Fibrocell Science, Inc.
Form 10-K
April 01, 2013
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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, 2012

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(g) of the Act:

Title of Each Class

Common Stock, $.001 par value

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. ¨

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

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

The aggregate market value of common stock held by non-affiliates of the registrant was $22.5 million as of June 30, 2012, 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 OTC Bulletin Board on June 30, 2012.

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 25, 2013, issuer had 655,747,608 shares issued and outstanding of common stock, par value $0.001.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the 2012 Annual Meeting of Stockholders (the Proxy Statement), to be filed within 120 days of the end of the fiscal year ended December 31, 2012, 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 1

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 intended to identify any forward-looking statements. You should not place undue reliance on these forward-looking statements. These statements reflect our current view of future events and are subject to certain risks and uncertainties as noted below. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, our actual results could differ materially from those anticipated in these forward-looking statements. Actual events, transactions and results may materially differ from the anticipated events, transactions or results described in such statements. Although we believe that our expectations are based on reasonable assumptions, we can give no assurance that our expectations will materialize. Many factors could cause actual results to differ materially from our forward looking statements including those set forth in Item 1A of this report. Other unknown, unidentified or unpredictable factors could materially and adversely impact our future results. We undertake no obligation and do not intend to update, revise or otherwise publicly release any revisions to our forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of any unanticipated events. Several of these factors include, without limitation:

- whether our clinical human trials relating to the use of autologous cellular 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 cellular 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, and our ability to retain any regulatory approvals that we may obtain; and the absence of adverse regulatory developments in the United States;

- 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;

- 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 administration of our product.

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.

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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 2012 mean the year ended December 31, 2012, and references to other Fiscal years mean the year ending December 31, of the year indicated.

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

We obtained 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.

Item 1. Business

Overview

We are a commercial-stage, autologous cellular therapeutic company focused on the development of innovative products for aesthetic, medical and scientific applications.

We have a pipeline of therapeutic and aesthetic product development programs based on the first Food and Drug Administration (FDA) approved cell-based product, LAVIV (azficel-T), in aesthetics, all of which are based on the autologous fibroblast cell. Our clinical and pre-clinical programs include treatments for restrictive burn scars, vocal cord scars, and acne scars. Through our collaboration with Intrexon Corporation (discussed in more detail below) we are working to discover and develop treatments for rare collagen deficient conditions such as recessive dystrophic epidermolysis bullosa.

Recent Financing and Corporate Restructuring

In October 2012, we completed the following significant financing and corporate restructuring (the offering):

- we sold 450 million shares of our common stock at a purchase price of $0.10 per share for a total offering amount of $45.0 million of which $2 million is still outstanding;

- we entered into an agreement with the holders of our outstanding debt pursuant to which we repaid approximately $1.7 million of the debt in cash, with the remaining $2.4 million of debt converting into shares of common stock at a conversion price of $0.10 per share. As a result, we currently have no outstanding debt obligations;

- upon the closing of the offering each outstanding share of our preferred stock was converted into that number of shares of common stock determined by dividing the stated value of such share of preferred stock by $0.25. As a result, we currently have no outstanding shares of preferred stock; and

- we entered into warrant modification agreements with the holders of warrants to purchase approximately 105 million shares of common stock at exercise prices of between $0.25 per share and $0.30 per share pursuant to which we extended the expiration date of the warrants by one year, and we deleted the full-ratchet anti-dilution adjustment provisions contained in the warrants (including with respect to the offering discussed above). As such, the exercise price and number of shares underlying the foregoing warrants were not modified due to the completion of the above offering.

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Our Strategy

Our goal is to unlock the potential of fibroblast cells and our unique autologous cellular platform. We plan to achieve this objective through the following strategies:

- Leveraging our FDA approved product, LAVIV, to expand applications of our core technology to areas of significant unmet medical needs such as restrictive burn scars, vocal cord scars, and acne scars.
- Initiating clinical development programs in burn scars and vocal scars in 2013.
- Maximizing the value of LAVIV by pricing and positioning the product as a best-in-class solution for improvement of the appearance of moderate to severe nasolabial fold wrinkles in adults.
- Collaborating with Intrexon Corporation to explore the use of genetically modified fibroblast cells to treat patients with collagen deficient diseases, such as recessive dystrophic epidermolysis bullosa.
- Commercializing the Fibrocell Science Autologous Crème ™, an autologous skin care cream that will be the first and only product containing personalized growth factors and proteins derived from a person s own fibroblasts.
- Developing enhancements and alternatives to our current manufacturing process that may reduce production costs, expand capacity and increase yields.

Clinical Development Programs

Our product development programs are focused on the medical and aesthetic markets 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 recessive dystrophic epidermolysis bullosa. Our primary aesthetics development program is focused on treating acne scarring. All of our product candidates are non-surgical and minimally invasive.

Medical Development Programs

Restrictive Burn Scars *Phase II Trial:* According to the American Burns Association, 45,000 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 are planning to initiate a Phase II trial of azficel-T for the treatment of restrictive burn scars in the second quarter of 2013. 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 20-30 patients.

Vocal Cord Scars *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 200,000 700,000 in the Unites States. We are planning to initiate a Phase II clinical study on vocal cord scars in the second half of 2013.

Recessive Dystrophic Epidermolysis Bullosa 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 modify 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. Epidermolysis

bullosa (EB) is a group of genetic conditions that cause the skin to be very fragile and to blister easily. Blisters and skin erosions form in response to minor injury or friction, such as rubbing or scratching, Dystrophic epidermolysis bullosa (DEB) is one of the major forms of epidermolysis bullosa and has an incidence of 6.5 per million newborns in the United States based on statistics from the National Institutes of Health (2008). The severe autosomal recessive forms of this disorder affect fewer than 1 per million newborns.

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Aesthetic Development Programs

Acne Scars *Phase II Trial:* An estimated 20 million Americans suffer from acne scarring according to the Acne Resource Center. Fibrocell conducted a Phase II, placebo-controlled study investigating the efficacy and safety of azficel-T for the treatment of moderate to severe acne scars. The study evaluated a total of 109 people at seven clinical sites across the United States. In the study, both the Patient and Evaluator assessments met the co-primary endpoints and were statistically significant, achieving p-values of 0.000011 and 0.016, respectively (p-values less than or equal to 0.05 are considered statistically significant).

Fibrocell held an end of Phase II meeting with FDA in 2012 to discuss the design of a Phase III clinical program. Fibrocell is currently in discussions with the FDA on the finalized study. The discussions have primarily focused on the photoguide scale used to measure the physician s assessment of the subject s acne scar improvement.

Facial cream: We have developed the Fibrocell Science Autologous Crème, an autologous skin care cream that will be the first and only product containing personalized growth factors and proteins derived from a person s own fibroblast cells. Our autologous cream will leverage the LAVIV manufacturing process to provide a personalized topical cosmetic product consisting of a cream vehicle blended with the conditioned media extract from the cell culture of a customer s own fibroblasts. The conditioned media used to promote fibroblast expansion contains protein extracts from the fibroblast cells produced *in vitro*. This media is collected from cell culture during routine feed and passage for use in formulation of the cosmetic product. Final formulation and distribution will be performed at Fibrocell s Exton, PA manufacturing facility.

Intrexon Collaboration

In October 2012, we entered into an Exclusive Channel Collaboration Agreement (the Channel Agreement) with Intrexon Corporation that governs 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 (the Fibroblast Program). 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 Field in the United States. The Field includes: (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 Channel Agreement, we engaged Intrexon for support services for the development of new products covered under the Channel Agreement and will reimburse Intrexon for its fully-loaded cost for time and materials for transgenes, cell processing, or other work performed by Intrexon for such research and manufacturing. 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. 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 currently marketed products (including new indications) are not subject to royalty payments unless they are improved upon through the Channel Agreement.

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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 currently have limited manufacturing capacity which we intend to use on clinical trials, evaluating a new automated manufacturing system, and commercial supply.

Our patented manufacturing process begins by 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 US Food and Drug Administration (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. 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, 10-20 million cells arrive at the doctor s office ready for intradermal injection of the patient.

Sales and Marketing

In June 2011, LAVIV became the first and only personalized aesthetic cell therapy approved by the FDA for the improvement of the appearance of moderate to severe nasolabial fold wrinkles in adults. Our strategy is to sell LAVIV directly in the United States. We plan to significantly increase the selling price of LAVIV on May 1, 2013 in order to more closely align product pricing with our cost structure. The new price will be $12,000 to the physician for the full treatment. We currently have limited manufacturing capacity in 2013.

Our Current Target Market Opportunities

LAVIV

LAVIV, is the first and only personalized aesthetic cell therapy approved by the FDA for the improvement of the appearance of moderate to severe nasolabial fold wrinkles in adults and is, thus, directed primarily at the aesthetic market. Aesthetic procedures have traditionally been performed by dermatologists, plastic surgeons and other cosmetic surgeons. According to the American Society for Aesthetic Plastic Surgery, or ASAPS, the total market for non-surgical cosmetic procedures (injectable and skin rejuvenation procedures) was approximately $3.8 billion in 2012. We believe the aesthetic procedure market is driven by:

- the desire of many individuals to improve their appearance;
- impact of managed care and reimbursement policies on physician economics, which has motivated physicians to establish or expand the menu of elective, private-pay aesthetic procedures that they offer; and
- broadening base of the practitioners performing cosmetic procedures beyond dermatologists and plastic surgeons to non-traditional providers.

According to the ASAPS, over 10 million surgical and non-surgical procedures were performed in 2012 by board certified doctors in the United States, as compared to 9.2 million in 2011. We believe that the concept of non-surgical cosmetic procedures involving injectable materials has become more mainstream and accepted. According to the ASAPS, the following table shows the top five non-surgical cosmetic procedures performed in 2012:

Procedure	Number
Botulinum toxin type A	3,257,913
Hyaluronic acid	1,423,705
Laser hair removal	883,893
Microdermabrasion	498,821

Chemical peel	443,824

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In 2012, procedures among the 35 to 50 year old age group made up approximately 43% of all procedures. The 51 to 64 year old age group made up 29% of all procedures in 2012, while the 19 to 34 year old age group made up 19% in 2012. The Botulinum toxin type A injection was the most popular treatment of the nonsurgical procedures for all age groups.

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, 2012, we had 11 issued U.S. patents, 8 pending U.S. patent applications, 28 granted foreign patents and 9 pending international 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. We are in the process of pursuing several other patent applications. We have also licensed pending patent applications.

Our success depends in part on our ability to maintain our proprietary position through effective patent claims and their enforcement against our competitors, and through the protection of our trade secrets. Although we believe our patents and patent applications provide a competitive advantage, the patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. We do not know whether any of our patent applications or those patent applications which we have acquired will result in the issuance of any patents. Our issued patents, those that may be issued in the future or those 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. Because of the extensive time required for the development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized or marketed, any related patent claim may expire or remain in force for only a short period following commercialization, thereby reducing the advantage of the patent.

We also rely upon trade secrets, confidentiality agreements, proprietary know-how and continuing technological innovation to remain competitive, especially where we do not believe patent protection is appropriate or obtainable. We continue to seek ways to protect our proprietary technology and trade secrets, including entering into confidentiality or license agreements with our employees and consultants, and controlling access to and distribution of our technologies and other proprietary information. While we use these and other reasonable security measures to protect our trade secrets, our employees or consultants may unintentionally or willfully disclose our proprietary information to competitors.

Our commercial success will depend in part on our ability to operate without infringing upon the patents and proprietary rights of third parties. It is uncertain whether the issuance of any third party patents would require us to alter our products or technology, obtain licenses or cease certain activities. Our failure to obtain a license to technology that we may require to discover, develop or commercialize our future products may have a material adverse impact on us. One or more third-party patents or patent applications may conflict with patent applications to which we have rights. Any such conflict may substantially reduce the coverage of any rights that may issue from the patent applications to which we have rights. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the United States Patent and Trademark Office to determine priority of invention.

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.

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Competition

The pharmaceutical and dermal aesthetics industries are characterized by intense competition, rapid product development and technological change. Competition is intense among manufacturers of prescription pharmaceuticals and dermal injection products.

Our commercial product LAVIV competes with a variety of companies in the dermatology and plastic surgery markets, many of which offer substantially different treatments for similar problems. These include silicone injections, laser procedures, facial surgical procedures, such as facelifts and eyelid surgeries, fat injections, dermabrasion, collagen, allogenic cell therapies, hyaluronic acid injections and Botulinum toxin injections, and other dermal fillers. Indirect competition comes from facial care treatment products. Items catering to the growing demand for therapeutic skin care products include facial scrubs, anti-aging treatments, tonics, astringents and skin-restoration formulas.

Many of our competitors are large, well-established pharmaceutical, chemical, cosmetic or health care companies with considerably greater financial, marketing, sales and technical resources than those available to us. Additionally, many of our present and potential competitors have research and development capabilities that may allow them to develop new or improved products that may compete with our product lines. Our products could be rendered obsolete or made uneconomical by the development of new products to treat the conditions addressed by our products, technological advances affecting the cost of production, or marketing or pricing actions by one or more of our competitors. Our facial aesthetics product may compete for a share of the existing market with numerous products and/or technologies that have become relatively accepted treatments recommended or prescribed by dermatologists and administered by plastic surgeons and aesthetic dermatologists.

The field for therapeutic treatments or tissue regeneration for use in wound healing is rapidly evolving. A number of companies are either developing or selling therapies involving stem cells, human-based, animal-based or synthetic tissue products. If approved as a therapy for restrictive burn scars, vocal scarring or acne scarring, our product candidates would or may compete with synthetic, human or animal derived cell or tissue products marketed by companies larger and better capitalized than us.

The market for skincare products is competitive with low barriers to entry.

Research and Development

We expense research and development costs as they are incurred. For the years ended December 31, 2012 and 2011, we incurred research and development expenses of $9.0 million and $7.2 million, respectively.

Government Regulation

Our Fibrocell Therapy technologies 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.

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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 will 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/Ps), 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 does 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) 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, or NDA, for a drug, or a Biologics License Application, or 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.

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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.

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, or 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 both parties, or 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, or 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. On February 17, 2009, the U.S. Small Business Administration issued a letter formally determining that we were a small business and therefore qualified for the Small Business Exception to the Prescription Drug and User fee Act of 1992 (21 USC § 379h(b)(2))related to our BLA submission for the nasolabial fold wrinkles indication. For fiscal year 2009, this fee was $1,247,200 for companies that did not receive an exception. The FDA also advised us that it was regulating our Fibrocell Therapy as a biologic. Therefore, we expect to submit BLAs to obtain 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 45 to 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 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, or REMS, or by changes to the application submitted by the applicant in the form of amendments.

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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 do 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 are 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 impose 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 is 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 test 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, if deemed necessary to manage a known or potential serious risk associated with the product. REMS can include additional educational materials for healthcare professionals and patients such as Medication Guides and Patient Package Inserts, a plan for communicating information to healthcare professionals, and restricted distribution of the product. In addition, the FDA may, in some circumstances, impose restrictions on the use of the product, which may be difficult and expensive to administer and may require prior approval of promotional materials. Following approval, FDA may require labeling changes or impose new post-approval study, risk management, or distribution restriction requirements.

Ongoing FDA Requirements

Before approving an NDA or BLA, the FDA usually will inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facilities are in compliance with the FDA s current Good Manufacturing Practices, or 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.

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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, standards and regulations for direct-to-consumer advertising, industry sponsored scientific and educational activities, and promotional activities involving the internet. In general, all product promotion must be consistent with the FDA approval for such product, contain a balanced presentation of information on the product s uses and benefits and important safety information and limitations on use, and otherwise not be false or misleading. The FDA and 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.

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 known serious risks or signals of serious risks or 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.

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, revocation or 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.

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HIPAA Requirements

Other federal legislation may affect our ability to obtain certain health information in conjunction with our research activities. The Health Insurance Portability and Accountability Act of 1996, or HIPAA, mandates, among other things, the adoption of standards designed to safeguard the privacy and security of individually identifiable health information. In relevant part, the U.S. Department of Health and Human Services, or HHS, has released two rules to date mandating the use of new standards with respect to such health information. The first rule imposes new standards relating to the privacy of individually identifiable health information. These standards restrict the manner and circumstances under which covered entities may use and disclose protected health information so as to protect the privacy of that information. The second rule released by HHS establishes minimum standards for the security of electronic health information. While we do not believe we are directly regulated as a covered entity under HIPAA, the HIPAA standards impose requirements on covered entities conducting research activities regarding the use and disclosure of individually identifiable health information collected in the course of conducting the research. As a result, unless they meet these HIPAA requirements, covered entities conducting clinical trials for us may not be able to share with us any results from clinical trials that include such health information.

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. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans 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, unfair competition, and other laws.

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 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 25, 2013, we employed 71 people on a full-time basis all located in the United States, and one employee, our Chief Operating and Chief Financial Officer, who is based in Ireland and works in both Ireland and the United States. We also have 4 people working on a contract basis in our manufacturing facility. 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.

Segment Information

The Company previously marketed a skin care line through its consolidated subsidiary, Agera, which was sold on August 31, 2012. The Company owned 57% of the outstanding shares of Agera. As a result of the sale of Agera, the Company operates in one segment and Agera is classified as discontinued operations.

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Corporate History

On August 10, 2001, our company, then known as American Financial Holding, Inc., acquired Isolagen Technologies through the merger of our 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 our wholly owned subsidiary. On November 13, 2001, we changed our name 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.

Unlike our Phase III nasolabial fold wrinkles trial, our Phase II acne scar trial was not subject to a SPA with the FDA. In addition, we have developed a photo guide for use in the evaluators assessment of acne study subjects. Our evaluator assessment scale and photo guide have not been previously used in a clinical trial. To obtain FDA approval with respect to the acne scar indication, we will require FDA concurrence with the use of our evaluator assessment scale and photo guide. Our Phase II restrictive burn scar trial that we expect to commence in the second quarter of 2013 is also not subject to a SPA with the FDA.

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 and the marketing and manufacturing of our product candidates are subject to rigorous testing procedures.

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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 and other clinical trial managers, to satisfy their contractual duties, comply with regulations or meet expected deadlines;
- lack of efficacy during clinical trials; or
- unforeseen safety issues.

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

We utilize bovine-sourced materials to manufacture LAVIV and our product candidates. Future FDA regulations, as well as currently proposed 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.

Even if marketing approval from the FDA is received for one or more of our product candidates, the FDA may impose post-marketing requirements, such as:

- labeling and advertising requirements, restrictions or limitations, including the inclusion of warnings, precautions, contra-indications 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 to conduct a post-marketing study of approximately 2,700 patients, which has not yet commenced.

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In order to increase our revenue from the sale of LAVIV, we will need to increase our manufacturing capacity, which will require significant expenditures and regulatory approval.

We currently have limited manufacturing capacity. To increase our revenue from the sale of LAVIV, we will need to add manufacturing capacity, which may require us to develop enhancements and alternatives to our current manufacturing process. Even if we are successful in developing such enhancements or finding alternatives to our current process, increasing manufacturing capacity will require additional expenditures, for which we may require external financing. In addition, our ability to increase manufacturing capacity will be subject to additional FDA review.

We intend to implement a significant price increase for LAVIV during the second quarter of 2013, and there is no assurance that the demand for LAVIV will not be materially reduced by such price increase.

During the introductory phase for LAVIV, we have been selling LAVIV at a significant loss and we are going to significantly increase its selling price commencing on May 1, 2013. The new price will be $12,000 to the physician for the full treatment. We can provide no assurance that the demand for LAVIV will not be adversely affected by such price increase. To the extent demand is adversely affected by the price increase, we will not be in a position to reduce the price of LAVIV unless, and until, we are able to lower our manufacturing costs sufficiently to allow us to sell LAVIV at positive gross margins.

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;

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compliance with regulatory requirements;

inclement weather and natural disasters;

changes in forecasts of future demand for product components;

timing and actual number of production runs for product components;

potential facility contamination by microorganisms or viruses;

updating of manufacturing specifications; and

product quality success rates and yields.

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

Our manufacturing processes and those of our suppliers must undergo a potentially lengthy FDA approval process, as well as other regulatory approval processes, and are subject to continued review by the FDA and other regulatory authorities. It is a multi-year process to build and license a new manufacturing facility and it can take significant time to qualify and license a new supplier. In order to maintain supply, mitigate risks and to satisfy anticipated demand for LAVIV, as well as for our clinical trials, we must successfully implement manufacturing projects on schedule, since we currently do not have sufficient manufacturing capacity to supply LAVIV if orders for LAVIV significantly increase.

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 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.

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 cellular 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 will be increasing the price we charge for LAVIV significantly commencing in the second quarter of 2013, which may reduce demand for LAVIV.

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We rely on a scheduling and product tracking system.

We have developed a tracking system for the intake of physician orders for LAVIV, to track product delivery, and to store patient-related data we obtain for purposes of manufacturing LAVIV. We rely on this system in order to maintain the chain of identity for each patient-specific dose of LAVIV, and to ensure timely delivery of product prior to expiration. If our system was to fail or be compromised, we could lose traceability of patient cells potentially resulting in loss of revenue and our reputation could suffer. A loss of traceability could cause our business to be materially harmed and our results of operations would be adversely impacted.

Our business, including conducting our clinical trials, depends on one facility, which is vulnerable to natural disasters, telecommunication and information systems failures, terrorism and similar problems, and we are not fully insured for losses caused by all of these incidents.

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 for the U.S. market takes place at a single U.S. facility. If regulatory, manufacturing or other problems require us to discontinue production at that facility, we will not be able to supply our product or supply our clinical trials, which would adversely impact our business.

Our Exton facility could be damaged by fire, floods, power loss, telecommunication and information systems failures or similar events. Our insurance policies have limited coverage levels for loss or damages in these events and may not adequately compensate us for any losses that may occur. In addition, terrorist acts or acts of war may cause harm to our employees or damage our Exton facility. The potential for future terrorist attacks, the national and international responses to terrorist attacks or perceived threats to national security, and other acts of war or hostility have created many economic and political uncertainties that could adversely affect our business and results of operations in ways that we cannot predict, and could cause our stock price to fluctuate or decline. We are uninsured for these types of losses.

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 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 more than $1 million in annual 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.

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

- FDA clinical trials and regulatory approvals;
- Other studies such as our facial cream and our study in mild to moderate acne scars;
- Our investigation of the automation of manufacturing;
- 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 commercializing our LAVIV product and conducting clinical trials. 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 commercializing our LAVIV product and of our clinical trials, 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 and revenues difficult to forecast accurately. We may be unable to adjust our operations in a timely manner to compensate for any unexpected increase in costs or shortfall in revenue. 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 or shortfall in revenue 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 level of demand and profitability of LAVIV;

the timing, implementation and cost of our clinical studies;

expenses in connection with our exclusive channel collaboration arrangement with Intrexon;

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;

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the amount and timing of expenditures by practitioners and their patients;

introduction of new technologies;

product liability litigation, class action and derivative action litigation, or other litigation;

the amount and timing of capital expenditures and other costs relating to the expansion of our operations;

the state of the debt and/or equity markets at the time of any proposed offering we choose to initiate;

our ability to successfully integrate new acquisitions into our operations;

government regulation and legal developments regarding LAVIV and our product candidates in the United States and in the foreign countries in which we may operate in the future; and

general economic conditions.

As a strategic response to changes in the competitive environment, we may from time to time make pricing, service, technology or marketing decisions or business or technology acquisitions that could have a material adverse effect on our operating results. Due to any of these factors, our operating results may fall below the expectations of securities analysts, stockholders and investors in any future period, which may cause our stock price to decline.

We 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 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;

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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.

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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.

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, marketing and production capabilities and greater financial resources than we do. 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.

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If we are unable to adequately protect our intellectual property and proprietary technology, the value of our technology and future products will be adversely affected, and if we are unable to enforce our intellectual property against unauthorized use by third parties our business may be materially harmed.

Our long-term success largely depends on our future ability to market technologically competitive products. Our ability to achieve commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our technology and future products, as well as successfully defending these patents against third party challenges. In order to do so we must:

- obtain and protect commercially valuable patents or the rights to patents both domestically and abroad;
- operate without infringing upon the proprietary rights of others; and
- prevent others from successfully challenging or infringing our proprietary rights.

As of December 31, 2012, we had 11 issued U.S. patents, 8 pending U.S. patent applications, 28 granted foreign patents and 9 pending international patent applications. However, we may not be able to obtain additional patents relating to our technology or otherwise protect our proprietary rights. If we fail to obtain or maintain patents from our pending and future applications, we may not be able to prevent third parties from using our proprietary technology. We will be able to protect our proprietary rights from unauthorized use only to the extent that these rights are covered by valid and enforceable patents that we control or are effectively maintained by us as trade secrets. Furthermore, the degree of future protection of our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep a competitive advantage.

The patent situation of companies in the markets in which we compete is highly uncertain and involves complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies patents has emerged to date in the United States. The laws of other countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in 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 biotechnology and/or pharmaceuticals, which could make it difficult for us to stop the infringement of our patents in foreign countries in which we hold patents. Proceedings to enforce our patent rights in the United States or in foreign jurisdictions would likely result in substantial cost and divert our efforts and attention from other aspects of our business. Changes in either the patent laws or in interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

Other risks and uncertainties that we face with respect to our patents and other proprietary rights include the following:

- the inventors of the inventions covered by each of our pending patent applications might not have been the first to make such inventions;
- we might not have been the first to file patent applications for these inventions or similar technology;
- the future and pending applications we will file or have filed, or to which we will or do have exclusive rights, may not result in issued patents or may take longer than we expect to result in issued patents;
- the claims of any patents that are issued may not provide meaningful protection;

our issued patents may not provide a basis for commercially viable products or may not be valid or enforceable;

we might not be able to develop additional proprietary technologies that are patentable;

the patents licensed or issued to us may not provide a competitive advantage;

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patents issued to other companies, universities or research institutions may harm our ability to do business;

other individual companies, universities or research institutions may independently develop or have developed similar or alternative technologies or duplicate our technologies and commercialize discoveries that we attempt to patent;

other companies, universities or research institutions may design around technologies we have licensed, patented or developed; and

many of our patent claims are method, rather than composition of matter, claims; generally composition of matter claims are easier to enforce and are more difficult to circumvent.

Our business may be harmed and we may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

A third party may assert that we, one of our subsidiaries or one of our strategic collaborators has infringed his, her or its patents and proprietary rights or challenge the validity or enforceability of our patents and proprietary rights. Likewise, we may need to resort to litigation to enforce our patent rights or to determine the scope and validity of a third party s proprietary rights.

We cannot be sure that other parties have not filed for or obtained relevant patents that could affect our ability to obtain patents or operate our business. Even if we have previously filed patent applications or obtain issued patents, others may file their own patent applications for our inventions and technology, or improvements to our inventions and technology. We have become aware of published patent applications filed after the issuance of our patents that, should the owners pursue and obtain patent claims to our inventions and technology could require us to challenge such patent claims. Others may challenge our patent or other intellectual property rights or sue us for infringement. In all such cases, we may commence legal proceedings to resolve our patent or other intellectual property disputes or defend against charges of infringement or misappropriation. An adverse determination in any litigation or administrative proceeding to which we may become a party could subject us to significant liabilities, result in our patents being deemed invalid, unenforceable or revoked, or drawn into an interference, require us to license disputed rights from others, if available, or to cease using the disputed technology. 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.

The outcome of these proceedings is uncertain and could significantly harm our business. If we do not prevail in this type of litigation, we or our strategic collaborators may be required to:

pay monetary damages;

expend time and funding to redesign our Fibrocell Therapy so that it does not infringe others patents while still allowing us to compete in the market with a substantially similar product;

obtain a license, if possible, in order to continue manufacturing or marketing the affected products or services, and pay license fees and royalties, which may be non-exclusive. This license may be non-exclusive, giving our competitors access to the same intellectual property, or the patent owner may require that we grant a cross-license to our patented technology; or

stop research and commercial activities relating to the affected products or services if a license is not available on acceptable terms, if at all.

Any of these events could materially adversely affect our business strategy and the value of our business.

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In addition, the defense and prosecution of intellectual property suits, interferences, oppositions and related legal and administrative proceedings in the United States and elsewhere, even if resolved in our favor, could be expensive and time consuming and could divert financial and managerial resources. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater financial resources.

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 March 25, 2013, there were 655,747,608 shares of common stock issued and outstanding. As of April 9, 2013, all of our outstanding shares will be freely transferable without restriction or further registration under the Securities Act. In addition to our common stock outstanding, as of such date, we had warrants outstanding that were exercisable for a total of 153,299,031 shares of common stock.

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There is a limited, volatile and sporadic public trading market for our common stock.

There is a limited, volatile and sporadic public trading market for our common stock. Without an active trading market, there can be no assurance of any liquidity or resale value of our common stock, and stockholders may be required to hold shares of our common stock for an indefinite period of time.

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 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 development activities of our products candidates.

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

Currently, our directors, executive officers, and principal stockholder beneficially own approximately 233.6 million shares of our common stock as of March 25, 2013. In addition, two of our seven directors are affiliates of our principal stockholder. As a result, our directors, officers and principal stockholder 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 anytime 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 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 additional personnel and expect to add additional personnel 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 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 have identified a material weakness in our internal control over financial reporting which could, if not remediated, result in material misstatements in our financial statements.

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. We are actively engaged in developing a remediation plan designed to address 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.

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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 has traded on the OTCBB since October 21, 2009 under the symbol FCSC. Currently, there is only a limited, sporadic and volatile market for our stock on the OTCBB. The following table sets forth, for the period indicated, the high and low sales prices of our common stock on the OTCBB. These prices represent prices between inter-dealer prices, without retail markup, markdown, or commission, and may not represent actual transactions.

	High	Low
Year Ended December 31, 2012		
First Quarter	$ 0.48	$ 0.37
Second Quarter	$ 0.37	$ 0.15
Third Quarter	$ 0.25	$ 0.14
Fourth Quarter	$ 0.23	$ 0.14
Year Ended December 31, 2011		
First Quarter	$ 0.90	$ 0.52
Second Quarter	$ 1.36	$ 0.72
Third Quarter	$ 0.86	$ 0.45
Fourth Quarter	$ 0.56	$ 0.39

The closing price of our common stock on March 25, 2013 was $0.15 as reported on the OTCBB.

Holders of Record

As of March 25, 2013, there were 655,747,608 shares of our common stock outstanding and held by 454 stockholders of record. As of March 25, 2013, we had no shares of preferred stock outstanding.

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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. Cash payments for Series D and Series E preferred stock dividends were approximately $0.5 million for 2012. Cash payments for Series A, Series B and Series D preferred stock dividends were approximately $0.6 million for 2011.

Penny Stock

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Our stock is currently a penny stock. Penny stocks are generally equity securities with a price of less than $5.00, other than securities registered on certain national securities exchanges. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from those rules, deliver a standardized risk disclosure document prepared by the SEC, which: (a) contains a description of the nature and level of risk in the market for penny stocks in both public offerings and secondary trading; (b) contains a description of the broker s or dealer s duties to the customer and of the rights and remedies available to the customer with respect to a violation to such duties or other requirements of securities laws; (c) contains a brief, clear, narrative description of a dealer market, including bid and ask prices for penny stocks and significance of the spread between the bid and ask price; (d) contains a toll-free telephone number for inquiries on disciplinary actions; (e) defines significant terms in the disclosure document or in the conduct of trading in penny stocks; and (f) contains such other information and is in such form as the SEC shall require by rule or regulation. The broker-dealer also must provide to the customer, prior to effecting any transaction in a penny stock, (a) bid and offer quotations for the penny stock; (b) the compensation of the broker-dealer and its salesperson in the transaction; (c) the number of shares to which such bid and ask prices apply, or other comparable information relating to the depth and liquidity of the market for such stock; and (d) monthly account statements showing the market value of each penny stock held in the customer s account. In addition, the penny stock rules require that prior to a transaction in a penny stock not otherwise exempt from those rules, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser s written acknowledgment of the receipt of a risk disclosure statement, a written agreement to transactions involving penny stocks, and a signed and dated copy of a written suitably statement.

These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our stock if it becomes subject to these penny stock rules.

Recent Sales of Unregistered Securities

All information regarding our issuance of unregistered securities during 2012 have been previously disclosed in current reports we have filed on Form 8-K.

Purchases of Equity Securities.

We did not repurchase any of our equity securities during the twelve months ended 2012.

Item 6. Selected Financial Data

We are a smaller reporting company, and are not required to report this information.

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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 cellular therapeutic company focused on the development of innovative products for aesthetic, medical and scientific applications.

We believe that we are well positioned in regenerative medicine and cell based therapies because we have a pipeline of clinical medical programs and the first Food and Drug Administration (FDA) approved cell based product, LAVIV (United States adopted name, or USAN, is azficel-T), in aesthetics, all of which are based on the autologous fibroblast cell. Given our limited resources, both financial and manufacturing, we intend to focus on clinical programs to treat medical conditions that have an unmet need. In particular, we will focus on restrictive burn scars, vocal cord scars, acne scars and potentially rare collagen deficient conditions such as recessive dystrophic epidermolysis bullosa. We believe that there is an unmet medical need and limited competition in these markets and we can obtain greater value per fibroblast cell through significantly higher prices than currently obtained in the aesthetics market. With respect to the aesthetics market, our introductory pricing is over and we are raising LAVIV s price significantly in the second quarter of 2013.

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 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 the Company s 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.

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

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Warrant Liability: We account for our warrants in accordance with U.S. GAAP. The warrants are measured at fair value and liability-classified under Accounting Standards Codification (ASC) 815, Derivatives and Hedging, (ASC 815) because certain of the 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 the Company s own stock which is a requirement for the scope exception as outlined under ASC 815. Effective December 31, 2011, 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.

Preferred Stock and Derivative Liability: The preferred stock has been classified within the mezzanine section between liabilities and equity in its consolidated balance sheets in accordance with ASC 480, Distinguishing Liabilities from Equity (ASC 480) because, prior to the conversion of the preferred stock into common stock in October 2012, any holder of Series D or E Preferred could have required the Company to redeem all of its Series D or E Preferred in the event of a triggering event which was outside of the control of the Company.

The embedded conversion option for the Series D Preferred has been recorded as a derivative liability under ASC 815 in the Company s consolidated balance sheet as of December 31, 2011, and was re-measured on the Company s reporting dates until all the preferred stock was converted into common stock in October 2012. The fair value of the derivative liability is determined using the Black-Scholes option pricing model and is affected by changes in inputs to that model including our stock price, expected stock price volatility, the contractual term, and the risk-free interest rate.

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, the Company accounts for stock-based compensation to nonemployees in accordance with the accounting guidance for equity instruments that are issued to other than employees. 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 the Company and our peer company s stock. 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.

Revenue Recognition: The Company recognizes revenue over the period LAVIV is shipped for injection in accordance with ASC 605, Revenue Recognition (ASC 605). In general, ASC 605 requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services rendered, (3) the fee is fixed and determinable and (4) collectability is reasonably assured.

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.

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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 10-K.

Results of Operations

Comparison of Years Ending December 31, 2012 and 2011

Revenue and Cost of Sales. Revenue and cost of sales for the years ended December 31, 2012 and 2011 were comprised of the following:

	Year ended December 31,		Increase (Decrease)	
	2012	2011	$000s	%
	(in thousands)			
Total revenue	$ 153	$	$ 153	
Cost of sales	8,355	13	8,342	64169%
Gross profit	$ (8,202)	$ (13)	$ (8,189)	62992%

Revenue was $0.2 million for the year ended December 31, 2012. Revenue is booked based on the shipment of cells to the patients for injection of LAVIV. We recorded no revenue in the year ended December 31, 2011 as no injections for paying customers had been shipped.

Cost of sales was $8.4 million for the year ended December 31, 2012. 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, 2012 was comprised of $3.8 million of compensation related expenses, $3.2 million of laboratory supplies and other related expenses and $1.4 million of rent, utilities, depreciation and amortization. The principal reasons for the relatively small level of revenue as compared to the large cost of sales are: (1) Timing costs are incurred starting with receipt of a patient s biopsy. Revenue is not recognized until at least three months after receipt of the biopsy, when injections are made ready for shipment to the patient s physician. Injections normally occur four weeks apart so the revenue cycle can be up to nine months or more (three injection sessions); (2) Manufacturing capacity our current manufacturing capacity is no more than twenty biopsies a week; (3) Charging for biopsies and injections we offered complimentary and reduced price biopsies and injections in our introductory period, and (4) Manufacturing complexity and quality control and assurance criteria. We are planning to implement a significant price increase for LAVIV on May 1, 2013. The new price will be $12,000 to the physician for the full treatment.

Selling, General and Administrative Expense. Selling, general and administrative expense for the year ended December 31, 2012 and 2011 was comprised of the following:

	Year Ended December 31,		Increase (Decrease)	
	2012	2011	$000s	%
	(in thousands)			
Compensation and related expense	$ 4,336	$ 4,506	$ (170)	(4)%
External services consulting	914	691	223	32%
Marketing expense	2,203	3,809	(1,606)	(42)%
License fees	664	803	(139)	(17)%
Facilities and related expense and other	4,050	2,986	1,064	36%
Total selling, general and administrative expense	$ 12,167	$ 12,795	$ (628)	(5)%

Selling, general and administrative expenses decreased by approximately $0.6 million, or 5%, to $12.2 million for the year ended December 31, 2012 as compared to $12.8 million for the year ended December 31, 2011. The decrease consists primarily of a reduction in marketing expenses

of $1.6 million due to significant pre-launch costs occurring in year 2011. Facilities and related expense and other increased as travel increased $0.4 million, corporate expense increased $0.2 million as a result of costs associated with the completion of multiple stock offerings during 2012, office and office related expenses $0.4 million as a result of increased headcount and more biopsy throughput.

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Research and Development Expense. Research and development expense for the year ended December 31, 2012 and 2011 was comprised of the following:

	Year Ended December 31,		Increase (Decrease)	
	2012	2011	$000s	%
	(in thousands)			
Compensation and related expense	$ 314	$ 2,108	$ (1,794)	(85)%
External services consulting	8,526	1,927	6,599	342%
Lab costs and related expense	170	1,620	(1,450)	(90)%
Facilities and related expense	11	1,516	(1,505)	(99)%
Total research and development expense	$ 9,021	$ 7,171	$ 1,850	25%

Research and Development expense increased $1.9 million to $9.0 million for the year ended December 31, 2012 as compared to $7.2 million for the year ended December 31, 2011. The increase is due primarily to a $6.9 million non-cash charge that was included in external services consulting related to the recording of the fair value of 32,938,000 shares of common stock valued at $0.21 per share issued to Intrexon as consideration for the Exclusive Channel Collaboration Agreement, offset by the classification of costs associated with the production of LAVIV in the year ended December 31, 2012, recorded in cost of goods sold in the consolidated statement of operations.

Research and development costs incurred in the year ended December 31, 2012 were related to other potential indications for our Fibrocell Therapy, such as acne scars and burn scars as well as costs to develop manufacturing, cell collection and logistical process improvements. Research and development costs incurred in the year ended December 31, 2011 included costs to bring LAVIV to market.

Interest expense. Interest expense remained relatively constant at approximately $1.1 million for the years ended December 31, 2012 and 2011. Our interest expense for the years ended December 31, 2012 and 2011 is related to our 12.5% notes. The 12.5% notes were either paid or converted into common stock with the close of the October 2012 financing.

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 (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, 2012 and 2011, we recorded non-cash income of $8.7 million and non-cash expense of $4.8 million for warrant expense in our statements of operations due to an increase in the fair value of the warrant liability as a result of a change in the contractual life of the warrants. In addition, the number of shares underlying the warrants increased in 2012 due to the issuance of our Series E preferred stock, which triggered the anti-dilution protection in the warrants resulting in the lowering of the exercise price of the warrants and the increase in the number of shares underlying such warrants.

Change in Revaluation of Derivative Liability. During the years ended December 31, 2012 and 2011, we recorded non-cash expense of less than $0.1 million and $5.5 million, respectively, 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, the preferred stock was converted to common stock and the related derivative liability was reclassified to shareholders deficit as it no longer required liability classification.

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Loss from Discontinued Operations. The net loss from discontinued operations for the year ended December 31, 2012 remained relatively constant to the net loss from discontinued operations for the year ended December 31, 2011.

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.

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 decreased $8.2 million to $23.2 million for the year ended December 31, 2012, as compared to $31.4 million for the year ended December 31, 2011, primarily due to the issuance of additional warrants and to the change in the fair value of the warrant liability and derivative liability related to the Series A, B, D and E preferred stock financings.

Liquidity and Capital Resources

We have experienced losses since our inception. As of December 31, 2012, we have an accumulated deficit of $72.1 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 for the two years ended December 31, 2012 and 2011:

	Year Ended December 31,	
	2012	2011
	(in thousands)	
Statement of Cash Flows Data:		
Total cash provided by (used in):		
Operating activities	$ (22,575)	$ (16,837)
Investing activities	509	(1,570)
Financing activities	42,613	28,336

Operating Activities. Cash used in operating activities during the year ended December 31, 2012 amounted to $22.6 million, an increase of $5.7 million over the year ended December 31, 2011. The increase in our cash used in operating activities over the prior year is primarily due to an increase in net losses (adjusted for non-cash items) of $3.2 million, in addition to operating cash outflows from changes in operating assets and liabilities.

Investing Activities. Cash used in investing activities during the year ended December 31, 2012 amounted to $0.5 million due to the purchase of property and equipment for the laboratory facility in Exton, Pennsylvania.

Financing Activities. There was $42.6 million cash proceeds received from financing activities during the year ended December 31, 2012, as compared to $28.3 million received from financing activities during the year ended December 31, 2011. During the years ended December 31, 2012 and 2011, we raised cash of $52.1 million and $30.4 million, respectively, from the issuance of common stock, preferred stock and warrants, offset primarily by principal debt payments of $4.8 and $1.3 million in 2012 and 2011, respectively, and dividend payments of $0.5 million and $0.6 million in 2012 and 2011, respectively. Of the $52.1 million received in 2012, we received $43.0 million in gross proceeds from the October 2012 offering with $2.0 million in subscribed proceeds still outstanding from a single foreign investor. The remaining $9.1 million was received during May, June and July 2012 when we sold to accredited investors in a private placement Series E Convertible Preferred Stock.

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Working Capital

As of December 31, 2012, we had cash and cash equivalents of $31.3 million and working capital of $31.6 million. We expect to have sufficient cash to operate for at least the next twelve months. However, we may require additional financing to complete the burn scars and vocal scars clinical trials we intend to commence in 2013. 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, 2012 or 2011.

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, 2012 (in thousands):

		Payments due by period			
Contractual Obligations	**Total**	**2013**	**2014 and 2015**	**2016 and 2017**	**2018 and thereafter**
License fee obligations[(1)]	$ 1,395	$ 520	$ 795	$ 40	$ 40
Operating lease obligations[(2)]	$ 13,321	$ 1,070	$ 2,292	$ 2,508	$ 7,451
Total	$ 14,716	$ 1,590	$ 3,087	$ 2,548	$ 7,491

(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 at 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 renewed 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.

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, 2012, we had cash and cash equivalents $31.3 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.

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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

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, 2012, the officers (the principal executive officer and principal financial officer) concluded that our disclosure controls and procedures were ineffective due to the treatment for the deferred tax liability relating to an intangible asset arising out of bankruptcy as discussed in more detail below. See Material Weakness.

Management s Report on Internal Control over Financial Reporting, including Remediation of Material Weakness

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 *Internal Control Integrated Framework* 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 *Internal Control Integrated Framework*, management concluded that our internal control over financial reporting was ineffective as of December 31, 2012 due to the accounting for the deferred tax liability as discussed in more detail below. This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. As the Company is a smaller reporting company, management s report is not subject to attestation by our registered public accounting firm pursuant to Section 404(c) of the Sarbanes-Oxley Act of 2002 that permits us to provide only management s report in this annual report.

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Changes in Internal Controls

Except as discussed below, there was no change in our internal control over financial reporting that occurred during the fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Material Weakness

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 constitutes a material deficiency 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.

Remediation

As noted above, a material weakness with respect to the accounting for the deferred tax liability associated with the intangible asset was identified at December 31, 2012 in our 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, we will reconsider the appropriate selection of our external advisors that we utilize in the future.

Item 9B. Other Information

None.

Part III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item 10 will be included in our Proxy Statement for the 2012 Annual Meeting of Stockholders which will be filed with the Securities and Exchange Commission no later than 120 days after the close of our fiscal year ended December 31, 2012, and is incorporated into this Item 10 by reference.

Code of Ethics. We have adopted a written code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller and any persons performing similar functions. The code of ethics is on our website at www.fibrocellscience.com.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, 2012.

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, 2012.

Equity Compensation Plan Information

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	13,450,625	$ 0.74	16,349,375
Equity compensation plans not approved by security holders	600,000(1)	$ 0.75	
Total	14,050,625	$ 0.74	16,349,375

(1) Consists of 600,000 shares underlying options issued to consultants outside of the 2009 Equity Incentive Plan, which have an exercise price of $0.75 per share.

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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, 2012.

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, 2012.

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, 2012 and 2011

Consolidated Statements of Operations for the years ended December 31, 2012 and 2011

Consolidated Statements of Shareholders Deficit and Comprehensive Income (Loss)

Consolidated Statements of Cash Flows for the years ended December 31, 2012 and 2011

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.

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

EXHIBIT NO. IDENTIFICATION OF EXHIBIT

EXHIBIT NO.	IDENTIFICATION OF EXHIBIT
2.1	Debtors First Amended Joint Plan of Reorganization dated July 30, 2009 and Disclosure Statement (filed 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	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	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	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	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)
4.11	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)
**10.2	Amended and Restated Employment Agreement between the Company and Declan Daly dated August 24, 2010 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed August 27, 2010)
**10.3	2009 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to our Form 10-Q filed November 14, 2012)
10.4	Lease Agreement between Isolagen, Inc and The Hankin Group dated April 7, 2005(previously filed as an exhibit to the company s Form 8-K, filed on April 12, 2005)
10.5	Purchase Option Agreement between Isolagen, Inc and 405 Eagleview Associates dated April 7, 2005 (previously filed as an exhibit to the company s Form 8-K, filed on April 12, 2005)
10.6	Intellectual Property Purchase Agreement between Isolagen Technologies, Inc., Gregory M. Keller, and PacGen Partners (previously filed as an exhibit to the company s amended Form S-1, as filed on October 24, 2003)
**10.7	

	Employment Agreement between the Company and David Pernock (incorporated by reference to Exhibit 10.1 to our Form 8-K filed February 1, 2010)
10.8	Securities Purchase Agreement dated March 2, 2010 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed March 3, 2010)
10.9	Registration Rights Agreement dated March 2, 2010 (incorporated by reference to Exhibit 10.2 to our Form 8-K filed March 3, 2010)
10.10	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)

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10.11	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)
10.12	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)
10.13	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).
10.14	Securities Purchase Agreement dated August 3, 2011 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed August 4, 2011)
10.15	Registration Rights Agreement dated August 3, 2011 (incorporated by reference to Exhibit 10.2 to our Form 8-K filed August 4, 2011)
10.16	Amendment to Lease Agreement between Fibrocell Science, Inc. and The Hankin Group dated February 17, 2012 (previously filed as an exhibit to the company s Annual Report on Form 10-K for the fiscal year ended December 31, 2011)
10.17	Securities Purchase Agreement dated October 5, 2012 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed October 9, 2012)
10.18	Registration Rights Agreement dated October 5, 2012 (incorporated by reference to Exhibit 10.2 to our Form 8-K filed October 5, 2012)
10.19	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)
10.20	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)
*10.21	Exclusive Channel Collaboration Agreement between Intrexon Corporation and Fibrocell Science, Inc.(1)
*21	List of Subsidiaries
*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.(2)
101.SCH	XBRL Taxonomy Extension Schema Document.(2)
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.(2)
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.(2)
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.(2)
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.(2)

* Filed herewith.

** Indicates management contract or compensatory plan or arrangement.

(1) Confidential portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

(2) 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: April 1, 2013

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)	April 1, 2013
/s/ Declan Daly Declan Daly	Chief Financial Officer and Chief Operating Officer (Principal Financial and Accounting Officer)	April 1, 2013
/s/ Kelvin Moore Kelvin Moore	Director	April 1, 2013
/s/ Marc Mazur Marc Mazur	Director	April 1, 2013
/s/ Julian Kirk Julian Kirk	Director	April 1, 2013
/s/ Marcus Smith Marcus Smith	Director	April 1, 2013
/s/ Christine St. Clare Christine St. Clare	Director	April 1, 2013
/s/ Douglas J. Swirsky Douglas J. Swirsky	Director	April 1, 2013

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Fibrocell Science, Inc.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Fibrocell Science, Inc.

Exton, Pennsylvania

We have audited the accompanying consolidated balance sheets of Fibrocell Science, Inc. as of December 31, 2012 and 2011 and the related consolidated statements of operations, shareholders equity (deficit) and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Fibrocell Science, Inc. at December 31, 2012 and 2011, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO USA, LLP

Houston, Texas

April 1, 2013

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Fibrocell Science, Inc.

Consolidated Balance Sheets

(amounts in thousands except per share and share data)

	December 31, 2012	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 31,346	$ 10,799
Accounts receivable, net of allowance for doubtful accounts of $25 and $0, respectively	62	27
Inventory, net	477	
Prepaid expenses and other current assets	1,271	1,175
Other current assets of discontinued operations		498
Total current assets	33,156	12,499
Property and equipment, net of accumulated depreciation of $434 and $166, respectively	1,658	1,434
Intangible assets and other assets, net	5,789	6,341
Total assets	$ 40,603	$ 20,274
Liabilities, Redeemable Preferred Stock, Shareholders Equity (Deficit) and Noncontrolling Interest		
Current liabilities:		
Current debt	$	$ 6,731
Accounts payable	921	1,887
Accrued expenses	494	918
Deferred revenue	139	56
Current liabilities of discontinued operations		20
Total current liabilities	1,554	9,612
Deferred tax liability		2,500
Warrant liability	374	13,087
Derivative liability		534
Other long-term liabilities	344	142
Total liabilities	2,272	25,875
Commitments		
Preferred stock series A, $0.001 par value; 9,000 shares authorized; 3,250 shares issued; 0 and 0 shares outstanding, respectively		
Preferred stock series B, $0.001 par value; 9,000 shares authorized; 4,640 shares issued; 0 and 0 shares outstanding, respectively		
Preferred stock series D, $0.001 par value; 8,000 shares authorized; 7,779 shares issued, and 0 and 3,641 shares outstanding, respectively		
Preferred stock series E, $0.001 par value; 12,000 and 0 shares authorized, respectively; 9,141 and 0 shares issued, respectively, and 0 and 0 shares outstanding, respectively		
Shareholders equity (deficit):		
Common stock, $0.001 par value; 1,100,000,000 shares authorized; 655,747,608 and 95,678,255 issued and outstanding, respectively	656	96
Common stock-subscription receivable	(2,004)	(550)
Additional paid-in capital	111,754	43,734
Accumulated deficit	(72,075)	(49,349)

Total Fibrocell Science, Inc. shareholders equity (deficit)	38,331	(6,069)
Noncontrolling interest		468
Total equity (deficit) and noncontrolling interest	38,331	(5,601)
Total liabilities, preferred stock, shareholders equity (deficit) and noncontrolling interest	$ 40,603	$ 20,274

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

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Fibrocell Science, Inc.

Consolidated Statements of Operations

(amounts in thousands except per share and share data)

	For the year ended December 31, 2012	For the year ended December 31, 2011
Revenue from product sales	$ 153	$
Cost of sales	8,355	13
Gross loss	(8,202)	(13)
Selling, general and administrative expenses	12,167	12,795
Research and development expenses	9,021	7,171
Operating loss	(29,390)	(19,979)
Other income (expense)		
Warrant revaluation income (expense)	8,725	(4,763)
Derivative revaluation expense	(23)	(5,451)
Interest expense	(1,017)	(1,062)
Loss on extinguishment of debt	(4,421)	
Loss from continuing operations before income taxes	(26,126)	(31,255)
Deferred tax benefit	2,500	
Loss from continuing operations	(23,626)	(31,255)
Loss from discontinued operations	(11)	(95)
Gain on sale of discontinued operations, net of tax	467	
Net loss	(23,170)	(31,350)
Net income attributable to noncontrolling interest	(24)	(18)
Net loss attributable to Fibrocell Science, Inc. common shareholders	$ (23,194)	$ (31,368)
Per share information:		
Loss from continuing operations-basic and diluted	$ (0.10)	$ (0.57)
Loss from discontinued operations-basic and diluted		
Net loss per common share basic and diluted	$ (0.10)	$ (0.57)
Weighted average number of basic and diluted common shares outstanding	224,127,430	54,857,520

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

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Fibrocell Science, Inc.

Consolidated Statements of Shareholders Equity (Deficit)

(Amounts in thousands except share data)

	Common stock		Subscription	Additional	Deficit	Noncontrolling	Total Equity
	Shares	Amount	Receivable	paid-in capital	accumulated	Interest	(Deficit)
Balance, December 31, 2010	20,375,498	$ 20	$	$ 2,438	$ (17,981)	$ 450	$ (15,073)
Proceeds from equity financing, net	43,318,350	44	(550)	22,675			22,169
Preferred stock warrants exercised	8,410,266	8		7,251			7,259
Preferred stock Series A, B and D converted	23,328,000	24		8,470			8,494
Stock-based compensation expense				2,900			2,900
Stock options exercised	246,141						
Net loss					(31,368)	18	(31,350)
Balance, December 31, 2011	95,678,255	96	(550)	43,734	(49,349)	468	(5,601)
Proceeds from equity financing, net	455,075,000	455	(2,004)	41,734			40,185
Preferred stock Series D and Series E converted	50,528,000	50		1,300			1,350
Reclass and exercise of warrants to equity	62,406			15,065			15,065
Conversion of note payable	22,465,947	23		2,362			2,385
Issuance of common stock for exclusive collaboration channel agreement	32,938,000	33		6,884			6,917
Cancellation of certificate	(1,000,000)	(1)	550	(549)			
Stock-based compensation expense				1,224			1,224
Net loss					(22,726)	(468)	(23,194)
Balance, December 31, 2012	655,747,608	$ 656	$ (2,004)	$ 111,754	$ (72,075)	$	$ 38,331

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

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Fibrocell Science, Inc.

Consolidated Statements of Cash Flows

(amounts in thousands except share data)

	Year ended December 31, 2012	Year ended December 31, 2011
Cash flows from operating activities:		
Net loss	$ (23,194)	$ (31,350)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on extinguishment of debt	4,421	
Gain on sale of Agera	(467)	
Stock issued for exclusive channel collaboration agreement	6,917	
Stock-based compensation expense	1,224	2,900
Warrant revaluation (income) expense	(8,725)	4,763
Derivative revaluation expense	23	5,451
Deferred tax benefit	(2,500)	
Depreciation and amortization	821	158
Provision for doubtful accounts	25	18
Provision for excessive and/or obsolete inventory		(46)
Amortization of debt issue costs	146	
Change in operating assets and liabilities:		
Increase in accounts receivable	(60)	(4)
Increase in other receivables		(1)
(Increase) decrease in inventory	(477)	38
Increase in prepaid expenses	(196)	(437)
Increase (decrease) in accounts payable	(966)	804
Increase in accrued expenses and other liabilities	407	816
Increase in deferred revenue	83	55
Increase in miscellaneous other	(57)	(2)
Net cash used in operating activities	(22,575)	(16,837)
Cash flows from investing activities:		
Purchase of property and equipment	(493)	(1,570)
Proceeds from the sale of Agera	1,002	
Net cash provided by (used in) investing activities	509	(1,570)
Cash flows from financing activities:		
Offering costs associated with the issuance of debt	(46)	(100)
Proceeds from the issuance of redeemable preferred stock series B, D and E, net	7,864	5,836
Proceeds from the exercise of warrants		2,419
Proceeds from the issuance of common stock, net	40,185	22,168
Payments on insurance loan	(97)	(81)
Principal payments on 12.5% note payable	(4,823)	(1,283)
Cash dividends paid on preferred stock	(470)	(623)
Net cash provided by financing activities	42,613	28,336
Effect of exchange rate changes on cash balances		2
Net increase in cash and cash equivalents	20,547	9,931

Cash and cash equivalents, beginning of period	10,799	868
Cash and cash equivalents, end of period	$ 31,346	$ 10,799

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

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Fibrocell Science, Inc.

Notes to Consolidated Financial Statements

(amounts in thousands except per share and share data)

Note 1 Business and Organization

Fibrocell Science, Inc. (Fibrocell or the Company) is the parent company of Fibrocell Technologies (Fibrocell Tech). Fibrocell Tech is the parent company of Isolagen Europe Limited, a company organized under the laws of the United Kingdom (Isolagen Europe), Isolagen Australia Pty Limited, a company organized under the laws of Australia (Isolagen Australia), and Isolagen International, S.A., a company organized under the laws of Switzerland (Isolagen Switzerland).

The Company is an autologous cellular therapeutic company focused on the development of innovative products for aesthetic, medical and scientific applications.

The Company previously marketed a skin care line with broad application in core target markets through its consolidated subsidiary, Agera, which was sold on August 31, 2012. The Company had owned 57% of the outstanding shares of Agera. As a result of the sale of Agera, the Company operates in one segment and Agera is classified as discontinued operations in 2011 consolidated balance sheet and consolidated statement of operations for the years ended December 31, 2012 and 2011. Please refer to Note 3 for more details.

The Company has transitioned from its development stage to operational activities as of July 1, 2012. As such, the financial statements have been updated to reflect that the Company is no longer a development stage company.

Note 2 Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with Generally Accepted Accounting Principles (GAAP) requires management to make estimates and assumptions that affect the reported amounts in the consolidated financial statements and notes. Actual results may differ materially from those estimates.

Cash and Cash Equivalents

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

Concentration of Credit Risk

As of December 31, 2012, the Company maintains the majority of its cash primarily with one major U.S. domestic bank. All of our non-interest bearing cash balances were fully insured at December 31, 2012 due to a temporary federal program in effect from December 31, 2011 through December 31, 2012. Under the program, there is no limit to the amount of insurance for eligible accounts. Beginning 2013, insurance coverage will revert to $250,000 per depositor at each financial institution, and our non-interest bearing cash balances may again exceed federally insured limits. The terms of these deposits are on demand to minimize risk. The Company has not incurred losses related to these deposits.

Allowance for Doubtful Accounts

The Company maintains an allowance for doubtful accounts related to its accounts receivable that have been deemed to have a high risk of collectability. Management reviews its accounts receivable on a monthly basis to determine if any receivables will potentially be uncollectible. Management analyzes historical collection trends and changes in its customer payment patterns, customer concentration, and creditworthiness when evaluating the adequacy of its allowance for doubtful accounts. In its overall allowance for doubtful accounts, the Company includes any receivable balances that are determined to be uncollectible. Based on the information available, management believes the allowance for doubtful accounts is adequate; however, actual write-offs might exceed the recorded allowance.

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Inventory

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

Property and equipment

Property and equipment is carried at cost less accumulated depreciation and amortization. Generally, depreciation and amortization for financial reporting purposes is provided by the straight-line method over the estimated useful life of three years, except for leasehold improvements which are amortized using the straight-line method over the remaining lease term or the life of the asset, whichever is shorter. The cost of repairs and maintenance is charged as an expense as incurred.

Intangible assets

Intangible assets are research and development assets related to the Company s primary study that was recognized upon emergence from bankruptcy. The portion of the reorganization value which was attributed to identified intangible assets was $6.3 million. This value is related to research and development assets that were not subject to amortization in 2011.

Effective January 1, 2012 the Company launched LAVIV and is now generating revenue. As a result, the research and development intangible assets related to the Company s primary study are considered finite-lived intangible assets and are being amortized over 12 years. For the year ended December 31, 2012, amortization expense was $0.6 million. We expect to amortize $0.6 million for each of the next five years.

Intangible assets 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. There was no impairment of the intangible assets as of December 31, 2012.

Revenue recognition

The Company recognizes revenue over the period LAVIV is shipped for injection in accordance with ASC 605. In general, ASC 605 requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services rendered, (3) the fee is fixed and determinable and (4) collectability is reasonably assured.

Revenue from the sale of Agera s products was recognized upon transfer of title, which is upon shipment of the product to the customer. The Company believes that the requirements of ASC 605 are met when the ordered product is shipped, as the risk of loss transfers to our customer at that time, the fee is fixed and determinable and collection is reasonably assured. Any advanced payments are deferred until shipment. As a result of the sale of Agera, these revenues have been reflected in discontinued operations. Revenue from the sale of LAVIV is not recognized until the first shipment for an injection is shipped.

Shipping and handling costs

LAVIV does not charge its customers for shipping and handling costs. These costs were included in cost of sales.

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Advertising cost

The Company s advertising costs were expensed as incurred and include the costs of public relations and certain marketing related activities. These costs were included in selling, general and administrative expenses in the accompanying consolidated statements of operations. There was total marketing expense of $2,203 and $3,809 for the years ended December 31, 2012 and 2011, respectively.

Research and development expenses

Research and development costs are expensed as incurred and include salaries and benefits, costs paid to third-party contractors to perform research, conduct clinical trials, develop and manufacture drug materials and delivery devices, and a portion of facilities cost. Research and development costs also include costs to develop manufacturing, cell collection and logistical process improvements.

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. Invoicing from third-party contractors for services performed can lag several months. The Company accrues the costs of services rendered in connection with third-party contractor activities based on its estimate of management fees, site management and monitoring costs and data management costs. Actual clinical trial costs may differ from estimated clinical trial costs and are adjusted for in the period in which they become known.

Warrant Liability

Certain warrants are measured at fair value and liability-classified under ASC 815, Derivatives and Hedging, (ASC 815) because the 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 the Company s own stock which is a requirement for the scope exception as outlined under ASC 815. Effective December 31, 2011, the Company utilized the Monte Carlo simulation valuation method to value the liability-classified warrants until September 30, 2012 when the Company 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 certain 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.

Preferred Stock and Derivative Liability

The preferred stock has been classified within the mezzanine section between liabilities and equity in its consolidated balance sheets in accordance with ASC 480, Distinguishing Liabilities from Equity (ASC 480) because, prior to the conversion of the preferred stock in October 2012, any holder of Series A, B, D and E Preferred may have required the Company to redeem all of its Series A, B, D or E Preferred in the event of a triggering event which was outside of the control of the Company. All preferred stock was converted in October 2012.

The embedded conversion option for the preferred stock had been recorded as a derivative liability under ASC 815 in the Company s consolidated balance sheet as of December 31, 2011 and was re-measured on the Company s reporting dates until the preferred stock was converted on October 2012. The fair value of the derivative liability was determined using the Black-Scholes option-pricing model and was affected by changes in inputs to that model including our stock price, expected stock price volatility, the expected term, and the risk-free interest rate.

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Stock-based Compensation

The Company accounts for stock-based awards to employees using the fair value based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. In addition, the Company accounts for stock-based compensation to nonemployees in accordance with the accounting guidance for equity instruments that are issued to other than employees. The Company uses a Black-Scholes option-pricing model to determine the fair value of each option grant as of the date of grant for expense incurred. The Black-Scholes model requires inputs for risk-free interest rate, dividend yield, volatility and expected lives of the options. Expected volatility is based on historical volatility of the Company and our peer company stock. 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. The Company estimates future forfeitures of options based upon expected forfeiture rates.

Income taxes

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

In the event the Company is charged interest or penalties related to income tax matters, the Company would record such interest as interest expense and would record such penalties as other expense in the consolidated statements of operations. No such charges have been incurred by the Company. As of December 31, 2012 and December 31, 2011, the Company had no uncertain tax positions.

At December 31, 2012 and December 31, 2011, the Company has provided a full valuation allowance for the net deferred tax assets, the large majority of which relates to the future benefit of loss carryovers. In addition, as a result of fresh-start accounting, the Company may be limited by section 382 of the Internal Revenue Service Code. The tax years 2009 through 2012 remain open to examination by the major taxing jurisdictions to which we are subject. The deferred tax liability at December 31, 2011, relates to the intangible assets recognized upon fresh-start accounting.

Loss per share data

Basic loss per share is calculated based on the weighted average common shares outstanding during the period. Diluted income per share (Diluted EPS) also gives effect to the dilutive effect of stock options, warrants, restricted stock and convertible preferred stock calculated based on the treasury stock method.

The following potentially dilutive securities have been excluded from the computations of diluted weighted-average shares outstanding as of December 31, 2012 and 2011, as they would be anti-dilutive:

	For the year ended December 31,	
	2012	2011
Shares of convertible preferred stock		7,282,000
Shares underlying options outstanding	14,050,625	13,608,500
Shares underlying warrants outstanding	153,299,031	49,135,602

Fair Value of Financial Instruments

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

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Note 3 Discontinued Operations

On August 31, 2012, the Company sold all of the shares of common stock of Agera held by the Company, which represented 57% of the outstanding common stock of Agera, to Rohto Pharmaceutical Co., Ltd. for approximately $1.0 million. Accordingly, all operating results from continuing operations exclude the results for Agera which are presented as discontinued operations for the years ended December 31, 2012 and 2011. The Company recorded a gain of approximately $0.4 million on the sale.

As of December 31, 2011, assets and liabilities classified as discontinued operations on the consolidated balance sheet are as follows:

	For the year ended December 31, 2011
Accounts receivable, net	$ 188
Inventory	266
Prepaid expenses	44
Current assets of discontinued operations	$ 498
Accounts payable	$ 12
Accrued expenses	8
Current liabilities of discontinued operations	$ 20

The financial results of Agera are classified as discontinued operations in the accompanying Consolidated Statement of Operations. Summary financial information related to discontinued operations is as follows:

	For the year ended December 31, 2012	For the year ended December 31, 2011
Product sales	$ 516	$ 812
Cost of sales	275	451
Gross profit	241	361
Operating income (loss)	$ 27	$ (55)
Net loss	$ (2)	$ (73)

In addition, there are other minimal losses from foreign subsidiaries which are classified as discontinued operations.

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Note 4 Supplemental Cash Flow Information

The following table contains additional cash flow information for the periods reported.

	December 31, 2012	December 31, 2011
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 1,885	$ 435
Non-cash investing and financing activities:		
Accrued preferred stock dividend	$	$ 487
Financing of insurance premiums		150
Subscription receivable	2,004	550
Conversion of note payable	2,385	
Issuance of additional warrants	11,077	4,994
Conversion of preferred stock into common stock		1,203
Conversion of preferred stock derivative balance into common stock	1,350	7,291
Cashless exercise of warrants recorded previously as a liability	17	4,842
Warrants liability reclassified to equity	15,048	
Accrued derivative liability	793	252

Note 5 Inventory

	December 31, 2012	December 31, 2011
Inventories consist of the following:		
Raw materials	$ 326	$
Work-in-process	151	
Total	$ 477	$

Note 6 Fair Value Measurements

The Company adopted the accounting guidance on fair value measurements for financial assets and liabilities measured on a recurring basis. The guidance requires fair value measurements be classified and disclosed in one of the following three categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices in markets that are not active or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability.

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

The following fair value hierarchy table presents information about each major category of the Company s liabilities measured at fair value on a recurring basis as of December 31, 2012 and 2011:

	Fair value measurement using			
	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
At December 31, 2012				
Liabilities				
Warrant liability	$	$	$ 374	$ 374
Derivative liability				
Total	$	$	$ 374	$ 374

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	Fair value measurement using			
	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
At December 31, 2011				
Liabilities				
Warrant liability	$	$	$ 13,087	$ 13,087
Derivative liability			534	534
Total	$	$	$ 13,621	$ 13,621

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

	Warrant Liability
Balance at January 1, 2011	$ 8,172
Issuance of additional warrants	4,994
Exercise of warrants	(4,842)
Change in fair value of warrant liability	4,763
Balance at December 31, 2011	$ 13,087
Issuance of additional warrants	11,077
Exercise of warrants	(17)
Warrants reclassified to equity due to change in term	(15,048)
Change in fair value of warrant liability	(8,725)
Balance at December 31, 2012	$ 374

The fair value of the warrant liability is based on Level 3 inputs. For this liability, the Company developed its own assumptions that do not have observable inputs or available market data to support the fair value. See Note 13 for further discussion of the warrant liability.

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

	Derivative Liability
Balance at January 1, 2011	$ 2,120
Issuance of additional preferred stock and other	252
Conversion of preferred stock	(7,290)
Change in fair value of derivative liability	5,452
Balance at December 31, 2011	534
Issuance of additional preferred stock and other	793
Conversion of preferred stock	(1,350)
Change in fair value of derivative liability	23
Balance at December 31, 2012	$

The fair value of the derivative liability is based on Level 3 inputs. For this liability, the Company developed its own assumptions that do not have observable inputs or available market data to support the fair value. See Note 12 for further discussion of the derivative liability.

Assets and Liabilities Measured at Fair Value on a Nonrecurring Basis

On June 1, 2012 the Company issued 12.5% Convertible Notes (Notes) (in exchange for certain outstanding notes), which provided that unpaid interest of 15% be accreted to the principal, and which had a maturity date of June 1, 2013. The Notes were measured at face value including interest in our consolidated balance sheets and not fair value. The Notes approximated fair value on June 1, 2012 as they bore interest at a rate approximating a market interest rate. The Notes were extinguished in October 2012 through partial conversions into common stock and partial repayments in cash.

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We believe that the fair values of our current assets and current liabilities approximate their reported carrying amounts. There were no transfers between Level 1, 2 and 3.

Note 7 Property and Equipment

As of December 31, 2012 and 2011, property and equipment consisted of the following:

	December 31, 2012	December 31, 2011
Laboratory equipment	$ 800	$ 402
Computer equipment and software	178	137
Furniture and fixtures	15	
Leasehold improvements	338	299
Construction-in-process	761	762
	2,092	1,600
Less: Accumulated depreciation	(434)	(166)
Property and equipment, net	$ 1,658	$ 1,434

Depreciation expense was $269 and $158 for the year ending December 31, 2012 and 2011, respectively.

Note 8 Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2012	December 31, 2011
Accrued professional fees	$ 58	$ 702
Accrued compensation	48	
Dividend on preferred stock payable		56
Accrued other	388	160
Accrued expenses	$ 494	$ 918

Note 9 Debt

Convertible Note Payable due 2013

On June 1, 2012, the Company entered into an Exchange Agreement with existing note holders pursuant to which the Company agreed to repay half of each Holder s 12.5% Promissory Notes due June 1, 2012 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 (Warrant) to purchase a number of shares of Common Stock equal to the number of shares of Common Stock underlying such Note on the date of issuance.

Details of Notes are as follows:

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

The maturity date of the Notes was September 1, 2013, provided that the Holders may require the Company to redeem 25% of the principal amount of the Notes on each of December 1, 2012, March 1, 2013, June 1, 2013 and September 1, 2013.

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To the extent that Holders of the Notes converted any portion of the Notes prior to any such redemption date, the amount of all future redemption payments will be reduced by such converted amount on a *pro rata* basis over the remaining redemption dates.

The Notes were convertible at a conversion price of $0.25 per share, provided that, with certain exceptions, if, at any time while the Notes are outstanding, the Company issues any Company common stock or common stock equivalents at an effective price per share that is lower than the then the conversion price of the Notes, then the conversion price of the Notes will be reduced to equal the lower price.

The Notes may be accelerated if any events of default occur, which include, in addition to certain customary default provisions, if at any time on or after October 1, 2012 the Company fails to have reserved, for conversion of the Notes and exercise of the Warrants, a sufficient number of available authorized but unissued shares of common stock.

The Notes were extinguished in October 2012 through partial conversions into common stock and partial repayments in cash.

Loss on Extinguishment of Debt

As a result of the June 1, 2012 debt exchange as discussed above, the Company recorded a loss on extinguishment of the 12.5% Promissory Note of $4.4 million in the consolidated statement of operations due to the significant modification of the original debt. The details of the loss included recording the fair value of the embedded conversion option of $1.2 million and the fair value of liability-classified warrants of $3.2 million. See note 12 for further discussion of the derivative liability and note 13 for further discussion of the warrant liability.

Note 10 Income Taxes

Fibrocell Science, Inc. and Fibrocell Technologies, Inc. file a consolidated U.S. Federal income tax return. The Company s foreign subsidiaries, which comprise loss from discontinued operations, file income tax returns in their respective jurisdictions. The geographic source of loss from continuing operations is the United States.

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

	Year ended December 31, 2012	Year ended December 31, 2011
U.S. Federal:		
Current	$	$
Deferred	(2,068)	
U.S. State:		
Current		
Deferred	(432)	
	$ (2,500)	$

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

	Year ended December 31, 2012	Year ended December 31, 2011
Tax benefit at U.S. federal statutory rate	$ (9,144)	$ (10,939)
Increase in domestic valuation allowance	11,127	8,767
State income taxes/(benefit) before valuation allowance, net of federal benefit	(1,971)	(1,367)
Capital Loss limitation	(817)	
Loss on extinguishment of debt	1,547	
Derivative revaluation expense	8	1,908
Warrant revaluation (gain)/expense	(3,054)	1,667
Other	(196)	(36)
	$ (2,500)	$

The components of the Company s net deferred tax liabilities at December 31, 2012 and 2011 are as follows:

	December 31, 2012	December 31, 2011
Deferred tax liabilities:		
Intangible assets	$ 2,282	$ 2,500
Total deferred tax liabilities	$ 2,282	$ 2,500
Deferred tax assets:		
Loss carryforwards	$ 49,598	$ 37,397
Capital loss carryforward	817	
Property and equipment	1,327	1,390
Accrued expenses and other	360	294
Stock compensation	2,492	2,104
Total deferred tax assets	54,594	41,185
Less: valuation allowance	(52,312)	(41,185)
Total deferred tax assets	$ 2,282	$
Net deferred tax liabilities	$	$ 2,500

As of December 31, 2012, the Company had generated U.S. net operating loss carryforwards of approximately $125.8 million which expire from 2011 to 2032 and net loss carryforwards in certain non-US jurisdictions of approximately $25.5 million. The net operating loss carryforwards are available to reduce future taxable income. However, a, change in ownership, as defined by federal income tax regulations, could significantly limit the Company s ability to utilize its U.S. net operating loss carryforwards. Additionally, because federal tax laws limit the time during which the net operating loss carryforwards may be applied against future taxes, if the Company fails to generate taxable income prior to the expiration dates it may not be able to fully utilize the net operating loss carryforwards to reduce future income taxes. As the Company has had cumulative losses and there is no assurance of future taxable income, valuation allowances have been recorded to fully offset the deferred tax asset at December 31, 2012 and 2011. The valuation allowance increased by $11.1 million and $8.8 million during 2012 and 2011, respectively, due to the impact from the current year net losses incurred.

Note 11 Commitments

Leases

On February 17, 2012, the Company renewed its lease for the office, warehouse and laboratory facilities in Exton, Pennsylvania under a non-cancelable operating lease through 2023. For each of the years ended December 31, 2012 and 2011, rental expense totaled $1.4 million.

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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 a non-refundable initial license fee of $10,000 thirty days post execution of the agreement and the Company also agreed to pay an annual license maintenance fee, 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 maintain the same subpopulations of dermal cell, produce clinically meaningful quantities and deliver them to the body. The agreement is currently scheduled to terminate in June 2015. 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.

The following table summarizes our contractual obligations as of December 31, 2012 (in thousands):

		Payments due by period					
	Total	**2013**	**2014**	**2015**	**2016**	**2017**	**Thereafter**
Contractual Obligations							
License fee obligations	$ 1,395	$ 520	$ 525	$ 270	$ 20	$ 20	$ 40
Operating lease obligations	13,321	1,070	$ 1,081	1,211	$ 1,254	1,254	7,451
Total	$ 14,716	$ 1,590	$ 1,606	$ 1,481	$ 1,274	$ 1,274	$ 7,491

Note 12 Equity

October 2012 financing

In October 2012, the Company closed a private placement transaction (the offering) with certain accredited investors pursuant to which the Company sold securities consisting of 450,000,000 shares of common stock at a purchase price of $0.10 per share. The Company received net proceeds of $40.2 million, incurred $2.7 million in offering costs and has a subscription receivable of $2.0 million.

On October 5, 2012, the Company entered into a Stock Issuance Agreement with Intrexon pursuant to which the Company agreed to issue to Intrexon, who is an affiliate of certain Purchasers in the Offering that are the significant stockholders of the Company described above, a number of shares of Company common stock valued at approximately $6.9 million based on a per share value of $0.21 per share (the Technology Access Shares), which issuance will be deemed paid in partial consideration for the execution and delivery of the Channel Agreement. In connection with the issuance of the Technology Access Shares, Intrexon became a party to the Registration Rights Agreement, which provides Intrexon with a demand registration right with respect to the resale of the Technology Access Shares.

On October 5, 2012, the Company entered into an Amendment and Conversion Agreement (the Debt Agreement) with the holders of its 12.5% Convertible Notes in the aggregate original principal amount of approximately $3.5 million (the Notes). Pursuant to the Debt Agreement, the Company and the Notes holders agreed that the Company would repay approximately $1.7 million of the Notes in cash (representing approximately $1.5 million in principal and $0.2 million in unpaid interest), and the remaining Notes (representing approximately $2.1 million in principal and $0.3 million in unpaid interest) would be converted into shares of Common Stock at a conversion price of $0.10 per share. The total number of shares of Common Stock issued upon the conversion of the Notes was 21,549,212 shares. There were conversions of notes into 916,735 common shares before the October 2012 offering.

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Effective upon the completion of the Offering, the Company entered into warrant modification agreements with the holders of warrants to purchase 105,232,857 shares of Common Stock at exercise prices of between $0.25 per share and $0.30 per share pursuant to which the parties agreed, among other items: (a) to extend the expiration date of the warrants by one year; and (b) to delete the full-ratchet anti-dilution adjustment provisions contained in the warrants (including with respect to the Offering discussed above). As such, the exercise price and number of shares underlying the foregoing warrants were not modified due to the completion of the Offering.

Redeemable Preferred stock

On October 5, 2012, upon the approval of the requisite number of holders of the Company s Series D 6% Cumulative Perpetual Convertible Preferred Stock (the Series D Preferred Stock) and Series E 8% Cumulative Convertible Preferred Stock (the Series E Preferred Stock), the Company filed amendments, effective on such date, to each of the Certificates of Designation for the Preferred Stock providing that if the Company completed an equity financing pursuant to which the Company received gross proceeds of no less than $35.0 million (a Qualified Financing), then immediately prior to the closing of such Qualified Financing each outstanding share of Preferred Stock shall be automatically converted into that number of shares of Common Stock determined by dividing the stated value of such share of Preferred Stock by $0.25. The Offering discussed above was a Qualified Financing, and as such, the Preferred Stock was automatically converted prior to the close of the October 2012 offering into 47,928,000 shares of Common Stock upon completion of the Offering. There were 2,600,000 common shares issued as a result of conversion of Series D preferred shares during 2012 before the conversion of the preferred shares with the October 2012 offering. As of the closing of the Offering, the Company had no shares of preferred stock outstanding.

The following table shows the activity of Series D and Series E Redeemable Preferred stock (Preferred), with a par value of $0.001 per share and a stated value of $1,000 per share:

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

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

Date of financing	# of shares of Series E Preferred	Net Proceeds	Warrant Exercise Price	# of Warrants Issued
May 14, 2012	3,353	$ 2,843	$ 0.30	14,753,200
May 24, 2012	2,364	2,042	0.30	10,401,600
May 30, 2012	945	822	0.30	4,158,000
June 7, 2012	1,192	1,037	0.30	5,244,800
June 28, 2012	507	441	0.30	2,230,800
July 16, 2012	780	679	0.30	3,432,000
	9,141	$ 7,864		40,220,400

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

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Preferred Stock Series D

On January 21, 2011, the Company completed a private placement of securities in which the Company sold to certain accredited investors in the aggregate: (i) 1,234 shares of Series D Convertible Preferred Stock, with a par value of $0.001 per share and a stated value of $1,000 per share, and (ii) warrants to purchase 2,468,000 shares of Company common stock at an exercise price of $0.50 per share. The aggregate purchase price paid by the Purchasers for the Series D Preferred and the Warrants was $1,234,000 (representing $1,000 for each share of Series D Preferred together with warrants). The Company intends to use the proceeds for working capital purposes. The placement agents for the offering received cash compensation of $98,720 and warrants to purchase 197,440 shares of Common Stock at an exercise price of $0.50 per share.

On January 28, 2011, the Company completed a private placement of securities in which the Company sold to certain accredited investors in the aggregate: (i) 1,414 shares of Series D at a stated value of $1,000 per share, and (ii) warrants to purchase 2,828,000 shares of Common Stock at an exercise price of $0.50 per share. The aggregate purchase price paid by the Purchasers for the Series D Preferred and the warrants was $1,414,000 (representing $1,000 for each share of Series D Preferred together with warrants). The Company intends to use the proceeds for working capital purposes. The placement agents for the offering received cash compensation of $113,120 and warrants to purchase 226,240 shares of Common Stock at an exercise price of $0.50 per share.

On February 9, 2011, the Company completed a private placement of securities in which the Company sold to certain accredited investors in the aggregate: (i) 3,436 shares of Series D at a stated value of $1,000 per share, and (ii) warrants to purchase 6,872,000 shares of Common Stock at an exercise price of $0.50 per share. The aggregate purchase price paid by the Purchasers for the Series D Preferred and the warrants was $3,436,000 (representing $1,000 for each share of Series D Preferred together with warrants). The Company intends to use the proceeds for working capital purposes. The placement agents for the offering received cash compensation of $274,880 and warrants to purchase 549,760 shares of Common Stock at an exercise price of $0.50 per share.

On March 1, 2011, the Company completed a private placement of securities in which the Company sold to certain accredited investors in the aggregate: (i) 50 shares of Series D at a stated value of $1,000 per share, and (ii) warrants to purchase 100,000 shares of Common Stock at an exercise price of $0.50 per share. The aggregate purchase price paid by the Purchasers for the Series D Preferred and the warrants was $50,000 (representing $1,000 for each share of Series D Preferred together with warrants). The Company intends to use the proceeds for working capital purposes. The placement agents for the offering received cash compensation of $4,000 and warrants to purchase 8,000 shares of Common Stock at an exercise price of $0.50 per share.

The Company recorded accrued dividends at a rate of 6% per annum on the Series D and 8% per annum on the Series E Preferred. The Company paid cash of $0.5 million and $0.6 million during the years ended December 31, 2012 and 2011, respectively.

The Series D and Series E Redeemable Preferred stock was converted into common stock in October 2012. During 2011, 4,138 Series D preferred shares were converted into 8,276,000 common shares.

On May 24, 2011, the Company sent a mandatory conversion notice to the holders of its outstanding Series A Convertible Preferred Stock and Series B Convertible Preferred Stock. Pursuant to the notice, each holder of Series A Convertible Preferred Stock and Series B Convertible Preferred Stock was notified that since the volume weighted average price of the Company s common stock had exceeded 200% of the then effective conversion price of the Preferred Stock for twenty consecutive trading days; the Company was permitted to force the conversion of the Preferred Stock into Company common stock. The conversion was effective on July 7, 2011; provided that holders of Preferred Stock had the right to voluntarily convert their shares of Preferred Stock prior to such date. During 2011, 2,886 Series A preferred shares were converted into 5,772,000 common shares. During 2011, 4,640 Series B preferred shares were converted into 9,280,000 common shares.

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Conversion option of Convertible Note Payable

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

Conversion option of Redeemable Preferred stock

The embedded conversion option for the Series D Preferred has been recorded as a derivative liability under ASC 815 in the consolidated balance sheet as of December 31, 2011. The fair value of the derivative liability is determined using the Black-Scholes option-pricing model and is affected by changes in inputs to that model including our stock price, expected stock price volatility, the contractual term, and the risk-free interest rate. The derivative liability was re-measured resulting in income of $0.1 million for the year ended December 31, 2012 in our statement of operations until the preferred stock was converted on October 9, 2012 into common stock and $1.4 million was recorded in equity.

The fair market value of the derivative liability was computed using the Black-Scholes option-pricing model with the following weighted average assumptions as of the dates indicated:

	December 31, 2011
Expected life (years)	1.1 years
Interest rate	0.1%
Dividend yield	
Volatility	61%

Common Stock Private Placements

On August 3, 2011, the Company entered into agreements with certain accredited investors, pursuant to which the Company agreed to sell to the purchasers an aggregate of 41,409,461 shares of Company common stock at a purchase price of $0.55 per share in a private placement. Each purchaser also received a warrant to purchase 0.35 shares of common stock for every share of common stock acquired in the offering with an exercise price of $0.75 per share and a term of 5 years from issuance. The warrants are callable by the Company if the common stock trades over $1.75 for 20 consecutive trading days at any time after the shares underlying the warrants are registered or eligible for resale pursuant to Rule 144. The aggregate purchase price paid by the purchasers at closing for the common stock and the warrants was $22.8 million. As of December 31, 2011, there was a subscription receivable of $0.6 million. The placement agents for the transaction received cash compensation of $1.6 million and warrants to purchase 1,252,761 shares of Company common stock at an exercise price of $0.5454 and fair value of $440,330. Cash issuance costs of $1.6 million were netted against the gross proceeds.

On June 16, 2011, the Company completed a private placement, pursuant to which it sold an aggregate of 1,908,889 shares of Company common stock to eight accredited investors for an aggregate purchase price of $1,718,000. The placement agent for the transaction received cash compensation of $137,440 and warrants to purchase 152,711 shares of Company common stock at an exercise price of $0.90 per share.

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Note 13 Warrants

The Company accounts for stock warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreement. Stock warrants are accounted for as a derivative in accordance with ASC 815 if the stock warrants contain down-round protection and therefore, do not meet the scope exception for treatment as a derivative. Since down-round protection is not an input into the calculation of the fair value of the warrants, the warrants cannot be considered indexed to the Company s own stock which is a requirement for the scope exception as outlined under ASC 815. The Company will continue to classify the fair value of the warrants that contain down-round protection 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. Effective December 31, 2011, the Company utilized the Monte Carlo simulation valuation method to value the liability-classified warrants until September 30, 2012 when the Company 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.

Modification of Outstanding Warrants

Pursuant to the October 5, 2012 Debt Agreement, the Company and the Note holders agreed to modify the warrants to purchase an aggregate of 14,069,696 shares of Common Stock previously issued in connection with the issuance of the Notes (the Debt Warrants): (a) to change the exercise price of the Debt Warrants from $0.30 to $0.10 per share; (b) to increase the number of shares of Common Stock underlying the Debt Warrants by two times the current number of shares rather than three times the current number; (c) to extend the expiration date of the Debt Warrants by one year to June 1, 2018; and (d) to delete the full-ratchet anti-dilution adjustment provisions contained in the Debt Warrants.

In addition, the Note holders agreed, among other items, to modify the warrants to purchase an aggregate of 7,770,902 shares of Common Stock previously issued to the Note holders (and their affiliates) in prior financings (the Prior Warrants): (a) to extend the expiration date of the Prior Warrants by one year; and (b) to delete the full-ratchet anti-dilution adjustment provisions contained in the Prior Warrants (including with respect to the Offering discussed above).

Effective upon the completion of the Offering, the Company entered into warrant modification agreements with the holders of warrants to purchase 105,232,857 shares of Common Stock at exercise prices of between $0.25 per share and $0.30 per share pursuant to which the parties agreed, among other items: (a) to extend the expiration date of the warrants by one year; and (b) to delete the full-ratchet anti-dilution adjustment provisions contained in the warrants (including with respect to the Offering discussed above). As such, the exercise price and number of shares underlying the foregoing warrants were not modified due to the completion of the Offering.

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The following table summarizes outstanding warrants to purchase Common Stock as of December 31, 2012 and 2011:

	Number of Warrants			
	As of December 31, 2012	As of December 31, 2011	Exercise Price as of December 31, 2012	Expiration Dates as of December 31, 2012
Liability-classified warrants				
Issued in Series A Preferred Stock offering		3,256,492	$ 0.25	Oct. 2014
Issued in March 2010 offering		4,917,602	0.25	Mar. 2015
Issued in Series B Preferred Stock offering	33,000	9,616,086	0.10	Jul. Nov. 2015
Issued in Series D Preferred Stock offering	995,000	15,446,640	0.10	Dec. 2015 Mar. 2016
Issued in Series E Preferred Stock offering	3,000,000		0.10	May June 2017
Subtotal	4,028,000	33,236,820		
Equity-classified warrants				
Issued in June 2011 equity financing	152,711	152,711	$ 0.90	June 2016
Issued in March 2010 and Preferred Stock offerings	105,232,857		0.25-0.30	May June 2018
Issued with Convertible Notes	28,139,392		0.30	June 2018
Issued to placement agents in August 2011 equity financing	1,252,761	1,252,761	0.55	August 2016
Issued in August 2011 equity financing	14,493,310	14,493,310	0.75	August 2016
Subtotal	149,271,031	15,898,782		
Total	153,299,031	49,135,602		

The following table summarizes the rollforward of the warrants for the two years ended December 31, 2012:

	Number of warrants
Outstanding at January 1, 2011	31,178,295
Warrants issued with financing	29,148,222
Exercised	(11,190,915)
Outstanding at December 31, 2011	49,135,602
Warrants issued with financing	54,290,096
Additional warrants issued due to anti-dilution provision	49,998,333
Exercised	(125,000)
Outstanding at December 31, 2012	153,299,031

There were 125,000 cashless warrants exercised for the year ended December 31, 2012 which resulted in the issuance of 62,406 shares of common stock for the year ended December 31, 2012. There were 4,837,291 warrants exercised for the year ended December 31, 2011 which resulted in receipts of approximately $2.4 million and the issuance of 4,837,291 shares of common stock. In addition, there were 6,387,235 cashless warrants exercised for the year ended December 31, 2011 which resulted in the issuance of 3,572,971 shares of common stock for the year ended December 31, 2011.

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Liability-classified Warrants

Effective December 31, 2011, the Company utilized the Monte Carlo simulation valuation method to value the liability classified warrants until September 30, 2012 when the Company 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 5, 2012. In addition, the warrants issued in connection with the June 2012 12.5% convertible notes as of a result of the October 2012 offering had a modification in the number of warrants and the exercise price was changed from $0.25 to $0.10 per share which increased the number of warrants by 14,069,696. As a result of the October 2012 offering, 133,372,249 of the liability-classified warrants were reclassified to equity-classified warrants due to the removal of the down-round protection As a result of the May 2012 financing, the exercise price of the liability-classified outstanding warrants was reduced from an exercise price of $0.50 to $0.25 per share. On October 9, 2012, $15,048 was reclassified from warrant liability to equity.

A portion of the warrant holders didn t sign the waivers to remove the down-round protection in October 2012, consequently the liability-classified warrants exercise price was reset to $0.10 per share and additional warrants were issued.

The following table summarizes the calculated aggregate fair values as of the dates indicated along with the assumptions utilized in each calculation (in thousands).

	December 31, 2012	October 9, 2012[1]	December 31, 2011
Calculated aggregate value	$ 374	$ 15,048	$ 13,087
Weighted average exercise price per share of warrant	$ 0.10	$ 0.25	$ 0.50
Closing price per share of common stock	$ 0.15	$ 0.21	$ 0.40
Volatility	70%	69%	70%
Expected term (years)	4.0	4.8	3.7
Risk-free interest rate	0.63%	0.45%	0.63%
Dividend yield	%	%	%

(1) - Calculated fair value after the modification.

Equity-classified Warrants

In connection with the private placement transaction on August 3, 2011, the Company issued warrants to purchase 14,493,310 shares of the Company common stock to certain accredited investors with an exercise price of $0.75 per share and a term of 5 years from issuance. The warrants are callable by the Company if the common stock trades over $1.75 for 20 consecutive trading days. The placement agents for the transaction received warrants to purchase 1,252,761 shares of Company common stock at an exercise price of $0.55. The Company determined the average fair value of the warrants as of the date of the grant was $0.31 per share utilizing the Black-Scholes option pricing model. In estimating the fair value of the warrants, the Company utilized the following inputs: closing price per share of common stock of $0.63, volatility of 61.4%, expected term of 5 years, risk-free interest rate of 1.25% and dividend yield of zero.

On June 16, 2011, the Company completed a private placement and issued warrants to the placement agents in the private placement to purchase 152,711 shares of Company common stock at an exercise price of $0.90 per share. The Company determined the fair value of the warrants as of the date of the grant was $0.62 per share utilizing the Black-Scholes option pricing model. In estimating the fair value of the warrants, the Company utilized the following inputs: closing price per share of common stock of $1.08, volatility of 61.6%, expected term of 5 years, risk-free interest rate of 1.52% and dividend yield of zero.

As of result of the October 2012 offering, 133,372,249 liability-classified warrants were reclassified to equity-classified warrants due to the removal of the down-round protection and the modification of the warrants issued for the June 2012 12.5% convertible notes.

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Note 14 Equity-based Compensation

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

	2012	2011
Stock option compensation expense for employees and directors	$ 1,200	$ 2,607
Restricted stock expense		48
Equity awards for nonemployees issued for services	24	245
Total stock-based compensation expense	$ 1,224	$ 2,900

Our board of directors adopted the 2009 Equity Incentive Plan (Plan) effective September 3, 2009. The Plan is intended to further align the interests of the Company and its stockholders with its employees, including its officers, non-employee directors, consultants and advisors by providing incentives for such persons to exert maximum efforts for the success of the Company. The Plan currently allows for the issuance of up to 30,000,000 shares of the Company s common stock. The types of awards that may be granted under the Plan include options (both nonqualified stock options and incentive stock options), stock appreciation rights, stock awards, stock units, and other stock-based awards. The term of each award is determined by the Board at the time each award is granted, provided that the terms of options may not exceed ten years. The Plan had 16,349,375 options available for grant as of December 31, 2012.

During the years ended December 31, 2012 and 2011, the weighted average fair market value using the Black-Scholes option-pricing model of the options granted was $0.20 and $0.40, respectively. The fair market value of the stock options at the date of grant was estimated using the Black-Scholes option-pricing model with the following weighted average assumptions for the year ended December 31:

	2012	2011
Expected life (years)	5.7 years	5.4 years
Interest rate	1.6%	2.1%
Dividend yield		
Volatility	64%	62%

There were 600,000 cashless stock options exercised during the year ended December 31, 2011, which resulted in the issuance of 246,141 shares of common stock.

	Number of shares	Weighted-average exercise price	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at January 1, 2011	5,677,000	$ 0.86	7.5	$
Granted	9,628,000	$ 0.72		
Exercised	(600,000)	$ 0.75		
Forfeited	(1,096,500)	$ 0.77		
Outstanding at December 31, 2011	13,608,500	$ 0.77	8.4	$
Granted	950,000	$ 0.32		
Exercised				
Forfeited	(507,875)	$ 0.62		
Outstanding at December 31, 2012	14,050,625	$ 0.74	7.0	$

Exercisable at December 31, 2012	11,388,567	$ 0.78	7.0	$

The total fair value of shares vested during the year ended December 31, 2012 was $1.3 million. As of December 31, 2012, there was $0.4 million of total unrecognized compensation cost, related to non-vested stock options which vest over time. That cost is expected to be recognized over a weighted-average period of 1.2 years.

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Restricted stock

The following table summarizes the Company s restricted stock activity for the year ended December 31, 2011:

	Non-vested Options	
	Number of Shares	Weighted-Average Fair Value
Non-vested at January 1, 2011	150,000	$ 0.48
Granted		
Vested	(150,000)	0.48
Forfeited		
Non-vested at December 31, 2011		$

Note 15 Deferred tax adjustment (unaudited)

During the quarter ended December 31, 2012, the Company discovered that the deferred tax liability reported in its quarters ended March 31, June 30, and September 30, 2012 consolidated financial statements was recorded incorrectly. In the first quarter ended March 31, the Company commenced amortizing the deferred tax liability over a twelve-year period to match the amortization of the related intangible. However, the full amount of the deferred tax liability should have been recorded as a deferred tax benefit in the first quarter of 2012 Consolidated Statement of Operations. This error was identified and recorded as an out-of-period adjustment in the quarter ended December 31, 2012. If the transaction was recorded in the first quarter of 2012, the deferred tax benefit would have increased by $2.4 million, resulting in the reduction of net loss by $2.4 million and the loss per share would have been reduced by $0.03 per share. The deferred tax liability would have been zero as of March 31, 2012. The effects on operations for the second and third quarters of 2012 were immaterial. The Company plans to restate the first quarter of 2012 with the filing of the first quarter of 2013.