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

FORM 10-K

☒ **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 ☒

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 ☒

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 ☒ 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 ☒ 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	☒

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

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 ☒ 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.

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.

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.

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.

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

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.

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.

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.

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.

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.

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.

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.

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.

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.

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;

- 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.

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.

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;

- 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;

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

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

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

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

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

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

Our sales, marketing, and scientific/educational grant programs, if any in the future, must also comply with applicable requirements of the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, the federal anti-kickback law, and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veteran's Health Care Act of 1992, each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws. The distribution of product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act.

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

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.

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;

- 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.

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.

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."

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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)

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

Fibrocell Science, Inc.

Index to Consolidated Financial Statements

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

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

	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.

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.

- 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)	$ —

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

Exhibit 10.21

EXECUTION COPY
CONFIDENTIAL

Portions herein identified by [*****] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

EXCLUSIVE CHANNEL COLLABORATION AGREEMENT

THIS EXCLUSIVE CHANNEL COLLABORATION AGREEMENT (the "**Agreement**") is made and entered into effective as of October 5, 2012 (the "**Effective Date**") by and between **INTREXON CORPORATION**, a Virginia corporation with offices at 20358 Seneca Meadows Parkway, Germantown, MD 20876 ("**Intrexon**"), and **FIBROCELL SCIENCE, INC.,** a Delaware corporation having its principal place of business at 405 Eagleview Boulevard, Exton, PA 19341 ("**Fibrocell**"). Intrexon and Fibrocell may be referred to herein individually as a " **Party**", and collectively as the "**Parties**."

RECITALS

WHEREAS, Intrexon has expertise in and owns or controls proprietary technology relating to the identification, design and production of genetically modified cells and DNA vectors, and the control of peptide expression; and

WHEREAS, Fibrocell now desires to become Intrexon's exclusive channel collaborator with respect to such technology for the purpose of developing the Fibroblast Program (as defined herein), and Intrexon is willing to appoint Fibrocell as a channel collaborator in the Field (as defined herein, and subject to amendments to the definition as permitted herein) under the terms and conditions of this Agreement.

NOW THEREFORE, in consideration of the foregoing and the covenants and promises contained herein, the Parties agree as follows:

ARTICLE 1

DEFINITIONS

As used in this Agreement, the following capitalized terms shall have the following meanings:

1.1 "**Affiliate**" means, with respect to a particular Party, any other person or entity that directly or indirectly controls, is controlled by, or is in common control with such Party. As used in this Section 1.1, the term "controls" (with correlative meanings for the terms "controlled by" and "under common control with") means the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of an entity, or the possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through the ownership of voting securities, by contract, or otherwise. Notwithstanding the foregoing, Third Security shall be deemed not to be an Affiliate of Intrexon. In addition, any other person, corporation, partnership, or other entity that would be an Affiliate of Intrexon solely because it and Intrexon are under common control by Randal J. Kirk or by investment funds managed by Third Security or an affiliate of Third Security shall also be deemed not to be an Affiliate of Intrexon.

1.2 "**Applicable Laws**" has the meaning set forth in Section 8.2(d)(xii).

1.3 "**Authorizations**" has the meaning set forth in Section 8.2(d)(xii).

1.4 "**CC**" has the meaning set forth in Section 2.2(b).

1.5 "**Channel-Related Program IP**" has the meaning set forth in Section 6.1(c).

1.6 "**Claims**" has the meaning set forth in Section 9.1.

1.7 "**CMCC**" has the meaning set forth in Section 2.2(b).

1.8 "**COGS Savings**" means the amount of COGS saved in the production of an Improved Product, as determined by subtracting the actual COGS of the Improved Product at the time of its respective sale (including any manufacturing royalties paid to any Third Parties) from the COGS of the Existing Product prior to it being improved under the Fibroblast Program (including any manufacturing royalties paid to any Third Parties). In accord with this Section 1.8, Fibrocell may exclude from COGS Savings any amount of saved COGS that is attributable to a COGS improvement realized in the Improved Product through Fibrocell's efforts independent of the Fibroblast Program and without use of the Intrexon Channel Technology, Intrexon IP, and Intrexon Materials. Before Fibrocell may exclude any amount from COGS Savings under the previous sentence, (i) Fibrocell must provide in advance of any payment due under Section 5.3(c) written documentation to the JSC identifying, and supplying a supporting calculation evidencing, any amount it believes should be excluded from COGS Savings, and (ii) the final amount that will ultimately be excluded will be established by mutual agreement of the Parties. For clarity, the mechanism of the previous sentence for establishing the final amount of any exclusion from COGS Savings is not subject to final decision making authority of the JSC or any other Committee, and if mutual agreement of the Parties cannot be reached any dispute will be resolved in accord with Article 11. Any caclulation by the Parties of COGS Savings under this Agreement shall apply consistent calculations to both the Existing Product and the Improved Product, and shall be exclusive of any payments made to Intrexon pursuant to Section 4.7 and Section 5.3.

1.9 "**Committees**" has the meaning set forth in Section 2.2(a).

1.10 "**Commercialize**" or "**Commercialization**" means any activities directed to marketing, promoting, distributing, importing for sale, offering to sell and/or selling Fibrocell Products.

1.11 "**Commercial Sale**" means for a given product and country the sale for value of that product by a Party (or, as the case may be, by an Affiliate or permitted sublicensee of a Party), to a Third Party after regulatory approval (if necessary) has been obtained for such product in such country.

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1.12 "Complementary In-Licensed Third Party IP" has the meaning set forth in Section 3.9(a).

1.13 "**Confidential Information**" means each Party's confidential Information, disclosed pursuant to this Agreement or any other confidentiality agreement between the Parties, regardless of whether in oral, written, graphic or electronic form.

1.14 "**Control**" means, with respect to Information, a Patent or other intellectual property right, that a Party owns or has a license from a Third Party to such right and has the ability to grant a license or sublicense as provided for in this Agreement under such right without violating the terms of any agreement or other arrangement with any Third Party.

1.15 "**Costs of Goods Sold**" or "**COGS**" means all Manufacturing Costs that are directly and reasonably attributable to manufacturing of an Existing Product or an Improved Product, as the case may be, in accordance with US GAAP for commercial sale in the countries where such product has been launched.

1.16 "**CRC**" has the meaning set forth in Section 2.2(b).

1.17 "**Diligent Efforts**" means, with respect to a Party's obligation under this Agreement, the level of efforts and resources reasonably required to diligently develop, manufacture, and/or Commercialize (as applicable) each Fibrocell Product in a sustained manner, consistent with the efforts and resources a similarly situated company working in the Field would typically devote to a product of similar market potential, profit potential, strategic value and/or proprietary protection, based on market conditions then prevailing. With respect to a particular task or obligation, Diligent Efforts requires that the applicable Party promptly assign responsibility for such task and consistently make and implement decisions and allocate resources designed to advance progress with respect to such task or obligation.

1.18 "**Equity Agreements**" has the meaning set forth in Section 5.1.

1.19 "**Excess Product Liability Costs**" has the meaning set forth in Section 9.3.

1.20 "**Executive Officer**" means : (i) the Chief Executive Officer of the applicable Party, or (ii) another senior executive officer of such Party who has been duly appointed by the Chief Executive Officer to act as the representative of the Party to resolve, as the case may be, (a) a Committee dispute, provided that such appointed officer is not a member of the applicable Committee and occupies a position senior to the positions occupied by the applicable Party's members of the applicable Committee, or (b) a dispute described in Section 11.1.

1.21 "**Existing Product**" means: (i) Fibrocell's autologous fibroblast therapeutic product indicated for improvement of the appearance of moderate to severe nasolabial fold wrinkles in adults, which was approved and marketed in the United States before the Effective Date under the trade name LAVIV ™, and (ii) any product that comprises a new indication for the LAVIV™ product identified under the previous clause "i", excluding an Improved Product or a Fibrocell Product.

1.22 "**FDA**" has the meaning set forth in Section 8.2(d)(xii).

1.23 "**Fibroblast Program**" has the meaning set forth in Section 2.1(a).

1.24 "**Fibrocell Indemnitees**" has the meaning set forth in Section 9.1.

1.25 "**Fibrocell Product**" means any product in the Field, excepting an Improved Product, that is created, produced, developed, or identified in whole or in part, directly or indirectly, by or on behalf of Fibrocell during the Term through use or practice of Intrexon Channel Technology, Intrexon IP, or the Intrexon Materials.

1.26 "**Fibrocell Program Patent**" has the meaning set forth in Section 6.2(b).

1.27 "**Fibrocell Termination IP**" means all Patents or other intellectual property that Fibrocell or any of its Affiliates Controls as of the Effective Date or during the Term that cover, or is otherwise necessary or useful for, the development, manufacture or Commercialization of a Reverted Product or necessary or useful for Intrexon to operate in the Field.

1.28 "**Field Infringement**" has the meaning set forth in Section 6.3(b).

1.29 "**Field**" means, as of the Effective Date and irrespective of whether such requires regulatory approval, (i) the enhanced production and purification of non-genetically modified human autologous fibroblasts for use in all aesthetic and therapeutic indications; (ii) the enhanced production and purification of non-genetically modified human autologous dermal cells for use in aesthetic and therapeutic treatment of dermal, vocal cord, and periodontal indications; (iii) the development of genetically modified autologous human fibroblasts for use in all aesthetic and therapeutic indications where an autologous fibroblast itself is the principal effector of the product in contrast to the use of autologous fibroblasts as the source of expression of a systemically available therapeutic protein in which that protein (and not the fibroblast per se) is the principal therapeutic effector; and (iv) the development of genetically modified autologous human dermal cells for aesthetic and therapeutic treatment of dermal, vocal cord, and periodontal indications. For clarity, the "Field" does not include inductive pluripotent cell products that are derived from autologous fibroblasts or dermal cells or products that are subject to an existing Intrexon collaboration.

1.30 "**Fully Loaded Cost**" means the direct cost of the applicable good, product or service plus indirect charges and overheads reasonably allocable to the provision of such good, product or service in accordance with US GAAP. Subject to the approval of a project and its associated budget by the JSC and the terms of Sections 4.6 and 4.7 (as appropriate), Intrexon will bill for its internal direct costs incurred through the use of annualized standard full-time equivalents; such rate shall be based upon the actual fully loaded costs of those personnel directly involved in the provision of such good, product or service. Intrexon may, from time to time, adjust such full-time equivalent rate based on changes to its actual fully loaded costs and will review the accuracy of its full-time equivalent rate at least quarterly. Intrexon shall provide Fibrocell with reasonable documentation indicating the basis for any direct and indirect charges, any allocable overhead, and any such adjustment in full-time equivalent rate.

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1.31 "Improved Product" means any non-genetically modified autologous fibroblast product in the Field that is created, produced, identified, or modified in whole or in part by or on behalf of Fibrocell during the Term using Intrexon Channel Technology, Intrexon IP, or the Intrexon Materials under the Fibroblast Program to improve the formulation or production process of the Existing Product.

1.32 "**In-Licensed Program IP**" has the meaning set forth in Section 3.9(a).

1.33 "**Information**" means information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including without limitation, databases, inventions, practices, methods, techniques, specifications, formulations, formulae, knowledge, know-how, skill, experience, test data including pharmacological, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, stability data, studies and procedures, and patent and other legal information or descriptions.

1.34 "**Infringement**" has the meaning set forth in Section 6.3(a).

1.35 "**Intrexon Channel Technology**" means Intrexon's current and future technology directed towards the design, identification, culturing, and/or production of genetically modified cells, including without limitation the technology embodied in the Intrexon Materials and the Intrexon IP, and specifically including without limitation the following of Intrexon's platform areas and capabilities: (1) UltraVector®, (2) LEAP™, (3) DNA and RNA MOD engineering, (4) protein engineering, (5) transcription control chemistry, (6) genome engineering, and (7) cell system engineering.

1.36 "**Intrexon Indemnitees**" has the meaning set forth in Section 9.2.

1.37 "**Intrexon IP**" means the Intrexon Patents and Intrexon Know-How.

1.38 "**Intrexon Know-How**" means all Information (other than Intrexon Patents) that (a) is Controlled by Intrexon as of the Effective Date or during the Term and (b) is reasonably required or useful for Fibrocell to conduct the Fibroblast Program. For the avoidance of doubt, the Intrexon Know-How shall include any Information (other than Intrexon Patents) in the Channel-Related Program IP.

1.39 "**Intrexon Materials**" means the genetic code and associated amino acids and gene constructs used alone or in combination and such other proprietary reagents including but not limited to plasmid vectors, virus stocks, cells and cell lines, antibodies, and ligand-related chemistry, in each case that are reasonably required or provided to Fibrocell by or on behalf of Intrexon to conduct the Fibroblast Program.

1.40 "**Intrexon Patents**" means all Patents that (a) are Controlled by Intrexon as of the Effective Date or during the Term; and (b) are reasonably required or useful for Fibrocell to conduct the Fibroblast Program. For the avoidance of doubt, the Intrexon Patents shall include any Patent in the Channel-Related Program IP.

1.41 "**Intrexon Trademarks**" means those trademarks related to the Intrexon Channel Technology that are established from time to time by Intrexon for use across its channel partnerships or collaborations.

1.42 "**Inventions**" has the meaning set forth in Section 6.1(b).

1.43 "**IPC**" has the meaning set forth in Section 2.2(b).

1.44 "**JSC**" has the meaning set forth in Section 2.2(b).

1.45 "**Losses**" has the meaning set forth in Section 9.1.

1.46 "Manufacturing Costs" means, with respect to Existing Products or Improved Products, as the case may be, the full-time equivalent costs (under a reasonable accounting mechanism to be agreed upon by the Parties) and out-of-pocket costs of a Party or any of its Affiliates incurred in manufacturing such products, including costs and expenses incurred in connection with (1) the development or validation of any manufacturing process, formulations or delivery systems, or improvements to the foregoing; (2) manufacturing scale-up; (3) in-process testing, stability testing and release testing; (4) quality assurance/quality control development; (5) internal and Third Party costs and expenses incurred in connection with qualification and validation of Third Party contract manufacturers, including scale up, process and equipment validation, and initial manufacturing licenses, approvals and inspections; (6) packaging development and final packaging and labeling; (7) shipping configurations and shipping studies; and (8) overseeing the conduct of any of the foregoing. "Manufacturing Costs" shall further include: (a) to the extent that any such Existing Product or Improved Product is manufactured by a Third Party manufacturer, the out-of-pocket costs incurred by such Party or any of its Affiliates to the Third Party for the manufacture and supply (including packaging and labeling) thereof, and any reasonable out-of-pocket costs and direct labor costs incurred by such Party or any of its Affiliates in managing or overseeing the Third Party relationship determined in accordance with the books and records of such Party or its Affiliates maintained in accordance with US GAAP; and (b) to the extent that any such Existing Product or Improved Product is manufactured by such Party or any of its Affiliates, direct material and direct labor costs attributable to such product, as well as reasonably allocable overhead expenses, determined in accordance with the books and records of such Party or its Affiliates maintained in accordance with US GAAP.

1.47 "**Net Sales**" means, with respect to any Fibrocell Product, the net sales of such Fibrocell Product by Fibrocell or an Affiliate of Fibrocell (including without limitation net sales of Fibrocell Product to a non-Affiliate sublicensee but not including net sales by such non-Affiliate sublicensee), as determined in accordance with US GAAP as the gross amount invoiced on account of sales of Fibrocell Product less the usual and customary discounts as determined in accordance with US GAAP. In the case of any sale for value, such as barter or counter-trade other than in an arm's length transaction exclusively for cash, Net Sales shall be deemed to be the net sales at which substantially similar quantities of the product are sold for cash in an arm's length transaction in the relevant country. If Fibrocell Product is sold to any third party together with other products or services, the price of such product, solely for purposes of the calculation of Net Sales, shall be deemed to be no less than the price at which such product would be sold in a similar transaction to a third party not also purchasing the other products or services.

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1.48 "**Patents**" means (a) all patents and patent applications (including provisional applications), (b) any substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, requests for continued examination, confirmations, re-examinations, extensions, supplementary protection certificates and the like of the foregoing, and (c) any foreign or international equivalents of any of the foregoing.

1.49 "**Product-Specific Program Patent**" means any issued Intrexon Patent where all the claims are directed to Inventions that relate solely and specifically to Fibrocell Products. In the event of a disagreement between the Parties as to whether a particular Intrexon Patent is or is not a Product-Specific Program Patent, the Parties shall seek to resolve the issue through discussions at the IPC, provided that if the Parties are unable to resolve the disagreement, the issue shall be submitted to arbitration pursuant to Section 11.2. Any Intrexon Patent that is subject to such a dispute shall be deemed not to be a Product-Specific Program Patent unless and until (a) Intrexon agrees in writing that such Patent is a Product-Specific Program Patent or (b) an arbitrator or arbitration panel determines, pursuant to Article 11, that such Intrexon Patent is a Product-Specific Program Patent.

1.50 "**Prosecuting Party**" has the meaning set forth in Section 6.2(c).

1.51 "**Recovery**" has the meaning set forth in Section 6.3(f).

1.52 "**Retained Product**" has the meaning set forth in Section 10.4(a).

1.53 "**Reverted Product**" has the meaning set forth in Section 10.4(c).

1.54 "**SEC**" means the United States Securities and Exchange Commission.

1.55 "**Sublicensing Revenue**" means any cash consideration, or the cash equivalent value of non-cash consideration, regardless of whether in the form of upfront payments, milestones, or royalties, actually received by Fibrocell or its Affiliate from a Third Party in consideration for a grant of a sublicense under the Intrexon IP or any rights to develop or Commercialize Fibrocell Products, but excluding: (a) any amounts paid as bona fide reimbursement for research and development costs to the extent incurred following such grant; (b) bona fide loans or any payments in consideration for a grant of equity of Fibrocell to the extent that such consideration is equal to or less than fair market value (i.e. any amounts in excess of fair market value shall be Sublicensing Revenue); and (c) amounts received from sublicensees in respect of any Fibrocell Product sales that are included in Net Sales.

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1.56 "**Superior Therapy**" means a therapy in the Field that, based on the data then available, (a) demonstrably appears to offer either superior efficacy or safety or significantly lower cost of therapy, as compared with both (i) those therapies that are marketed (either by Fibrocell or others) at such time for the indication and (ii) those therapies that are being actively developed by Fibrocell for such indication; (b) demonstrably appears to represent a substantial improvement over such existing therapies; and (c) has intellectual property protection and a regulatory approval pathway that, in each case, would not present a significant barrier to commercial development.

1.57 "**Supplemental In-Licensed Third Party IP**" has the meaning set forth in Section 3.9(a).

1.58 "**Support Memorandum**" has the meaning set forth in Section 11.2.

1.59 "**Technology Access Fee**" for the purposes of this Agreement has the meaning as set forth in Section 5.1.

1.60 "**Term**" has the meaning set forth in Section 10.1.

1.61 "**Territory**" means the United States of America.

1.62 "Third Party" means any individual or entity other than the Parties or their respective Affiliates.

1.63 "**Third Security**" means Third Security, LLC.

1.64 "**US GAAP**" means generally accepted accounting principles in the United States.

ARTICLE 2

SCOPE OF CHANNEL COLLABORATION; MANAGEMENT

2.1 Scope.

(a) Generally. The general purpose of the channel collaboration described in this Agreement will be to use the Intrexon Channel Technology to research, develop and Commercialize products for use in the Field (collectively, the " **Fibroblast Program**"). As provided below, the JSC shall establish, monitor, and govern projects for the Fibroblast Program. Either Party may propose potential projects in the Field for review and consideration by the JSC.

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2.2 Committees.

(a) Generally. The Parties desire to establish several committees (collectively, "**Committees**") to oversee the Fibroblast Program and to facilitate communications between the Parties with respect thereto. Each of such Committees shall have the responsibilities and authority allocated to it in this Article 2. Each of the Committees shall have the obligation to exercise its authority consistent with the respective purpose for such Committee as stated herein and any such decisions shall be made in good faith.

(b) Formation and Purpose. Promptly following the Effective Date, the Parties shall confer and then create the Committees listed in the chart below, each of which shall have the purpose indicated in the chart. To the extent that after conferring both Parties agree that a given Committee need not be created until a later date, the Parties may agree to defer the creation of the Committee until one Party informs the other Party of its then desire to create the so-deferred Committee, at which point the Parties will thereafter promptly create the so-deferred Committee and schedule a meeting of such Committee within one (1) month.

Committee	Purpose
Joint Steering Committee ("**JSC**")	Establish projects for the Fibroblast Program and establish the priorities, as well as approve budgets for such projects. Approve all subcommittee projects and plans. The JSC shall establish budgets not less than on a quarterly basis.
Chemistry, Manufacturing and Controls Committee ("**CMCC**")	Establish project plans and review and approve activities and budgets for chemistry, manufacturing, and controls under the Fibroblast Program.
Clinical/Regulatory Committee ("**CRC**")	Review and approve all research and development plans, clinical projects and publications, and regulatory filings and correspondence under the Fibroblast Program; review and approve itemized budgets with respect to the foregoing.
Commercialization Committee ("**CC**")	Establish project plans and review and approve activities and budgets for Commercialization activities under the Fibroblast Program.
Intellectual Property Committee ("IPC")	Evaluate intellectual property issues in connection with the Fibroblast Program; review and approve itemized budgets with respect to the foregoing.

2.3 General Committee Membership and Procedure .

(a) Membership. For each Committee, each Party shall designate an equal number of representatives (not to exceed four (4) for each Party) with appropriate expertise to serve as members of such Committee. For the JSC the representatives must all be employees of such Party or an Affiliate of such Party, and for Committees other than the JSC the representatives must all be employees of such Party or an Affiliate of such Party with the caveat that each Party may designate for each such other Committee up to one (1) representative who is not an employee if : (i) such non-employee representative agrees in writing to be bound to the terms of this Agreement for the treatment and ownership of Confidential Information and Inventions of the Parties, and (ii) the other Party consents to the designation of such non-employee representative, which consent shall not be unreasonably withheld. For purposes of this Section 2.3, employees of Third Security may, at Intrexon's election, serve as members of a Committee as if they were employees of Intrexon. Each representative as qualified above may serve on more than one (1) Committee as appropriate in view of the individual's expertise. Each Party may replace its Committee representatives at any time upon written notice to the other Party. Each Committee shall have a chairperson; the chairperson of each committee shall serve for a two-year term and the right to designate which representative to the Committee will act as chairperson shall alternate between the Parties, with Fibrocell selecting the chairperson first for the JSC, CRC and CC, and Intrexon selecting the chairperson first for the CMCC and IPC. The chairperson of each Committee shall be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting of such Committee, and preparing and issuing minutes of each meeting within fifteen (15) days thereafter.

(b) Meetings. Each Committee shall hold meetings at such times as it elects to do so, but in no event shall such meetings be held less frequently than once every six (6) months, with the caveat that both Parties may agree to suspend activities of a given Committee other than the JSC until such time as one Party informs the other Party of its then desire to reactivate the so-suspended Committee, at which point the Parties will thereafter schedule and hold the next meeting for the reactivated Committee within one (1) month. Meetings of any Committee may be held in person or by means of telecommunication (telephone, video, or web conferences). To the extent that a Committee holds any meetings in person, the Parties will alternate in designating the location for such in-person meetings, with Fibrocell selecting the first meeting location for each Committee. A reasonable number of additional representatives of a Party may attend meetings of a Committee in a non-voting capacity. Each Party shall be responsible for all of its own expenses of participating in any Committee excepting that an Intrexon employee or agent serving on a Committee shall not prevent Intrexon from recouping the Fully Loaded Costs otherwise derived from the labor of that employee or agent in the course of providing manufacturing or support services as set forth in Sections 4.6 and 4.7 below.

(c) Meeting Agendas. Each Party will disclose to the other proposed agenda items along with appropriate information at least three (3) business days in advance of each meeting of the applicable Committee; provided, that a Party may provide its agenda items to the other Party within a lesser period of time in advance of the meeting, or may propose that there not be a specific agenda for a particular meeting, so long as such other Party consents to such later addition of such agenda items or the absence of a specific agenda for such Committee meeting.

(d) Limitations of Committee Powers. Each Committee shall have only such powers as are specifically delegated to it hereunder or from time to time as agreed to in writing by the mutual consent of the Parties and shall not be a substitute for the rights of the Parties. Without limiting the generality of the foregoing, no Committee shall have any power to amend this Agreement. Any amendment to the terms and conditions of this Agreement shall be implemented pursuant to Section 12.7 below.

2.4 Committee Decision-Making. If a Committee is unable to reach unanimous consent on a particular matter within thirty (30) days of its initial consideration of such matter, then either Party may provide written notice of such dispute to the Executive Officer of the other Party. The Executive Officers of each of the Parties will meet at least once in person or by means of telecommunication (telephone, video, or web conferences) to discuss the dispute and use their good faith efforts to resolve the dispute within thirty (30) days after submission of such dispute to the Executive Officers. If any such dispute is not resolved by the Executive Officers within thirty (30) days after submission of such dispute to such officers, then the Executive Officer of the Party specified in the applicable subsection below shall have the authority to finally resolve such dispute acting in good faith.

(a) Casting Vote at JSC. If a dispute at the JSC is not resolved pursuant to Section 2.4 above, then the Executive Officer of Fibrocell shall have the authority to finally resolve such dispute.

(b) Casting Vote at CMCC. If a dispute at the CMCC is not resolved pursuant to Section 2.4 above, then (i) in the case of any disputes relating to the Intrexon Materials, the manufacture of a Fibrocell Product's active pharmaceutical ingredient, the use of Intrexon Channel Technology or Intrexon IP in the manufacture of an Improved Product's active pharmaceutical ingredient, or the manufacturing of other components of Fibrocell Products or Improved Products contracted for or manufactured by Intrexon or reasonable controls regarding the dissemination of Intrexon Technology, Intrexon IP or Intrexon Materials, the Executive Officer of Intrexon shall have the authority to finally resolve such dispute; and (ii) in the case of any other disputes, the Executive Officer of Fibrocell shall have the authority to finally resolve such dispute.

(c) Casting Vote at CRC. If a dispute at the CRC is not resolved pursuant to Section 2.4 above, then the Executive Officer of Fibrocell shall have the authority to finally resolve such dispute.

(d) Casting Vote at CC. If a dispute at the CC is not resolved pursuant to Section 2.4 above, then the Executive Officer of Fibrocell shall have the authority to finally resolve such dispute.

(e) Casting Vote at IPC. If a dispute at the IPC is not resolved pursuant to Section 2.4 above, then the Executive Officer of Intrexon shall have the authority to finally resolve such dispute, provided that such authority shall be shared by the Parties with respect to Product-Specific Program Patents (i.e., neither Party shall have the casting vote on such matters, and any such disputes shall be resolved pursuant to Article 11).

(f) Other Committees. If any additional Committee other than those set forth in Section 2.2(b) is formed, then the Parties shall, at the time of such formation, agree on which Party shall have the authority to finally resolve a dispute that is not resolved pursuant to Section 2.4 above.

(g) Restrictions. Neither Party shall exercise its right to finally resolve a dispute at a Committee in accordance with this Section 2.4 in a manner that (i) excuses such Party from any of its obligations specifically enumerated under this Agreement; (ii) expands the obligations of the other Party under this Agreement; (iii) negates any consent rights or other rights specifically allocated to the other Party under this Agreement; (iv) purports to resolve any dispute involving the breach or alleged breach of this Agreement; (v) resolves a matter if the provisions of this Agreement specify that mutual agreement is required for such matter; or (vi) would require the other Party to perform any act that is inconsistent with applicable law.

ARTICLE 3

LICENSE GRANTS

3.1 Licenses to Fibrocell.

(a) Subject to the terms and conditions of this Agreement, Intrexon hereby grants to Fibrocell a license under the Intrexon IP to research, develop, use, make, have made, sell, and offer for sale Fibrocell Products and Improved Products in the Field in the Territory. Such license shall be exclusive (even as to Intrexon) with respect to any clinical development, selling, offering for sale or other Commercialization of Fibrocell Products and Improved Products in the Field, and shall be otherwise non-exclusive.

(b) Subject to the terms and conditions of this Agreement, Intrexon hereby grants to Fibrocell a non-exclusive, royalty-free license to use and display the Intrexon Trademarks, solely in connection with the Commercialization of Fibrocell Products and Improved Products in the promotional materials, packaging, and labeling for Fibrocell Products and Improved Products, as provided under and in accordance with Section 4.9.

Portions herein identified by [*****] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

3.2 Sublicensing. Except as provided below, Fibrocell shall not sublicense the rights granted under Section 3.1 to any Third Party, or transfer the Intrexon Materials to any Third Party, or otherwise grant any Third Party the right to research, develop, use, or Commercialize Fibrocell Products or Improved Products or use or display the Intrexon Trademarks, in each case except with Intrexon's written consent, which written consent may be withheld in Intrexon's sole discretion. Notwithstanding the foregoing, Fibrocell shall have a limited right to sublicense under the circumstances described in Sections 3.2(a) and 3.2(b).

(a) Fibrocell may transfer, to the extent reasonably necessary, Intrexon Materials that are or express active pharmaceutical ingredients to a Third Party contractor performing contract manufacturing, fill, and/or finish responsibilities for Fibrocell Products or Improved Products, and may in connection therewith grant limited sublicenses necessary to enable such Third Party to perform such activities. If Fibrocell transfers any Intrexon Materials under this Section 3.2(a), Fibrocell will remain obligated to ensure that the rights of Intrexon in and to the Intrexon Materials and Intrexon IP and under the provisions of Articles 6 and 7 of this Agreement are not violated by any such Third Party contractor.

(b) Fibrocell may, with Intrexon's written consent, which consent cannot be unreasonably withheld, sublicense the rights granted under Section 3.1 to an Affiliate, or transfer the Intrexon Materials to an Affiliate, or grant an Affiliate the right to research, develop, use, or Commercialize Fibrocell Products or Improved Products or use or display the Intrexon Trademarks. In the event that Intrexon consents to any such grant or transfer to an Affiliate, Fibrocell shall remain responsible for, and be guarantor of, the performance by any such Affiliate and shall cause such Affiliate to comply with the provisions of this Agreement in connection with such performance (as though such Affiliate were Fibrocell), including any payment obligations owed to Intrexon hereunder.

3.3 Limitation on Sublicensees. None of the enforcement rights under the Intrexon Patents that are granted to Fibrocell pursuant to Section 6.3 shall be transferred to, or exercised by, a sublicensee except with Intrexon's prior written consent, which may be withheld in Intrexon's sole discretion.

3.4 No Non-Permitted Use. Fibrocell hereby covenants that it shall not, nor shall it permit any Affiliate or, if applicable, (sub)licensee, to use or practice, directly or indirectly, any Intrexon IP, Intrexon Channel Technology, or Intrexon Materials for any purposes other than those expressly permitted by this Agreement.

3.5 Exclusivity. Neither Intrexon nor its Affiliates shall make the Intrexon Channel Technology or Intrexon Materials available to any Third Party for the purpose of developing or Commercializing products in the Field (except as set forth in Section 3.2), and neither Intrexon nor any Affiliate shall pursue (either by itself or with a Third Party or Affiliate) the research, development or Commercialization of any product for purpose of sale in the Field, outside of the Fibroblast Program. Further, other than with respect to developing new indications for the Existing Product outside of the Fibroblast Program, neither Fibrocell nor its Affiliates shall pursue (either by itself or with a Third Party or Affiliate) outside of the Fibroblast Program the research, development or Commercialization of any product for purpose of sale in the Field where such products would compete with Fibrocell Products. For the avoidance of doubt, Fibrocell may pursue development and implementation of manufacturing changes designed to reduce the COGS of the Existing Product outside of the Fibroblast Program so long as such does not utilize Intrexon Channel Technology or utilize Third Party gene or cell modification technology in leiu of using Intrexon Channel Technology.

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3.6 Off Label Use. For purpose of clarity, (a) following the Commercial Sale of a Fibrocell Product or Improved Product, the use by direct or indirect purchasers or other users of Fibrocell Products or Improved Products outside the Field (i.e. "off label use") shall not constitute a breach by Fibrocell of the terms of Section 3.3, 3.4 or 3.5, provided that neither Fibrocell nor its Affiliate (nor any Third Party under contract with either of them) marketed or promoted Fibrocell Products or Improved Products for such off-label use; and (b) following the Commercial Sale of a product by Intrexon, an Intrexon Affiliate, or a Third Party sublicensee, collaborator, or partner of Intrexon, the use by direct or indirect purchasers or other users of such products in the Field (i.e. "off label use") shall not constitute a breach by Intrexon of the terms of Section 3.5, provided that neither Intrexon nor its Affiliate (nor any Third Party under contract with either of them) marketed or promoted such products for such off-label use.

3.7 No Prohibition on Intrexon. Except as explicitly set forth in Sections 3.1 and 3.5, nothing in this Agreement shall prevent Intrexon from practicing or using the Intrexon Materials, Intrexon Channel Technology, and Intrexon IP for any purpose, and to grant to Third Parties the right to do the same. Without limiting the generality of the foregoing, Fibrocell acknowledges that Intrexon has all rights, in Intrexon's sole discretion, to make the Intrexon Materials, Intrexon Channel Technology (including any active pharmaceutical ingredient used in a Fibrocell Product), and Intrexon IP available to Third Party channel partners or collaborators for use in fields outside the Field.

3.8 Rights to Clinical and Regulatory Data . Fibrocell shall own and control all clinical data and regulatory filings relating to Commercialization of Fibrocell Products and Improved Products during the Term. Fibrocell shall provide at Intrexon's request full copies of all clinical and non-clinical data and reports, regulatory filings, and communications from regulatory authorities that relate specifically and solely to Fibrocell Products. To the extent that there exist any clinical and non-clinical data and reports, regulatory filings, and communications from regulatory authorities owned by Fibrocell that relate both to Fibrocell Products and other products produced by Fibrocell outside the Field or relate to an Improved Product, Fibrocell shall provide to Intrexon upon Intrexon's request copies of the portions of such data, reports, filings, and communications that relate to Fibrocell Products or relate to Intrexon's contribution to the Improved Product. Subject to its ongoing obligations of exclusivity under Section 3.5 and regarding off label use under 3.6, Intrexon shall be permitted, directly or in conjunction with or through partners or other channel collaborators, to reference this data, reports, filings, and communications relating to Fibrocell Products and Improved Products in regulatory filings made to obtain regulatory approval for products indicated for use in fields outside the Field. Intrexon shall have the right to use any such information in developing and Commercializing products outside the Field and to license any Third Parties to do so. Notwithstanding the provisions of this Section 3.8, Intrexon shall not, outside of the Fibroblast Program, utilize knowingly any Fibrocell clinical and non-clinical data or reports in support of obtaining regulatory approval for a product for use in the Field.

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3.9 Third Party Licenses.

(a) [*****] shall obtain [*****] any licenses from Third Parties that are required in order to practice the Intrexon Channel Technology in the Field where the licensed intellectual property is reasonably necessary for Intrexon to conduct genetic and cell engineering and related analytic activities under JSC established plans for the Fibroblast Program (but specifically excluding intellectual property directed to any processes or methods for harvesting, culturing, formulating, or otherwise manufacturing Fibrocell Products or Improved Products, or to any methods of treating humans with fibroblasts or administering fibroblasts for purposes of therapy in the Field) (" **Supplemental In-Licensed Third Party IP** "). Other than with respect to Supplemental In-Licensed Third Party IP, [*****] shall be solely responsible for obtaining [*****] any licenses from Third Parties that [*****] determines, in its sole discretion, are required in order to lawfully make, use, sell, offer for sale, or import Fibrocell Products (" **Complementary In-Licensed Third Party IP** "). Supplemental In-Licensed Third Party IP and Complementary In-Licensed Third Party IP are collectively referred to as " **In-Licensed Program IP** ".

(b) In the event that either Party desires to license from a Third Party any Supplemental In-Licensed Third Party IP or Complementary In-Licensed Third Party IP, such Party shall so notify the other Party, and the IPC shall discuss such In-Licensed Program IP and its applicability to the Fibrocell Products and to the Field. As provided above in Section 3.9(a), [*****] shall have the sole right and responsibility to pursue a license under Supplemental In-Licensed Third Party IP, and [*****] hereby covenants that it shall not itself directly license such Supplemental In-Licensed Third Party IP at any time, provided that [*****] may (but shall not be obligated to) obtain such a license directly if the Third Party owner or licensee of such Supplemental In-Licensed Third Party IP brings an infringement action against [*****] or its Affiliates and, after written notice to [*****] of such action, [*****] fails to obtain a license to such Supplemental In-Licensed Third Party IP using Diligent Efforts within ninety (90) days after such notice. Following the IPC's discussion of any Complementary In-Licensed Third Party IP, subject to Section 3.9(c), [*****] shall have the right to pursue a license under Complementary In-Licensed Third Party IP [*****]. For the avoidance of doubt, [*****] may at any time obtain a license under Complementary In-Licensed Third Party IP outside the Field [*****] provided that if [*****] decides to seek to obtain such a license, it shall use reasonable efforts to coordinate its licensing activities in this regard with [*****].

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(c) [*****] shall provide the proposed terms of any license under Complementary In-Licensed Third Party IP and the final version of the definitive license agreement for any Complementary In-Licensed Third Party IP to the IPC for review and discussion prior to signing, and shall consider [*****] comments thereto in good faith. To the extent that [*****] obtains a license under Supplemental In-Licensed Third Party IP, [*****] shall provide the final version of the definitive license agreement for such Supplemental In-Licensed Third Party IP to the IPC. If [*****] acquires rights under any In-Licensed Program IP outside the Field, it will do so on a non-exclusive basis unless it obtains the prior written consent of [*****] for such license outside the Field to be exclusive. Any Party that is pursuing a license to any In-Licensed Program IP with respect to the Field under this Section 3.9 shall keep the other Party reasonably informed of the status of any negotiations relating thereto. For purposes of clarity, (i) any costs incurred by [*****] in obtaining and maintaining licenses to Supplemental In-Licensed Third Party IP shall be borne solely by [*****], and (ii) any costs incurred by [*****] in obtaining and maintaining licenses to Complementary In-Licensed Third Party IP (and, to the limited extent provided in subsection (b), Supplemental In-Licensed Third Party IP) shall be borne solely by [*****].

(d) For any Third Party license under which Fibrocell or its Affiliates obtain a license under Patents claiming inventions or know-how specific to or used or incorporated into the development, manufacture, and/or Commercialization of Fibrocell Products, Fibrocell shall use commercially reasonable efforts to ensure that Fibrocell will have the ability, pursuant to Section 10.4(h), to assign such agreement to Intrexon or grant a sublicense to Intrexon thereunder (having the scope set forth in Section 10.4(h)).

(e) The licenses granted to Fibrocell under Section 3.1 may include sublicenses under Intrexon IP that has been licensed to Intrexon by one or more Third Parties. Any such sublicenses are subject to the terms and conditions set forth in the applicable upstream license agreement, subject to the cost allocation set forth in Section 3.9(c), provided that Intrexon shall either provide unredacted copies of such upstream license agreements to Fibrocell or shall disclose in writing to Fibrocell all of such terms and conditions that are applicable to Fibrocell. Fibrocell shall not be responsible for complying with any provisions of such upstream license agreements unless, and to the extent that, such provisions have been disclosed to Fibrocell as provided in the preceding sentence.

(f) If either Party receives notice from a Third Party concerning activities of a Party taken in conjunction with performance of obligations under this Agreement, which notice alleges infringement by a Party of, or offers license under, Patents or other intellectual property rights owned or controlled by that Third Party, the receiving Party shall inform the other party thereof within five (5) business days.

3.10 Licenses to Intrexon. Subject to the terms and conditions of this Agreement, Fibrocell hereby grants to Intrexon a non-exclusive, worldwide, fully-paid, royalty-free license, under any applicable Patents or other intellectual property Controlled by Fibrocell or its Affiliates, solely to the extent necessary for Intrexon to conduct those responsibilities assigned to it under this Agreement, which license shall be sublicensable solely to Intrexon's Affiliates or to any of Intrexon's permitted subcontractors.

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3.11 Restrictions Relating to Intrexon Materials. Fibrocell and its permitted sublicensees shall use the Intrexon Materials solely for purposes of the Fibroblast Program and not for any other purpose without the prior written consent of Intrexon. With respect to the Intrexon Materials comprising Intrexon's vector assembly technology, Fibrocell shall not, and shall ensure that Fibrocell personnel and permitted sublicensees do not, except as otherwise permitted in this Agreement (a) distribute, sell, lend or otherwise transfer such Intrexon Materials to any Third Party; (b) co-mingle such Intrexon Materials with any other proprietary biological or chemical materials without Intrexon's written consent; or (c) analyze such Intrexon Materials or in any way attempt to reverse engineer or sequence such Intrexon Materials.

ARTICLE 4

OTHER RIGHTS AND OBLIGATIONS

4.1 Development and Commercialization. Subject to Sections 4.6 and 4.7, Fibrocell shall be solely responsible for the development and Commercialization of Fibrocell Products and Improved Products. Fibrocell shall be responsible for all costs incurred in connection with the Fibroblast Program except that Intrexon shall be responsible for the following: (a) costs of establishing manufacturing capabilities and facilities in connection with Intrexon's manufacturing obligation under Section 4.6 (provided, however, that Intrexon may include an allocable portion of such costs, through depreciation and amortization, when calculating the Fully Loaded Cost of manufacturing a Fibrocell Product, to the extent such allocation, depreciation, and amortization is permitted by US GAAP, it being recognized that the majority of non-facilities scale-up costs cannot be capitalized and amortized under US GAAP); (b) costs of basic research with respect to the Intrexon Channel Technology and Intrexon Materials (i.e., platform improvements) but, for clarity, excluding research described in Section 4.7 or research requested by the JSC for the development of a Fibrocell Product or an Improved Product (which research costs shall be reimbursed by Fibrocell); (c) [*****]; and (d) costs of filing, prosecution and maintenance of Intrexon Patents. The costs encompassed within subsection (a) above shall include the scale-up of Intrexon Materials and related active pharmaceutical ingredients for clinical trials and Commercialization of Fibrocell Products undertaken pursuant to Section 4.6, which shall be at Intrexon's cost whether it elects to conduct such efforts internally or through Third Party contractors retained by either Intrexon or Fibrocell (with Intrexon's consent).

4.2 Transfer of Technology and Information. The JSC shall develop a plan and protocol for each project and timing for the transfer of relevant Information and materials between the Parties.

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4.3 Information and Reporting. Fibrocell will keep Intrexon informed about Fibrocell's efforts to develop and Commercialize Fibrocell Products and Improved Products, including reasonable and accurate summaries of Fibrocell's (and its Affiliates' and, if applicable, (sub)licensees') development plans (as updated), including preclinical, clinical and regulatory plans, marketing plans (as updated), progress towards meeting the goals and milestones in such plans and explanations of any material deviations, significant developments in the development and/or Commercialization of the Fibrocell Products and Improved Products, including initiation or completion of a clinical trial, submission of a United States or international regulatory filing, receipt of a response to such United States or international regulatory filing, clinical safety event, receipt of Regulatory Approval, or commercial launch, and manufacturing and pricing information, including data evidencing current COGS for any Existing Products. As set forth in Section 3.8 above, Fibrocell shall also provide to Intrexon copies of all final preclinical protocols and reports, final clinical protocols and reports, and regulatory correspondence and filings generated by Fibrocell as soon as practical after they become available. Intrexon will keep Fibrocell informed about Intrexon's efforts (a) to establish manufacturing capabilities and facilities for Fibrocell Products and Improved Products (and Intrexon Materials relevant thereto) and otherwise perform its manufacturing responsibilities under Section 4.6 and (b) to undertake discovery-stage research for the Fibroblast Program with respect to the Intrexon Channel Technology and Intrexon Materials. Unless otherwise provided herein or directed by the JSC in accord with Section 4.2 above, such disclosures by Fibrocell and Intrexon will be made in the course of JSC meetings at least once every six (6) months while Fibrocell Products and Improved Products are being developed or Commercialized anywhere in the world, and shall be reflected in the minutes of such meetings.

4.4 Regulatory Matters. At all times after the Effective Date, Fibrocell shall own and maintain, at its own cost, all regulatory filings and regulatory approvals for Fibrocell Products and Improved Products that Fibrocell is developing or Commercializing pursuant to this Agreement. As such, Fibrocell shall be responsible for reporting all adverse events related to such Fibrocell Products and Improved Products to the appropriate regulatory authorities in the relevant countries, in accordance with the applicable laws and regulations of such countries. To the extent that Intrexon will itself develop, or in collaboration with other third parties develop, Intrexon Materials outside of the Field, Intrexon may request that Fibrocell and Intrexon establish and execute a separate safety data exchange agreement, which agreement will address and govern the timely exchange of safety information generated by Fibrocell, Intrexon, and relevant third parties with respect to specific Intrexon Materials. The decision to list or not list Patents in any regulatory filing for a Fibrocell Product (for example, as required by 21 C.F.R. § 314.53(b)), add or delete a Patent from a regulatory filing, or to otherwise identify a Patent to a third party in compliance with laws or regulations relating to regulatory approvals (for example, in compliance with 42 U.S.C. § 262(a)(1)(A)(k) et seq.) shall be determined by Intrexon, after consultation with Fibrocell, except with respect to Product Specific Program Patents, which will be mutually determined by the Parties.

4.5 Diligence.

(a) Fibrocell shall use, and shall require its sublicensees to use, Diligent Efforts to develop and Commercialize Fibrocell Products and Improved Products.

(b) Without limiting the generality of the foregoing, Intrexon may, from time to time, notify Fibrocell that it believes it has identified a Superior Therapy, and in such case Intrexon shall provide to Fibrocell its then-available information about such therapy and reasonable written support for its conclusion that the therapy constitutes a Superior Therapy. Fibrocell shall have the following obligations with respect to such proposed Superior Therapy: (i) within sixty (60) days after such notification, Fibrocell shall prepare and deliver to the JSC for review and approval a development plan detailing how Fibrocell will pursue the Superior Therapy (including a proposed budget); (ii) Fibrocell shall revise the development plan as directed by the JSC; and (iii) following approval of the development plan by the JSC, Fibrocell shall use Diligent Efforts to pursue the development of the Superior Therapy under the Fibroblast Program in accordance with such development plan. If Fibrocell fails to comply with the foregoing obligations, or if Fibrocell unreasonably exercises its casting vote at the JSC to either (x) prevent the approval of a development plan for a Superior Therapy; (y) delay such approval more than sixty (60) days after delivery of the development plan to the JSC; or (z) approve a development plan that is insufficient in view of the nature and magnitude of the opportunity presented by the Superior Therapy, then Intrexon shall have the termination right set forth in Section 10.2(c) (subject to the limitation set forth therein). For clarity, any dispute arising under this 4.5, including any dispute as to whether a proposed project constitutes a Superior Therapy (as with any other dispute under this Agreement) shall be subject to dispute resolution in accordance with Article 11.

(c) The activities of Fibrocell's Affiliates and any permitted sublicensees shall be attributed to Fibrocell for the purposes of evaluating Fibrocell's fulfillment of the obligations set forth in this Section 4.5.

4.6 Manufacturing. Intrexon shall have the option and, in the event it so elects, shall use Diligent Efforts, to perform any manufacturing activities in connection with the Fibroblast Program that relate to the Intrexon Materials. To the extent that Intrexon so elects, Intrexon may request that Fibrocell and Intrexon establish and execute a separate manufacturing and supply agreement, which agreement will establish and govern the production, quality assurance, and regulatory activities associated with manufacture of Intrexon Materials. Except as provided in Section 4.1, any manufacturing undertaken by Intrexon pursuant to the preceding sentence shall be performed in exchange for cash payments equal to Intrexon's Fully Loaded Cost in connection with such manufacturing, on terms to be negotiated by the Parties in good faith. In the event that Intrexon does not manufacture Intrexon Materials, bulk drug product or bulk quantities of other components of Fibrocell Products, then Intrexon shall provide to Fibrocell or a contract manufacturer selected by Fibrocell and approved by Intrexon all Information Controlled by Intrexon that is related to the manufacturing of such Intrexon Materials, bulk drug product or bulk qualities of other components of Fibrocell Products, for use in the Field and is reasonably necessary to enable Fibrocell or such contract manufacturer (as appropriate) for the sole purpose of manufacturing such Intrexon Materials, bulk drug product or bulk quantities of other components of Fibrocell Products, in each case as manufactured by Intrexon. The costs and expenses incurred by Intrexon in carrying out such transfer shall be borne by Intrexon. Any manufacturing Information transferred hereunder to Fibrocell or its contract manufacturer shall not be further transferred to any Third Party, including any Product Sublicensee, or any Fibrocell Affiliate without the prior written consent of Intrexon; provided, however, that Intrexon shall not unreasonably withhold such consent if necessary to permit Fibrocell to switch manufacturers.

4.7 Support Services. The JSC will meet promptly following the Effective Date and establish a plan under which Intrexon will provide support services to Fibrocell for the research and development of Fibrocell Products and Improved Products under the Fibroblast Program, which initial plan may be amended from time to time by the JSC. Fibrocell will compensate Intrexon for such support services with cash payments equal to Intrexon's Fully Loaded Cost in connection with such services. Additionally, from time to time, on an ongoing basis, Fibrocell shall request, or Intrexon may propose, that Intrexon perform certain additional support services with respect to researching and developing new Fibrocell Products or improving the manufacturing or processing methods for the Existing Product to produce Improved Products. To the extent that the Parties mutually agree that Intrexon should perform such additional services, the Parties shall negotiate in good faith the terms under which services would be performed, it being understood that Intrexon would be compensated for such services by cash payments equal to Intrexon's Fully Loaded Cost in connection with such services.

4.8 Compliance with Law. Each Party shall comply, and shall ensure that its Affiliates, (sub)licensees and Third Party contractors comply, with all applicable laws, regulations, and guidelines applicable to the Fibroblast Program, including without limitation those relating to the transport, storage, and handling of Intrexon Materials, Fibrocell Products, and Improved Products.

4.9 Trademarks and Patent Marking. To the extent permitted by applicable law and regulations, Fibrocell shall ensure that the packaging, promotional materials, and labeling for Fibrocell Products and Improved Products shall carry, in a conspicuous location, the applicable Intrexon Trademark(s), subject to Fibrocell's reasonable approval of the size, position, and location thereof. Consistent with the U.S. patent laws, Fibrocell shall ensure that Fibrocell Products and Improved Products, or their respective packaging or accompanying literature as appropriate, bear applicable and appropriate patent markings for Intrexon Patent numbers. Fibrocell shall provide Intrexon with copies of any materials containing the Intrexon Trademarks or patent markings prior to using or disseminating such materials, in order to obtain Intrexon's approval thereof. Fibrocell's use of the Intrexon Trademarks and patent markings shall be subject to prior review and approval of the IPC. Fibrocell acknowledges Intrexon's sole ownership of the Intrexon Trademarks and agrees not to take any action inconsistent with such ownership. Fibrocell covenants that it shall not use any trademark confusingly similar to any Intrexon Trademarks in connection with any products (including any Fibrocell Product or Improved Product). From time to time during the Term, Intrexon shall have the right to obtain from Fibrocell samples of Fibrocell Product or Improved Product sold by Fibrocell or its Affiliates or sublicensees, or other items which reflect public uses of the Intrexon Trademarks or patent markings, for the purpose of inspecting the quality of such Fibrocell Products or Improved Products, the use of the Intrexon Trademarks, or the accuracy of the patent markings. In the event that Intrexon inspects under this Section 4.9, Intrexon shall notify the result of such inspection to Fibrocell in writing thereafter. Fibrocell shall comply with reasonable policies provided by Intrexon from time-to-time to maintain the goodwill and value of the Intrexon Trademarks.

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4.10 Reporting Compliance. During the Term, in the event that Intrexon notifies Fibrocell that Intrexon has reasonably concluded, after consultation with its outside advisors, that Intrexon will have to consolidate Fibrocell's financial statements with its own, for so long as Intrexon reasonably believes that such consolidation is necessary, Fibrocell shall comply with the following additional obligations:

(a) Fibrocell shall maintain at its principal place of business or, upon notice to Intrexon, at such other place as Fibrocell shall determine:

(i) a copy of Fibrocell's certificate of incorporation or organizational document and all amendments thereto, together with executed copies of any powers of attorney pursuant to which any amendment has been executed;

(ii) a copy of this Agreement;

(iii) a copy of Fibrocell's federal, state, and local income tax returns and reports, if any; and

(iv) minutes of meetings of Fibrocell's board of directors and shareholders or actions by written consent in lieu thereof, redacted as necessary by Fibrocell to exclude any sensitive or confidential information that Intrexon, by operation of law or contractual stipulation, is not permitted to receive.

(b) Fibrocell shall keep its books and records consistent with US GAAP.

(c) Intrexon at its own expense and upon reasonable notice, may examine any information it may reasonably request (including, to the extent Fibrocell has the right to provide such, the work papers of Fibrocell's internal and independent auditors) and make copies of and abstracts from the financial and operating records and books of account of Fibrocell, and discuss the affairs, finances and accounts of Fibrocell with Fibrocell and independent auditors of Fibrocell, all at such reasonable times and as often as Intrexon or any agents or representatives of Intrexon may reasonably request. The rights granted pursuant to this Section 4.10(c) are expressly subject to compliance by Intrexon with the safety, security and confidentiality procedures and guidelines of Fibrocell, as such procedures and guidelines may be established from time to time.

(d) As soon as available but no later than ninety (90) days after the end of each fiscal year, Fibrocell shall cause to be prepared and Intrexon to be furnished with an audited balance sheet as of the last day of such fiscal year and an audited income statement, a statement of stockholders' equity and statement of cash flows for Fibrocell for such fiscal year and notes associated with each, in each case prepared in accordance with US GAAP, together with a report of Fibrocell's independent auditor that such statements have been prepared in accordance with US GAAP and present fairly, in all material respects, the financial position, results of operations and cash flows of Fibrocell.

(e) As soon as available but no later than forty five (45) days after the end of each calendar quarter, Fibrocell shall furnish the following to Intrexon an unaudited balance sheet as of the last day of such period, and an unaudited income statement, a statement of cash flows and a statement of stockholders' equity for Fibrocell for such period, in each case prepared in accordance with US GAAP.

(f) As requested by Intrexon on no more than a quarterly basis, a certificate, executed by the Executive Officer of Fibrocell, certifying on behalf of Fibrocell the following:

(i) Fibrocell maintains accurate books and records reflecting its assets and liabilities and maintains proper and adequate internal accounting controls that provide assurance that (1) transactions are executed with management's authorization; (2) transactions are recorded as necessary to permit preparation of the consolidated financial statements of Fibrocell and to maintain accountability for Fibrocell's consolidated assets; (3) access to the assets of Fibrocell is permitted only in accordance with management's authorization; (4) the reporting of assets of Fibrocell is compared with existing assets at regular intervals; and (5) accounts, notes and other receivables and inventory are recorded accurately, and proper and adequate procedures are implemented to effect the collection of accounts, notes and other receivables on a current and timely basis.

(ii) under the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder; any such controls and procedures are effective to ensure that all material information concerning (ii)Fibrocell is made known on a timely basis to those individuals responsible for the preparation of any filings that may be required to be made by Intrexon with the SEC and other public disclosure documents.

(g) Fibrocell shall promptly prepare and furnish to Intrexon any information, whether written or oral, requested by Intrexon that is reasonably necessary for purposes of Intrexon's ongoing compliance with applicable law.

4.11 Modification of Deadlines. The parties agree that the delivery deadlines in Section 4.10 will be modified to the extent necessary to ensure that such deliverables are provided by Fibrocell no less than thirty (30) days prior (inclusive of any cure period set forth in Section 10.2(a)) to the date necessary for Intrexon to meet any disclosure obligation under rules or regulations to which Intrexon may be or become subject from time to time. Intrexon will provide Fibrocell with notice as promptly as practicable regarding any changes in Intrexon's disclosure obligations that would require a change in delivery deadlines or cure periods under this Section 4.11.

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ARTICLE 5

COMPENSATION

5.1 Technology Access Fee. In partial consideration for Fibrocell's appointment as an exclusive channel collaborator in the Field and the other rights granted to Fibrocell hereunder, Fibrocell shall issue to Intrexon, as an access fee for commercial license rights to the Intrexon IP granted under Section 3.1, certain equity interests in Fibrocell (each, a "**Technology Access Fee**") in accordance with the terms and conditions of the Stock Issuance Agreement and the Registration Rights Agreement, each of even date herewith (collectively, the "**Equity Agreements**"). As set forth in the Equity Agreements, the Technology Access Fee will be that number of shares of Fibrocell common stock having a value equaling $3,293,800 (the number of shares to be calculated according to the terms of the Equity Agreements), and such shares issuance will occur contemporaneously with the execution of this Agreement and the Equity Agreements. Provided that all closing conditions for the Technology Access Fee Shares (as defined in the Equity Agreements) that are within the reasonable control of Intrexon have been satisfied or waived, the issuance of the Technology Access Fee Shares (as set forth in the Equity Agreements) is a condition subsequent to the effectiveness of this Agreement.

5.2 Equity Agreements Control. All issuances of equity interests to Intrexon, or cash payments to Intrexon in lieu of equity, shall be in accordance with the terms and conditions of the Equity Agreements, which Equity Agreements shall control to the extent they may conflict with Section 5.1 of this Agreement.

5.3 Revenue Sharing.

(a) No later than thirty (30) days after each calendar quarter in which there were positive aggregate Net Sales arising from the sale of Fibrocell Products in the Field and Territory, Fibrocell shall pay to Intrexon a royalty based upon the aggregate net sales for all Fibrocell Products for the preceding calendar quarter as follows: a seven percent (7%) royalty on the first twenty-five million dollars ($25M) of aggregate Net Sales during that quarter, and a fourteen percent (14%) royalty on the portion of aggregate Net Sales during that quarter that exceed twenty-five million dollars ($25M). Commencing with the Effective Date, in the event that there are negative Net Sales for a particular Fibrocell Product in any calendar quarter, neither Fibrocell nor Intrexon shall owe any payments hereunder with respect to such Fibrocell Product. Any negative Net Sales that results from Excess Product Liability Costs may be carried forward to future quarters and offset against positive Net Sales in such future quarters for the same Fibrocell Product. Except as set forth in the preceding sentence, Fibrocell shall not be permitted to carry forward any negative Net Sales to subsequent quarters.

(b) No later than thirty (30) days after each calendar quarter in which Fibrocell or any Fibrocell Affiliate receives Sublicensing Revenue, Fibrocell shall pay to Intrexon fifty percent (50%) of such Sublicensing Revenue.

Portions herein identified by [*****] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

(c) No later than thirty (30) days after each calendar quarter in which there were COGS Savings realized from the sale of any Improved Product in the Field, Fibrocell shall pay to Intrexon a royalty equal to one-third (1/3) of the COGS Savings.

5.4 Method of Payment. Except for payments payable as and made in the form of equity interests, payments due to Intrexon under this Agreement shall be paid in United States dollars by wire transfer to a bank in the United States designated in writing by Intrexon. All references to "dollars" or "$" herein shall refer to United States dollars.

5.5 Payment Reports and Records Retention. Within thirty (30) days after the end of each calendar quarter during which Net Sales or COGS Savings have been generated, during which Sublicensing Revenue has been received, or during which a negative Net Sales has occurred, Fibrocell shall deliver to Intrexon a written report that shall contain at a minimum for the applicable calendar quarter:

(a) gross sales of each Fibrocell Product and each Improved Product (both on a country-by-country basis);

(b) itemized calculation of Net Sales, showing all applicable deductions;

(c) itemized calculation of Sublicensing Revenue;

(d) itemized calculation of COGS Savings, showing the calculation of COGS for the Existing Product prior to being improved under the Fibroblast Program and the COGS calculation for the Improved Product (including any mutually agreed exclusions per Section 1.8);

(e) the amount of any negative Net Sales for the applicable calendar quarter, and any negative Net Sales amount carried forward from a prior quarter and applied during the present quarter (as per Section 5.3(a));

(f) the amount of the payment (if any) due pursuant to each of Sections 5.3(a) through 5.3(c);

(g) the amount of taxes, if any, withheld to comply with any applicable law; and

(h) the exchange rates used in any of the foregoing calculations.

For three (3) years after each sale of Fibrocell Product or Improved Product, or after incurring any component item Fibrocell incorporated into its calculation of Net Sales as reported to Intrexon, Fibrocell shall keep (and shall ensure that its Affiliates and, if applicable, (sub)licensees shall keep) complete and accurate records of such sales or component item in sufficient detail to confirm the accuracy of the payment calculations hereunder.

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5.6 Audits.

(a) Upon the written request of Intrexon, Fibrocell shall permit an independent certified public accounting firm of internationally recognized standing selected by Intrexon, and reasonably acceptable to Fibrocell, to have access to and to review, during normal business hours and upon no less than thirty (30) days prior written notice, the applicable records of Fibrocell and its Affiliates to verify the accuracy and timeliness of the reports and payments made by Fibrocell under this Agreement. Such review may cover the records for sales made in any calendar year ending not more than three (3) years prior to the date of such request. The accounting firm shall disclose to both Parties whether the royalty reports and/or know-how reports conform to the provisions of this Agreement and/or US GAAP, as applicable, and the specific details concerning any discrepancies. Such audit may not be conducted more than once in any calendar year.

(b) If such accounting firm concludes that additional amounts were owed during such period, Fibrocell shall pay additional amounts, with interest from the date originally due as set forth in Section 5.8, within thirty (30) days of receipt of the accounting firm's written report. If the amount of the underpayment is greater than five percent (5%) of the total amount actually owed for the period audited, then Fibrocell shall in addition reimburse Intrexon for all costs related to such audit; otherwise, Intrexon shall pay all costs of the audit. In the event of overpayment, any amount of such overpayment shall be fully creditable against amounts payable for the immediately succeeding calendar quarter(s).

(c) Intrexon shall (i) treat all information that it receives under this Section 5.6 in accordance with the confidentiality provisions of Article 7 and (ii) cause its accounting firm to enter into an acceptable confidentiality agreement with Fibrocell obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement, in each case except to the extent necessary for Intrexon to enforce its rights under this Agreement.

5.7 Taxes. The Parties will cooperate in good faith to obtain the benefit of any relevant tax treaties to minimize as far as reasonably possible any taxes which may be levied on any amounts payable hereunder. Fibrocell shall deduct or withhold from any payments any taxes that it is required by applicable law to deduct or withhold. Notwithstanding the foregoing, if Intrexon is entitled under any applicable tax treaty to a reduction of the rate of, or the elimination of, applicable withholding tax, it may deliver to Fibrocell or the appropriate governmental authority (with the assistance of Fibrocell to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve Fibrocell of its obligation to withhold tax, and Fibrocell shall apply the reduced rate of withholding tax, or dispense with withholding tax, as the case may be, provided that Fibrocell has received evidence of Intrexon's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least fifteen (15) days prior to the time that the payment is due. If, in accordance with the foregoing, Fibrocell withholds any amount, it shall make timely payment to the proper taxing authority of the withheld amount, and send to Intrexon proof of such payment within forty-five (45) days following that latter payment.

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5.8 Late Payments. Any amount owed by Fibrocell to Intrexon under this Agreement that is not paid within the applicable time period set forth herein shall accrue interest at the lower of (a) two percent (2%) per month, compounded, or (b) the highest rate permitted under applicable law.

ARTICLE 6

INTELLECTUAL PROPERTY

6.1 Ownership.

(a) Subject to the license granted under Section 3.1, all rights in the Intrexon IP shall remain with Intrexon.

(b) Fibrocell and/or Intrexon may solely or jointly conceive, reduce to practice or develop discoveries, inventions, processes, techniques, and other technology, whether or not patentable, in the course of performing the Fibroblast Program (collectively " **Inventions**"). Each Party shall promptly provide the other Party with a detailed written description of any such Inventions that relate to the Field. Inventorship shall be determined in accordance with United States patent laws.

(c) Intrexon shall solely own all right, title and interest in all Inventions made with, using, or otherwise incorporating Intrexon Channel Technology, together with all Patent rights and other intellectual property rights therein (the " **Channel-Related Program IP**"). Fibrocell hereby assigns all of its right, title and interest in and to the Channel-Related Program IP to Intrexon. Fibrocell agrees to execute such documents and perform such other acts as Intrexon may reasonably request to obtain, perfect and enforce its rights to the Channel-Related Program IP and the assignment thereof.

(d) Notwithstanding anything to the contrary in this Agreement, any discovery, invention, process, technique, or other technology, whether or not patentable, that is conceived, reduced to practice or developed by Fibrocell solely or jointly through the use of the Intrexon Channel Technology, Intrexon IP, or Intrexon Materials in breach of the terms and conditions of this Agreement, together with all patent rights and other intellectual property rights therein, shall be solely owned by Intrexon and shall be included in the Channel-Related Program IP.

(e) All Information regarding Channel-Related Program IP shall be Confidential Information of Intrexon. Fibrocell shall be under appropriate written agreements with each of its employees, contractors, or agents working on the Fibroblast Program, pursuant to which such person shall grant all rights in the Inventions to Fibrocell (so that Fibrocell may convey certain of such rights to Intrexon, as provided herein) and agree to protect all Confidential Information relating to the Fibroblast Program.

Portions herein identified by [*****] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

6.2 Patent Prosecution.

(a) Intrexon shall have the sole right, but not the obligation, to (a) conduct and control the filing, prosecution and maintenance of the Intrexon Patents, and (b) conduct and control the filing, prosecution, and maintenance of any applications for patent term extension and/or supplementary protection certificates that may be available as a result of the regulatory approval of any Fibrocell Product. At the reasonable request of Intrexon, Fibrocell shall cooperate with Intrexon in connection with such filing, prosecution, and maintenance, at Intrexon's expense. Under no circumstances shall Fibrocell (a) file, attempt to file, or assist anyone else in filing, or attempting to file, any Patent application, either in the United States or elsewhere, that claims or uses or purports to claim or use or relies for support upon an Invention owned by Intrexon, (b) use, attempt to use, or assist anyone else in using or attempting to use, the Intrexon Know-How, Intrexon Materials, or any Confidential Information of Intrexon to support the filing of a Patent application, either in the United States or elsewhere, that contains claims directed to the Intrexon IP, Intrexon Materials, or the Intrexon Channel Technology, or (c) without prior approval of the IPC, file, attempt to file, or assist anyone else in filing, or attempting to file, any application for patent term extension or supplementary protection certificate, either in the United States or elsewhere, that relies upon the regulatory approval of a Fibrocell Product.

(b) Fibrocell shall have the sole right, but not the obligation, to conduct and control the filing, prosecution and maintenance of any Patents claiming Inventions that are owned by Fibrocell or its Affiliates and not assigned to Intrexon under Section 6.1(c) (" **Fibrocell Program Patents**"). At the reasonable request of Fibrocell, Intrexon shall cooperate with Fibrocell in connection with such filing, prosecution, and maintenance, at Fibrocell's expense.

(c) The Prosecuting Party shall be entitled to use patent counsel selected by it and reasonably acceptable to the non-Prosecuting Party (including in-house patent counsel as well as outside patent counsel) for the prosecution of the Intrexon Patents and Fibrocell Program Patents, as applicable. The Prosecuting Party shall:

(i) regularly provide the other Party in advance with reasonable information relating to the Prosecuting Party's prosecution of Patents hereunder, including by providing copies of substantive communications, notices and actions submitted to or received from the relevant patent authorities and copies of drafts of filings and correspondence that the Prosecuting Party proposes to submit to such patent authorities (it being understood that, to the extent that any such information is readily accessible to the public, the Prosecuting Party may, in lieu of directly providing copies of such information to such other Party, provide such other Party with sufficient information that will permit such other Party to access such information itself directly);

(ii) consider in good faith and consult with the non-Prosecuting Party regarding its timely comments with respect to the same; provided, however, that if, within fifteen (15) days after providing any documents to the non-Prosecuting Party for comment, the Prosecuting Party does not receive any written communication from the non-Prosecuting Party indicating that it has or may have comments on such document, the Prosecuting Party shall be entitled to assume that the non-Prosecuting Party has no comments thereon;

(iii) consult with the non-Prosecuting Party before taking any action that would reasonably be expected to have a material adverse impact on the scope of claims within the Intrexon Patents and Fibrocell Program Patents, as applicable.

As used above "**Prosecuting Party**" means Intrexon in the case of Intrexon Patents and Fibrocell in the case of Fibrocell Program Patents.

6.3 Infringement of Patents by Third Parties.

(a) Except as expressly provided in the remainder of this Section 6.3, Intrexon shall have the sole right to take appropriate action against any person or entity directly or indirectly infringing any Intrexon Patent (or asserting that an Intrexon Patent is invalid or unenforceable) (collectively, "**Infringement**"), either by settlement or lawsuit or other appropriate action.

(b) Notwithstanding the foregoing, Fibrocell shall have the first right, but not the obligation, to take appropriate action to enforce Product-Specific Program Patents against any Infringement that involves a commercially material amount of allegedly infringing activities in the Field (" **Field Infringement**"), either by settlement or lawsuit or other appropriate action. If Fibrocell exercises the foregoing right, Intrexon agrees to be named in any such action if required. If Fibrocell fails to take the appropriate steps to enforce Product-Specific Program Patents against any Field Infringement within one hundred eighty (180) days of the date one Party has provided notice to the other Party pursuant to Section 6.3(g) of such Field Infringement, then Intrexon shall have the right (but not the obligation), at its own expense, to enforce Product-Specific Program Patents against such Field Infringement, either by settlement or lawsuit or other appropriate action.

(c) With respect to any Field Infringement that cannot reasonably be abated through the enforcement of Product-Specific Program Patents pursuant to Section 6.3(b) but can reasonably be abated through the enforcement of Intrexon Patent(s) (other than the Product-Specific Program Patents), Intrexon shall be obligated to choose one of the following courses of action: (i) enforce one or more of the applicable Intrexon Patent(s) in a commercially reasonable manner against such Field Infringement, or (ii) [*****]. To the extent Fibrocell shall be entitled to a share of the Recovery a set forth in Section 6.3(f), Intrexon and Fibrocell shall bear the costs and expenses of such enforcement equally. The determination of which Intrexon Patent(s) to assert shall be made by Intrexon in its sole discretion; provided, however, that Intrexon shall consult in good faith with Fibrocell on such determination. For the avoidance of doubt, Intrexon has no obligations under this Agreement to enforce any Intrexon Patents against, or otherwise abate, any Infringement that is not a Field Infringement.

(d) In the event a Party pursues an action under this Section 6.3, the other Party shall reasonably cooperate with the enforcing Party with respect to the investigation and prosecution of any alleged, threatened, or actual Infringement, at the enforcing Party's expense (except with respect to an action under Section 6.3(c), where all costs and expenses will be shared equally in accordance with terms thereof).

(e) Fibrocell shall not settle or otherwise compromise any action under this Section 6.3 in a way that diminishes the rights or interests of Intrexon outside the Field or adversely affects any Intrexon Patent without Intrexon's prior written consent, which consent shall not be unreasonably withheld. Intrexon shall not settle or otherwise compromise any action under this Section 6.3 in a way that diminishes the rights or interests of Fibrocell in the Field or adversely affects any Intrexon Patent with respect to the Field without Fibrocell's prior written consent, which consent shall not be unreasonably withheld.

(f) Except as otherwise agreed to by the Parties in writing, any settlements, damages or other monetary awards recovered pursuant to a suit, proceeding, or action brought pursuant to Section 6.3 will be allocated first to the costs and expenses of the Party controlling such action, and second, to the costs and expenses (if any) of the other Party (to the extent not otherwise reimbursed), and any remaining amounts (the **"Recovery"**) will be shared by the Parties as follows: In any action initiated by Intrexon pursuant to Section 6.3(a) that does not involve Field Infringement, or in any action initiated by Intrexon pursuant to Section 6.3(b), Intrexon shall retain one hundred percent (100%) of any Recovery. In any action initiated by Fibrocell pursuant to Section 6.3(b), Fibrocell shall retain one hundred percent (100%) of any Recovery, but such Recovery shall be shared with Intrexon as Sublicensing Revenue. In any action initiated by Intrexon or Fibrocell pursuant to Section 6.3(c), the Parties shall share the Recovery equally, and such Recovery shall not be deemed to constitute Sublicensing Revenue.

(g) Fibrocell shall promptly notify Intrexon in writing of any suspected, alleged, threatened, or actual Infringement of which it becomes aware, and Intrexon shall promptly notify Fibrocell in writing of any suspected, alleged, threatened, or actual Field Infringement of which it becomes aware.

ARTICLE 7

CONFIDENTIALITY

7.1 Confidentiality. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party agrees that it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement any Confidential Information disclosed to it by the other Party pursuant to this Agreement, except to the extent that the receiving Party can demonstrate by competent evidence that specific Confidential Information:

(a) was already known to the receiving Party and can be demonstrated by written records, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) was disclosed to the receiving Party, other than under an obligation of confidentiality to a Third Party, by a Third Party who had no obligation to the disclosing Party not to disclose such information to others; or

(e) was independently discovered or developed by the receiving Party without the use of Confidential Information belonging to the disclosing Party, as documented by the receiving Party's written records.

The foregoing non-use and non-disclosure obligation shall continue (i) indefinitely, for all Confidential Information that qualifies as a trade secret under applicable law; or (ii) for the Term of this Agreement and for seven (7) years thereafter, in all other cases.

7.2 Authorized Disclosure. Notwithstanding the limitations in this Article 7, either Party may disclose the Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following instances:

(a) complying with applicable laws or regulations or valid court orders, *provided that* the Party making such disclosure provides the other Party with reasonable prior written notice of such disclosure and makes a reasonable effort to obtain, or to assist the other Party in obtaining, a protective order preventing or limiting the disclosure and/or requiring that the terms and conditions of this Agreement be used only for the purposes for which the law or regulation required, or for which the order was issued;

(b) to regulatory authorities in order to seek or obtain approval to conduct clinical trials, or to gain regulatory approval, of Fibrocell Products or any products being developed by Intrexon or its other licensees and/or channel partners or collaborators, provided that the Party making such disclosure (i) provides the other Party with reasonable opportunity to review any such disclosure in advance and to suggest redactions or other means of limiting the disclosure of such other Party's Confidential Information and (ii) does not unreasonably reject any such suggestions;

(c) disclosure to investors and potential investors, acquirers, or merger candidates who agree to maintain the confidentiality of such information, *provided that* such disclosure is used solely for the purpose of evaluating such investment, acquisition, or merger (as the case may be);

(d) disclosure on a need-to-know basis to Affiliates, licensees, sublicensees, employees, consultants or agents (such as CROs and clinical investigators) who agree to be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article 7; and

(e) disclosure of the terms of this Agreement by Intrexon to collaborators and other channel partners or collaborators who agree to be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article 7.

7.3 Publicity; Publications. The Parties agree that the public announcement of the execution of this Agreement shall be substantially in the form of a press release and/or the filing of a Form 8-K by Fibrocell, which shall be mutually agreed to by the Parties. Each Party will provide the other Party with the opportunity to review and comment, prior to submission or presentation, on external reports, publications and presentations (e.g., press releases, reports to government agencies, abstracts, posters, manuscripts and oral presentations) that refer to the Fibroblast Program or programs that are approved by the JSC. For such reports, publications, and presentations, the disclosing Party will provide the other Party at least fifteen (15) calendar days for review of the proposed submission or presentation. In the case of a Form 8-K filing, such shall be provided to Intrexon by Fibrocell as soon as practicable prior to filing. For reports and manuscripts, the disclosing Party will provide the other Party at least thirty (30) days for review of the report or manuscript. The presenting Party will act in good faith to incorporate the comments of the other Party and shall, in any event, redact any Confidential Information of the other Party and cooperate with the other Party to postpone such submissions or presentations if necessary to provide the other Party with sufficient time to prepare and file any related Patent applications before the submission or presentation occurs, as appropriate.

7.4 Terms of the Agreement. Each Party shall treat the terms of this Agreement as the Confidential Information of other Party, subject to the exceptions set forth in Section 7.2. Notwithstanding the foregoing, each Party acknowledges that the other Party may be obligated to file a copy of this Agreement with the SEC, either as of the Effective Date or at some point during the Term. Each Party shall be entitled to make such a required filing, provided that it requests confidential treatment of certain commercial terms and sensitive technical terms hereof to the extent such confidential treatment is reasonably available to it. In the event of any such filing, the filing Party shall provide the other Party with a copy of the Agreement marked to show provisions for which the filing Party intends to seek confidential treatment and shall reasonably consider and incorporate the other Party's comments thereon to the extent consistent with the legal requirements governing redaction of information from material agreements that must be publicly filed. The other Party shall promptly provide any such comments.

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7.5 Proprietary Information and Operational Audits.

(a) For the purpose of confirming compliance with the Field-limited licenses granted in Article 3, the diligence obligations of Article 4, and the confidentiality obligations under Article 7, Fibrocell acknowledges that Intrexon's authorized representative(s), during regular business hours may (i) examine and inspect Fibrocell's facilities and (ii) inspect all data and work products relating to this Agreement, subject to restrictions imposed by applicable laws. Any examination or inspection hereunder shall require five (5) business days written notice from Intrexon to Fibrocell. Fibrocell will make itself and the pertinent employees and/or agents available, on a reasonable basis, to Intrexon for the aforementioned compliance review.

(b) For the purpose of confirming compliance with the diligence obligations of Section 4.6, and the confidentiality obligations under Article 7, Intrexon acknowledges that Fibrocell authorized representative(s), during regular business hours may (i) examine and inspect Intrexon's facilities and (ii) inspect all data and work products relating to this Agreement. Any examination or inspection hereunder shall require five (5) business days written notice from Fibrocell to Intrexon. Intrexon will make itself and the pertinent employees and/or agents available, on a reasonable basis, to Fibrocell for the aforementioned compliance review.

(c) In view of the Intrexon Confidential Information, Intrexon Know-How, and Intrexon Materials transferred to Fibrocell hereunder, Intrexon from time-to-time, but no more than quarterly, may request that Fibrocell confirm the status of the Intrexon Materials at Fibrocell (i.e. how much used, how much shipped, to whom and any unused amounts destroyed (by whom, when) as well as any amounts returned to Intrexon or destroyed). Within ten (10) business days of Fibrocell's receipt of any such written request, Fibrocell shall provide the written report to Intrexon.

7.6 Intrexon Commitment. Intrexon shall use reasonable efforts to obtain an agreement with its other licensees and channel partners or collaborators to enable Fibrocell to disclose confidential information of such licensees and channel partners or collaborators to regulatory authorities in order to seek or obtain approval to conduct clinical trials, or to gain regulatory approval of, Fibrocell Products, in a manner consistent with the provisions of Section 7.2(b).

ARTICLE 8

REPRESENTATIONS AND WARRANTIES

8.1 Representations and Warranties of Fibrocell. Fibrocell hereby represents and warrants to Intrexon that, as of the Effective Date:

(a) Corporate Power. Fibrocell is duly organized and validly existing under the laws of Delaware and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof.

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(b) Due Authorization. Fibrocell is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person executing this Agreement on Fibrocell's behalf has been duly authorized to do so by all requisite corporate action.

(c) Binding Agreement. This Agreement is a legal and valid obligation binding upon Fibrocell and enforceable in accordance with its terms, except as such enforcement may be limited by applicable bankruptcy, insolvency, reorganization, arrangement, moratorium or other similar laws affecting creditors' rights, and subject to general equity principles and to limitations on availability of equitable relief, including specific performance. The execution, delivery and performance of this Agreement by Fibrocell does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound. Fibrocell is aware of no action, suit or inquiry or investigation instituted by any governmental agency which questions or threatens the validity of this Agreement.

8.2 Representations and Warranties of Intrexon. Intrexon hereby represents and warrants to Fibrocell that, as of the Effective Date:

(a) Corporate Power. Intrexon is duly organized and validly existing under the laws of Virginia and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof.

(b) Due Authorization. Intrexon is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person executing this Agreement on Intrexon's behalf has been duly authorized to do so by all requisite corporate action.

(c) Binding Agreement. This Agreement is a legal and valid obligation binding upon Intrexon and enforceable in accordance with its terms, except as such enforcement may be limited by applicable bankruptcy, insolvency, reorganization, arrangement, moratorium or other similar laws affecting creditors' rights, and subject to general equity principles and to limitations on availability of equitable relief, including specific performance. The execution, delivery and performance of this Agreement by Intrexon does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound. Intrexon is aware of no action, suit or inquiry or investigation instituted by any governmental agency which questions or threatens the validity of this Agreement.

(d) Additional Intellectual Property Representations.

(i) Intrexon possesses sufficient rights to enable Intrexon to grant all rights and licenses it purports to grant to Fibrocell with respect to the Intrexon Patents under this Agreement;

(ii) The Intrexon Patents existing as of the Effective Date constitute all of the Patents Controlled by Intrexon as of such date that are necessary for the development, manufacture and Commercialization of Fibrocell Products;

(iii) Intrexon has not granted, and during the Term Intrexon will not grant, any right or license, to any Third Party under the Intrexon IP that conflicts with the rights or licenses granted or to be granted to Fibrocell hereunder;

(iv) There is no pending litigation, and Intrexon has not received any written notice of any claims or litigation, seeking to invalidate or otherwise challenge the Intrexon Patents or Intrexon's rights therein;

(v) None of the Intrexon Patents is subject to any pending re-examination, opposition, interference or litigation proceedings;

(vi) All of the Intrexon Patents have been filed and prosecuted in accordance with all applicable laws and have been maintained, with all applicable fees with respect thereto (to the extent such fees have come due) having been paid;

(vii) Intrexon has entered into agreements with each of its current and former officers, employees and consultants involved in research and development work, including development of the Intrexon's products and technology providing Intrexon, to the extent permitted by law, with title and ownership to patents, patent applications, trade secrets and inventions conceived, developed, reduced to practice by such person, solely or jointly with other of such persons, during the period of employment by Intrexon (except where the failure to have entered into such an agreement would not have a material adverse effect on the rights granted to Fibrocell herein), and Intrexon is not aware that any of its employees or consultants is in material violation thereof;

(viii) To Intrexon's knowledge, there is no infringement, misappropriation or violation by third parties of any Intrexon Channel Technology or Intrexon IP in the Field;

(ix) There is no pending or, to Intrexon's knowledge, threatened action, suit, proceeding or claim by others against Intrexon that Intrexon infringes, misappropriates or otherwise violates any intellectual property or other proprietary rights of others in connection with the use of the Intrexon Channel Technology or Intrexon IP, and Intrexon has not received any written notice of such claim;

(x) To Intrexon's knowledge, no employee of Intrexon is the subject of any claim or proceeding involving a violation of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, non-disclosure agreement or any restrictive covenant to or with a former employer (A) where the basis of such violation relates to such employee's employment with Intrexon or actions undertaken by the employee while employed with Intrexon and (B) where such violation is relevant to the use of the Intrexon Channel Technology in the Field;

(xi) None of the Intrexon Patents owned by Intrexon or its Affiliates, and, to Intrexon's knowledge, the Intrexon Patents licensed to Intrexon or its Affiliates, have been adjudged invalid or unenforceable by a court of competent jurisdiction or applicable government agency, in whole or in part, and there is no pending or, to Intrexon's knowledge, threatened action, suit, proceeding or claim by others challenging the validity or scope of any such Intrexon Patents; and

(xii) Except as otherwise disclosed in writing to Fibrocell, Intrexon: (A) is in material compliance with all statutes, rules or regulations applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product that is under development, manufactured or distributed by Intrexon in the Field (" **Applicable Laws**"); (B) has not received any FDA Form 483, notice of adverse finding, warning letter, untitled letter or other correspondence or notice from the United States Food and Drug Administration (the "**FDA**") or any other federal, state, local or foreign governmental or regulatory authority alleging or asserting material noncompliance with any Applicable Laws or any licenses, certificates, approvals, clearances, authorizations, permits and supplements or amendments thereto required by any such Applicable Laws ("**Authorizations**"), which would, individually or in the aggregate, result in a material adverse effect; (C) possesses all material Authorizations necessary for the operation of its business as described in the Field and such Authorizations are valid and in full force and effect and Intrexon is not in material violation of any term of any such Authorizations; and (D) since January 1, 2011, (1) has not received notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from the FDA or any other federal, state, local or foreign governmental or regulatory authority or third party alleging that any product operation or activity is in material violation of any Applicable Laws or Authorizations and has no knowledge that the FDA or any other federal, state, local or foreign governmental or regulatory authority or third party is considering any such claim, litigation, arbitration, action, suit investigation or proceeding; (2) has not received notice that the FDA or any other federal, state, local or foreign governmental or regulatory authority has taken, is taking or intends to take action to limit, suspend, modify or revoke any material Authorizations and has no knowledge that the FDA or any other federal, state, local or foreign governmental or regulatory authority is considering such action; (3) has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were materially complete and correct on the date filed (or were corrected or supplemented by a subsequent submission); and (4) has not, either voluntarily or involuntarily, initiated, conducted, or issued or caused to be initiated, conducted or issued, any recall, market withdrawal or replacement, safety alert, post sale warning, "dear doctor" letter, or other notice or action relating to the alleged lack of safety or efficacy of any product or any alleged product defect or violation and, to Intrexon's knowledge, no third party has initiated, conducted or intends to initiate any such notice or action.

except, in each of (ix) through (xii), for any instances which would not, individually or in the aggregate, result in a material adverse effect on the rights granted to Fibrocell hereunder or Intrexon's ability to perform its obligations hereunder.

8.3 Warranty Disclaimer. EXCEPT FOR THE EXPRESS WARRANTIES PROVIDED IN THIS ARTICLE 8 OR IN THE EQUITY AGREEMENTS, EACH PARTY HEREBY DISCLAIMS ANY AND ALL OTHER WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF TITLE, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

ARTICLE 9

INDEMNIFICATION

9.1 Indemnification by Intrexon. Intrexon agrees to indemnify, hold harmless, and defend Fibrocell and its Affiliates and their respective directors, officers, employees, and agents (collectively, the "**Fibrocell Indemnitees**") from and against any and all liabilities, damages, costs, expenses, or losses (including reasonable legal expenses and attorneys' fees) (collectively, "**Losses**") resulting from any claims, suits, actions, demands, or other proceedings brought by a Third Party (collectively, "**Claims**") to the extent arising from (a) the gross negligence or willful misconduct of Intrexon or any of its Affiliates, or their respective employees or agents, (b) the use, handling, storage or transport of Intrexon Materials by or on behalf of Intrexon or its Affiliates, licensees (other than Fibrocell) or sublicensees; or (c) breach by Intrexon of any representation, warranty or covenant in this Agreement. Notwithstanding the foregoing, Intrexon shall not have any obligation to indemnify the Fibrocell Indemnitees to the extent that a Claim arises from (i) the gross negligence or willful misconduct of Fibrocell or any of its Affiliates, licensees, or sublicensees, or their respective employees or agents; or (ii) a breach by Fibrocell of a representation, warranty, or covenant of this Agreement.

9.2 Indemnification by Fibrocell. Fibrocell agrees to indemnify, hold harmless, and defend Intrexon, its Affiliates and Third Security, and their respective directors, officers, employees, and agents (and any Third Parties which have licensed to Intrexon intellectual property rights within Intrexon IP on or prior to the Effective Date, to the extent required by the relevant upstream license agreement) (collectively, the " **Intrexon Indemnitees**") from and against any Losses resulting from Claims, to the extent arising from any of the following: (a) the gross negligence or willful misconduct of Fibrocell or any of its Affiliates or their respective employees or agents; (b) the use, handling, storage, or transport of Intrexon Materials by or on behalf of Fibrocell or its Affiliates, licensees, or sublicensees; (c) breach by Fibrocell of any material representation, warranty or covenant in this Agreement; or (d) the design, development, manufacture, regulatory approval, handling, storage, transport, distribution, sale or other disposition of any Fibrocell Product or Improved Product by or on behalf of Fibrocell or its Affiliates, licensees, or sublicensees. Notwithstanding the foregoing, Fibrocell shall not have any obligation to indemnify the Intrexon Indemnitees to the extent that a Claim arises from (i) the gross negligence or willful misconduct of Intrexon or any of its Affiliates, or their respective employees or agents; or (ii) a breach by Intrexon of a representation, warranty, or covenant of this Agreement.

Portions herein identified by [*****] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

9.3 Product Liability Claims. Notwithstanding the provisions of Section 9.2, any Losses arising out of any Third Party claim, suit, action, proceeding, liability or obligation involving any actual or alleged death or bodily injury arising out of or resulting from the development, manufacture or Commercialization of any Fibrocell Products or Improved Products for use or sale in the Field, to the extent that such Losses exceed the amount (if any) covered by the applicable Party's product liability insurance ("**Excess Product Liability Costs**"), shall be paid by [*****], except to the extent such Losses arise out of any Third-Party Claim based on the gross negligence or willful misconduct of a Party, its Affiliates, or its Affiliates' sublicensees, or any of the respective officers, directors, employees and agents of each of the foregoing entities, in the performance of obligations or exercise of rights under this Agreement.

9.4 Control of Defense. As a condition precedent to any indemnification obligations hereunder, any entity entitled to indemnification under this Article 9 shall give written notice to the indemnifying Party of any Claims that may be subject to indemnification, promptly after learning of such Claim. If such Claim falls within the scope of the indemnification obligations of this Article 9, then the indemnifying Party shall assume the defense of such Claim with counsel reasonably satisfactory to the indemnified Party. The indemnified Party shall cooperate with the indemnifying Party in such defense. The indemnified Party may, at its option and expense, be represented by counsel of its choice in any action or proceeding with respect to such Claim. The indemnifying Party shall not be liable for any litigation costs or expenses incurred by the indemnified Party without the indemnifying Party's written consent, such consent not to be unreasonably withheld. The indemnifying Party shall not settle any such Claim if such settlement (a) does not fully and unconditionally release the indemnified Party from all liability relating thereto or (b) adversely impacts the exercise of the rights granted to the indemnified Party under this Agreement, unless the indemnified Party otherwise agrees in writing.

9.5 Insurance. Immediately prior to, and during marketing, Fibrocell shall maintain in effect and good standing a product liability insurance policy issued by a reputable insurance company in amounts considered standard for the industry. Immediately prior to, and during the conduct of any clinical trials, Fibrocell shall maintain in effect and good standing a clinical trials liability insurance policy issued by a reputable insurance company in amounts considered standard for the industry. At Intrexon's reasonable request, Fibrocell shall provide Intrexon with all details regarding such policies, including without limitation copies of the applicable liability insurance contracts. Fibrocell shall use reasonable efforts to include Intrexon as an additional insured on any such policies.

Portions herein identified by [*****] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

ARTICLE 10

TERM; TERMINATION

10.1 Term. The term of this Agreement shall commence upon the Effective Date and shall continue until terminated pursuant to Section 10.2 or 10.3 (the "**Term**").

10.2 Termination for Material Breach; Termination Under Section 4.5(b)

(a) Either Party shall have the right to terminate this Agreement upon written notice to the other Party if the other Party commits any material breach of this Agreement that such breaching Party fails to cure within sixty (60) days following written notice from the nonbreaching Party specifying such breach; provided, however, that if Fibrocell commits any breach of the provisions of Section 4.10 of this Agreement, Intrexon shall have the right to terminate this Agreement if Fibrocell fails after notice from Intrexon to cure such breach within thirty (30) days following written notice thereof.

(b) Intrexon shall have the right to terminate this Agreement, at its sole discretion, if any necessary shareholder, member, exchange, and/or board of director approvals of Fibrocell have not been obtained, and the Technology Access Fee Shares (as defined in the Equity Agreements) have not been issued, within the time frames set forth in the Equity Agreements.

(c) Intrexon shall have the right to terminate this Agreement under the circumstances set forth in Section 4.5(b) upon written notice to Fibrocell, such termination to become effective sixty (60) days following such written notice unless Fibrocell remedies the circumstances giving rise to such termination within such sixty (60) day period.

(d) Intrexon shall have the right to terminate this Agreement should Fibrocell execute any purported assignment of this Agreement contrary to the prohibitions in Section 12.8, such termination occurring upon Intrexon providing written notice to Fibrocell and becoming effective immediately upon such written notice.

10.3 Termination by Fibrocell. Fibrocell shall have the right to voluntarily terminate this Agreement in its entirety upon ninety (90) days written notice to Intrexon at any time.

Portions herein identified by [*****] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

10.4 Effect of Termination. In the event of termination of this Agreement pursuant to Section 10.2 or Section 10.3, the following shall apply:

(a) Retained Products. Fibrocell shall be permitted to continue the clinical development and Commercialization in the Field of any product resulting from the Fibroblast Program that, at the time of termination, satisfies at least one of the following criteria (a " **Retained Product**"):

(i) the particular product is an Improved Product,

(ii) the particular product is a Fibrocell Product that is being sold by Fibrocell (or, as may be permitted under this Agreement, its Affiliates and, if applicable, (sub)licensees) triggering profit sharing payments therefor under Section 5.3(a) or (b) of this Agreement,

(iii) the particular product is a Fibrocell Product that has received regulatory approval,

(iv) the particular product is a Fibrocell Product that is the subject of an application for regulatory approval in the Field that is pending before the applicable regulatory authority,

(v) the particular product is a Fibrocell Product that is the subject of at least an ongoing Phase 2 or Phase 3 clinical trial in the Field (in the case of a termination by Intrexon due to a Fibrocell uncured breach pursuant to Section 10.2(a) or a termination by Fibrocell pursuant to Section 10.3).

Such right to continue development and Commercialization shall be subject to Fibrocell's full compliance with the payment provisions in Article 5, a continuing obligation for Fibrocell to use in accord with Sections 4.5(a) and 4.5(c) Diligent Efforts to develop and Commercialize any Retained Products, and all other provisions of this Agreement that survive termination.

(b) Termination of Licenses. Except as necessary for Fibrocell to continue to obtain regulatory approval for, clinically develop, use, manufacture and Commercialize the Retained Products in the Field as permitted by Section 10.4(a), all rights and licenses granted by Intrexon to Fibrocell under this Agreement shall terminate and shall revert to Intrexon without further action by either Intrexon or Fibrocell. Fibrocell's license with respect to Retained Products shall be exclusive or non-exclusive, as the case may be, on the same terms as set forth in Section 3.1.

(c) Reverted Products. All Fibrocell Products other than the Retained Products shall be referred to herein as the " **Reverted Products**." Fibrocell shall immediately cease, and shall cause its Affiliates and, if applicable, (sub)licensees to immediately cease, all development and Commercialization of the Reverted Products, and Fibrocell shall not use or practice, nor shall it cause or permit any of its Affiliates or, if applicable, (sub)licensees to use or practice, directly or indirectly, any Intrexon IP with respect to the Reverted Products. Fibrocell shall immediately discontinue making any representation regarding its status as a licensee or channel collaborator of Intrexon with respect to the Reverted Products.

(d) Intrexon Materials. Fibrocell shall promptly return, or at Intrexon's request, destroy, any Intrexon Materials in Fibrocell's possession or control at the time of termination other than any Intrexon Materials necessary for the continued development, regulatory approval, use, manufacture and Commercialization of the Retained Products in the Field.

(e) Licenses to Intrexon. Fibrocell is automatically deemed to grant to Intrexon a worldwide, fully paid, royalty-free, exclusive (even as to Fibrocell and its Affiliates), irrevocable, license (with full rights to sublicense) under the Fibrocell Termination IP, to make, have made, import, use, offer for sale and sell Reverted Products and to use the Intrexon Channel Technology, the Intrexon Materials, and/or the Intrexon IP in the Field, subject to any exclusive rights held by Fibrocell in Reverted Products pursuant to Section 10.4(c). The Parties shall also take such actions and execute such other instruments and documents as may be reasonably necessary to document such license to Intrexon.

(f) Regulatory Filings. Fibrocell shall promptly assign to Intrexon, and will provide full copies of, all regulatory approvals and regulatory filings that relate specifically and solely to Reverted Products. Fibrocell shall also take such actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights thereunder to Intrexon. To the extent that there exist any regulatory approvals and regulatory filings that relate both to Reverted Products and other products, Fibrocell shall provide copies of the portions of such regulatory filings that relate to Reverted Products and shall reasonably cooperate to assist Intrexon in obtaining the benefits of such regulatory approvals with respect to the Reverted Products.

(g) Data Disclosure. Fibrocell shall provide to Intrexon copies of the relevant portions of all material reports and data, including clinical and non-clinical data and reports, obtained or generated by or on behalf of Fibrocell or its Affiliates to the extent that they relate to Reverted Products, within sixty (60) days of such termination unless otherwise agreed, and Intrexon shall have the right to use any such Information in developing and Commercializing Reverted Products and to license any Third Parties to do so.

(h) Third-Party Licenses. At Intrexon's request, Fibrocell shall promptly provide to Intrexon copies of all Third-Party agreements under which Fibrocell or its Affiliates obtained a license under Patents claiming inventions or know-how specific to or used or incorporated into the development, manufacture and/or Commercialization of the Reverted Products. At Intrexon's request such that Intrexon may Commercialize the Reverted Products, Fibrocell shall promptly work with Intrexon to either (A) assign to Intrexon the Third Party agreement(s), or (B) grant a sublicense (with an appropriate scope) to Intrexon under the Third Party agreement(s). Thereafter Intrexon shall be fully responsible for all obligations due for its actions under the sublicensed or assigned Third Party agreements. Notwithstanding the above, if Intrexon does not wish to assume any financial or other obligations associated with a particular Third Party agreement identified to Intrexon under this Section 10.4(h), then Intrexon shall so notify Fibrocell and Fibrocell shall not make such assignment or grant such sublicense (or cause it to be made or granted).

(i) Remaining Materials. At the request of Intrexon, Fibrocell shall transfer to Intrexon all quantities of Reverted Product (including active pharmaceutical ingredient or work-in-process) in the possession of Fibrocell or its Affiliates. Fibrocell shall transfer to Intrexon all such quantities of Reverted Products without charge, except that Intrexon shall pay the reasonable costs of shipping.

(j) Third Party Vendors. At Intrexon's request, Fibrocell shall promptly provide to Intrexon copies of all agreements between Fibrocell or its Affiliates and Third Party suppliers, vendors, or distributors that relate to the supply, sale, or distribution of Reverted Products in the Territory. At Intrexon's request, Fibrocell shall promptly: (A) with respect to such Third Party agreements relating solely to the applicable Reverted Products and permitting assignment, immediately assign (or cause to be assigned), such agreements to Intrexon, and (B) with respect to all other such Third Party agreements, Fibrocell shall reasonably cooperate to assist Intrexon in obtaining the benefits of such agreements. Fibrocell shall be liable for any costs associated with assigning a Third Party agreement to Intrexon or otherwise obtaining the benefits of such agreement for Intrexon, to the extent such costs are directly related to Fibrocell's breach. For the avoidance of doubt, Intrexon shall have no obligation to assume any of Fibrocell's obligations under any Third Party agreement.

(k) Commercialization. Intrexon shall have the right to develop and Commercialize the Reverted Products itself or with one or more Third Parties, and shall have the right, without obligation to Fibrocell, to take any such actions in connection with such activities as Intrexon (or its designee), at its discretion, deems appropriate.

(l) Confidential Information. Each Party shall promptly return, or at the other Party's request destroy, any Confidential Information of the other Party in such Party's possession or control at the time of termination; provided, however, that each Party shall be permitted to retain (i) a single copy of each item of Confidential Information of the other Party in its confidential legal files for the sole purpose of monitoring and enforcing its compliance with Article 7, (ii) Confidential Information of the other Party that is maintained as archive copies on the recipient Party's disaster recovery and/or information technology backup systems, or (iii) Confidential Information of the other Party necessary to exercise such Party's rights in Retained Products (in the case of Fibrocell) or Reverted Products (in the case of Intrexon). The recipient of Confidential Information shall continue to be bound by the terms and conditions of this Agreement with respect to any such Confidential Information retained in accordance with this Section 10.4(l).

10.5 Surviving Obligations. Termination or expiration of this Agreement shall not affect any rights of either Party arising out of any event or occurrence prior to termination, including, without limitation, any obligation of Fibrocell to pay any amount which became due and payable under the terms and conditions of this Agreement prior to expiration or such termination. The following portions of this Agreement shall survive termination or expiration of this Agreement: Sections 3.1 (as applicable with respect to 10.4(b), 5.4, 5.6, 6.1, 6.2 (with subsection (c) surviving only to the extent relating to Intrexon Patents that are relevant to Retained Products that, to Intrexon's knowledge, are being developed or Commercialized at such time, if any), 7.1, 7.2, 7.4, 7.5, 10.4, and 10.5; Articles 9, 11, and 12; and any relevant definitions in Article 1. Further, Article 7 and Sections 4.5(a), 4.5(c), 5.2 through 5.7, and 9.5 will survive termination of this Agreement to the extent there are applicable Retained Products.

ARTICLE 11

DISPUTE RESOLUTION

11.1 Disputes. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. In the event of any disputes, controversies or differences which may arise between the Parties out of or in relation to or in connection with this Agreement (other than disputes arising from a Committee), including, without limitation, any alleged failure to perform, or breach, of this Agreement, or any issue relating to the interpretation or application of this Agreement, then upon the request of either Party by written notice, the Parties agree to meet and discuss in good faith a possible resolution thereof, which good faith efforts shall include at least one in-person meeting between the Executive Officers of each Party. If the matter is not resolved within thirty (30) days following the written request for discussions, either Party may then invoke the provisions of Section 11.2. For the avoidance of doubt, any disputes, controversies or differences arising from a Committee pursuant to Article 2 shall be resolved solely in accordance with Section 2.4.

11.2 Arbitration. Any dispute, controversy, difference or claim which may arise between the Parties and not from a Committee, out of or in relation to or in connection with this Agreement (including, without limitation, arising out of or relating to the validity, construction, interpretation, enforceability, breach, performance, application or termination of this Agreement) that is not resolved pursuant to Section 11.1 shall, subject to Section 11.10, be settled by binding "baseball arbitration" as follows. Either Party, following the end of the thirty (30) day period referenced in Section 11.1, may refer such issue to arbitration by submitting a written notice of such request to the other Party, with the arbitration to be held in the state where the other Party's principal office is located (or some other place as may be mutually agreed by the Parties). Promptly following receipt of such notice, the Parties shall meet and discuss in good faith and seek to agree on an arbitrator to resolve the issue, which arbitrator shall be neutral and independent of both Parties and all of their respective Affiliates, shall have significant experience and expertise in licensing and partnering agreements in the pharmaceutical and biotechnology industries, and shall have some experience in mediating or arbitrating issues relating to such agreements. If the Parties cannot agree on a single arbitrator within fifteen (15) days of request by a Party for arbitration, then each Party shall select an arbitrator meeting the foregoing criteria and the two (2) arbitrators so selected shall select within ten (10) days of their appointment a third arbitrator meeting the foregoing criteria. Within fifteen (15) days after an arbitrator(s) is selected (in the case of the three-person panel, when the third arbitrator is selected), each Party will deliver to both the arbitrator(s) and the other Party a detailed written proposal setting forth its proposed terms for the resolution for the matter at issue (the "**Proposed Terms**" of the Party) and a memorandum (the "**Support Memorandum**") in support thereof. The Parties will also provide the arbitrator(s) a copy of this Agreement, as it may be amended at such time. Within fifteen (15) days after receipt of the other Party's Proposed Terms and Support Memorandum, each Party may submit to the arbitrator(s) (with a copy to the other Party) a response to the other Party's Support Memorandum. Neither Party may have any other communications (either written or oral) with the arbitrator(s) other than for the sole purpose of engaging the arbitrator or as expressly permitted in this Section 11.2; provided that, the arbitrator(s) may convene a hearing if the arbitrator(s) so chooses to ask questions of the Parties and hear oral argument and discussion regarding each Party's Proposed Terms. Within sixty (60) days after the arbitrator's appointment, the arbitrator(s) will select one of the two Proposed Terms (without modification) provided by the Parties that he or she believes is most consistent with the intention underlying and agreed principles set forth in this Agreement. The decision of the arbitrator(s) shall be final, binding, and unappealable. For clarity, the arbitrator(s) must select as the only method to resolve the matter at issue one of the two sets of Proposed Terms, and may not combine elements of both Proposed Terms or award any other relief or take any other action.

11.3 Governing Law. This Agreement shall be governed by and construed under the substantive laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

11.4 Award. Any award to be paid by one Party to the other Party as determined by the arbitrator(s) as set forth above under Section 11.2 shall be promptly paid in United States dollars free of any tax, deduction or offset; and any costs, fees or taxes incident to enforcing the award shall, to the maximum extent permitted by law, be charged against the losing Party. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this Article 11, and agrees that, subject to the United States Federal Arbitration Act, 9 U.S.C. §§ 1-16, judgment may be entered upon the final award in any United States District Court located in New York and that other courts may award full faith and credit to such judgment in order to enforce such award. The award shall include interest from the date of any damages incurred for breach of the Agreement, and from the date of the award until paid in full, at a rate fixed by the arbitrator(s). With respect to money damages, nothing contained herein shall be construed to permit the arbitrator(s) or any court or any other forum to award consequential, incidental, special, punitive or exemplary damages. By entering into this agreement to arbitrate, the Parties expressly waive any claim for consequential, incidental, special, punitive or exemplary damages. The only damages recoverable under this Agreement are direct compensatory damages.

11.5 Costs. Each Party shall bear its own legal fees. The arbitrator(s) shall assess his or her costs, fees and expenses against the Party losing the arbitration.

11.6 Injunctive Relief. Nothing in this Article 11 will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding. Specifically, the Parties agree that a material breach by either Party of its obligations in Section 3.5 or Article 7 of this Agreement may cause irreparable harm to the other Party, for which damages may not be an adequate remedy. Therefore, in addition to its rights and remedies otherwise available at law, including, without limitation, the recovery of damages for breach of this Agreement, upon an adequate showing of material breach of such Section 3.5 or Article 7, and without further proof of irreparable harm other than this acknowledgement, such non-breaching Party shall be entitled to seek (a) immediate equitable relief, specifically including, but not limited to, both interim and permanent restraining orders and injunctions, without bond, and (b) such other and further equitable relief as the court may deem proper under the circumstances. For the avoidance of doubt, nothing in this Section 11.6 shall otherwise limit a breaching Party's opportunity to cure a material breach as permitted in accordance with Section 10.2.

11.7 Confidentiality. The arbitration proceeding shall be confidential and the arbitrator(s) shall issue appropriate protective orders to safeguard each Party's Confidential Information. Except as required by law, no Party shall make (or instruct the arbitrator(s) to make) any public announcement with respect to the proceedings or decision of the arbitrator(s) without prior written consent of the other Party. The existence of any dispute submitted to arbitration, and the award, shall be kept in confidence by the Parties and the arbitrator(s), except as required in connection with the enforcement of such award or as otherwise required by applicable law.

11.8 Survivability. Any duty to arbitrate under this Agreement shall remain in effect and be enforceable after termination of this Agreement for any reason.

11.9 Jurisdiction. For the purposes of this Article 11, the Parties acknowledge their diversity and agree to accept the jurisdiction of any United States District Court located in New York for the purposes of enforcing or appealing any awards entered pursuant to this Article 11 and for enforcing the agreements reflected in this Article 11 and agree not to commence any action, suit or proceeding related thereto except in such courts.

11.10 Patent Disputes. Notwithstanding any other provisions of this Article 11, and subject to the provisions of Section 6.2, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Intrexon Patents shall be submitted to a court of competent jurisdiction in the country in which such Patent was filed or granted.

ARTICLE 12

GENERAL PROVISIONS

12.1 Use of Name. No right, express or implied, is granted by this Agreement to either Party to use in any manner the name of the other or any other trade name or trademark of the other in connection with the performance of this Agreement, except that (a) either Party may use the name of the other Party as required by regulations and in press releases accompanying quarterly and annual earnings reports approved by the issuer's Board of Directors, and (b) Fibrocell may use the Intrexon Trademarks in accord with licenses and restrictions set forth herein.

12.2 LIMITATION OF LIABILITY. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS PARAGRAPH IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER ARTICLE 9, OR DAMAGES AVAILABLE FOR BREACHES OF THE OBLIGATIONS SET FORTH IN ARTICLE 7.

12.3 Independent Parties. The Parties are not employees or legal representatives of the other Party for any purpose. Neither Party shall have the authority to enter into any contracts in the name of or on behalf of the other Party. This Agreement shall not constitute, create, or in any way be interpreted as a joint venture, partnership, or business organization of any kind.

Portions herein identified by [*****] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

12.4 Notice. All notices, including notices of address change, required or permitted to be given under this Agreement shall be in writing and deemed to have been given when delivered if personally delivered or sent by facsimile (provided that the party providing such notice promptly confirms receipt of such transmission with the other party by telephone), on the business day after dispatch if sent by a nationally-recognized overnight courier and on the third business day following the date of mailing if sent by certified mail, postage prepaid, return receipt requested. All such communications shall be sent to the address or facsimile number set forth below (or any updated addresses or facsimile number communicated to the other Party in writing):

If to Intrexon:	Intrexon Corporation 20358 Seneca Meadows Parkway Germantown, MD 20876 Attention: President, Human Therapeutics Division Fax: (301) 556-9901
with a copy to:	Intrexon Corporation 20358 Seneca Meadows Parkway Germantown, MD 20876 Attention: Legal Department Fax: (301) 556-9902
If to Fibrocell:	Fibrocell Science, Inc. 405 Eagleview Boulevard Exton, PA 19341 Attention: Chief Executive Officer Fax: (484) 713-6001

12.5 Severability. In the event any provision of this Agreement is held to be invalid or unenforceable, the valid or enforceable portion thereof and the remaining provisions of this Agreement will remain in full force and effect.

12.6 Waiver. Any waiver (express or implied) by either Party of any breach of this Agreement shall not constitute a waiver of any other or subsequent breach.

12.7 Entire Agreement; Amendment . This Agreement, including any exhibits attached hereto, constitute the entire, final, complete and exclusive agreement between the Parties and supersede all previous agreements or representations, written or oral, with respect to the subject matter of this Agreement (including any prior confidentiality agreement between the Parties). All information of Intrexon or Fibrocell to be kept confidential by the other Party under any prior confidentiality agreement, as of the Effective Date, shall be maintained as Confidential Information by such other Party under the obligations set forth in Article 7 of this Agreement. This Agreement may not be modified or amended except in a writing signed by a duly authorized representative of each Party.

12.8 Non-assignability; Binding on Successors . Any attempted assignment of the rights or delegation of the obligations under this Agreement shall be void without the prior written consent of the non-assigning or non-delegating Party; provided, however, that either Party may assign its rights or delegate its obligations under this Agreement without such consent (a) to an Affiliate of such Party or (b) to its successor in interest in connection with any merger, acquisition, consolidation, corporate reorganization, or similar transaction, or sale of all or substantially all of its assets, provided that such assignee agrees in writing to assume and be bound by the assignor's obligations under this Agreement. This Agreement shall be binding upon, and inure to the benefit of, the successors, executors, heirs, representatives, administrators and permitted assigns of the Parties. Notwithstanding the foregoing, in the event that either Party assigns this Agreement to its successor in interest by way of merger, acquisition, consolidation, corporate reorganization, or similar transaction, or sale of all or substantially all of its assets (whether this Agreement is actually assigned or is assumed by such successor in interest or its affiliate by operation of law (e.g., in the context of a reverse triangular merger)), the intellectual property rights of such successor in interest or any of its Affiliates other than those licensed in this Agreement shall be automatically excluded from the rights licensed to the other Party under this Agreement.

Portions herein identified by [*****] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

12.9 Force Majeure. Neither Party shall be liable to the other for its failure to perform any of its obligations under this Agreement, except for payment obligations, during any period in which such performance is delayed because rendered impracticable or impossible due to circumstances beyond its reasonable control, including without limitation earthquakes, governmental regulation, fire, flood, labor difficulties, civil disorder, acts of terrorism and acts of God, provided that the Party experiencing the delay promptly notifies the other Party of the delay.

12.10 No Other Licenses. Neither Party grants to the other Party any rights or licenses in or to any intellectual property, whether by implication, estoppel, or otherwise, except to the extent expressly provided for under this Agreement.

12.11 Non-Solicitation. During the Term and for a period of one (1) year following the end of the Term, neither Fibrocell nor Intrexon may directly or indirectly solicit in order to offer to employ, engage in any discussion regarding employment with, or hire any employee of the other Party or an individual who was employed by the other party with one (1) year prior to such solicitation, discussion, or hire, without the prior approval of such other Party. General employment solicitations or advertisements shall not be considered direct or indirect solicitations, and are not prohibited under this Agreement.

12.12 Legal Compliance. The Parties shall review in good faith and cooperate in taking such actions to ensure compliance of this Agreement with all applicable laws.

12.13 Counterparts. This Agreement may be executed in any number of counterparts (including by facsimile, PDF, or other means of electronic communication), each of which taken together will constitute one and the same instrument, and any of the Parties hereto may execute this Agreement by signing any such counterpart.

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, the Parties hereto have duly executed this Exclusive Channel Collaboration Agreement.

INTREXON CORPORATION

By: /s/ Jayson M. Rieger
Name: Jayson M. Rieger
Title: President of Human Therapeutics Division, and Senior Vice President

FIBROCELL SCIENCE, INC.

By: /s/ David Pernock
Name: David Pernock
Title: Chairman and Chief Executive Officer

Exhibit 21

List of Subsidiaries

Fibrocell Technologies, Inc., a Delaware corporation (wholly owned by Fibrocell Science, Inc.)

Isolagen Europe Limited, a company organized under the laws of the United Kingdom (wholly owned by Fibrocell Technologies, Inc.)

Isolagen Australia Pty Limited, a company organized under the laws of Australia (wholly owned by Fibrocell Technologies, Inc.)

Isolagen International, S.A., a company organized under the laws of Switzerland (wholly owned by Fibrocell Technologies, Inc.)

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (File No.333-172776) of Fibrocell Science, Inc. of our report dated April 1, 2013, relating to the consolidated financial statements appearing in the Company's Annual Report on Form 10-K for the year ended December 31, 2012.

/s/ BDO USA, LLP

Houston, Texas
April 1, 2013

Exhibit 31.1

OFFICER'S CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David Pernock, Chief Executive Officer of Fibrocell Science, Inc., certify that:

1. I have reviewed this Annual Report on Form 10-K of Fibrocell Science, Inc.;

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

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

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

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

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

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

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

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

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

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

Dated: April 1, 2013

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

Exhibit 31.2

OFFICER'S CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Declan Daly, Chief Financial Officer of Fibrocell Science, Inc., certify that:

1. I have reviewed this Annual Report on Form 10-K of Fibrocell Science, Inc.;

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

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

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

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

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

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

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

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

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

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

Dated: April 1, 2013

By: /s/ Declan Daly
Declan Daly, Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO SECTION 1350 OF
CHAPTER 63 OF TITLE 18 OF THE UNITED STATES CODE

For purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned, David Pernock, Chief Executive Officer of Fibrocell Science, Inc. (the Company), hereby certifies that:

i. the Annual Report on Form 10-K of the Company for the year ended December 31, 2012, as filed with the Securities and Exchange Commission on the date hereof (the Report) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Commission Act of 1934; and

ii. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: April 1, 2013

By: /s/ David Pernock
David Pernock
Chief Executive Officer
Fibrocell Science, Inc.

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

Exhibit 32.2

CERTIFICATION PURSUANT TO SECTION 1350 OF
CHAPTER 63 OF TITLE 18 OF THE UNITED STATES CODE

For purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned, Declan Daly, Chief Financial Officer of Fibrocell Science, Inc. (the Company), hereby certifies that:

i. the Annual Report on Form 10-K of the Company for the year ended December 31, 2012, as filed with the Securities and Exchange Commission on the date hereof (the Report) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Commission Act of 1934; and

ii. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: April 1, 2013

By: /s/ Declan Daly
Declan Daly
Chief Financial Officer
Fibrocell Science, Inc.

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