Fibrocell Science, Inc.
Form 10-K
March 17, 2014

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

FORM 10-K

x **Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the fiscal year ended December 31, 2013

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
(Issuer'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	NYSE MKT

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 ¨ No x

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

Indicate by check mark whether the registrant: (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for any shorter period that the registrant was required to file such

reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

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

Indicate by check mark if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-K contained in this form, and no disclosure will be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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 ¨	Accelerated filer x	Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

The approximate aggregate market value of common stock held by non-affiliates of the registrant was $87.2 million as of June 30, 2013, 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, 2013.

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Section 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes x No ¨

As of March 7, 2014, registrant had 40,837,615 shares issued and outstanding of common stock, par value $0.001.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the 2013 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed within 120 days of the end of the fiscal year ended December 31, 2013, are incorporated by reference in Part III hereof. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part hereof.

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PART IV

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, and Section 21E of the Securities Exchange Act of 1934, as amended, as well as information relating to Fibrocell Science, Inc. and its subsidiaries (referred to as "Fibrocell," "Company," "we," 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 intend 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:

- whether our clinical human trials relating to the use of autologous cell therapy applications, in particular, for restrictive burn scars, vocal cord scars and genetically-modified orphan indications, 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;

- our ability to meet requisite regulations or receive regulatory approvals in the United States, our ability to retain any regulatory approvals that we may obtain and the absence of adverse regulatory developments in the United States;

- our dependence on one 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 production at such facility;

- new entrance of competitive products or further penetration of existing products in our markets;

- the effect on us from adverse publicity related to our products or the company itself;

- any adverse claims relating to our intellectual property; 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

2013" mean the year ended December 31, 2013, and references to other "Fiscal" years mean the year ending December 31, of the year indicated.

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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 statistical data, market data and other industry data and forecasts used in this Form 10-K from publicly available information. While we believe that the statistical data, industry data, forecasts and market research are reliable, we have not independently verified the data, and we do not make any representation as to the accuracy of that information.

Part I

Item 1. Business

Overview

We are an autologous cell therapy company primarily focused on developing first-in-class treatments for skin diseases and conditions with high unmet medical needs. Based on our proprietary autologous fibroblast technology, we are pursuing breakthrough medical applications of azficel-T for restrictive burn scarring and vocal cord scarring.

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 conditions and diseases represent an ideal therapeutic focus for Fibrocell's 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, a localized approach is an optimum choice for treating these debilitating conditions in skin and connective tissue.

Driving Fibrocell's innovative therapies is its Personalized Biologics platform, which embraces two product engines: the Azficel-T Autologous Fibroblast Product Engine and the Protein Expression Product Engine. With these two product engines, Fibrocell plans to harness the favorable characteristics of fibroblasts to develop new therapies for diseases and conditions of the skin and connective tissues where there are limited or no treatment options. The Azficel-T Autologous Fibroblast Product Engine is developing biologic solutions for the treatment of serious and debilitating scarring conditions. The Protein Expression Product Engine is creating biologic products by genetically modifying fibroblasts to express target proteins that are inactive or missing from patients with rare genetic skin and tissue disorders.

Our collaboration with Intrexon Corporation (NYSE:XON), a leader in synthetic biology, includes using genetically-modified fibroblasts for treating orphan skin diseases for which there are no currently approved products and exploring the localized treatment of the most common autoimmune skin disease, moderate-to-severe psoriasis. This collaboration with Intrexon is discussed in more detail below. Additional collaborations with the University of California, Los Angeles ("UCLA") and the Massachusetts Institute of Technology ("MIT") focus on skin-derived stem cells.

We made the strategic decision in 2013 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. As a result, we have reduced sales and marketing efforts of the LAVIV® aesthetic product line. We performed a nominal amount of LAVIV® aesthetic procedures in 2013 and will continue to do so in 2014.

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Our Strategy

Fibrocell's personalized biologics approach represents a new dimension to the field of cell therapy and regenerative medicine, aimed at treating the underlying cause of disease by extracting cells from skin to create localized therapies that are compatible with the unique biology of each patient.

Currently, Fibrocell's Personalized Biologics platform embodies two separate product engines, each of which uses our proprietary fibroblast technology.

The fibroblast cells that are the foundation of our azficel-T product platforms are generated by our patented manufacturing process begin 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 FDA pharmaceutical standards (current Good Manufacturing Practices, "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 simultaneously 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, 10 million to 20 million cells arrive at the doctor's office, ready for intradermal injection of the patient.

The Azficel-T Autologous Fibroblast Product Engine utilizes autologous fibroblast cells to treat scarring conditions. Fibrocell is expanding medical applications of azficel-T to create therapeutics comprised of fibroblast cells, which can treat conditions based on the inherent characteristics of the fibroblast. Azficel-T is FDA approved through a biologic license application ("BLA"). We initially introduced azficel-T as an aesthetics product, but have shifted its focus to serious skin and connective tissue conditions. Currently, we are conducting clinical studies for azficel-T product indications for Restrictive Burn Scarring and Vocal Cord Scarring. With these conditions, the autologous fibroblast cell offers a new therapeutic approach.

Fibrocell's Azficel-T Autologous Fibroblast Product Engine offers the potential for future therapeutic applications that employ fibroblast technology to target diseases with unmet medical needs.

Fibrocell is conducting research and development with UCLA. An autologous fibroblast program for targeted protein therapeutics is a preclinical program in collaboration with UCLA for developing a fibroblast personalized biologic with bone morphogenetic protein 2 ("BMP-2") for bone repair.

In addition, UCLA has discovered a media supplement that contributes to the genomic stability of induced pluripotent stem cells ("iPSC") while growing in culture. Issues common to genomic stability with iPSC culture has prevented significant advance into clinical trials. This media supplement may allow for the advance in this technology.

Under a collaborative agreement with MIT, university researchers are developing a scalable method to cost effectively culture and grow the cell types identified by UCLA into clinically relevant quantities

Our Protein Expression Product Engine combines its autologous fibroblast technology with the synthetic biology expertise of its collaborator, Intrexon, to develop genetically-modified personalized biologics therapies for orphan skin diseases. The integration of Fibrocell's Azficel-T Autologous Fibroblast Product Engine and Intrexon's UltraVector® technology enables the development of genetically-modified personalized biologics to address the fundamental source of serious and rare skin diseases that have unmet medical needs.

The Protein Expression Product Engine brings several distinct advantages to Fibrocell's pursuit of therapies for serious and rare skin diseases.

- 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 Fibrocell a rapid method to screen and construct the best genetic therapeutic solutions for rare and serious skin diseases.

- In certain therapeutic applications with the Protein Expression Product Engine, Fibrocell 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.

Clinical and Pre-Clinical Development Programs

Our clinical development programs are focused on the medical market where there are unmet needs. These programs are supported by a number of clinical trial programs at various stages of development. Our medical development programs are designed to treat restrictive burn scars, vocal cord scarring and genetically-modified indications, for example recessive dystrophic epidermolysis bullosa. All our product candidates are non-surgical and minimally invasive.

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Our clinical and medical development programs consist of the following:

Program	Indication	Status
azficel-T sBLA	Restrictive Burn Scarring	Phase II Clinical Trial
azficel-T sBLA	Vocal Cord Scarring	Phase II Clinical Trial
Rare Disease	Recessive Dystrophic Epidermolysis Bullosa ("RDEB")	Pre-Clinical
Rare Disease	Morphea Profunda / Linear Scleroderma	Pre-Clinical
Rare Disease	Cutaneous Eosinophilias	Pre-Clinical
Rare Disease	Ehlers-Danlos Hypermobility Type (Tenascin-X Deficiency)	Pre-Clinical

Restrictive Burn Scarring 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. We have initiated a Phase II trial of azficel-T for the treatment of restrictive burn scars and have begun enrolling patients. This trial will evaluate the use of azficel-T to improve range of motion, function and flexibility, among other parameters, in existing restrictive burn scars in approximately 20 to 30 patients.

The Phase II study was based on previous safety experience with azficel-T and a number of case reports. These case reports from the United Kingdom ("UK") used azficel-T for burn scars and wounds with no adverse effects. These anecdotal cases suggest that azficel-T may provide an alternative to skin grafts which leave a significant cosmetic and sometimes functional deformity.

Vocal Cord Scarring Phase II Trial: The exact incidence of vocal cord scaring is difficult to determine. However, it can be interpreted from various studies by Cohen, 2010; Poels et al, 2003; Dailey et al, 2007; Painter, 1990 that the incidence of vocal cord scarring is in the range of 200,000 to 700,000 in the Unites States. We have initiated a Phase II clinical study on vocal cord scarring and have begun enrolling patients.

One clinical study has been conducted to evaluate the efficacy and safety of azficel-T for the treatment of vocal fold scarring in subjects who had failed to improve following anti-reflux regimen, speech therapy, or vocal fold injection with collagen. Phase 1 study IT-V-001 entitled "A Phase 1 Feasibility Study to Determine the Safety and Effects of Isolagen Injections for the treatment of Vocal Fold Scarring," 5 subjects 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. Starting in Month 3, a sustained improvement was noted through Month 12 in the mucosal wave grade, voice handicap index, and subject-assessed voice quality.

Three of the 5 subjects reported a total of 16 adverse events ("AE"). All reported AEs other than ear pain (12 events in 3 subjects) 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 subject population.

Recessive Dystrophic Epidermolysis Bullosa Preclinical: Through our collaboration with Intrexon, we are exploring the use of genetically-modified fibroblast cells to treat patients with collagen deficient diseases. We are working to genetically modify fibroblasts with the gene to produce collagen VII to treat patients with recessive dystrophic epidermolysis bullosa ("RDEB"). This product concept utilizes genetically-modified fibroblasts to up-regulate and produce collagen VII in a controlled manner for localized or systematic treatment of RDEB. We are collaborating with Intrexon to employ Intrexon's synthetic biology platforms for optimal gene expression from genetically-modified fibroblasts. RDEB is the most severe form of Epidermolysis Bullosa ("EB"), a devastatingly debilitating 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 current RDEB patient population in the U.S. is

approximately 2,800 to 5,600 patients.

Autoimmune Disorders Pre-Clinical: We expanded our agreement with Intrexon to broaden 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. Intrexon plans to engineer transgenes to optimize the functionality of Fibrocell's 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. Morphea profunda/ linear scleroderma is an autoimmune disease that primarily affects skin and connective tissues causing hardened plaques and joint contractures. The total prevalence of morphea profunda / linear scleroderma in the United States is estimated to be approximately 10,000 patients with similar prevalence in Europe and Asia. Cutaneous eosinophilias are inflammatory diseases that manifest in dermal and subcutaneous layers including the fascia. Similar to morphea profunda / linear scleroderma, plaques and connective tissue contractures form and persist on a chronic basis. The prevalence of cutaneous eosinophilias in the United States is estimated to be approximately 4,000 patients with similar prevalence in Europe and Asia respectively. In aggregate, approximately 40,000 patients worldwide suffer from morphea profunda and the cutaneous eosinophilias each year. Psoriasis is an immune-mediated, chronic skin disease that is characterized by the overproduction of new skin cells, which results in the formation of scaly patches. The total prevalence of psoriasis in the United States is estimated to be greater than 4.5 million patients, of which approximately twenty five percent are patients with moderate to severe disease, the indication targeted by Fibrocell's new therapeutic program. Current treatment options for patients with moderate to severe psoriasis include phototherapy (light- or laser-based treatments) or systemic therapies such as immunosuppressant and biologic therapies, which have varying degrees of effectiveness and potential adverse side effects.

Ehlers-Danlos Syndrome - Hypermobility Type Pre-Clinical: We expanded our agreement with Intrexon to explore the treatment of Ehlers-Danlos Syndrome Hypermobility Type ("EDS-HT"). We are exploring the use of genetically-modified engineer autologous fibroblast cells genetically corrected to produce tenascin-X ("TN-X"), a protein that is deficient in the connective tissue of a subset of EDS-HT patients. Patients with EDS-HT often experience significant musculoskeletal complications, including frequent joint dislocations, subluxations and early onset osteoarthritis. The goal is to employ the TN-X-expressing cells in the clinic, where they would be injected into EDS-HT patients at the disease sites most likely lower limbs like knees, hips and feet, as well as the jaw to correct connective tissue malfunction caused by deficient TN-X expression. There are approximately 2,000 to 6,000 patients with this disease in the U.S.

Intrexon Collaboration

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. Through the original collaboration with Intrexon, we are exploring the use of genetically-modified fibroblast cells to treat patients with collagen deficient diseases. We are working to genetically modify fibroblasts with the gene to produce collagen VII to treat patients with recessive dystrophic epidermolysis bullosa. This development concept utilizes genetically-modified fibroblasts to up-regulate and produce collagen VII in a controlled manner for localized or systematic treatment of RDEB.

On June 28, 2013, we and Intrexon entered into a First Amendment ("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.

On January 10, 2014, we and Intrexon entered into a Second Amendment (the "Second Amendment") to the parties' Channel Agreement dated October 5, 2012, as previously amended on June 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 genetically-modified and non-genetically-modified autologous fibroblasts and autologous dermal cells in the United States.

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The Channel Agreement 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 non-genetically-modified autologous fibroblasts for all aesthetic and therapeutic indications; (b) the enhanced production and purification of non-genetically-modified autologous dermal cells for aesthetic and therapeutic treatment of dermal, vocal cord, and periodontal indications; (c) the development of genetically-modified autologous fibroblasts for all aesthetic and therapeutic indications; and (d) the development of genetically-modified autologous dermal cells for aesthetic and therapeutic treatment of dermal, vocal cord, and periodontal indications. Pursuant to the First Amendment executed on June 28, 2013, the "Field" in the Channel Agreement was amended to add autologous human fibroblasts genetically-modified to express a therapeutic protein and/or bioactive RNA for the treatment of autoimmune and non-infectious inflammatory disorders that manifest in cutaneous tissues, fascia and/or muscle. Pursuant to the Second Amendment executed on January 10, 2014, the "Field" in the Channel Agreement was further amended to add autologous human fibroblasts genetically-modified to express bioactive Tenascin-X locally to correct connective tissue disorders. The remainder of the Channel Agreement was unchanged and the terms of the Channel Agreement will apply to the amended "Field."

Pursuant to the Channel Agreement and Amendments, we engage Intrexon for support services for the development of new products covered under the Channel Agreement and Amendments, 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 cost of goods sold savings less any such savings developed by us outside of the Channel Agreement or Amendments. 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.

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 collaboration between the University of California, Los Angeles ("UCLA") and Fibrocell Science, Inc. Under the terms of the license agreement, the Company agreed to pay UCLA a non-refundable initial license fee of $10,000 thirty days post execution of the agreement and the Company also agreed 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. 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 May 3, 2012, the Company also entered into a sponsored research agreement with the Massachusetts Institute of Technology ("MIT") to progress the research currently underway at UCLA above. Under the agreement, MIT researchers will investigate viable techniques to isolate, separate, and expand subpopulations of mesenchymal stem cells from dermal cell populations. The goal is to produce relevant quantities of the cells and performs ex vivo studies to determine the ability of these cells to produce clinically meaningful outcomes, such as bone production. If successful, in vivo studies will be evaluated for safety and efficacy analysis. The agreement is currently scheduled to terminate in September 2015

Manufacturing

We currently have one manufacturing facility located in Exton, Pennsylvania. All component parts used in our Exton, Pennsylvania manufacturing process are readily available with short lead times, and all machinery is maintained and calibrated. We believe we currently have adequate manufacturing capacity to clinical demand, as well as the limited

commercial demand we expect during 2014.

The fibroblast cells that are the foundation of our azficel-T product platforms are generated by our patented manufacturing process begin 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 FDA pharmaceutical standards (current Good Manufacturing Practices, "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 simultaneously 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, 10 million to 20 million cells arrive 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, 2013, we had 12 issued U.S. patents, 8 pending U.S. patent applications, 3 pending international patents, 28 granted foreign patents and 15 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 use of LAVIV, as well as azficel-T for the treatment of restrictive burn scars and vocal cord scars, and which naturally expire in July 2015. We are currently applying for the maximum 5 year extension of this patent term in the U.S. In addition, we own an issued U.S. patent and pending applications in Australia, Canada, China, Europe, India, Japan, South Korea and the U.S. directed to frozen 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 restrictive burn scars and vocal cord 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

Our competitors in the autologous cell therapy and drug development space include, but are not limited to, bluebird bio, Inc. and Sangamo BioSciences, Inc. We are not aware of any competitors for our azficel-T drug development programs for the treatment of restrictive burn scarring or vocal cord scarring. There are many companies currently competing in drug development for rare diseases. These include, but are not limited to, Vertex Pharmaceuticals, Inc., Alexion Pharmaceuticals, Inc. and Genzyme Corporation.

Many 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.

Recent Financing Activity

In October of 2013, we 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 us, 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 us, after underwriting discounts and commissions and estimated offering expenses, from approximately $42.1 million to approximately $47.1 million.

Research and Development

We expense research and development costs as they are incurred. For the years ended December 31, 2013 and 2012, we incurred research and development expenses of $12.6 million and $9.0 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 Federal Food, Drug, and Cosmetic Act ("FFDCA"), the Public Health Service Act ("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.

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 such products 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 Biologics License Application ("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, we concluded that it was reasonably safe to initiate clinical trials 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 subjects 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, or may authorize trials only on specified terms. 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 subject 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, new clinical trials will be initiated to further demonstrate clinical efficacy, optimal dosage and safety within an expanded and diverse subject population at geographically dispersed clinical study sites; and

- 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.

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 Practices. 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 subjects. Data safety monitoring committees, who monitor certain studies to protect the welfare of study subjects, 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 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, preclinical 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 may 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.

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.

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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 current Good Manufacturing Practices ("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 DOJ, or the Office of the Inspector General of 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.

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 leukocytoclasticvasculitis), which has not yet commenced and must be completed by 2016. The FDA concluded that analysis of spontaneous post-marketing adverse events 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. We are about to begin enrolling patients into a post-market study and, once the study begins, we will be in a better position to continue negotiating with the FDA on a revised study design.

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.

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 U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, 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.

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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, or DoD, 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 7, 2014, we employed 58 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.

Available Information

We file reports with the Securities and Exchange Commission (“SEC” or “Commission”). We make available on our website (www.Fibrocellscience.com) free of charge our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports as soon as reasonably practicable after we electronically file such materials with or furnish them to the SEC. Information appearing at our website is not a part of this Annual Report on Form 10-K. You can also read and copy any materials we file with the Commission at its Public Reference Room at 100 F Street, NE, Washington, DC 20549. You can obtain additional information about the operation of the Public Reference Room by calling the Commission at 1-800-SEC-0330. In addition, the Commission maintains an Internet site (www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the Commission, including Fibrocell Science.

Corporate History

On August 10, 2001, the company then known as 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. 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, or Confirmation 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.

Item 1A. Risk Factors

Investing in our company involves a high degree of risk. Before investing in our company you should carefully consider the following risks, together with the financial and other information contained in this Form 10-K. If any of the following risks actually occurs, our business, prospects, financial condition and results of operations could be adversely affected. In that case, the trading price of our common stock would likely decline and you may lose all or a part of your investment.

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' 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. 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 Institutional Review Boards 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;
- 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 institutional review board, or IRB, to conduct a clinical trial at a prospective study site;
- delays in the enrollment of subjects;
- manufacturing difficulties;
- failure of our clinical trials and clinical investigators to be in compliance with the FDA's Good Clinical Practices, or 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.

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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.

We utilize bovine-sourced materials to manufacture LAVIV®, our Autologous Crème product and 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 commercialization of LAVIV®, our Autologous Crème product and any of our product candidates, if approved.

With respect to LAVIV® and any of our product candidates, if marketing approval is received from the FDA, the FDA may impose post-marketing requirements, such as:

- labeling and advertising requirements, restrictions or limitations, including the inclusion of warnings, precautions, contraindications or use limitations that could have a material impact on the future profitability of our product candidates;
- testing and surveillance to further evaluate or monitor our future products and their continued compliance with regulatory standards and requirements;
- submitting products for inspection; or
- imposing a risk evaluation and mitigation strategy, or REMS, to ensure that the benefits of the drug outweigh the risks.

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 leukocytoclasticvasculitis), which has not yet commenced and must be completed by 2016. The FDA concluded that analysis of spontaneous post-marketing adverse events 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. We are about to begin enrolling patients into a post-market study and, once the study begins, we will be in better position to continue negotiating with the FDA on a revised study design. 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®

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 genetically engineered products, 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 of genetically-modified organisms has received negative publicity. This adverse publicity could lead to greater regulation of genetically altered products. Further, there is a risk that our product candidates could cause adverse health effects or other adverse events, which could also lead to negative publicity.

The synthetic biological technologies that are being utilizing 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.

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, preclinical 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 our collaboration with Intrexon is relatively new, we have only recently assumed development responsibility and costs associated with such program. In addition, 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 "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.

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

All of those involved in the preparation of a cellular therapy for clinical trials or commercial sale, including our existing supply contract manufacturers and clinical trial investigators, are subject to extensive 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 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.

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® at one facility in the U.S. and we also plan to manufacture our product candidates in the same facility. 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.

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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.

Our research, development and manufacturing operations depend on one facility. 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 all our research, development and manufacturing operations in one facility located in Exton, Pennsylvania. As a result, all of the commercial manufacturing of LAVIV® and our Autologous Crème product for the U.S. market takes place at a single U.S. facility. In addition, most of our clinical trials for our product candidates primarily depend upon the manufacturing of such product candidates in the same facility. If regulatory, manufacturing or other problems require us to discontinue production at that 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 this facility or the equipment in it is significantly damaged or destroyed by fire, flood, power loss or similar events, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace our facility at all. In the event of a temporary or protracted loss of this facility or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing 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 have yet to be profitable, we expect losses to increase from current levels and we will continue to experience significant negative cash flow as we expand our operations and undertake additional clinical trials, which may limit or delay our ability to become profitable.

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. We are focused on product development and the commercialization of LAVIV® but we have limited manufacturing capacity. We expect to continue to experience increasing operating losses and negative cash flow as we continue our clinical trials for medical applications and as we continue our collaboration efforts with Intrexon.

We expect to continue to incur significant additional costs and expenses related to:

- FDA clinical trials and regulatory approvals;

- our collaborations with Intrexon;
- our investigation of the automation of manufacturing and our future expansion of manufacturing capabilities;

- the commercialization of LAVIV®;
- research and development;
- personnel costs; and
- development of relationships with strategic business partners, including physicians who might use our future products.

If our product candidates fail in clinical trials or do not gain regulatory approval, if our product candidates do not achieve market acceptance, or if we do not succeed in effectively and efficiently implementing manufacturing process and technology improvements to make our product commercially viable, we will not be profitable. If we fail to become and remain profitable, or if we are unable to fund our continuing losses, our business may fail.

We will continue to experience operating losses and significant negative cash flow from operations until we begin to generate significant revenue from LAVIV® or our new product candidates, which will require a significant increase in our manufacturing capacity, as well as FDA's approval for this increased capacity and significant capital expenditures. As a result of our limited operating history, we may not be able to correctly estimate our future operating expenses, which could lead to cash shortfalls.

We have a limited operating history and our primary business activities consist of conducting clinical trials, 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 and our collaboration with Intrexon, which depend on the success of such trials and our ability to effectively and efficiently conduct such trials, 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.

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 studies;
- 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;

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- 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 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.

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, adverse event 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 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 future 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
- 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 intend to disseminate peer-reviewed articles on our future products 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 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.

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, 2013, we had warrants and options outstanding that were exercisable for a total of 6,736,487 shares of common stock.

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 was listed on the NYSE MKT in May 2013, 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.

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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. Between that date and December 31, 2013, our common stock has traded between $3.28 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 burn scars and 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;
- 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.

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

Currently, our directors, executive officers, and principal stockholder beneficially own approximately 15.3 million shares of our common stock as of March 7, 2014. 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.

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.

We have in the past identified a material weakness in our internal control over financial reporting.

Management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended. As disclosed in Item 9A of this report, our management identified a material weakness in our internal control over financial reporting related to the deferred tax liability associated with intangible asset as of December 31, 2012. A material weakness is defined as a deficiency, or 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 a result of this material weakness, our management concluded that our internal control over financial reporting was not effective as of December 31, 2012, based on criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control An Integrated Framework (1992). As set forth in Item 9A of this report, we believe we have remediated this material weakness. If our remedial measures are insufficient to address the material weakness, or if additional material weaknesses in our internal control are discovered or occur in the future, our consolidated financial statements may contain material misstatements and we could be required to restate our financial results. For more information see "Item 9A. Controls and Procedures."

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.

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.

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.

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 employment agreements with our chief executive officer and chief financial 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.

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 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 compounds 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, market and sell LAVIV, and other product candidates, if approved,, 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 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.

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 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 term 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 new product, such as LAVIV, and 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.

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 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.

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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 LAVIV or 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;
- We may not develop additional proprietary technologies that are patentable; and
- The patents of others may have an adverse effect on our business.

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

If LAVIV® or any of our potential product candidates were to become the subject of problems related to their efficacy, safety, or otherwise, our revenues from LAVIV® could decrease and our business would be seriously harmed.

LAVIV®, in addition to any other of our potential 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. With the use of any newly marketed drug by a wider patient population, serious adverse events 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. In the event of a withdrawal of LAVIV® from the market, our revenues would decline significantly and our business would be seriously harmed and could fail.

Adoption of LAVIV® for the treatment of the appearance of moderate to severe nasolabial fold wrinkles in adults may be slow or limited for a variety of reasons including the cost we must charge for the treatment, competing therapies and, perceived difficulties in the treatment process. If LAVIV® is not successful in gaining broad acceptance as a treatment option for nasolabial fold wrinkles, our business could be harmed.

The rate of adoption of LAVIV® for nasolabial fold wrinkles will be dependent on several factors, including the cost we must charge for the treatment, educating and training physicians and their offices on the patient treatment process with LAVIV® and autologous cell therapy generally. As a first in class therapy, LAVIV® utilizes a unique treatment approach, which can have associated challenges in practice for physicians. The logistics of the product, the injection technique required and the fact that the product constitutes a patient's own cells represent different challenges for physicians. In addition, the tight manufacturing and injection timelines required for treatment with LAVIV® will require physicians to adjust practice mechanics, which may result in delay in market adoption of LAVIV® as a preferred therapy. Finally, we increased the price we charge for LAVIV® significantly in the second quarter of 2013, which may reduce demand for LAVIV®.

In order to potentially increase our revenue from the sale of LAVIV® or 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 with LAVIV®, our Autologous Crème product and our other product candidates. In addition, our current manufacturing process is primarily a manual process. To potentially increase our revenue from the sale of LAVIV® and our Autologous Crème product, and 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 potentially increase our revenue from LAVIV®, our Autologous Crème product, as well as any new 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.

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

None.

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.

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, 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.

	High	Low
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
Year Ended December 31, 2012		
First Quarter	$ 12.50	$ 8.00
Second Quarter	$ 10.00	$ 3.25
Third Quarter	$ 6.75	$ 3.50
Fourth Quarter	$ 6.00	$ 3.25

The closing price of our common stock on March 7, 2014 was $5.66 as reported on the NYSE MKT.

Holders of Record

As of March 7, 2014, there were 40,837,615 shares of our common stock outstanding and held by 78 stockholders of record. As of March 7, 2014, we had no shares of preferred stock outstanding.

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 2013 and approximately $0.5 million in cash payments for 2012.

Recent Sales of Unregistered Securities

All information regarding our issuance of unregistered securities during 2013 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.

On January 10, 2014, we and Intrexon entered into a second amendment ("Second Amendment") to the parties' Exclusive Channel Collaboration Agreement dated October 5, 2012. In connection with the execution of the Second Amendment, on January 10, 2014, we entered into a Supplemental Stock Issuance Agreement with Intrexon pursuant to which we issued Intrexon 1,024,590 shares of our common stock. The closing of the transaction occurred on January 24, 2014. The shares were issued in a transaction exempt from registration under the Securities Act of 1933, as amended (the "Securities Act"), in reliance on Section 4(2) thereof. Intrexon represented that it was an "accredited investor" as defined in Regulation D of the Securities Act. For additional information see Note 17 in the accompanying Notes to the Consolidated Financial Statements included in this Form 10-K.

Purchases of Equity Securities

We did not repurchase any of our equity securities during the year ended December 31, 2013.

Item 6. Selected Financial Data

Not applicable.

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 Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, 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. 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 skin diseases and conditions with high unmet medical needs. Based on our proprietary autologous fibroblast technology, we are pursuing breakthrough medical applications of azficel-T for restrictive burn scarring and vocal cord scarring. Driving Fibrocell's innovative therapies is its Personalized Biologics platform, which embraces two product engines: the Azficel-T Autologous Fibroblast Product Engine and the Protein Expression Product Engine. These two product engines enable Fibrocell to harness the favorable characteristics of fibroblasts to develop new therapies for diseases and conditions of the skin and connective tissues where there are limited or no treatment options. The Azficel-T Autologous Fibroblast Product Engine is developing biologic solutions for the treatment of serious and debilitating scarring conditions. The Protein Expression Product Engine is creating biologic products by genetically modifying fibroblasts to express target proteins that are inactive or missing from patients with rare genetic skin and tissue disorders.

Our collaboration with Intrexon, a leader in synthetic biology, includes using genetically-modified fibroblasts for treating orphan skin diseases for which there are no currently approved products and exploring the localized treatment of the most common autoimmune skin disease, moderate-to-severe psoriasis. This collaboration with Intrexon is discussed in more detail below. Additional collaborations with the University of California, Los Angeles ("UCLA") and the Massachusetts Institute of Technology ("MIT") focus on skin-derived stem cells.

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: Warrants are measured at fair value and liability-classified under the Financial Accounting Standards Board Accounting Standard Codification ("ASC") 815, *Derivatives and Hedging* ("ASC 815") because certain of our warrants contain "down-round protection" and therefore, do not meet the scope exception for treatment as a derivative under ASC 815. 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 common stock which is a requirement for the scope exception as outlined under ASC 815. We utilized the Monte Carlo simulation valuation method to value the liability-classified warrants until September 30, 2012 when we concluded that the Black-Scholes option pricing model was an appropriate valuation method due to the assumption that no future financing would be expected at a price lower than the current exercise price and the majority of the warrants were converted to equity-classified warrants on October 9, 2012. The fair value 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. We will continue to classify the fair value of the warrants 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.

Revenue Recognition: We recognize 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.

Cost of Sales: Cost of sales includes the costs related to the processing of cells for LAVIV®, including direct and indirect costs. These direct costs include the majority of costs incurred in our manufacturing, facility, quality control, and quality assurance operations along with an allocation of overhead costs. The principal reason for the relatively small level of revenue as compared to the cost of sales is that we changed corporate strategy in 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.

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 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 ("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, 2013 and 2012

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

($ in thousands)	Year ended December 31, 2013	2012	Increase (Decrease) $	%
Total revenue	$ 200	$ 153	$ 47	31 %
Cost of sales	8,052	8,355	(303)	(4) %
Gross loss	$ (7,852)	$ (8,202)	$ 350	(4) %

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 $8.1 million and $8.4 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 $1.6 million of rent, utilities, depreciation and amortization. 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 and $1.5 million of rent, utilities, depreciation and amortization. Cost of sales decreased mainly due to a reduction in compensation and related expense of $0.3 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 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 by the FDA to no more than twenty biopsies a week; (3) Charging for biopsies and injections we offered complimentary and reduced price biopsies and injections throughout 2012 and 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 2014. We believe that cost of sales will remain at or above 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:

($ in thousands)	Year Ended December 31, 2013	2012	Increase (Decrease) $	%
Compensation and related expense	$ 3,841	$ 4,336	$ (495)	(11) %
External services consulting	935	914	21	2 %
Marketing expense	295	2,203	(1,908)	(87) %
License fees	698	664	34	5 %
Facilities and related expense and other	4,304	4,050	254	6 %
Total selling, general and administrative expense	$ 10,073	$ 12,167	$ (2,094)	(17) %

Selling, general and administrative expense decreased by approximately $2.1 million, or 17%, to $10.1 million for the year ended December 31, 2013 as compared to $12.2 million for the year ended December 31, 2012. Compensation and related expense decreased $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 which were incurred with the reduction of sales and marketing personnel employed. Marketing expense decreased $1.9 million as there was increased spending for the initial launch of LAVIV® during the year ended December 31, 2012. Facilities and related expense and other increased $0.3 million due to an increase of $0.5 million in office costs offset by a decrease in travel costs of $0.2 million. External services consulting and license fees remained 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.

Research and development expense was comprised of the following:

($ in thousands)	Year Ended December 31, 2013	2012	Increase (Decrease) $	%
Direct costs:				
Restrictive Burn Scarring	$ 344	$ 163	$ 181	111 %
Vocal Cord Scarring	322	158	164	104 %
Recessive Dystrophic Epidermolysis Bullosa	1,773	6,979	(5,206)	(75) %
Morphea Profunda/ Linear Scleroderma	3,570	-	3,570	-
Cutaneous Eosinophilias	3,570	-	3,570	-
azficel-T	1,555	293	1,262	431 %
Other	631	554	77	14 %
Total direct costs	11,765	8,147	3,618	44 %
Indirect costs:				
Regulatory costs	290	357	(67)	(19) %
Indirect lab costs	241	170	71	42 %
Compensation and related expense	270	323	(53)	(16) %
Other indirect costs	12	24	(12)	(50) %
Total indirect costs	813	874	(61)	(7) %
Total research and development expense	$ 12,578	$ 9,021	$ 3,557	39 %

Total research and development expense increased $3.6 million to $12.6 million for the year ended December 31, 2013 as compared to $9.0 million for the year ended December 31, 2012. The increase is due primarily to a $3.7 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 offset by a $0.2 million decrease in other spending.

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

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.

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.

Recessive Dystrophic Epidermolysis Bullosa ("RDEB") Costs to date on this program are approximately $8.8 million and include the $6.9 million cost of the 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 DNA Recombinant Advisory Committee ("RAC") meeting preparation and design and execution of the Phase I clinical trial protocol.

Morphea Profunda / Linear Scleroderma ("MP / LS") and Cutaneous Eosinophilias ("CE") - Costs to date on these programs, which are being co-developed, include the $6.4 million cost of the 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. Going forward, 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 2013 as compared to $1.1 million for the year ended December 31, 2012. Our interest expense for the year ended December 31, 2012 was related to our 12.5% notes. The 12.5% notes were either paid or converted into common stock with the close of the financing we completed in October 2012.

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 $4.4 million in the consolidated statement of operations due to a significant restructuring of the original debt in June 2012. 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 $3.2 million.

Change in Revaluation of Warrant Liability. During the years ended December 31, 2013 and 2012, respectively, we recorded non-cash expense of $0.1 million and non-cash income of $8.7 million for warrant revaluation in our statements of operations due to a change in the fair value of the warrant liability as a result of a change in the contractual life of the warrants. As a result of the October 2012 offering, a significant portion of outstanding warrants that were previously liability-classified warrants were reclassified to equity-classified warrants due to the removal of the "down-round protection," and therefore a smaller number of warrants are subject to revaluation.

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 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 which was sold in the 3rd quarter of 2012.

Gain on Sale of Discontinued Operations. On August 31, 2012 we sold all of the shares of common stock of Agera we held for approximately $1.0 million. As a result of the sale we recorded a gain of approximately $0.4 million, net of tax.

Net Loss. Net loss increased $7.4 million to $30.6 million for the year ended December 31, 2013, as compared to $23.2 million for the year ended December 31, 2012. The increase is primarily due to the change in the warrant revaluation of approximately $8.8 million, as more fully described above, offset by the $0.3 million decrease in cost of sales and the $1.0 million decrease in interest expense.

Liquidity and Capital Resources

We have experienced losses since our inception. As of December 31, 2013, we have an accumulated deficit of $102.7 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)	2013	2012
Statement of Cash Flows Data:		
Total cash provided by (used in):		
Operating activities	$ (20,075)	$ (22,575)
Investing activities	(360)	509
Financing activities	49,122	42,613

Operating Activities. 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 the prior year is primarily due to a$2.0 million increase in operating cash inflows from changes in operating assets and liabilities, mostly related to accounts payable.

Investing Activities. Cash used in investing activities during the year ended December 31, 2013 amounted to $0.4 million due to the purchase of property and equipment. Cash provided by investing activities during the year ended December 31, 2012 amounted to $0.5 million due to the proceeds from the sale of Agera in the third quarter of 2012 offset by the purchase of property and equipment.

Financing Activities. There were $49.1 million cash proceeds provided by financing activities during the year ended December 31, 2013, as compared to $42.6 million provided by financing activities during the year ended December 31, 2012. 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 $52.1 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. Of the $52.1 million received in 2012, we received $43.0 million in gross proceeds from the October 2012 offering. The remaining $9.1 million was received during May, June and July of 2012 when we sold to accredited investors in a private placement Series E Convertible Preferred Stock.

Working Capital

As of December 31, 2013, we had cash and cash equivalents of $60.0 million and working capital of $58.3 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 partner 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, 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, 2013:

($ in thousands)	Payments due by period				
	Total	2014	2015 and 2016	2017 and 2018	2019 and thereafter
License fee obligations[1]	$ 895	$ 525	$ 290	$ 40	$ 40
Operating lease obligations[2]	$ 12,251	$ 1,081	$ 2,465	$ 2,509	$ 6,196
Total	$ 13,146	$ 1,606	$ 2,755	$ 2,549	$ 6,236

(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, 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.

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

There have been no recently issued accounting pronouncements that we believe will have a material impact on our consolidated results of operations, cash flows or financial position upon adoption.

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, 2013, we had cash and cash equivalents $60.0 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 fluctuations due to changes in interest rates in our investment portfolio.

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 (a) material information relating to us, including our consolidated subsidiaries, is made known to management, including these officers, by our other employees, and (b) this information is recorded, processed, summarized, evaluated and reported, as applicable, within the time periods specified in the SEC's rules and forms. As of December 31, 2013, the officers (the principal executive officer and principal financial officer) concluded that our disclosure controls and procedures were effective.

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* (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

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 the assets of the company; (ii) 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 (iii) 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.

Based on our evaluation under the framework in the Internal Control Integrated Framework (1992), the chief executive officer and chief financial officer concluded that our internal control over financial reporting was effective as of December 31, 2013. The effectiveness of our internal control over financial reporting as of December 31, 2013 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.

Changes in Internal Controls

Remediation of Prior Year Material Weakness

In Item 9A of the Company's Annual Report on Form 10K for the fiscal year ended December 31, 2012, management reported a material weakness in its internal control over financial reporting.

Specifically, when the Company emerged from bankruptcy in September 2009, an intangible asset was recorded in respect of our primary clinical study on LAVIV®, and the related deferred tax liability was also recorded. In the first quarter of 2012, the Company commercially launched LAVIV®, and commenced generating revenue. As a result, the intangible asset was considered a finite-lived intangible asset and the Company commenced amortizing it over 12 years, and also initiated the amortization of the related deferred tax liability over the same period. In connection with the finalization of our audit for the year ended December 31, 2012, it came to management's attention that the accounting treatment adopted for the deferred tax liability related to the intangible asset in the first quarter of 2012 and for the subsequent second and third quarters of 2012 was incorrect. Rather than the deferred tax liability being a permanent timing difference for the calculation of deferred tax, we concluded that it would have been more appropriately treated as a temporary timing difference. The impact of this adjustment is that the full deferred tax liability of $2.5 million should have been released to the Consolidated Statement of Operations in the first quarter of 2012.

As a result of this adjustment, it was determined that a control deficiency that constituted a material weakness in the design and operation of our internal control over financial reporting in connection with deferred tax liability relating to the intangible asset was present.

Management's remediation plan to address the material weakness described above was initiated in 2013 and included the following steps taken to strengthen the Company's internal control over financial reporting:

In the past, management has utilized external accounting and taxation advisors to assist us. However, notwithstanding that the specific issue that caused the material weakness no longer exists as a result of the adjustment noted above, due to the fact that an adjustment was still required, management reconsidered the appropriate selection of our external advisors that we utilize for these advisory services. Management selected and engaged a new taxation advisor in 2013.

Other Changes in Internal Control Over Financial Reporting

Other than the internal control improvement discussed above, there have been no changes in our internal control over financial reporting during the fourth quarter ended December 31, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Part III

Item 10. Directors, Executive Officers and Corporate Governance

The information required under this Item 10 is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2013.

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. We intend to disclose any future amendments to, or waivers from, the code of ethics within four business days of the waiver or amendment through a website posting or by filing a Current Report on Form 8-K with the SEC.

Item 11. Executive Compensation

The information required under this Item 11 is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2013.

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 our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2013.

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

The information required under this Item 13 is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2013.

Item 14. Principal Accountant Fees and Services

The information required under this Item 14 is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2013.

Part IV

Item 15. Exhibits and Financial Statement Schedule

(a)(1) Financial Statements.

- Report of Independent Registered Public Accounting Firm
- Consolidated Balance Sheets as of December 31, 2013 and 2012
- Consolidated Statements of Operations for the years ended December 31, 2013 and 2012
- Consolidated Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2013 and 2012
- Consolidated Statements of Cash Flows for the years ended December 31, 2013 and 2012

· Notes to Consolidated Financial Statements

(a)(2) 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 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:

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	Securities Purchase Agreement dated October 13, 2009 between the Company and the Series A Preferred Stock Purchasers (incorporated by reference to Exhibit 10.1 to our Form 8-K filed October 14, 2009)

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**10.2	2009 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to our Form 10-Q filed November 14, 2012)
10.3	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)
10.4	Purchase Option Agreement between Isolagen, Inc and 405 Eagleview Associates dated April 7, 2005 (incorporated by reference to Exhibit 10.2 to our Form 8-K filed on April 12, 2005)
10.5	Intellectual Property Purchase Agreement between Isolagen Technologies, Inc., Gregory M. Keller, and PacGen Partners (incorporated by reference to Exhibit 10.13 to the company's amended Form S-1, as filed on October 24, 2003)
10.6	Securities Purchase Agreement dated March 2, 2010 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed March 3, 2010)
10.7	Registration Rights Agreement dated March 2, 2010 (incorporated by reference to Exhibit 10.2 to our Form 8-K filed March 3, 2010)
10.8	Registration Rights Agreement between the Company and the Series A Preferred Stock Purchasers, dated October 13, 2009 (incorporated by reference to Exhibit 10.2 to our Form 8-K filed October 14, 2009)
10.9	Securities Purchase Agreement between the Company and Series B Preferred Stock Purchasers (incorporated by reference to Exhibit 10.1 to our Form 8-K filed July 20, 2010)
10.10	Form of Registration Rights Agreement between the Company and Series B Preferred Stock Purchasers (incorporated by reference to Exhibit 10.2 to our Form 8-K filed July 20, 2010)
10.11	Form of Securities Purchase Agreement between the Company and Series B Preferred Stock Purchasers (incorporated by reference to Exhibit 4.1 of the Form 8-K filed October 22, 2010).
10.12	Securities Purchase Agreement dated August 3, 2011 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed August 4, 2011)
10.13	Registration Rights Agreement dated August 3, 2011 (incorporated by reference to Exhibit 10.2 to our Form 8-K filed August 4, 2011)
10.14	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)
10.15	Securities Purchase Agreement dated October 5, 2012 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed October 9, 2012)
10.16	Registration Rights Agreement dated October 5, 2012 (incorporated by reference to Exhibit 10.2 to our Form 8-K filed October 5, 2012)
10.17	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)
10.18	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)
+ 10.19	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)
10.20	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)
10.21	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)

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10.22	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)
+ 10.23	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)
10.24	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)
** 10.25	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)
** 10.26	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)
**10.27	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)
10.28	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)
10.29	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)
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 pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002
*31.2	Certification pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002
*32.1	Certification pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
*32.2	Certification 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)

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* Filed herewith.

** Indicates management contract or compensatory plan or arrangement.

\+ 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 17, 2014

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 17, 2014
/s/ Gregory Weaver Gregory Weaver	Chief Financial Officer (Principal Financial and Accounting Officer)	March 17, 2014
/s/ Kelvin Moore Kelvin Moore	Director	March 17, 2014
/s/ Marc Mazur Marc Mazur	Director	March 17, 2014
/s/ Julian Kirk		