intangible amortization	551	551	—	—	%
Indirect lab costs and other expenses	2,402	253	2,149	849.4	%
Compensation and related expenses	273	270	3	1.1	%
Total indirect costs	4,238	1,997	2,241	112.2	%

Total research and development expense	$16,199	$13,762	$2,437	17.7 %

Total research and development expense increased approximately $2.4 million, or 18%, to $16.2 million for the year ended December 31, 2014 as compared to $13.8 million for the year ended December 31, 2013. The increase is due primarily

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to the increase of $2.1 million in indirect lab costs and other expenses resulting from the Fiscal 2014 implementation of a standard cost system, a $0.2 million increase in total direct costs and a $0.1 million increase in other indirect costs. A portion of our operational and overhead costs not related to commercial sales were allocated to research and development expense as indirect lab costs. Similar costs would have been included in cost of sales for the year ended December 31, 2013.

Direct research and development expense by major clinical and pre-clinical development program were as follows.

Vocal Cord Scarring ("VCS") — Costs to date on this program are approximately $1.3 million. These funds have been utilized to author and review clinical trial protocols, hire a Contract Research Organization ("CRO"), recruit investigator sites and initiate recruitment. Going forward, VCS research and development investments will support execution of the Phase II clinical trial, clinical product manufacturing, statistical analyses, report generation and future clinical development. Costs increased $0.5 million compared to the year ended December 31, 2013 due to additional costs for enrollment, clinical site fees and manufacturing costs related to our Phase II clinical trial.

RDEB — Costs to date on this program are approximately $12.6 million, and include the $6.9 million cost of the Fiscal 2012 stock issuance in connection with the Channel Agreement with Intrexon. Going forward, RDEB research and development investments will support additional product and assay development, pre-clinical trial execution, key opinion leader development, pre-IND and DNA Recombinant Advisory Committee ("RAC") meeting preparation and design and execution of the Phase I clinical trial protocol. Costs increased approximately $2.0 million compared to the year ended December 31, 2013 due to the expansion of our pre-clinical development program and pre-clinical manufacturing costs.

Restrictive Burn Scarring ("RBS") — Costs to date on this program are approximately $1.1 million. These funds have been utilized to author and review clinical trial protocols, hire a CRO, recruit investigator sites and initiate recruitment. Going forward, RBS research and development investments will support execution of the Phase II clinical trial, clinical product manufacturing, statistical analyses, report generation and future clinical development. Costs increased approximately $0.3 million compared to the year ended December 31, 2013 due to additional costs for enrollment, clinical site fees and manufacturing costs related to our Phase II clinical trial. In the fourth quarter of 2014, enrollment for the Phase II clinical trial was closed and will continue with its current study design.

Autoimmune diseases — Costs to date on these programs are approximately $7.7 million, and include the $6.4 million cost of the Fiscal 2013 supplemental stock issuance in connection with the First Amendment to the Channel Agreement with Intrexon. Going forward, autoimmune research and development investments will support product and assay development, pre-clinical trial execution, key opinion leader development, pre-IND and DNA RAC meeting preparation and design and execution of the Phase I clinical trial protocol. The autoimmune disease program began in the second half of Fiscal 2013. The cutaneous eosinophilias indication is no longer being targeted.

Azficel-T — Costs to date on this program of approximately $2.3 million represent the costs of process improvements for the production of azficel-T. These process improvements include rapid mycoplasma assay, media optimization, raw material selection assays, cryo-preservative analysis and alternate disassociation enzymes. Costs decreased approximately $1.0 million compared to the year ended December 31, 2013 as costs incurred in Fiscal 2014 were internal costs required to validate studies for azficel-T that were performed by outside vendors in Fiscal 2013.

Ehlers-Danlos Syndrome hypermobility type — Costs to date are approximately $5.2 million and represent the cost of the first quarter of Fiscal 2014 supplemental stock issuance in connection with the second amendment to the exclusive channel collaboration agreement with Intrexon. No substantive work has yet begun on the development of this pre-clinical program.

Change in Revaluation of Warrant Liability. During the years ended December 31, 2014 and 2013, respectively, we recorded non-cash income of approximately $3.9 million and non-cash expense of approximately $1.1 million for warrant revaluation and other finance charges in our statements of operations due to a change in the fair value of the warrant liability as a result of a change in our stock price and a change in the contractual life of the warrants.

Other Income. During the year ended December 31, 2014, we recorded approximately $0.4 million of other income, primarily in a settlement agreement with one of our suppliers. There was no such income during the year ended December 31, 2013.

Net Loss. Net loss decreased approximately $5.9 million to $25.7 million for the year ended December 31, 2014, as compared to $31.6 million for the year ended December 31, 2013. The decrease is primarily due to the change in the warrant revaluation and other finance charges of approximately $5.0 million, as more fully described above, an overall decrease in cost of sales and operating expenses of approximately $0.5 million and an increase in other income of approximately $0.4 million.

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Comparison of Years Ending December 31, 2013 and 2012

Revenue and Cost of Sales. Revenue and cost of sales were comprised of the following:

	Year Ended December 31,		Increase (Decrease)	
($ in thousands)	2013	2012	$	%
Total revenue	$200	$153	$47	30.7 %
Cost of sales	7,501	7,804	(303)	(3.9)%
Gross loss	$(7,301)	$(7,651)	$350	(4.6)%

Revenue was approximately $0.2 million for each of the years ended December 31, 2013 and 2012. Revenue is booked based on the shipment of cells to the patients for injection of LAVIV®.

Cost of sales was approximately $7.5 million and $7.8 million for the years ended December 31, 2013 and 2012, respectively. Cost of sales includes the costs related to the processing of cells for LAVIV®, including direct and indirect costs. The cost of sales for the year ended December 31, 2013 was comprised of approximately $3.4 million of compensation and related expense, $3.0 million of laboratory supplies and other related expenses and $1.1 million of rent, utilities and depreciation. The cost of sales for the year ended December 31, 2012 was comprised of approximately $3.8 million of compensation and related expense, $3.0 million of laboratory supplies and other related expenses, $1.0 million of rent, utilities, depreciation and other. Cost of sales decreased $0.3 million, mainly due to a reduction in compensation and related expense of $0.4 million coinciding with the reduction of manufacturing personnel employed.

The principal reasons for the relatively small level of revenue as compared to the cost of sales are: (1) We changed corporate strategy in Fiscal 2013 to de-emphasize sales of azficel-T into the aesthetic markets, and strategically transition to focus on high-value therapeutic applications for treatment of unmet medical conditions of the skin and connective tissue; (2) Manufacturing capacity — our current manufacturing capacity is limited to no more than twenty biopsies a week as assessed by the FDA in connection with the approval of our BLA; (3) Charging for biopsies and injections — we offered complimentary and reduced price biopsies and injections throughout Fiscal 2012 and Fiscal 2013; and (4) Manufacturing complexity and quality control and assurance criteria.

Selling, General and Administrative Expense. Selling, general and administrative expense was comprised of the following:

	Year Ended December 31,		Increase (Decrease)	
($ in thousands)	2013	2012	$	%
Compensation and related expense	$3,841	$4,336	$(495)	(11.4)%
Professional fees	964	877	87	9.9 %
Marketing expense	295	2,203	(1,908)	(86.6)%
Legal fees	697	527	170	32.3 %
Facilities and related expense and other	3,643	3,603	40	1.1 %
Total selling, general and administrative expense	$9,440	$11,546	$(2,106)	(18.2)%

Selling, general and administrative expense decreased approximately $2.1 million, or 18%, to $9.4 million for the year ended December 31, 2013 as compared to $11.5 million for the year ended December 31, 2012. Compensation and related expense decreased approximately $0.5 million due to reduced salary and related expense of $0.7 million offset by an increase in severance costs of $0.2 million incurred with the reduction of sales and marketing personnel employed. Professional fees increased approximately $0.1 million due to higher audit fees in the year ended December 31, 2013. Marketing expense decreased approximately $1.9 million due to increased spending for the initial launch of LAVIV® during Fiscal 2012. Legal fees increased approximately $0.2 million due to increased patent costs of $0.1 million and clinical trial review costs of $0.1 million. Facilities and related expense and other were relatively constant year over year.

Research and Development Expense.

For each of our research and development programs, we incur both direct and indirect expenses. Direct expenses include third party costs related to these programs such as contract research, consulting, pre-clinical and clinical

development costs. Indirect expenses include regulatory, lab costs, personnel, facility, stock compensation and other overhead costs that are not attributable to any one program. We expect research and development costs to continue to be significant for the foreseeable future as a result of our clinical trials and our collaboration with Intrexon.

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Research and development expense was comprised of the following:

($ in thousands)	Year Ended December 31, 2013	2012	Increase (Decrease) $	%
Direct costs:				
Vocal Cord Scarring	$322	158	$164	103.8 %
RDEB	1,773	6,979	(5,206)	(74.6)%
Restrictive Burn Scarring	344	163	181	111.0 %
Autoimmune diseases	7,140	—	7,140	100.0 %
azficel-T	1,555	293	1,262	430.7 %
Other	631	554	77	13.9 %
Total direct costs	11,765	8,147	3,618	44.4 %
Indirect costs:				
Regulatory costs	923	978	(55)	(5.6)%
Intangible amortization	551	551	—	— %
Indirect lab costs and other	253	194	59	30.4 %
Compensation and related expense	270	323	(53)	(16.4)%
Total indirect costs	1,997	2,046	(49)	(2.4)%
Total research and development expense	$13,762	$10,193	$3,569	35.0 %

Total research and development expense increased $3.6 million, or 35%, to $13.8 million for the year ended December 31, 2013 as compared to $10.2 million for the year ended December 31, 2012. The increase is due primarily to a $3.1 million increase in consulting fees related to research and development costs incurred in the year ended December 31, 2013 in connection with our collaboration with Intrexon and increased costs of $0.4 million related to our two Phase II clinical trials that began enrollment in Fiscal 2013.

Direct research and development expense by major clinical and pre-clinical development program were as follows:

Vocal Cord Scarring (“VCS”) — Costs to date on this program are approximately $0.5 million. These funds have been utilized to author and review clinical trial protocols, hire a CRO, recruit investigator sites and initiate recruitment. Going forward, VCS research and development investments will support execution of the Phase II clinical trial, clinical product manufacturing, statistical analyses, report generation and future clinical development.

RDEB — Costs to date on this program are approximately $8.8 million and include the $6.9 million cost of the Fiscal 2012 stock issuance in connection with the Channel Agreement with Intrexon. In addition, there were approximately $1.9 million in costs associated with product and assay development. Going forward, RDEB research and development investments will support additional product and assay development, pre-clinical trial execution, key opinion leader development, pre-IND and Recombinant DNA Advisory Committee (“RAC”) meeting preparation and design and execution of the Phase I clinical trial protocol.

Restrictive Burn Scarring (“RBS”) — Costs to date on this program are approximately $0.5 million. These funds have been utilized to author and review clinical trial protocols, hire a Contract Research Organization (“CRO”), recruit investigator sites and initiate recruitment. Going forward, RBS research and development investments will support execution of the Phase II clinical trial, clinical product manufacturing, statistical analyses, report generation and future clinical development.

Autoimmune diseases - Costs to date on this program, which includes morphea profunda/ linear scleroderma ("MP/LS") and cutaneous eosinophilias ("CE"), are approximately $7.1 million and include the $6.4 million cost of the Fiscal 2013 supplemental stock issuance in connection with the First Amendment to the Channel Agreement with Intrexon and approximately $0.8 million in early stage pre-clinical development. Future MP / LS and CE research and development investments will support product and assay development, pre-clinical trial execution, key opinion leader development, pre-IND and DNA RAC meeting preparation and design and execution of the Phase I clinical trial protocol.

Azficel-T - Costs to date on this program of approximately $1.8 million represent the costs of process improvements for the production of azficel-T. These process improvements include rapid mycoplasma assay, media optimization,

raw material selection assays, cryo-preservative analysis and alternate disassociation enzymes.

Interest Expense. We incurred no interest expense in Fiscal 2013 as compared to approximately $1.0 million for the year ended December 31, 2012. Our interest expense for the year ended December 31, 2012 was related to our 12.5% convertible notes. The 12.5% notes were either paid or converted into common stock with the close of our October 2012 financing.

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Loss on Extinguishment of Debt. On June 1, 2012, we entered into an exchange agreement with existing note holders pursuant to which we agreed to repay half of each holder's 12.5% promissory notes due June 1, 2012 and exchange the balance of each holder's original note, for (i) a new 12.5% note with a principal amount equal to such balance, and (ii) a five-year warrant to purchase a number of shares of common stock equal to the number of shares of common stock underlying such note on the date of issuance. As a result of the exchange agreement on June 1, 2012, we recorded a loss on extinguishment of the 12.5% notes of $4.1 million and $1.5 million in the consolidated statement of operations due to a significant restructuring of the original debt in June 2012 and December 2012, respectively. The details of the loss included recording the fair value of the embedded conversion option of approximately $1.2 million and the fair value of liability-classified warrants of approximately $4.4 million. As the debt was extinguished in Fiscal 2012, there was no comparable activity in Fiscal 2013.

Change in Revaluation of Warrant Liability. During the years ended December 31, 2013 and 2012, respectively, we recorded non-cash expense of approximately $1.1 million and non-cash income of approximately $20.4 million for warrant revaluation and other finance charges in our statements of operations due to a change in the fair value of the warrant liability as a result of a change in our stock price and a change in the contractual life of the warrants.

Change in Revaluation of Derivative Liability. During the year ended December 31, 2012, we recorded non-cash expense of less than $0.1 million for derivative revaluation expense, in our statements of operations, due to the change in the fair value of the derivative liability related to the Series D and E preferred stock financings. In October 2012, this preferred stock was converted to common stock and the related derivative liability was reclassified to stockholders deficit as it no longer required liability classification and accordingly, we did not incur a non-cash expense in Fiscal 2013 related to the revaluation of the derivative liability.

Deferred Tax Benefit. During the year ended December 31, 2012, we recorded a deferred tax benefit of $2.5 million due to the favorable impact to the computation of the valuation allowance recorded against our net deferred tax asset as a result of the reclassification of the intangible assets recognized upon emergence from bankruptcy as a finite-lived intangible asset. The reclassification freed-up the related deferred tax liability by allowing it to offset our net deferred tax asset before applying the valuation allowance. There was no deferred tax benefit recorded for the year ended December 31, 2013.

Loss from Discontinued Operations. The net loss from discontinued operations for the year ended December 31, 2012 relates to Agera Laboratories, Inc. which was sold in the third quarter of Fiscal 2012.

Gain on Sale of Discontinued Operations. On August 31, 2012 we sold all of the shares of common stock of Agera Laboratories, Inc. that we held for approximately $1.0 million. As a result of the sale, we recorded a gain of approximately $0.5million, net of tax.

Net Loss. Net loss increased approximately $18.9 million to $31.6 million for the year ended December 31, 2013, as compared to $12.7 million for the year ended December 31, 2012. The increase is primarily due to the change in the warrant revaluation and other finance charges of approximately $21.5 million, more fully described above. Other contributing factors were an increase in operating expenses of approximately $1.4 million the offset by decreases of $0.3 million in cost of sales and $1.0 million in interest expense as well as the $5.6 million in the loss on extinguishment of debt, the $2.5 million deferred tax benefit and the $0.5 million gain on sale of discontinued operations that only occurred in Fiscal 2012.

Liquidity and Capital Resources for Years Ending December 31, 2014, 2013 and 2012

We have experienced losses since our inception. As of December 31, 2014, we have an accumulated deficit of $112.7 million. The process of developing and commercializing our product candidates requires significant research and development work and clinical trial work, as well as significant manufacturing and process development efforts. These activities, together with our selling, general and administrative expenses, are expected to continue to result in significant operating losses for the foreseeable future.

The following table summarizes our cash flows from operating, investing and financing activities:

	Year Ended December 31,		
($ in thousands)	2014	2013	2012
Statement of Cash Flows Data:			

Total cash provided by (used in):			
Operating activities	$(22,296)	$(20,075)	$(22,575)
Investing activities	(242)	(360)	509
Financing activities	—	49,122	42,613

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Operating Activities. Cash used in operating activities during the year ended December 31, 2014 amounted to $22.3 million, an increase of $2.2 million over the year ended December 31, 2013. The increase in our cash used in operating activities is primarily due to a $2.7 million decrease in Accounts payable and Accrued expenses and other liabilities positions, which included balances with our partner Intrexon, building related costs and other items. These uses of cash were partially offset by establishment of $0.5 million accrual related to our new bonus plan.

Cash used in operating activities during the year ended December 31, 2013 amounted to $20.1 million, a decrease of $2.5 million over the year ended December 31, 2012. The decrease in our cash used in operating activities over 2012 is primarily due to a $2.8 million increase in Accounts payable and Accrued expenses and other liabilities positions, which included balances with our partner Intrexon and other items. These uses of cash were partially offset by increases in Other assets positions and other account movements of $0.3 million.

Investing Activities. Cash used in investing activities during the year ended December 31, 2014 and December 31, 2013 of $0.2 million and $0.4 million, respectively was due to the purchase of property and equipment. The cash provided by investing activities during the year ended December 31, 2012 was $0.5 million related to the sale of Agera Laboratories, Inc. in the third quarter of Fiscal 2012 offset by the purchase of property and equipment.

Financing Activities. There were no financing activities for the year ended December 31, 2014. During the year ended December 31, 2013, we had net proceeds of $47.1 million from the issuance of common stock related to our October 2013 financing, and received $2.0 million from a common stock subscription receivable. During the year ended December 31, 2012, we raised cash of $48.1 million from the issuance of common stock, preferred stock and warrants, offset primarily by principal debt payments of $4.8 million and dividend payments of $0.5 million.

Working Capital

As of December 31, 2014, we had cash and cash equivalents of $37.5 million and working capital of $35.9 million. We expect to have sufficient cash to operate for at least the next twelve months. In addition, we expect we will require additional financing prior to our business achieving significant net cash from operations. We would likely raise such additional capital through the issuance of our equity or equity-linked securities, which may result in dilution to our investors, or by entering into strategic partnerships. Our ability to raise additional capital is dependent on, among other things, the state of the financial markets at the time of any proposed offering. To secure funding through strategic partnerships, it may be necessary to license one or more of our technologies at an earlier stage of development, which could cause us to share a greater portion of the potential future economic value of those programs with our partners. There is no assurance that additional funding, through any of the aforementioned means, will be available on acceptable terms, or at all. If adequate capital cannot be obtained on a timely basis and on satisfactory terms, our operations could be materially negatively impacted.

Factors Affecting Our Capital Resources

Inflation did not have a significant impact on our results during the year ended December 31, 2014, 2013 or 2012.

Off-Balance Sheet Transactions

We do not engage in material off-balance sheet transactions.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2014:

	Payments due by period				
($ in thousands)	Total	2015	2016 and 2017	2018 and 2019	2020 and thereafter
License fee obligations(1)	$950	$483	$308	$106	$53
Operating lease obligations(2)	$11,168	$1,211	$2,508	$2,670	$4,779
Total	$12,118	$1,694	$2,816	$2,776	$4,832

(1)Obligations for license agreements with UCLA and the sponsored research agreement with MIT. The amounts in the table assume the foregoing agreements are continued through their respective terms. The agreements may be terminated at the option of either party. In such event, our obligation would be limited to costs through the date of such termination.

(2)Operating lease obligations are stated based on the amended lease agreement for the office, warehouse and laboratory facilities executed in February 2012.

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Historically we have entered into agreements with academic medical institutions and contract research organizations to perform research and development activities and with clinical sites for the treatment of patients under clinical protocols. Such contracts expire at various dates and have differing renewal and expiration clauses.

Collaboration with Related Party

Intrexon is an affiliate of our largest shareholder, NRM VII Holdings I, LLC. In addition, two of our seven directors are also affiliates of NRM VII Holdings I, LLC. On October 5, 2012, we entered into an Exclusive Channel Collaboration Agreement ("Channel Agreement") with Intrexon that governs a "channel collaboration" arrangement. The Channel Agreement grants us an exclusive license to use proprietary technologies and other intellectual property of Intrexon to develop and commercialize certain products in the United States. As consideration for our Channel Agreement and related amendments, we issued shares of our common stock to Intrexon. For additional details, see Note 13 in the accompanying financial statements included as part of this Annual Report on Form 10-K.

Recently Issued Accounting Pronouncements

See Note 3 in the accompanying notes to the consolidated financial statements for discussion on recently issued accounting pronouncements.

Item 7A. Quantitative and Qualitative Disclosure about Market Risk

The primary objective of our investment activities is to preserve our capital until it is required to fund operations. As of December 31, 2014, we had cash and cash equivalents of $37.5 million. Our exposure to market risk is confined to cash and cash equivalents, which consist of instruments having original maturities of three months or less. Our cash flow and earnings are subject to immaterial fluctuations due to changes in interest rates in our investment portfolio, and we do not believe that a
10% change in average interest rates would have a significant impact on our interest income.

Item 8. Financial Statements and Supplementary Data

The financial statements, including the notes thereto and report of the independent registered public accounting firm thereon are included in this report as set forth in the "Index to Financial Statements." See F-1 for Index to Consolidated Financial Statements.

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

Not applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, including our principal executive officer and principal financial officer, evaluated the disclosure controls and procedures related to the recording, processing, summarization and reporting of information in the periodic reports that we file with the SEC. These disclosure controls and procedures have been designed to ensure that (i) material information relating to us, including our consolidated subsidiaries, is made known to management, including these officers, by our other employees, and (ii) this information is recorded, processed, summarized, evaluated and reported, as applicable, within the time periods specified in the SEC's rules and forms. Based on our evaluation, including the existence of the material weakness in our internal control over financial reporting referenced below, our management, including our Chief Executive Officer and Chief Financial Officer, concluded that our disclosure controls and procedures were not effective to provide reasonable assurance as of December 31, 2014.

Management's Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in the Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO 2013").

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America. Our internal control over financial reporting

includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to

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permit preparation of financial statements in accordance with generally accepted accounting principles, and our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

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

Based on our evaluation under the framework in COSO 2013, our principal executive officer and principal financial officer concluded that our internal control over financial reporting was not effective as of December 31, 2014 due to the material weakness discussed below with respect to internal control over management's review of the assumptions used in the valuation modeling of our liability classified warrants. The effectiveness of our internal control over financial reporting as of December 31, 2014 has been audited by BDO USA, LLP, an independent registered public accounting firm, as stated in their report included in this Annual Report on Form 10-K in the accompanying Consolidated Financial Statements.

Notwithstanding the material weakness described below, management has concluded that our audited consolidated financial statements and unaudited condensed consolidated financial statements for the periods included in this Annual Report on Form 10-K are fairly stated in all material respects in accordance with generally accepted accounting principles for each of the periods presented herein.

Material Weakness

We utilize the Monte Carlo simulation valuation method to value our liability-classified warrants. Due to the complex nature of this valuation method, we outsource financial modeling of the Monte Carlo simulation valuation to a third party. Management provides the third party with certain assumptions for inclusion in their financial modeling regarding the probability of possible future events that could impact the fair value of the warrants. Management receives a report from the third party detailing the assumptions used in the financial model, including these probabilities, which management then reviews for reasonableness and accuracy. For the valuation of its warrants at December 31, 2014, management provided certain assumptions to the third party to be used in its financial model. While management provided the third party with appropriate assumptions, the assumptions ultimately used in the financial model at December 31, 2014 did not agree with management's expectations or with its review of third party's valuation report. The difference in assumptions used from the assumptions expected was identified as part of procedures performed by our independent auditors during their annual audit and resulted in an adjustment to our financial statements at December 31, 2014. This audit adjustment related only to the fourth quarter of 2014 and not to any prior periods. As management's review of the third party's valuation report failed to uncover this inconsistency, management determined that a control deficiency that constitutes a material deficiency in the design of our internal control over financial reporting in connection with management's review of the assumptions used in the valuation of the Company's warrants was present.

Remediation

As noted above, a material weakness with respect to the internal control over management's review of the assumptions used in the valuation of our liability-classified warrants was identified at December 31, 2014 in our internal control over financial reporting.

To respond to this material weakness, we have devoted, and plan to continue to devote, significant effort and resources to the remediation and improvement of our internal control over financial reporting. We will require additional information in the valuation report provided by any third parties to which we outsource financial modeling to verify that Management's assumptions were used as expected during the valuation process. In the past, Management has utilized such third parties to assist us and will reconsider the appropriate selection of its external advisors that it will utilize in the future. The elements of Management's remediation plan can only be accomplished over time and Management can offer no assurance that these initiatives will ultimately have the intended effects.

Other Changes in Internal Control Over Financial Reporting

Other than the material weakness discussed above, there have been no other changes in our internal control over financial reporting during the fourth quarter ended December 31, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

On March 11, 2015 the Company and its Chief Executive Officer, David Pernock, entered into an amendment (the "Amendment") to the Nonqualified Stock Option Grant Agreement, between Fibrocell Science, Inc. and David Pernock, dated

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as of July 19, 2013 (the "Grant Agreement"). Prior to the amendment, the Grant Agreement provided that the vested portion of the option awarded under the Grant Agreement (the "Option") would remain exercisable for 10 years from the date of grant, even if Mr. Pernock's employment with the Company terminated. Under the Amendment, the Option will now expire one year after Mr. Pernock's termination of employment with the Company for death or disability or six months after any other termination of Mr. Pernock's employment. The remainder of the terms of the Grant Agreement remain in effect.

The foregoing description of the material terms of the Amendment does not purport to be complete and is qualified in its entirety by reference to the Amendment, a copy of which is filed herewith as Exhibit 10.22 and is incorporated herein by reference.

Part III

Item 10. Directors, Executive Officers and Corporate Governance

The information regarding executive officers and directors required by this Item 10 will be included in Proxy Statement, under "Information About Directors and Executive Officers", "Proposal 1-Election of Directors", and "Governance of the Company" and is incorporated herein by reference. Other information required by this Item 10 will be included in the Proxy Statement under "Section 16(a) Beneficial Ownership Reporting Compliance" and is incorporated herein by reference.

Code of Ethics. We have adopted a written code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller and any persons performing similar functions. The code of ethics is on our website at www.fibrocellscience.com. In addition, we intend to promptly disclose (1) the nature of any amendment to our code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date the waiver on our website in the future.

Item 11. Executive Compensation

The information required under this Item 11 is incorporated herein by reference to the Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required under this Item 12 is incorporated herein by reference to the Proxy Statement.

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

The information required under this Item 13 is incorporated herein by reference to the Proxy Statement.

Item 14. Principal Accountant Fees and Services

The information required under this Item 14 is incorporated herein by reference to the Proxy Statement.

Part IV

Item 15. Exhibits and Financial Statement Schedule

(a)(1) Consolidated Financial Statements.

The Consolidated Financial Statements are filed as part of this report.

(a)(2) Consolidated Financial Statement Schedule.

All schedules are omitted because of the absence of conditions under which they are required or because the required information is presented in the Consolidated Financial Statements or notes thereto.

(a)(3) The exhibits listed under Item 15(b) are filed or incorporated by reference herein.

(b) Exhibits.

The following exhibits are filed as part of this annual report:

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EXHIBIT NO.	IDENTIFICATION OF EXHIBIT
2.1	Debtors' First Amended Joint Plan of Reorganization dated July 30, 2009 and Disclosure Statement (incorporated by reference to as Exhibit 10.2 to the Company's Form 10-Q for quarter ended June 30, 2009, filed on August 12, 2009 and as Exhibit 99.1 to our Form 8-K filed September 2, 2009)
3.1	Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to our Form 8-K filed December 13, 2012)
3.2	Certificate of Amendment of the Restated Certificate of Incorporation filed April 26, 2013 (incorporated by reference to Exhibit 3.1 of the Form 8-K filed on April 29, 2013)
3.3	Certificate of Amendment to the Company's Restated Certificate of Incorporation, as amended, filed July 19, 2013 (incorporated by reference to Exhibit 3.1 of the Form 8-K filed on July 22, 2013)
3.4	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to our Form 8-K filed September 2, 2009)
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to our Form 10-Q filed November 23, 2009)
4.2	Form of Class A/B Common Stock Purchase Warrant issued in October 2009 offering (incorporated by reference to Exhibit 4.1 to our Form 8-K filed October 14, 2009)
4.3	Form of Placement Agent Warrant issued in November 2009 offering (incorporated by reference to Exhibit 4.2 to our Form 10-Q filed November 23, 2009)
4.4	Form of Common Stock Purchase Warrant issued in March 2010 offering (incorporated by reference to Exhibit 4.1 to our Form 8-K filed March 3, 2010)
4.5	Form of Common Stock Purchase Warrant issued in July 2010 Series B Preferred Stock offering (incorporated by reference to Exhibit 4.1 to our Form 8-K filed July 20, 2010)
4.6	Form of Placement Agent Warrant issued in July 2010 Series B Preferred Stock offering (incorporated by reference to Exhibit 4.2 to our Form 8-K filed July 20, 2010)
4.7	Form of Common Stock Purchase Warrant used for Series B Preferred Stock offering (incorporated by reference to Exhibit 4.1 of the Form 8-K filed October 22, 2010).
4.8	Form of Common Stock Purchase Warrant used for the Series D Preferred Stock offering (incorporated by reference to Exhibit 4.1 of the Form 8-K filed February 15, 2011).
4.9	Form of Common Stock Purchase Warrant issued in August 2011 offering (incorporated by reference to Exhibit 4.1 to our Form 8-K filed August 4, 2011)
4.10	Form of Amended and Restated Common Stock Purchase Warrant issued to our prior 12.5% Note holders (incorporated by reference to Exhibit 10.5 of the Form 8-K filed October 9, 2012).
10.1	Lease Agreement between Isolagen, Inc. and The Hankin Group dated April 7, 2005 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed on April 12, 2005)
10.2	Amendment to Lease Agreement between Fibrocell Science, Inc. and The Hankin Group dated February 17, 2012 (incorporated by reference to Exhibit 10.17 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2011)
10.3	Securities Purchase Agreement dated October 5, 2012 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed October 9, 2012)
10.4	Registration Rights Agreement dated October 5, 2012 (incorporated by reference to Exhibit 10.2 to our Form 8-K filed October 5, 2012)
10.5	Stock Issuance Agreement dated October 5, 2012 between the Company and Intrexon Corporation (incorporated by reference to Exhibit 10.3 to our Form 8-K filed October 5, 2012)
10.6	Amendment and Conversion Agreement dated October 5, 2012 between the Company and the Holders of the Company's Notes (incorporated by reference to Exhibit 10.4 to our Form 8-K filed October 5, 2012)
10.7	Exclusive Channel Collaboration Agreement between Intrexon Corporation and Fibrocell Science, Inc. (incorporated by reference to Exhibit 10.21 of the Form 10-K filed on April 1, 2013)

**10.8	Employment Transition Letter between Fibrocell Science, Inc. and Declan Daly dated June 28, 2013 (incorporated by reference to Exhibit 10.1 of the Form 8-K filed on June 28, 2013)
10.9	First Amendment to Exclusive Channel Collaboration Agreement between the Company and Intrexon Corporation dated June 28, 2013 (incorporated by reference to Exhibit 10.1 of the Form 8-K filed on July 1, 2013)
10.10	Supplemental Stock Issuance Agreement between the Company and Intrexon Corporation dated June 28, 2013 (incorporated by reference to Exhibit 10.2 of the Form 8-K filed on July 1, 2013)
10.11	Massachusetts Institute of Technology Office of Sponsored Programs Research Agreement (incorporated by reference to Exhibit 10.1 of the Form 10-Q filed on November 14, 2013)

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10.12		The Regents of the University of California Research Agreement (incorporated by reference to Exhibit 10.2 of the Form 10-Q filed on November 14, 2013)
**10.13		Employment Agreement between the Company and Gregory Weaver dated August 26, 2013 (incorporated by reference to Exhibit 10.1 of the Form 8-K filed on August 26, 2013)
**10.14		Stock Option Agreement between the Company and Gregory Weaver issued pursuant to Employment Agreement between the Company and Gregory Weaver dated August 26, 2013 (incorporated by reference to Exhibit 10.4 of the Form 10-Q filed on November 14, 2013)
**10.15		Employment Agreement between the Company and David Pernock dated November 15, 2013 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed November 18, 2013)
10.16		Second Amendment to Exclusive Channel Collaboration Agreement between the Company and Intrexon Corporation dated January 10, 2014 (incorporated by reference to Exhibit 10.1 of the Form 8-K filed on January 13, 2014)
10.17		Supplemental Stock Issuance Agreement between the Company and Intrexon Corporation dated January 10, 2014 (incorporated by reference to Exhibit 10.2 of the Form 8-K filed on January 13, 2014)
**10.18		Fibrocell Science, Inc. 2009 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on June 20, 2014)
10.19	U	Exclusive License Agreement, dated June 1, 2014, by and between The Regents of the University of California and the Company (which we refer to as the "BMP2 Agreement") (incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q/A filed on October 7, 2014)
10.20	U	Exclusive License Agreement, dated June 1, 2014, by and between The Regents of the University of California and the Company (which we refer to as the "Genomic Stability Agreement") (incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q/A filed on October 7, 2014)
10.21		Amendment to Employment Agreement, dated September 2, 2014, by and between the Company and Gregory Weaver. (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on September 3, 2014)
***10.22		Amendment to Stock Option Agreement by and between the Company and David Pernock dated March 11, 2015
21		List of Subsidiaries. (incorporated by reference to Exhibit 21 of the Form 10-K filed on April 1, 2013)
*23.1		Consent of BDO USA, LLP
*31.1		Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002
*31.2		Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002
*32.1		Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
*32.2		Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS		XBRL Instance Document. (1)
101.SCH		XBRL Taxonomy Extension Schema Document. (1)
101.CAL		XBRL Taxonomy Extension Calculation Linkbase Document. (1)
101.LAB		XBRL Taxonomy Extension Label Linkbase Document. (1)
101.PRE		XBRL Taxonomy Extension Presentation Linkbase Document. (1)
101.DEF		XBRL Taxonomy Extension Definition Linkbase Document. (1)

* Filed herewith.

** Indicates management contract or compensatory plan or arrangement.

U Confidential treatment has been granted as to certain portions of this exhibit pursuant to Rule 406 of the Securities Act of 1933, as amended, or Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

(1) Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

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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.

FIBROCELL SCIENCE, INC.

By: /s/ David Pernock
David Pernock
Chief Executive Officer

Date: March 13, 2015

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

Signature	Title	Date
/s/ David Pernock David Pernock	Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	March 13, 2015
/s/ Kimberly M. Smith Kimberly M. Smith	Interim Chief Financial Officer (Principal Financial and Accounting Officer)	March 13, 2015
/s/ Kelvin Moore Kelvin Moore	Director	March 13, 2015
/s/ Marc Mazur Marc Mazur	Director	March 13, 2015
/s/ Julian Kirk Julian Kirk	Director	March 13, 2015
/s/ Marcus Smith Marcus Smith	Director	March 13, 2015
/s/ Christine St.Clare Christine St.Clare	Director	March 13, 2015
/s/ Douglas J. Swirsky Douglas J. Swirsky	Director	March 13, 2015

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Fibrocell Science, Inc.
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Fibrocell Science, Inc.
Exton, Pennsylvania

We have audited the accompanying consolidated balance sheets of Fibrocell Science, Inc. as of December 31, 2014 and 2013 and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Fibrocell Science, Inc. at December 31, 2014 and 2013, and the results of its operations and its 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.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Fibrocell Science Inc.'s internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 13, 2015 expressed an adverse opinion thereon.

/s/ BDO USA, LLP
Philadelphia, Pennsylvania
March 13, 2015

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Fibrocell Science, Inc.
Exton, Pennsylvania

We have audited Fibrocell Science Inc.'s internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Fibrocell Science Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying "Item 9A, Management's Report on Internal Control Over Financial Reporting". Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

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. A material weakness regarding management's failure to design and maintain controls over the fair value calculation of the Company's warrant liability has been identified and described in management's assessment. This material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2014 financial statements, and this report does not affect our report dated March 13, 2015 on those financial statements.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Fibrocell Science, Inc. as of December 31, 2014 and 2013, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2014 and our report dated March 13, 2015 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP
Philadelphia, Pennsylvania
March 13, 2015

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Fibrocell Science, Inc.
Consolidated Balance Sheets
($ in thousands, except share data)

	December 31, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$37,495	$60,033
Accounts receivable, net of allowance for doubtful accounts of $17 and $5, respectively	4	28
Inventory	571	597
Prepaid expenses and other current assets	1,278	1,202
Total current assets	39,348	61,860
Property and equipment, net	1,598	1,701
Intangible assets, net of accumulated amortization of $1,653 and $1,102, respectively	4,687	5,238
Other assets	1	215
Total assets	$45,634	$69,014
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$1,124	$2,958
Accrued expenses	1,675	487
Deferred revenue	416	148
Warrant liability, current	278	—
Total current liabilities	3,493	3,593
Warrant liability, long term	11,008	15,216
Other long term liabilities	724	539
Total liabilities	15,225	19,348
Commitments:		
Common stock, $0.001 par value; 100,000,000 shares authorized; 40,856,815 and 39,832,225 shares issued and outstanding, respectively	41	40
Additional paid-in capital	143,086	136,694
Accumulated deficit	(112,718)	(87,068)
Total stockholders' equity	30,409	49,666
Total liabilities and stockholders' equity	$45,634	$69,014

The accompanying notes are an integral part of these consolidated financial statements.

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Fibrocell Science, Inc.
Consolidated Statements of Operations
($ in thousands, except per share data)

Year Ended	Year Ended December 31, 2014	Year Ended December 31, 2013	Year Ended December 31, 2012
Revenue from product sales	$180	$200	$153
Cost of sales	2,312	7,501	7,804
Gross loss	(2,132)	(7,301)	(7,651)
Selling, general and administrative expenses	11,623	9,440	11,546
Research and development expenses	16,199	13,762	10,193
Operating loss	(29,954)	(30,503)	(29,390)
Other income (expense):			
Warrant revaluation and other finance income (expense)	3,930	(1,053)	20,404
Derivative revaluation expense	—	—	(23)
Interest income (expense)	6	2	(1,017)
Loss on extinguishment of debt	—	—	(5,617)
Other income	368	—	—
Loss from continuing operations before income taxes	(25,650)	(31,554)	(15,643)
Deferred tax benefit	—	—	2,500
Loss from continuing operations	(25,650)	(31,554)	(13,143)
Loss from discontinued operations, net of tax	—	—	(11)
Gain on sale of discontinued operations, net of tax	—	—	467
Net loss	(25,650)	(31,554)	(12,687)
Net loss attributable to non-controlling interest	—	—	(24)
Net loss attributable to Fibrocell Science, Inc. common stockholders	$(25,650)	$(31,554)	$(12,711)
Per Share Information:			
Loss from continuing operations - basic	$(0.63)	$(1.06)	$(1.47)
Gain on sale of discontinued operations, net of tax - basic	—	—	0.05
Net loss per common share - basic	(0.63)	(1.06)	(1.42)
Loss from continuing operations - diluted	(0.70)	(1.12)	(2.65)
Gain on sale of discontinued operations, net of tax - diluted	—	—	0.05
Net loss per common share - diluted	(0.70)	(1.12)	(2.60)
Weighted average number of common shares outstanding			
— Basic	40,789,445	29,830,207	8,965,098
— Diluted	40,969,399	30,196,616	9,147,060

The accompanying notes are an integral part of these consolidated financial statements.

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Fibrocell Science, Inc.
Consolidated Statements of Stockholders' Equity (Deficit)
($ in thousands)

	Common Stock Shares	Amount	Subscription receivable	Additional paid-in capital	Accumulated deficit	Non-controlling interest	Total Equity (Deficit)
Balance, December 31, 2011	3,827,132	$4	$(550)	$27,081	$(43,271)	$ 468	$(16,268)
Proceeds from equity financing, net	18,203,000	18	(2,004)	42,171	—	—	40,185
Fair value of warrants issued with financing	—	—	—	1,098	—	—	1,098
Preferred stock series D and E converted	2,021,120	2	—	1,348	—	—	1,350
Conversion of note payable	898,641	1	—	2,384	—	—	2,385
Issuance of common stock	1,317,520	1	—	6,916	—	—	6,917
Cancellation of certificate	(40,000)	—	550	(550)	—	—	—
Stock-based compensation expense	—	—	—	1,224	—	—	1,224
Exercise of warrants	2,496	—	—	10	—	—	10
Net loss	—	—	—	—	(12,243)	(468)	(12,711)
Balance, December 31, 2012	26,229,909	$26	$(2,004)	$81,682	$(55,514)	$ —	$24,190
Proceeds from equity financing, net	12,311,698	12	—	47,106	—	—	47,118
Subscription received	—	—	2,004	—	—	—	2,004
Issuance of common stock	1,243,781	2	—	6,404	—	—	6,406
Stock-based compensation expense	—	—	—	1,150	—	—	1,150
Exercise of warrants	46,837	—	—	352	—	—	352
Net loss	—	—	—	—	(31,554)	—	(31,554)
Balance, December 31, 2013	39,832,225	$40	$—	$136,694	$(87,068)	$ —	$49,666
Issuance of common stock	1,024,590	1	—	5,153	—	—	5,154
Stock-based compensation expense	—	—	—	1,239	—	—	1,239
Net loss	—	—	—	—	(25,650)	—	(25,650)
Balance, December 31, 2014	40,856,815	$41	$—	$143,086	$(112,718)	$ —	$30,409

The accompanying notes are an integral part of these consolidated financial statements.

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Fibrocell Science, Inc.
Consolidated Statements of Cash Flows
($ in thousands)

	Year Ended December 31, 2014	Year Ended December 31, 2013	Year Ended December 31, 2012
Cash flows from operating activities:			
Net loss	$(25,650)	$(31,554)	$(12,687)
Adjustments to reconcile net loss to net cash used in operating activities:			
Loss on extinguishment of debt	—	—	5,617
Gain on sale of Agera	—	—	(467)
Stock issued for exclusive channel collaboration agreement	5,154	6,406	6,917
Stock-based compensation expense	1,239	1,150	1,224
Warrant revaluation and other finance (income) expense	(3,930)	1,053	(20,404)
Derivative revaluation expense	—	—	23
Deferred tax benefit	—	—	(2,500)
Loss on disposal of property and equipment	13	5	—
Depreciation and amortization	883	863	821
Provision for doubtful accounts	12	(20)	25
Amortization of debt issuance costs	—	—	146
Change in operating assets and liabilities:			
Accounts receivable	12	54	(60)
Inventory	26	(120)	(477)
Prepaid expenses	(76)	69	(196)
Other assets	214	(215)	—
Accounts payable	(1,834)	2,037	(966)
Accrued expenses and other liabilities	1,373	188	407
Deferred revenue	268	9	83
Miscellaneous other	—	—	(81)
Net cash used in operating activities	(22,296)	(20,075)	(22,575)
Cash flows from investing activities:			
Purchase of property and equipment	(242)	(360)	(493)
Proceeds from the sale of Agera	—	—	1,002
Net cash (used in) provided by investing activities	(242)	(360)	509
Cash flows from financing activities:			
Debt issuance costs	—	—	(46)
Net proceeds from preferred stock	—	—	7,864
Net proceeds from common stock	—	47,118	40,185
Subscription received	—	2,004	—
Payments on insurance loan	—	—	(97)
Principal payments on note payable	—	—	(4,823)
Dividends paid on preferred stock	—	—	(470)
Net cash provided by financing activities	—	49,122	42,613
Net (decrease) increase in cash and cash equivalents	(22,538)	28,687	20,547
Cash and cash equivalents, beginning of period	60,033	31,346	10,799
Cash and cash equivalents, end of period	$37,495	$60,033	$31,346

The accompanying notes are an integral part of these consolidated financial statements.

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Fibrocell Science, Inc.
Notes to Consolidated Financial Statements
Note 1. Business and Organization

Fibrocell Science, Inc. (as used herein, "we," "us," "our," "Fibrocell" or the "Company") is the parent company of Fibrocell Technologies, Inc. ("Fibrocell Tech") and Fibrocell Science Hong Kong Limited ("Fibrocell Hong Kong"), a company organized under the laws of Hong Kong. Fibrocell Tech is the parent company of Isolagen Europe Limited, a company organized under the laws of the United Kingdom ("Isolagen Europe"), Isolagen Australia Pty Limited, a company organized under the laws of Australia ("Isolagen Australia"), and Isolagen International, S.A., a company organized under the laws of Switzerland ("Isolagen Switzerland"). The Company's international activities are currently immaterial.

The Company is an autologous cell therapy company focused on developing first-in-class treatments for rare and serious skin and connective tissue diseases with high unmet medical needs. Fibrocell's lead orphan drug program is in late-stage pre-clinical development for the treatment of RDEB (recessive dystrophic epidermolysis bullosa). The Company's collaboration with Intrexon Corporation (NYSE:XON) ("Intrexon"), a leader in synthetic biology, includes using genetically-modified autologous fibroblast cells to express target proteins that are inactive or missing from patients with rare genetic skin and connective tissue disorders. The Company is also pursuing medical applications for azficel-T, the Company's proprietary autologous fibroblast technology, for vocal cord scarring and restrictive burn scarring. Both indications are currently in Phase II clinical trials. The Company's ongoing scientific research collaboration with the University of California, Los Angeles ("UCLA") has yielded discoveries and technologies related to stem cells and regenerative cells in human skin. The technologies from this collaboration and the Company's exclusive license agreements with UCLA enable the Company to expand its proprietary personalized biologics platform which uses human fibroblasts and stem cells from skin to create localized therapies that are compatible with the unique biology of each patient.

The Company's securities ceased trading on the NYSE MKT effective at the close of business on August 28, 2014 and commenced trading on NASDAQ on August 29, 2014. The Company's common stock continues to trade under its current trading symbol "FCSC".

The Company previously marketed a skin care line with broad application in core target markets through its consolidated subsidiary, Agera Laboratories, Inc. ("Agera"), which was sold on August 31, 2012. The Company had owned 57% of the outstanding shares of Agera. As a result of the sale of Agera, the Company operates in one segment and Agera is classified as discontinued operations. Please refer to Note 16 for more details.

Note 2. Basis of Presentation

The prior year financial statements contain certain reclassifications to the results of operations for the years ended December 31, 2013 and 2012 to conform to the presentation for the year ended December 31, 2014 in this Form 10-K. These reclassifications were made in conjunction with the Company's de-emphasis on its commercial product LAVIV® and towards further research and development of the underlying azficel-T process as well as on developing first-in-class treatments for rare and serious skin and connective tissue diseases with high unmet medical needs.

For the year ended December 31, 2014, amortization expense of approximately $0.6 million was included in research and development expense on the Consolidated Statements of Operations. For the years ended December 31, 2013 and 2012, amortization expense of approximately $0.6 million and $0.6 million, respectively, was reclassed from cost of sales to research and development expense on the Consolidated Statements of Operations to conform to the current presentation. For the year ended December 31, 2014, the Company's Food and Drug Administration ("FDA") license fees related to its Biologics License Application ("BLA") of approximately $0.6 million were included in research and development expense on the Consolidated Statements of Operations. For the years ended December 31, 2013 and 2012, FDA license fees of approximately $0.6 million and $0.6 million, respectively, were reclassed from selling, general and administrative expense to research and development expense on the Consolidated Statements of Operations to conform to the current presentation.

On April 30, 2013, the Company completed a reverse stock split on the basis of one share of common stock for each currently outstanding 25 shares of pre-split common stock. All common share and per share data included in these financial statements reflect this reverse stock split.

Note 3. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. Generally Accepted Accounting Principles ("GAAP") requires management to make estimates and assumptions that affect the reported amounts in the consolidated financial statements and notes. In addition, management's assessment of the Company's ability to continue as a going concern involves

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the estimation of the amount and timing of future cash inflows and outflows. Actual results may differ materially from those estimates.

Principles of Consolidation

These consolidated financial statements include the accounts of Fibrocell and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Cash and Cash Equivalents

The Company considers highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents.

Concentration of Credit Risk

As of December 31, 2014, the Company maintains its operating cash with one major U.S. domestic bank and the remainder of its cash and cash equivalents as a money market fund with one major global bank. Federal insurance coverage on our operating cash amounted to $250,000 per depositor at each financial institution, and the Company's non-interest bearing cash balances may exceed federally insured limits. The terms of these deposits are on demand to minimize risk. The Company has not incurred losses related to these deposits.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are recorded at the invoiced amount, net of related cash discounts, and do not bear interest. The Company does not have any off-balance sheet exposure related to the Company's customers. The Company maintains an allowance for doubtful accounts related to its accounts receivable that have been deemed to have a high risk of collectability. Management reviews its accounts receivable on a monthly basis to determine if any receivables will potentially be uncollectible. Management analyzes historical collection trends and changes in its customer payment patterns, customer concentration and creditworthiness when evaluating the adequacy of its allowance for doubtful accounts. In its overall allowance for doubtful accounts, the Company includes any receivable balances that are determined to be uncollectible. Based on the information available, management believes the allowance for doubtful accounts is adequate; however, actual write-offs might exceed the recorded allowance.

The following table summarizes the changes in the allowance for doubtful accounts receivable for the indicated periods:

	Balance at beginning of year	Additions charged to earnings	Uncollectible receivables written off, net of recoveries	Balance at end of year
December 31, 2014	5	12	(2)	17
December 31, 2013	25	(20)	—	5
December 31, 2012	—	25	—	25

Inventory

Inventories are determined at the lower of cost or market value, with cost determined under specific identification and on the first-in-first-out method. Inventories consist of raw materials and work-in-process.

Property and Equipment

Property and equipment is carried at acquisition cost less accumulated depreciation. Depreciation is computed on a straight-line basis over the estimated useful life of the asset. The cost of repairs and maintenance is charged to expense as incurred. As of December 31, 2013, the useful life for all property and equipment was three years, except for leasehold improvements which were depreciated over the remaining lease term or the life of the asset, whichever was shorter. In the first quarter of 2014, the Company adjusted its useful lives to reflect the expected consumption of the economic benefit of these assets as noted in the following table:

Property and equipment category	Useful life
Laboratory equipment	6 years
Computer equipment and software	3 years

Furniture and fixtures	10 years
Leasehold improvements	Lesser of remaining lease term or life of asset

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In accordance with Financial Accounting Standards Board ("FASB") Accounting Standard Codification ("ASC") ASC Topic 250 Accounting Changes and Error Corrections, the Company accounted for this change in useful lives as a change in estimate, with prospective application only. The impact of this change in estimate on depreciation expense was immaterial to the results on the Consolidated Statements of Operations.

Intangible Assets

Intangible assets are research and development assets related to the Company's primary study on azficel-T that was recognized upon emergence from bankruptcy. The portion of the reorganization value which was attributed to identified intangible assets was $6.3 million. Effective January 1, 2012, the Company launched LAVIV® and as a result, the research and development intangible assets related to the Company's primary study are considered finite-lived intangible assets and are being amortized over 12 years. For each of the years ended December 31, 2014, 2013 and 2012, amortization expense was approximately $0.6 million. The Company expects to amortize approximately $0.6 million for each of the next five years.

Finite-lived intangible assets are recorded at cost, net of accumulated amortization and, if applicable, impairment charges. Amortization of finite-lived intangible assets is provided over their estimated useful lives on a straight-line basis. In accordance with Financial Accounting Standards Board Accounting Standard Codification ("ASC") 360-10-35 Impairment or Disposal of Long-Lived Assets, the Company reviews its finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. There was no impairment expense recognized for the years ended December 31, 2014, 2013 or 2012.

Warrant Liability

The Company accounts for stock warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreement. Stock warrants are accounted for as a derivative in accordance with Accounting Standards Codification 815, Derivatives and Hedging ("ASC 815") if the stock warrants contain "down-round protection" or other terms that could potentially require "net cash settlement" and therefore, do not meet the scope exception for treatment as a derivative. Since "down-round protection" is not an input into the calculation of the fair value of the warrants, the warrants cannot be considered indexed to the Company's own stock which is a requirement for the scope exception as outlined under ASC 815. Warrant instruments that could potentially require "net cash settlement" in the absence of express language precluding such settlement and those which include "down-round provisions" are initially classified as derivative liabilities at their estimated fair values, regardless of the likelihood that such instruments will ever be settled in cash. The Company will continue to classify the fair value of the warrants that contain "down-round protection" and "net cash settlement" as a liability until the warrants are exercised, expire or are amended in a way that would no longer require these warrants to be classified as a liability. For additional discussion on warrants, see Note 7.

Revenue Recognition

The Company recognizes revenue over the period LAVIV® is shipped for injection in accordance with ASC 605 Revenue Recognition ("ASC 605"). In general, ASC 605 requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services rendered, (3) the fee is fixed and determinable and (4) collectability is reasonably assured. Revenue from the sale of LAVIV® is not recognized until the first shipment for an injection is shipped.

Cost of Sales

Cost of sales includes the costs related to the processing of cells for LAVIV®, including direct and indirect costs. Beginning in 2014, cost of sales is accounted for using a standard cost system which allocates the direct costs associated with the Company's manufacturing, facility, quality control, and quality assurance operations as well as overhead costs. The principal reason for the relatively small level of revenue as compared to the cost of sales is that the Company changed corporate strategy in late 2013 to de-emphasize sales of LAVIV® into the aesthetic markets, and towards further research and development of the underlying azficel-T process as well as on developing first-in-class treatments for rare and serious skin and connective tissue diseases with high unmet medical needs.

Research and Development Expenses

Research and development costs are expensed as incurred and include salaries and benefits, costs paid to third party contractors to perform research, conduct clinical trials, develop and manufacture drug materials and delivery devices,

and a portion of facilities cost. Research and development costs also include costs to manufacture product for clinical trial use and to develop manufacturing, cell collection and logistical process improvements.

Clinical trial costs are a significant component of research and development expenses and include costs associated with third party contractors. Invoicing from third party contractors for services performed can lag several months. The

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Company accrues the costs of services rendered in connection with third party contractor activities based on its estimate of management fees, site management and monitoring costs and data management costs.

Stock-based Compensation

The Company accounts for stock-based awards to employees using the fair value based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. In addition, the Company accounts for stock-based compensation to nonemployees in accordance with the accounting guidance for equity instruments that are issued to other than employees. The Company uses a Black-Scholes option-pricing model to determine the fair value of each option grant as of the date of grant for expense incurred. The Black-Scholes model requires inputs for risk-free interest rate, dividend yield, expected stock price volatility and expected life of the options. Expected stock price volatility is based on historical volatility of the Company's stock and the stock of the Company's peer companies. The risk-free interest rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of the grant. The expected life for options granted represents the period of time that options granted are expected to be outstanding and is derived from the contractual terms of the options granted. The Company estimates future forfeitures of options based upon expected forfeiture rates.

Income Taxes

An asset and liability approach is used for financial accounting and reporting for income taxes. Deferred income taxes arise from temporary differences between income tax and financial reporting and principally relate to recognition of revenue and expenses in different periods for financial and tax accounting purposes and are measured using currently enacted tax rates and laws. In addition, a deferred tax asset can be generated by net operating loss (NOLs) carryover. If it is more likely than not that some portion or all of a deferred tax asset will not be realized, a valuation allowance is recognized.

In the event the Company is charged interest or penalties related to income tax matters, the Company would record such interest as interest expense and would record such penalties as other expense in the consolidated statements of operations. No such charges have been incurred by the Company. For each of the years ended December 31, 2014, 2013 and 2012, the Company had no uncertain tax positions.

At December 31, 2014, and December 31, 2013, the Company has provided a full valuation allowance for the net deferred tax assets, the large majority of which relates to the future benefit of loss carryovers. The tax years 2011 through the present remain open to examination by the major taxing jurisdictions to which the Company is subject.

Loss Per Share Data

Basic loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock outstanding during a period. The diluted loss per share calculation gives effect to dilutive options, warrants, convertible notes, convertible preferred stock, and other potential dilutive common stock including selected restricted shares of common stock outstanding during the period. Diluted loss per share is based on the treasury stock method and includes the effect from potential issuance of common stock, such as shares issuable pursuant to the exercise of stock options and warrants, assuming the exercise of all in-the-money stock options and warrants. Common share equivalents have been excluded where their inclusion would be anti-dilutive.

	For the Twelve Months Ended December 31,		
($ in thousands except share and per share data)	2014	2013	2012
Loss per share — Basic:			
Numerator for basic loss per share	$(25,650)	$(31,554)	$(12,711)
Denominator for basic loss per share	40,789,445	29,830,207	8,965,098
Basic loss per common share	$(0.63)	$(1.06)	$(1.42)
Loss per share — Diluted:			
Numerator for basic loss per share	$(25,650)	$(31,554)	$(12,711)
Adjust: Fair value of dilutive warrants outstanding	2,840	2,270	11,091
Numerator for diluted loss per share	$(28,490)	$(33,824)	$(23,802)
Denominator for basic loss per share	40,789,445	29,830,207	8,965,098

Plus: Incremental shares underlying “in the money” warrants outstanding	179,954	366,409	181,962
Denominator for diluted loss per share	40,969,399	30,196,616	9,147,060
Diluted loss per common share	$(0.70)	$(1.12)	$(2.60)

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The following potentially dilutive securities have been excluded from the computations of diluted weighted-average shares outstanding, as their effect would be anti-dilutive:

	For the Twelve Months Ended December 31,		
	2014	2013	2012
Shares underlying “out of the money” options outstanding	2,086,450	1,070,720	562,025
Shares underlying “in the money” options outstanding	—	998,000	—
Shares underlying “out of the money” warrants outstanding	4,831,352	4,831,352	4,845,352
Shares underlying “in the money” warrants outstanding	—	—	1,320

Fair Value of Financial Instruments

The carrying values of certain of the Company’s financial instruments, including cash equivalents and accounts payable approximates fair value due to their short maturities. Warrant liability is also recorded at fair value. The fair values of the Company’s long term obligations are based on assumptions concerning the amount and timing of estimated future cash flows and assumed discount rates reflecting varying degrees of risk. The carrying values of the Company’s long term obligations approximate their fair values.

Recently Issued Accounting Pronouncements

In January 2015, the FASB issued ASU No. 2015-01, "Income Statement - Extraordinary and Unusual Items (Subtopic 225-20): Simplifying Income Statement Presentation by Eliminating the Concept of Extraordinary Items", which eliminates from U.S. GAAP the concept of extraordinary items. The pronouncement is effective for annual reporting periods ending after December 15, 2015 with early adoption permitted. The adoption of this guidance is not expected to have a material impact on the Company’s financial statements.

In August 2014, the FASB issued ASU No. 2014-15, "Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern", which defines management’s responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provided related footnote disclosures. The pronouncement is effective for annual reporting periods ending after December 15, 2016 with early adoption permitted. The adoption of this guidance will require the Company to disclose its evaluation of its ability to continue as a going concern in the footnotes to the financial statements.

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09, “Revenue from Contracts with Customers (Topic 606)” which supersedes the current revenue recognition requirements under ASC Topic 605, “Revenue Recognition”. The standard’s core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. It also provides a five step approach to achieve this principle. For public entities, the new guidance is effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Early application is not permitted. Based on current operating conditions, the adoption of this guidance does not have a material impact on the Company’s financial statements; however, it may have a material impact in the future.

Note 4. Inventory

Inventories consisted of the following as of:

($ in thousands)	December 31, 2014	December 31, 2013
Raw materials	$357	$511
Work-in-process	214	86
Inventory	$571	$597

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Note 5. Property and Equipment

Property and equipment consisted of the following as of:

($ in thousands)	December 31, 2014	December 31, 2013
Laboratory equipment	$1,279	$1,045
Computer equipment and software	206	179
Furniture and fixtures	49	15
Leasehold improvements	772	448
Construction-in-process	343	749
	2,649	2,436
Less: Accumulated depreciation	(1,051)	(735)
Property and equipment, net	$1,598	$1,701

Depreciation expense was approximately $0.3 million, $0.3 million and $0.3 million for the years ended December 31, 2014, 2013 and 2012, respectively.

Note 6. Accrued Expenses

Accrued expenses consisted of the following as of:

($ in thousands)	December 31, 2014	December 31, 2013
Accrued professional fees	$881	$194
Accrued compensation	540	40
Accrued other	254	253
Accrued expenses	$1,675	$487

Note 7. Warrants

The Company accounts for stock warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreement. Stock warrants are accounted for as a derivative in accordance with Accounting Standards Codification 815, Derivatives and Hedging ("ASC 815") if the stock warrants contain "down-round protection" or other terms that could potentially require "net cash settlement" and therefore, do not meet the scope exception for treatment as a derivative. Since "down-round protection" is not an input into the calculation of the fair value of the warrants, the warrants cannot be considered indexed to the Company's own stock which is a requirement for the scope exception as outlined under ASC 815. Warrant instruments that could potentially require "net cash settlement" in the absence of express language precluding such settlement and those which include "down-round provisions" are initially classified as derivative liabilities at their estimated fair values, regardless of the likelihood that such instruments will ever be settled in cash. The Company will continue to classify the fair value of the warrants that contain "down-round protection" and "net cash settlement" as a liability until the warrants are exercised, expire or are amended in a way that would no longer require these warrants to be classified as a liability.

The following table summarizes outstanding liability classified warrants to purchase common stock as of:

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	Number of Warrants			
	December 31, 2014	December 31, 2013	Exercise Price	Expiration Dates
Issued in Series A, B and D Preferred Stock offering	2,247,118	2,247,118	$6.25	Oct 2015 - Dec 2016
Issued in March 2010 financing	393,416	393,416	$6.25	Mar 1, 2016
Issued in June 2011 financing	6,113	6,113	$22.50	Jun 1, 2016
Issued in August 2011 financing	565,759	565,759	$18.75	Aug 1, 2016
Issued to placement agents in August 2011 financing	50,123	50,123	$13.635	Aug 1, 2016
Issued in Series B, D and E Preferred Stock offerings	76,120	76,120	$2.50	Nov 2015 - Dec 2017
Issued with Convertible Notes	1,125,578	1,125,578	$2.50	Jun 1, 2018
Issued in Series E Preferred Stock offering	1,568,823	1,568,823	$7.50	Dec 1, 2018
Total	6,033,050	6,033,050		

There were no exercises of warrants during the year ended December 31, 2014. There were 85,000 warrants exercised on a cashless basis resulting in the issuance of 46,837 shares of common stock for the year ended December 31, 2013.

Liability-classified Warrants

The foregoing warrants are recorded as liabilities at their estimated fair value at the date of issuance, with the subsequent changes in estimated fair value recorded in other income (expense) in the Company's statement of operations in each subsequent period. The change in the estimated fair value of our warrant liability for the years ended December 31, 2014, 2013 and 2012 resulted in non-cash income of $3.9 million, non-cash expense of $1.1 million, and non-cash income of $20.4 million, respectively. The Company utilizes the Monte Carlo simulation valuation method to value the liability classified warrants.

The estimated fair value of these warrants is determined using Level 3 inputs. Inherent in the Monte Carlo 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 following table summarizes the calculated aggregate fair values, along with the assumptions utilized in each calculation:

($ in thousands, except per share data)	December 31, 2014	December 31, 2013	December 31, 2012
Calculated aggregate value	11,281	15,216	14,515
Weighted average exercise price per share of warrant	7.08	7.08	7.04
Closing price per share of common stock	$2.59	$4.06	$3.75
Volatility	68 %	70 %	65 %
Weighted average remaining expected life (years)	2 years, 7 months	3 years, 6 months	4 years, 6 months
Risk-free interest rate	0.86 %	1.20 %	0.60 %
Dividend yield	— %	— %	— %

Note 8. Debt

Convertible Note Payable

On June 1, 2012, the Company entered into an exchange agreement with existing note holders pursuant to which the Company agreed to repay half of each holder's 12.5% promissory notes due June 1, 2012 (the "Notes" and exchange the balance of each holder's original note, for (i) a new 12.5% note (the "Convertible Notes") with a principal amount equal to such balance, and (ii) a five-year warrant ("Warrant") to purchase a number of shares of common stock equal to

the number of shares of common stock underlying such note on the date of issuance. Details of Notes are as follows:

- The Notes accrued interest at a rate of 12.5% per annum payable quarterly in cash or, at the Company's option, 15% per annum payable in kind by capitalizing such unpaid amount and adding it to the principal as of the date it was due.

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- The maturity date of the Notes was September 1, 2013, provided that the Holders may require the Company to redeem 25% of the principal amount of the Notes on each of December 1, 2012, March 1, 2013, June 1, 2012 and September 1, 2013.
- To the extent that Holders of the Notes converted any portion of the Notes prior to any such redemption date, the amount of all future redemption payments will be reduced by such converted amount on a pro rata basis over the remaining redemption dates.
- The Notes were convertible at a conversion price of $6.25 per share, provided that, with certain exceptions, if, at any time while the Notes are outstanding, the Company issues any Company common stock or common stock equivalents at an effective price per share that is lower than the then the conversion price of the Notes, then the conversion price of the Notes will be reduced to equal the lower price.
- The Notes may be accelerated if any events of default occur, which include, in addition to certain customary default provisions, if at any time on or after October 1, 2012 the Company fails to have reserved, for conversion of the Notes and exercise of the Warrants, a sufficient number of available authorized but unissued shares of common stock.

The Notes were converted at a conversion price of $6.25 per share. To the extent that holders of the Notes converted any portion of the Notes prior to any such redemption date, the amount of all future redemption payments was reduced by such converted amount on a pro rata basis over the remaining redemption dates. The Notes were extinguished in October 2012 through partial conversions into common stock and partial repayments in cash.

Loss on Extinguishment of Debt

As a result of the June 1, 2012 debt exchange as discussed above, the Company recorded a loss on extinguishment of the 12.5% promissory note of $5.6 million in the consolidated statement of operations for the year ended December 31, 2012 due to the significant modification of the original debt. The details of the loss included recording the fair value of the embedded conversion option of $1.2 million and the fair value of liability-classified warrants of $4.4 million. See Note 7 for further discussion of the warrant liability.

Note 9. Equity

Common stock

In October of 2012, the Company closed a private placement transaction (the “Offering”) with certain accredited investors pursuant to which the Company sold securities consisting of 18,000,000 shares of common stock at a purchase price of $2.50 per share. An additional 203,000 shares were given to placement agents in connection with the Offering. The Company received net proceeds of $40.2 million, incurred $2.7 million in offering costs and had a subscription receivable of $2.0 million which was subsequently collected in July of 2013.

In connection with the execution of the exclusive channel collaboration (the “Channel Agreement”) on October 5, 2012, the Company entered into a Stock Issuance Agreement with Intrexon Corporation ("Intrexon"), who is an affiliate of NRM VII Holdings I, LLC, the Company’s largest shareholder. The Company agreed to issue to Intrexon a number of shares of Company common stock based on a per share value of the price at which the Company sold shares of common stock in the Offering (the “Technology Access Shares”). The closing took place on October 9, 2012. The Company recorded a fair value of $6.9 million for 1,317,520 shares, on a per share value of $5.25 based on the closing price of the Company’s common stock on the closing date, issued to Intrexon for the closing of the Stock Issuance Agreement as a research and development expense in the fourth quarter of 2012. In connection with the issuance of the Technology Access Shares, Intrexon became a party to a Registration Rights Agreement, which provides Intrexon with a demand registration right with respect to the resale of the Technology Access Shares. See Note 13 for further discussion on the collaboration with Intrexon.

On October 5, 2012, the Company entered into an amendment and conversion agreement (the “Debt Agreement”) with the holders of its 12.5% Convertible Notes in the aggregate original principal amount of approximately $3.5 million. Pursuant to the Debt Agreement, the Company and the Note holders agreed that the Company would repay approximately $1.7 million of the Notes in cash (representing approximately $1.5 million in principal and $0.2 million in unpaid interest), and the remaining Notes (representing approximately $2.1 million in principal and $0.3 million in unpaid interest) would be converted into shares of common stock at a conversion price of $2.50 per share. The total number of shares of common stock issued upon the conversion of the Notes was 861,970 shares. There were conversions of notes into 36,671 common shares before the Offering.

Effective upon the completion of the Offering, the Company entered into warrant modification agreements with the holders of warrants to purchase 4,209,357 shares of common stock at exercise prices of between $6.25 per share and $7.50 per share pursuant to which the parties agreed, among other items: (a) to extend the expiration date of the warrants by one year; and (b) to delete the full-ratchet anti-dilution adjustment provisions contained in the warrants (including with respect to the Offering

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discussed above). As such, the exercise price and number of shares underlying the foregoing warrants were not modified due to the completion of the Offering.

In connection with the execution of the first amendment to the exclusive channel collaboration agreement (the "Amendment") on June 28, 2013, the Company entered into a Supplemental Stock Issuance Agreement with Intrexon. The Company agreed to issue to Intrexon a number of shares of Company common stock based on a per share value of the closing price of the Company's common stock on the NYSE MKT on the day prior to execution of the Supplemental Stock Issuance Agreement (the "Supplemental Access Fee Shares"). The Supplemental Access Fee Shares were issued upon the satisfaction of customary closing conditions, including the approval for the listing of the Supplemental Access Fee Shares on the NYSE MKT. The closing took place on July 26, 2013. The Company recorded a fair value of $6.4 million for 1,243,781 shares, on a per share value of $5.15 based on the closing price of the Company's common stock on the closing date, issued to Intrexon for the closing of the Supplemental Stock Issuance Agreement as a research and development expense in the third quarter of 2013. See Note 13 for further discussion on the collaboration with Intrexon.

In October of 2013, the Company completed an underwritten public offering of 11,000,000 shares of common stock at a public offering price of $4.10 per share. The net proceeds to the Company, after underwriting discounts and commissions and estimated offering expenses, were approximately $42.1 million. The underwriters for the public offering of common stock partially exercised their over-allotment option to purchase an additional 1,311,698 shares of common stock at a public offering price of $4.10 per share. The partial exercise of the over-allotment option increased the aggregate net proceeds to the company, after underwriting discounts and commissions and estimated offering expenses, from approximately $42.1 million to approximately $47.1 million.

In connection with the execution of the second amendment to the exclusive channel collaboration agreement (the "Second Amendment") on January 10, 2014 between the Company and Intrexon, the Company entered into a Supplemental Stock Issuance Agreement with Intrexon. The Company agreed to issue to Intrexon a number of shares of Company common stock based on a per share value of the closing price of the Company's common stock on the NYSE MKT on the day prior to execution of the Supplemental Stock Issuance Agreement (the "Supplemental Access Fee Shares"). The Supplemental Access Fee Shares were issued upon the satisfaction of customary closing conditions, including the approval for the listing of the Supplemental Access Fee Shares on the NYSE MKT. The closing took place on January 24, 2014. The Company recorded a research and development expense in the first quarter of 2014 for the 1,024,590 shares issued to Intrexon as a technology access fee. The shares were issued based on a per share value of $5.03 based on the closing price of the Company's common stock on the closing date, totaling approximately $5.2 million, which was recorded as Research and development expenses. For additional discussion on the Company's collaboration with Intrexon, see Note 13.

Preferred Stock

The Company is authorized to issue 5,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges, and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. The issuance of the Company's preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change of control of the Company or other corporate action. There were no preferred shares issued or outstanding as of December 31, 2014 or December 31, 2013.

Redeemable Preferred stock

On October 5, 2012, upon the approval of the requisite number of holders of the Company's Series D 6% Cumulative Perpetual Convertible Preferred Stock (the "Series D Preferred Stock") and Series E 8% Cumulative Convertible Preferred Stock (the "Series E Preferred Stock"), the Company filed amendments, effective on such date, to each of the Certificates of Designation for the Preferred Stock providing that if the Company completed an equity financing pursuant to which the Company received gross proceeds of no less than $35.0 million (a "Qualified Financing"), then immediately prior to the closing of such Qualified Financing each outstanding share of preferred stock shall be

automatically converted into that number of shares of common stock determined by dividing the stated value of such share of Series D and Series E preferred stock by $6.25. The Offering discussed above was a Qualified Financing, and as such, the Series D and E preferred stock was automatically converted into 1,917,120 shares of common stock upon completion of the Offering, 454,560 of which were Series D and 1,462,560 of which were Series E. There were 104,000 common shares issued as a result of conversion of Series D preferred shares during 2012 before the automatic conversion of the preferred shares pursuant to the Offering. As of the closing of the Offering, the Company had no shares of preferred stock outstanding

The following table shows the activity of Series D and Series E Redeemable Preferred stock, with a par value of $0.001 per share and a stated value of $25,000 per share:

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	Series D Preferred	Series E Preferred	Total
Balance at December 31, 2011	3,641	—	3,641
Issuance of Series E Preferred stock	—	9,141	9,141
Series D and Series E Preferred converted to common stock	(3,641)	(9,141)	(12,782)
Balance at December 31, 2012	—	—	—

During May, June and July 2012 the Company sold to accredited investors in a private placement Series E Convertible Preferred Stock as follows:

Date of financing	# of shares of Series E Preferred	Net Proceeds ($ in 000's)	Warrant Exercise Price	# of Warrants Issued
May 14, 2012	3,353	$2,843	$7.50	590,128
May 24, 2012	2,364	2,042	7.50	416,064
June 2, 2012	945	822	7.50	166,320
June 7, 2012	1,192	1,037	7.50	209,792
June 28, 2012	507	441	7.50	89,232
July 16, 2012	780	679	7.50	137,280
	9,141	$7,864		1,608,816

As a result of the May, June and July 2012 private placement Series E Convertible Preferred Stock transaction, the net proceeds of $7.8 million were allocated to the fair value of the warrants upon issuance. The July 16, 2012 sale represented the final closing of the Offering and effective on such date, the Company closed the Offering.

Conversion option of Convertible Note Payable

In connection with the issuance of the June 1, 2012 Convertible Notes, an embedded conversion option was recorded as a derivative liability under ASC 815, Derivatives and Hedging, in the 2012 consolidated balance sheet until October 2012 when the notes were converted to common stock. The derivative liability was re-measured on the Company's reporting dates until October 9, 2012 when the Notes were converted into common stock resulting in revaluation expense of less than $0.1 million for the year ended December 31, 2012 in our statement of operations. The fair value of the derivative liability was determined using the Black-Scholes option-pricing model and is affected by changes in inputs to that model including our stock price, expected stock price volatility, the contractual term, and the risk-free interest rate. The Convertible Notes were reclassified to equity which amounted to $2.4 million.

Conversion option of Redeemable Preferred stock

The embedded conversion option for the Series D Preferred was recorded as a derivative liability under ASC 815 in the consolidated balance sheet until its conversion to common stock in 2012. The fair value of the derivative liability was determined using the Black-Scholes option-pricing model and is affected by changes in inputs to that model including the Company's stock price, expected stock price volatility, the contractual term, and the risk-free interest rate. The derivative liability was re-measured resulting in income of $0.1 million for the year ended December 31, 2012 in the Company's Consolidated Statement of Operations until the preferred stock was converted on October 9, 2012 into common stock and $1.4 million was recorded in equity.

Note 10. Fair Value Measurements

The Company adopted the accounting guidance on fair value measurements for financial assets and liabilities measured on a recurring basis. The guidance requires fair value measurements be 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;
- 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).

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The following fair value hierarchy table presents information about each major category of the Company's financial assets and liability measured at fair value on a recurring basis as of December 31, 2014 and 2013:

	Fair value measurement using			
($ in thousands)	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Balance at December 31, 2014				
Assets:				
Cash and cash equivalents	$37,495	$ —	$—	$37,495
Liabilities:				
Warrant liability	$—	$ —	$11,286	$11,286

	Fair value measurement using			
($ in thousands)	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Balance at December 31, 2013				
Assets:				
Cash and cash equivalents	$60,033	$ —	$—	$60,033
Liabilities:				
Warrant liability	$—	$ —	$15,216	$15,216

The reconciliation of warrant liability measured at fair value on a recurring basis using unobservable inputs (Level 3) is as follows:

($ in thousands)	Warrant Liability
Balance at December 31, 2011	$23,754
Issuance of additional warrants	6,766
Exercise of warrants	(11)
Extinguishment of debt related to warrants	4,410
Change in fair value of warrant liability	(20,404)
Balance at December 31, 2012	$14,515
Exercise of warrants	(352)
Cancellation of warrants	(41)
Change in fair value of warrant liability	1,094
Balance at December 31, 2013	$15,216
Exercise of warrants	—
Cancellation of warrants	—
Change in fair value of warrant liability	(3,930)
Balance at December 31, 2014	$11,286

The fair value of the warrant liability is based on Level 3 inputs. For this liability, the Company developed its own assumptions that do not have observable inputs or available market data to support the fair value. See Note 7 for further discussion of the warrant liability.

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The reconciliation of derivative liability measured at fair value on a recurring basis using unobservable inputs (Level 3) is as follows:

	Derivative Liability
Balance at January 1, 2012	534
Issuance of additional preferred stock and other	793
Conversion of preferred stock	(1,350)
Change in fair value of derivative liability	23
Balance at December 31, 2012	—

The fair value of the derivative liability is based on Level 3 inputs. For this liability, the Company developed its own assumptions that do not have observable inputs or available market data to support the fair value.

Note 11. Share-Based Compensation

Our board of directors (the "Board") adopted the 2009 Equity Incentive Plan (as amended to date, the "Plan") effective September 3, 2009. The Plan is intended to further align the interests of the Company and its stockholders with its employees, including its officers, non-employee directors, consultants and advisors by providing incentives for such persons to exert maximum efforts for the success of the Company. The Plan allows for the issuance of up to 5,600,000 shares of the Company's common stock. In addition, there were 206,000 options issued outside of the Plan to consultants.

The types of awards that may be granted under the Plan include options (both nonqualified stock options and incentive stock options), stock appreciation rights, stock awards, stock units, and other share-based awards. The term of each award is determined by the Board at the time each award is granted, provided that the terms of options may not exceed ten years. Vesting schedules for the stock options vary, but generally vest 25% per year, over four years . The Plan had 3,530,553 options available for grant as of December 31, 2014.

Total stock-based compensation expense recognized using the straight-line attribution method in the consolidated statement of operations for the years ended December 31 is as follows:

($ in thousands)	2014	2013	2012
Stock option compensation expense for employees and directors	$1,236	$1,045	$1,200
Equity awards for nonemployees issued for services	3	105	24
Total stock-based compensation expense	$1,239	$1,150	$1,224

During the years ended December 31, 2014, 2013 and 2012, the weighted average fair market value using the Black-Scholes option-pricing model of the options granted was $2.64, $2.79 and $5.00, respectively.

The fair market value of the stock options at the date of grant was estimated using the Black-Scholes option-pricing model with the following weighted average assumptions for the years ended December 31:

	2014	2013	2012
Expected life	5 years, 11 months	5 years, 7 months	5 years, 8 months
Interest rate	1.9%	1.6%	1.6%
Dividend yield	—	—	—
Volatility	70%	71%	64%

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	Number of shares	Weighted-average exercise price	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2011	544,340	$19.25	7 years, 6 months	$—
Granted	38,000	$8.02		
Forfeited	(20,315)	$15.48		
Outstanding at December 31, 2012	562,025	$18.56	7 years	$—
Granted	1,532,000	$4.15		
Forfeited	(25,305)	$14.71		
Outstanding at December 31, 2013	2,068,720	$7.93	8 years, 5 months	$544
Granted	348,000	$4.19		
Expired	(51,637)	$21.61		
Forfeited	(278,633)	$4.45		
Outstanding at December 31, 2014	2,086,450	$7.43	7 years, 2 months	$—
Exercisable at December 31, 2014	1,100,250	$10.63	7 years, 2 months	$—

The total fair value of shares vested during the years ended December 31, 2014, 2013 and 2012 was $1.2 million, $1.2 million, and $1.3 million, respectively. There were no exercises of vested stock options during the years ended 2014, 2013 and 2012. As of December 31, 2014, there was $2.1 million of total unrecognized compensation cost, related to nonvested stock options which vest over time. That cost is expected to be recognized over a weighted-average period of 3.8 years. As of December 31, 2014, there were 986,200 nonvested stock options, with a weighted average exercise price of $3.86 and an average intrinsic value of $0. As of December 31, 2014, there was no unrecognized compensation cost related to performance-based nonvested consultant options.

Note 12. Income Taxes

Fibrocell Science, Inc. and Fibrocell Technologies, Inc. file a consolidated U.S. Federal income tax return, and file U.S. state income tax returns in several jurisdictions as well. In general, the U.S. federal and state income tax returns remain open to examination by taxing authorities for tax years beginning in 2011 to present. However, if and when the Company claims net operating loss (“NOL”) carryforwards from years prior to 2011 against future taxable income, those losses may be examined by the taxing authorities as well. The Company's foreign subsidiaries file income tax returns in their respective jurisdictions.

The components of the income tax expense/(benefit) related to continuing operations, are as follows:

($ in thousands)	Year ended December 31, 2014	Year ended December 31, 2013	Year ended December 31, 2012
U.S. Federal:			
Current	$—	$—	$—
Deferred	—	—	(2,068)
U.S. State:			
Current	—	—	—
Deferred	—	—	(432)
	$—	$—	$(2,500)

The reconciliation between income taxes/(benefit) at the U.S. federal statutory rate and the amount recorded in the accompanying consolidated financial statements is as follows:

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($ in thousands)	Year ended December 31, 2014	Year ended December 31, 2013	Year ended December 31, 2012
Tax benefit at U.S. federal statutory rate	$(8,977)	$(11,044)	$(5,475)
Increase in domestic valuation allowance	11,109	11,626	11,127
State income taxes/(benefit) before valuation allowance, net of federal benefit	(846)	(1,026)	(1,971)
Capital loss limitation	—	—	(817)
Loss on extinguishment of debt	—	—	1,966
Derivative revaluation expense	—	—	8
Warrant revaluation and other finance (income)/expense	(1,375)	369	(7,141)
Other	89	75	(197)
	$—	$—	$(2,500)

The components of the Company's net deferred tax assets and liabilities at December 31, 2014, 2013 and 2012 are as follows:

($ in thousands)	December 31, 2014	December 31, 2013	December 31, 2012
Deferred tax liabilities:			
Intangible assets	$2,001	$2,247	$2,282
Total deferred tax liabilities	$2,001	$2,247	$2,282
Deferred tax assets:			
Loss carryforwards	$63,560	$54,253	$49,598
Capital loss carryforward	841	844	817
Property and equipment	1,135	1,149	1,327
License fees	7,055	5,393	—
Accrued expenses and other	602	412	360
Stock compensation	2,953	2,698	2,492
Total deferred tax assets	76,146	64,749	54,594
Less: valuation allowance	(74,145)	(62,502)	(52,312)
Total deferred tax assets	$2,001	$2,247	$2,282
Net deferred tax assets	$—	$—	$—

As of December 31, 2014, the Company had generated U.S. net operating loss carryforwards of approximately $167.5 million which expire from 2018 to 2034. The NOL carryforwards are available to reduce future taxable income. However, the NOL carryforwards become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, as well as similar state tax provisions. This could limit the amount of NOLs that we can utilize annually to offset future taxable income or tax liabilities. The amount of the annual limitation, if any, will be determined based on the value of our company immediately prior to an ownership change. Subsequent ownership changes may further affect the limitation in future years. Additionally, U.S. tax laws limit the time during which these carryforwards may be applied against future taxes, therefore, we may not be able to take full advantage of these carryforwards for federal income tax purposes. In addition, the Company has NOL carryforwards in certain non-US jurisdictions of approximately $25.5 million. However, it is not expected that these non-U.S. loss carryforwards will ever be utilized, so they are not included in the components of deferred taxes listed above. The Company does not plan to have material operations in the non-U.S. jurisdictions in the foreseeable future, and does not know when or if income will ever be generated in these foreign jurisdictions. Finally, there are no unremitted earnings in foreign jurisdictions, so no provision for taxes thereupon is required.

As the Company has had cumulative losses and there is no assurance of future taxable income, valuation allowances have been recorded to fully offset the deferred tax asset at December 31, 2014, 2013, and 2012. The valuation allowance increased by $11.6 million, $10.2 million, and $11.1 million during 2014, 2013, and 2012, respectively,

primarily due to the impact from the current year net losses incurred.

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Note 13. Collaboration with Related Party

Intrexon is an affiliate of our largest shareholder, NRM VII Holdings I, LLC. In addition, two of our seven directors are also affiliates of NRM VII Holdings I, LLC.

On October 5, 2012, the Company entered into a Channel Agreement with Intrexon that governs a "channel collaboration" arrangement. The Channel Agreement grants the Company an exclusive license to use proprietary technologies and other intellectual property of Intrexon to develop and commercialize certain products in the United States. Through the original collaboration with Intrexon, the Company is exploring the use of gene therapy applied to fibroblast cells to treat patients with collagen deficient diseases. The Company is working to apply gene therapy to fibroblasts with the gene to produce collagen VII to treat patients with recessive dystrophic epidermolysis bullosa ("RDEB"). This development concept utilizes applying gene therapy to fibroblasts to up-regulate and produce collagen VII in a controlled manner for localized or systematic treatment of RDEB.

In connection with the execution of the Channel Agreement on October 5, 2012, the Company entered into a Stock Issuance Agreement with Intrexon. In connection with the stock issuance, Intrexon became a party to the Registration Rights Agreement, which provides Intrexon with a demand registration right with respect to the resale of the Technology Access Shares. For additional details see Note 9.

On June 28, 2013, the Company and Intrexon entered into a First Amendment to the parties' Channel Agreement. The Amendment broadens the existing collaboration to include potential treatments based on engineered autologous fibroblast cells for the localized treatment of autoimmune and inflammatory disorders including morphea profunda / linear scleroderma, cutaneous eosinophilias and moderate to severe psoriasis. In connection with the execution of the First amendment to the Channel Agreement on June 28, 2013, the Company entered into a Supplemental Stock Issuance Agreement with Intrexon. For additional details see Note 9.

On January 10, 2014, the Company and Intrexon entered into a Second Amendment to the parties' Exclusive Channel Collaboration Agreement dated October 5, 2012, as previously amended on September 28, 2013 (the "Channel Agreement" and such previous amendment, the "First Amendment"). The Channel Agreement provides for a "channel collaboration" arrangement governing a strategic collaboration for the development and commercialization of autologous fibroblasts and autologous dermal cells, with and without gene therapy, in the United States. The Channel Agreement originally granted the Company an exclusive license to use proprietary technologies and other intellectual property of Intrexon to research, develop, use, import, export, make, have made, sell, and offer for sale certain products in the field in the United States.

Pursuant to the Channel Agreement and Amendments, the Company engaged Intrexon for support services for the development of new products covered under the Channel Agreement and Amendment, and will reimburse Intrexon for its fully-loaded cost for time and materials for transgenes, cell processing, or other work performed by Intrexon for such research and manufacturing. For the years ended December 31, 2014, 2013 and 2012, the Company incurred expenses of $4.2 million, $3.7 million and $0.1 million, respectively, for work performed. As of December 31, 2014 and 2013, the Company had outstanding trade payables with Intrexon of $1.0 million and $1.3 million, respectively.

The Company will pay quarterly cash royalties on improved products equal to one-third of cost of goods sold savings less any such savings developed by the Company outside of the Channel Agreement or Amendment. On all other developed products, the Company will pay Intrexon quarterly cash royalties of 7% on aggregate annualized net sales up to $100 million, and 14% on aggregate annualized net sales greater than $100 million. Sales from the Company's products (including new indications) marketed at the time of the Channel Agreement are not subject to royalty payments unless they are improved upon through the Channel Agreement.

Note 14. Commitments and Contingencies

Leases

On April 6, 2005, the Company entered into a non-cancellable operating lease (the "Lease") for its office, warehouse and laboratory facilities in Exton, Pennsylvania. The lease agreement had a term of 8 years. On February 17, 2012, the Company entered into an amended and restated lease (the "Amended Lease") for an additional term of 10 years through the year 2023. The Lease and the Amended Lease provide for rent payments escalating on an annual basis. In accordance with ASC 840-20 Operating Leases, the Company calculated the total minimum payments under the lease and divided them equally over the life of the lease to account for the lease on a straight-line basis. The Company

has the option to renew the lease for an additional 5 years at fair market value. Rental expense totaled $1.6 million, $1.5 million and $1.4 million for the years ended December 31, 2014, 2013 and 2012, respectively.

License Agreements

On May 3, 2012, the Company entered into an exclusive license agreement with The Regents of the University of California, under which the Company acquired the rights to commercially apply discoveries resulting from the scientific

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collaboration between the University of California, Los Angeles ("UCLA") and the Company. Under the terms of the license agreement, the Company agreed to pay UCLA a non-refundable initial license fee and to pay UCLA an annual license maintenance fee of a percentage of product royalties, and milestone payments based on the Company's achievement of certain clinical and regulatory related milestones for these rights. The Company's ability to meet the milestones is dependent on a number of factors including final approvals by regulatory agencies and the continued enforceability of patent claims.

On June 13, 2014 the Company entered into two exclusive license agreements with The Regents of the University of California. Pursuant to the first exclusive license agreement (the "BMP2 Agreement"), UCLA granted to the Company an exclusive, sublicensable right and license to use certain patent rights developed in collaboration between UCLA and the Company relating to the use of human skin cells to produce Bone Morphogenetic Protein (BMP2) for use in osteogenic therapies. In consideration of the license granted under the BMP2 Agreement, the Company will pay UCLA a license issue fee, certain one-time milestone payments, a license maintenance fee, earned royalties on net sales of all licensed products (including sales by sublicensees and affiliates) and a percentage of amounts received from sublicensing activities. The Company is subject to minimum annual royalty payments to UCLA beginning after first commercial sale of a licensed product.

Under the terms of the second of the exclusive license agreements (the "Genomic Stability Agreement"), UCLA granted to the Company an exclusive, sublicensable right and license to use certain patent rights developed in collaboration between UCLA and the Company relating to media that promotes genomic stability in induced pluripotent stem cell cultures for all research and commercialization purposes. In consideration of the license granted under the Genomic Stability Agreement, the Company will pay to UCLA a license issue fee, certain one-time milestone payments, a license maintenance fee, earned royalties on net sales of all licensed products (including sales by affiliates) and a percentage of amounts received from sublicensing activities. The Company is subject to minimum annual royalty payments to UCLA beginning after first commercial sale of a licensed product.

On May 3, 2012, the Company also entered into a sponsored research agreement with the Massachusetts Institute of Technology ("MIT"). Research is currently focused on mesenchymal stem cells derived from adult human skin. The agreement is currently scheduled to terminate in June 2015.

The amounts in the table below assume the foregoing agreements are continued through their respective terms. The agreements may be terminated at the option of either party. In such event, the Company's obligation would be limited to costs through the date of such termination.

Contractual Obligations

The following table summarizes the Company's contractual obligations as of December 31, 2014:

	Payments due by period				
($ in thousands)	Total	2015	2016 and 2017	2018 and 2019	2020 and thereafter
License fee obligations(1)	$950	$483	$308	$106	$ 53
Operating lease obligations(2)	$11,168	$1,211	$2,508	$2,670	$ 4,779
Total	$12,118	$1,694	$2,816	$2,776	$ 4,832

(1)Obligations for license agreement with the University of California, Los Angeles (UCLA) and sponsored research agreement with the Massachusetts Institute of Technology (MIT). The amounts in the table assume the foregoing agreements are continued through their respective terms. The agreements may be terminated at the option of either party. In such event, the Company's obligation would be limited to costs through the date of such termination.

(2)Operating lease obligations are stated based on the Amended Lease agreement for the office, warehouse and laboratory facilities executed in February 2012.

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Note 15. Supplemental Cash Flow Information

The following table contains additional cash flow information for the years ended:

($ in thousands)	December 31, 2014	December 31, 2013	December 31, 2012
Supplemental disclosures of cash flow information:			
Cash paid for interest	$—	$—	$1,885
Cash paid for income taxes	$—	$—	$—
Non-cash investing and financing activities:			
Subscription receivable	$—	$—	$2,004
Conversion of note payable	$—	$—	$2,385
Issuance of additional warrants	$—	$—	$11,077
Conversion of preferred stock derivative balance into common stock	$—	$—	$1,350
Cashless exercise of warrants previously recorded as a liability	$—	$298	$17
Warrant liability reclassified to equity	$—	$—	$15,048
Accrued derivative liability	$—	$—	$793

Note 16. Discontinued Operations

On August 31, 2012, the Company sold all of the shares of common stock of Agera held by the Company, which represented 57% of the outstanding common stock of Agera, to Rohto Pharmaceutical Co., Ltd. for approximately $1.0 million. Accordingly, all operating results from continuing operations exclude the results for Agera which are presented as discontinued operations. The Company recorded a gain for the year ended December 31, 2012 of approximately $0.5 million on the sale.

The financial results of Agera are classified as discontinued operations in the accompanying Consolidated Statement of
Operations for the year ended December 31, 2012.

Summary financial information related to discontinued operations is as follows:

($ in thousands)	Year ended, December 31, 2012
Product sales	$516
Cost of sales	275
Gross profit	241
Operating income (loss)	$27
Net loss	$(2)

In addition, there were other minimal losses from foreign subsidiaries which were classified as discontinued operations
for the year ended December 31, 2012.

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Note 17. Quarterly Financial Information (unaudited)

This table summarizes the unaudited consolidated financial results of operations for the quarters ended (amounts in thousands except per share data):

	March 31,	June 30,	September 30,	December 31,
2014 Quarter Ended				
Net product sales	$46	$58	$20	$56
Cost of sales	793	547	512	460
Gross loss	(747)	(489)	(492)	(404)
Operating expenses	10,253	6,107	5,699	5,763
Other income (expense)	(3,009)	4,339	179	2,795
Net loss	$(14,009)	$(2,257)	$(6,012)	$(3,372)
Basic net loss per share	$(0.35)	$(0.06)	$(0.15)	$(0.08)
Diluted net loss per share	$(0.35)	$(0.09)	$(0.17)	$(0.09)
2013 Quarter Ended				
Net product sales	$26	$62	$68	$44
Cost of sales	2,213	2,104	1,792	1,392
Gross loss	(2,187)	(2,042)	(1,724)	(1,348)
Operating expenses	3,721	3,777	11,401	4,303
Other income (expense)	1,338	(8,818)	6,520	(91)
Net loss	$(4,570)	$(14,637)	$(6,605)	$(5,742)
Basic net loss per share	$(0.17)	$(0.63)	$(0.24)	$(0.15)
Diluted net loss per share	$(0.18)	$(0.63)	$(0.31)	$(0.15)

EXHIBIT INDEX

EXHIBIT NO.	IDENTIFICATION OF EXHIBIT
*10.22	Amendment to Stock Option Agreement by and between the Company and David Pernock dated March 11, 2015
*23.1	Consent of BDO USA, LLP
*31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002
*31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002
*32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
*32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

* Filed herewith.