Fibrocell Science, Inc.
Form 10-K
March 30, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x **Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the fiscal year ended December 31, 2011

OR

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

Fibrocell Science, Inc.

(Exact name of registrant as specified in its Charter.)

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

405 Eagleview Boulevard

Exton, Pennsylvania 19341

(Address of principal executive offices, including zip code)

(484) 713-6000

(Issuer s telephone number, including area code)

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

Title of Each Class

Common Stock, $.001 par value

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

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

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

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

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

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

Large accelerated filer ¨ Accelerated filer ¨

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

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

The aggregate market value of common stock held by non-affiliates of the registrant was $39.1 million as of June 30, 2011, 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, 2011. For purposes of determining this amount only, the registrant has defined affiliates as including (a) the executive officers of the registrant as of June 30, 2011 and (b) all directors of the registrant as of June 30, 2011.

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

As of March 26, 2012, issuer had 96,078,253 shares issued and outstanding of common stock, par value $0.001.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the 2011 Annual Meeting of Stockholders (the Proxy Statement), to be filed within 120 days of the end of the fiscal year ended December 31, 2011, 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:

our ability to finance our business and continue in operations;

our ability to increase our manufacturing capacity and improve our manufacturing costs through the improvement of our manufacturing process, and our ability to validate any such improvements with the relevant regulatory agencies;

our ability to meet requisite regulations or receive regulatory approvals in the United States, Europe, Asia and the Americas, and our ability to retain any regulatory approvals that we may obtain; and the absence of adverse regulatory developments in the United States, Europe, Asia and the Americas or any other country where we plan to conduct commercial operations;

whether our clinical human trials relating to the use of autologous cellular therapy applications, 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 develop autologous cellular therapies that have specific applications in cosmetic dermatology, and our ability to explore (and possibly develop) applications for periodontal disease, reconstructive dentistry, treatment of restrictive scars and burns and other health-related markets;

our ability to reduce our need for fetal bovine calf serum by improved use of less expensive media combinations and different media alternatives;

continued availability of supplies at satisfactory prices;

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

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

any adverse claims relating to our intellectual property;

the adoption of new, or changes in, accounting principles;

our issuance of certain rights to our shareholders that may have anti-takeover effects; 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 2011 mean the year ended December 31, 2011, 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 Science Process, Agera and Agera Rx, (LAVIV et al). 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 cellular aesthetic and therapeutic development stage biotechnology company focused on developing novel skin and tissue rejuvenation products. Our approved and clinical development product candidates are designed to improve the appearance of skin injured by the effects of aging, sun exposure, acne and burn scars with a patient s own, or autologous, fibroblast cells produced by our proprietary Fibrocell process.

We use our proprietary process to harvest autologous fibroblasts from a small skin punch biopsy from behind the ear with the use of a local anesthetic. We chose this location both because of limited exposure to the sun and to avoid creating a visible scar. The biopsy is then packed in a vial in a special shipping container and shipped to our laboratory where the fibroblast cells are released from the biopsy and initiated into our cell culture process where the cells proliferate until they reach the required cell count. The fibroblasts are then harvested, cryopreserved, tested by quality control and released by quality assurance prior to preparation of drug product. After wash and preparation of cells to formulate the drug product, additional quality testing is performed prior to release and distribution to the medical clinic. The number of cells and the frequency of injections may vary and will depend on the indication or application being studied.

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Our lead product, LAVIV (United States adopted name, or USAN, is azficel-T), is the first and only personalized aesthetic cell therapy approved by the Food and Drug Administration (FDA) for the improvement of the appearance of moderate to severe nasolabial fold wrinkles in adults. LAVIV offers patients their own living fibroblast cells in a personalized therapy designed to improve the appearance of wrinkles. Our clinical development programs encompass both aesthetic and therapeutic indications.

We believe that because LAVIV and our product candidates are autologous, the risk of an immunological or allergic response is low. With regard to the therapeutic markets, we believe that our product candidates may address an insufficiently met medical need for the treatment of each of restrictive burn scars, acne scars and vocal scarring. There are also numerous other potential areas of interest for our technology in the body. Certain of our product candidates are still in clinical development and, as such, benefits we expect to see associated with our product candidates may not be validated in our clinical trials. In addition, disadvantages of our product candidates may become known in the future.

Going Concern

We emerged from Bankruptcy in September 2009 and continues to operate as a going concern. At December 31, 2011, we had cash and cash equivalents of approximately $10.8 million and working capital of $2.9 million.

As of March 26, 2012, we had cash and cash equivalents of approximately $4.7 million and our accounts payable and accrued expenses were approximately $1.6 million. In addition, the Company has approximately $7.0 million of outstanding debt which is due in June 2012. Our current monthly cash run-rate is approximately $2.2 million. We will need to access the capital markets in the near future in order to fund future operations. There is no guarantee that any such required financing will be available on terms satisfactory to us or available at all. These matters create uncertainty relating to its ability to continue as a going concern. The accompanying consolidated financial statements do not reflect any adjustments relating to the recoverability and classification of assets or liabilities that might result from the outcome of these uncertainties.

Through December 31, 2011, we have been primarily engaged in developing our initial product technology. In the course of our development activities, we have sustained losses and expects such losses to continue through at least 2012. During the year ended December 31, 2011, we financed our operations primarily through our existing cash received from external equity financings, but as discussed above we now require additional financing. There is substantial doubt about our ability to continue as a going concern.

Our ability to complete additional offerings is dependent on the state of the debt and/or equity markets at the time of any proposed offering, and such market s reception of us and the offering terms. Our ability to complete an offering is also dependent on the status of FDA regulatory milestones and our clinical trials. There is no assurance that capital in any form would be available to us, and if available, on terms and conditions that are acceptable.

As a result of the conditions discussed above, and in accordance with GAAP, there exists substantial doubt about our ability to continue as a going concern, and our ability to continue as a going concern is contingent, among other things, upon our ability to secure additional adequate financing or capital in the near future. If we do not obtain additional funding, or do not anticipate additional funding, in the very near future, we will likely enter into bankruptcy and/or cease operations. Further, if we do raise additional cash resources in the near future, it may be raised in contemplation of or in connection with bankruptcy. If we enter into bankruptcy, it is likely that our common stock and common stock equivalents will become worthless and our creditors, including preferred stock, will receive significantly less than what is owed to them.

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Our Strategy

Our business strategy is focused on our unique autologous cellular platform. This strategy will be heavily dependent upon raising sufficient funds and/or enter relevant strategic partnerships. Our key areas of focus are as follows:

Firstly, aesthetics and dermatology is our first focus. In June 2011, our lead product, LAVIV (United States adopted name, or USAN, is azficel-T), 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 and we are currently in the process of launching the product in the United States. Other possible aesthetic indications that we are considering pursuing include acne scarring, fine lines and wrinkles around the eyes and mouth, the décolletage and total facial treatment. We are developing 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. At present, we are conducting characterization and safety testing in anticipation of launch in the third quarter, 2012.

Secondly, we plan to pursue in the future indications for burn scars and vocal scarring. Other potential areas of interest include wound healing and periodontal disease (recessive gum lines).

Thirdly, our long term vision is, in cooperation with UCLA, to biotransform autologous dermal fibroblasts to factor free IPSC cells capable of differentiation into multiple cell types for toxicological, research use and therapeutic areas.

Clinical Development Programs

Our product development programs are focused on the aesthetic and therapeutic markets. These programs are supported by a number of clinical trial programs at various stages of development.

Our aesthetics development programs include product candidates to treat acne scarring and to provide full-face rejuvenation that includes the improvement of fine lines, wrinkles, skin texture and appearance. Our therapeutic development programs are designed to treat restrictive burn scars and vocal scarring. All of our product candidates are non-surgical and minimally invasive. Although the discussions below may include estimates of when we expect trials to be completed, the prediction of when a clinical trial will be completed is subject to a number of factors and uncertainties. Also, please refer to Part I, Item 1A of our Form 10-K for the year ended December 31, 2011, for a discussion of certain of our risk factors related to our clinical development programs, as well as other risk factors related to our business.

Aesthetic Development Programs

Acne Scars *Phase II Trial:* In November 2007, we commenced an acne scar Phase II study. This study included approximately 95 subjects. This placebo controlled trial was designed to evaluate the use of azficel-T to correct or improve the appearance of acne scars. Each subject served as their own control, receiving azficel-T on one side of their face and placebo on the other. The subjects received three treatments two weeks apart. The follow-up and evaluation period was completed four months after each subject s last injection. In March 2009, we disclosed certain trial data results, which included statistically significant efficacy results for the treatment of moderate to severe acne scars. Compilation of safety data and data related to the validation of the study photo guide assessment scale discussed below is ongoing and is also subject to additional financing.

In connection with this acne scar program, we developed a photo guide for use in the evaluators assessment of acne study subjects. We had originally designed the acne scar clinical program as two randomized, double-blind, Phase III, placebo-controlled trials. However, our evaluator assessment scale and photo guide have not previously been utilized in a clinical trial. In November 2007, the FDA recommended that we consider conducting a Phase II study in order to address certain study issues, including additional validation related to our evaluator assessment scale. As such, we modified our clinical plans to initiate a single Phase II trial. This Phase II study, was powered to demonstrate efficacy, and has allowed for a closer assessment of the evaluator assessment scale and photo guide that is ongoing. We submitted on August 9, 2010, a clinical study report for its Phase II study of azficel-T for the treatment of moderate to severe acne scars to the FDA. We are currently in discussions with the FDA concerning the validation of the evaluator assessment scale and agreeing the path forward for the acne program. These steps will be subject to obtaining sufficient financial resources.

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Full Face Rejuvenation *Phase II Open Label Trial:* In March 2007, we commenced an open label (unblinded) trial of approximately 50 subjects. Injections of azficel-T began to be administered in July 2007. This trial was designed to further evaluate the safety and use of azficel-T to treat fine lines and wrinkles for the full face. Five investigators across the United States participated in this trial. The subjects received two series of injections approximately one month apart. In late December 2007, all 45 remaining subjects completed injections. The subjects were followed for twelve months following each subject s last injection. Data results related to this trial were disclosed in August 2008, which included top line positive efficacy results related to this open label Phase II trial.

Additional safety data from this trial, collected through telephone calls placed to participating subjects twelve months from the date of their final study treatment, were submitted to the FDA on November 1, 2009. No changes to the safety profile of azficel-T were identified during our review of this data.

Facial cream: We are developing 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. At present, we are conducting characterization and safety testing in anticipation of launch in the third quarter, 2012.

Therapeutic Development Programs

Restrictive Burn Scars *Phase II Trial:* In January 2007, the Predecessor Company met with the FDA to discuss our clinical program for the use of azficel-T for restrictive burn scar patients. This Phase II trial would 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. However, the Company delayed the screening and enrollment in this trial until such time as we raise sufficient additional financing and gather additional data regarding the burn scar market. The Company is currently finalizing a Phase II protocol for submission to the FDA. We expect this protocol to be finalized and submitted to the FDA in Q2 of 2012. The development of this program will be subject to obtaining sufficient financial resources.

Agera Skincare Systems

We market and sell a skin care product line through our majority-owned subsidiary, Agera Laboratories, Inc., which was acquired in August 2006. Agera offers a complete line of skincare systems based on a wide array of proprietary formulations, trademarks and nano-peptide technology. These skincare products can be packaged to offer anti-aging, anti-pigmentary and acne treatment systems. Agera primarily markets its products in both the United States and Europe (primarily the United Kingdom).

Our Target Market Opportunities

Aesthetic Market Opportunity

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 was approximately $4.1 billion in 2010. We believe the aesthetic procedure market is driven by:

- aging of the baby boomer population, which currently includes ages approximately 47 to 65;
- the desire of many individuals to improve their appearance;

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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, 9.3 million surgical and non-surgical cosmetic procedures were performed in 2010, as compared to 10.0 million in 2009. Also according to the ASAPS, approximately 7.7 million and 8.5 million non-surgical procedures were performed in 2010 and 2009, respectively. 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 2010:

Procedure	Number
Botulinum toxin type A	2,437,165
Hyaluronic acid	1,315,121
Laser hair removal	936,270
Laser skin resurfacing	562,706
Chemical peel	493,896

In 2010, procedures among the 35 to 50 year old age group made up approximately 44% of all cosmetic procedures. The 51 to 64 year old age group made up 28% of all cosmetic procedures in 2010, while the 19 to 34 year old age group made up 20% of cosmetic procedures in 2010. The Botulinum toxin type A injection was the most popular treatment of the nonsurgical procedures among the 35 to 50 year old age group.

Therapeutic Market Opportunities

In addition to the aesthetic market, we believe there are opportunities for our Fibrocell Therapy to treat certain medical conditions such as acne scars, restrictive burn scars and tissue loss due to papillary recession. Presently, we are studying therapeutic applications of our technology for acne scars. We are not aware of other autologous cell-based treatments for any of these therapeutic applications.

Sales and Marketing

In June 2011, our lead product, 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. We formally launched LAVIV in the United States in the fourth quarter of 2011. Our strategy is to launch LAVIV directly via our own sales force in the United States. As of the filing date of this 10-K, we have seven sales representatives covering the east and west coast and key metropolitan cities. We also have four customer service representatives in Exton, PA supporting our field sales representatives. Our Agera skincare products are primarily sold directly to our established distributors and salons, with historically and recently very little focus on marketing efforts. We continue to attempt to identify additional third party distributors for our Agera product line.

Intellectual Property

We believe that patents, trademarks, copyrights, proprietary formulations (related to our Agera skincare products) 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, 2011, we had 10 issued U.S. patents, 3 pending U.S. patent applications, 30 granted foreign patents and 3 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.

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In August 2006, we acquired 57% of the common stock of Agera Laboratories. Agera has a number of trade names, trademarks, exclusive proprietary rights to product formulations and specified peptides that are used in the Agera skincare products.

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 core products are considered dermal injection products.

Now that our lead product, LAVIV, is approved by the FDA for the improvement of the appearance of moderate to severe nasolabial fold wrinkles in adults, we will compete 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. However, we believe that LAVIV, a first to market autologous cellular technology, can complement other modalities of treatment and represent a significant additional market opportunity.

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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.

Our ability to commercialize LAVIV and our other potential products and compete effectively will depend on, amongst other things, the following:

- the effectiveness of our sales and marketing efforts;
- the willingness of physicians to adopt an autologous cellular therapy;
- the perception by physicians and other members of the health care community of the safety, efficacy and benefits of LAVIV or our other products compared to those of competing products or therapies;
- our ability to manufacture LAVIV and other products we may develop on a commercial scale, which will require us, in the short-term, to add personnel to our current manufacturing operation and, in the long-term, to build-out our current manufacturing facility;
- the price of LAVIV and that of other products we may develop and commercialize relative to competing products;
- our ability to advance our other product candidates through clinical trials and through the FDA approval process;
- our ability to recruit, train, retain, manage and motivate our employees; and
- our ability to sustain our commercial scale infrastructure, including our manufacturing facilities, development of a distribution network, information technology infrastructure and configure existing operational, manufacturing and financial systems and other operational and financial systems necessary to support our increased scale as we grow our commercial organization.

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 periodontal disease, 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 quite competitive with low barriers to entry.

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.

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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 do not trigger any of those regulatory factors to be commercially distributed without marketing approval. In contrast, products that trigger those factors, such as if they are more than minimally manipulated when processed or manufactured, are regulated as drugs, biologics, or medical devices and require FDA approval. We have determined that our Fibrocell Therapy (TM) triggers regulatory factors that make it a biologic, in addition to an HCT/P, and consequently, we must obtain approval from FDA before marketing Fibrocell Therapy (TM) and must also satisfy all regulatory requirements for HCT/Ps.

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

- completion of pre-clinical laboratory tests or trials and formulation studies;
- submission to the FDA of an Investigational New Drug (IND) 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

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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

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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 are a small business and therefore qualify 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 has advised us it is 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

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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

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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.

Manufacturing

We currently have one operational manufacturing facility located in Exton, Pennsylvania. All component parts used in our Exton, Pennsylvania manufacturing process are readily available with short lead times, and all machinery is maintained and calibrated. We believe we have made improvements in our manufacturing processes, and we expect to continue such efforts in the future.

We currently have limited manufacturing capacity, although we have sufficient manufacturing capacity to fill the orders for LAVIV we have received since the launch of the product during the fourth quarter of 2011. To the extent we are successful in increasing the demand for LAVIV, we will need to add manufacturing capacity, which will require us, in the short-term, to add personnel to our current manufacturing operation and, in the long-term, to build-out our current manufacturing facility.

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Our Agera products are manufactured by a third-party contract manufacturer under a contract manufacturing agreement. The agreement is effective through July 2014.

Research and Development

In addition to our clinical development activities, our research and development activities include improving our manufacturing processes and reducing manufacturing costs. We expense research and development costs as they are incurred. For the years ended December 31, 2011 and 2010, we incurred research and development expenses of $7.2 million and $5.5 million, respectively.

Employees

As of March 26, 2012, we employed 59 people on a full-time basis and one person on a part-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 9 people working on a contract basis in our manufacturing facility. We also employ one full-time and one part-time Agera employees. 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

Financial information concerning the Company s business segments and geographic areas of operation is included in Note 15 in the Notes to Consolidated Financial Statements contained in this Form 10-K.

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.

Corporate Website

Our Internet website address is http://www.fibrocellscience.com. Our filings on Form 10-K, Form 10-Q, Form 3, Form 4, Form 5, Form 8-K and any and all amendments thereto are available free of charge through this internet website as soon as reasonably practicable after they are filed or furnished to the Securities and Exchange Commission, or the SEC. They are also available through the SEC at http://www.sec.gov/edgar/searchedgar/companysearch.html. The information contained in our website does not constitute part of this Form 10-K.

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.

We could fail to remain a going concern. We will need to raise substantial additional capital to fund our operations through commercialization of our product candidates, and we do not have any commitments for that capital.

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There exists substantial doubt regarding our ability to continue as a going concern. As of December 31, 2011 we had cash and cash equivalents of $10.8 million and working capital of $2.9 million.

As of March 26, 2012, we had cash and cash equivalents of approximately $4.7 million and our accounts payable and accrued expenses were approximately $1.6 million. In addition, the Company has approximately $7.0 million of outstanding debt which is due in June 2012. Our current monthly cash run-rate is approximately $2.2 million. We will be required to raise additional cash resources in the near future in order to fund future operations, or we will likely cease operations. There is no guarantee that any such required financing will be available on terms satisfactory to us or available at all. These matters create uncertainty relating to our ability to continue as a going concern.

We will need additional capital to achieve commercialization of our product candidates, expansion of our manufacturing capacity, development of our clinical development program and to execute our business strategy, and if we are unsuccessful in raising additional capital we will be unable to achieve commercialization of our product candidates or unable to fully execute our business strategy on a timely basis, if at all. If we raise additional capital through the issuance of debt securities, the debt securities may be secured and any interest payments would reduce the amount of cash available to operate and grow our business. If we raise additional capital through the issuance of equity securities, such issuances will likely cause dilution to our stockholders, particularly if we are required to do so during periods when our common stock is trading at low price levels. If we file for bankruptcy, it is likely that our common stock will become worthless, given that there currently exists approximately $7.0 million of debt as of March 26, 2012, which has a priority over common shareholders. In addition, our Series D Preferred Stock is senior to our common stock, and would be given a liquidation preference prior to the common stock in a bankruptcy event. Additionally, we do not know whether any financing, if obtained, will be adequate to meet our capital needs and to support our growth. If adequate capital cannot be obtained on satisfactory terms, we may terminate or delay our efforts related to regulatory approval of one or more of our product candidates, curtail or delay the implementation of manufacturing process improvements or delay the expansion of our sales and marketing capabilities, any of which could cause our business to fail.

If we do not obtain additional funding, we will likely enter into bankruptcy and/or cease operations. Further, if we do raise additional cash resources in the near future, it may be raised in contemplation of or in connection with bankruptcy. If we enter into bankruptcy, it is likely that our common stock and common stock equivalents will become worthless and our creditors will receive significantly less than what is owed to them.

Our independent registered public accounting firm issued their report for our fiscal year ended December 31, 2011, which included an explanatory paragraph for our uncertainty to continue as a going concern. If we became unable to continue as a going concern, we would have to liquidate our assets and we may likely receive significantly less than the values at which they are carried on our consolidated financial statements. The inclusion of a going concern explanatory paragraph in our independent registered public accounting firm s audit opinion for the year ended December 31, 2011 may materially and adversely affect our stock price and our ability to raise new capital.

We have significant risks relating to the commercialization of LAVIV including the following:

LAVIV is our only FDA-approved product. If we fail to achieve and sustain commercial success for LAVIV, our business will suffer, our future prospects may be harmed and our stock price would likely decline.

On June 21, 2011, the FDA licensed our autologous cellular therapy product, LAVIV, as 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. Prior to the launch of LAVIV in October 2011, we had never sold or marketed an autologous cellular product in the U.S. Unless we can successfully commercialize another product candidate or acquire the right to market other approved products, we will continue to rely on LAVIV to generate substantially all of our revenue. Our ability to increase our revenues for LAVIV will depend on, and may be limited by, a number of factors, including the following:

acceptance of and ongoing satisfaction with LAVIV as the first in a new class of therapy in the United States;

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- our ability to develop and expand market share in the United States;
- successfully expanding and sustaining our manufacturing capacity to meet demand;
- whether physicians are willing to adopt LAVIV as part of their aesthetics treatment paradigm;
- our ability to properly train a sufficient number of physicians to administer LAVIV, and whether or not the physicians correctly follow our protocols; and
- the proper pricing of LAVIV relative to the market it serves.

If for any reason we became unable to continue selling or manufacturing LAVIV, our business would be seriously harmed and could fail.

If LAVIV were to become the subject of problems related to its efficacy, safety, or otherwise, our revenues from LAVIV could decrease.

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 competing therapies, perceived difficulties in the treatment process and cost. If LAVIV is not successful in gaining broad acceptance as a treatment option for nasolabial fold wrinkles, our business would be harmed.

The rate of adoption of LAVIV for nasolabial fold wrinkles will be dependent on several factors including 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.

We are rapidly expanding our operations to support commercial launch of LAVIV, which has significantly increased our costs, and until we achieve economies of scale, we will incur negative margins on sales of LAVIV.

We have and expect to continue to significantly increase our investment in commercial infrastructure. We will need to effectively manage the expansion of our operations and facilities and continue to grow our infrastructure to commercialize LAVIV. We must effectively manage our supply chain, third-party vendors and distribution network, all of which requires strict planning in order to meet production timelines for LAVIV. We continue to add manufacturing, quality control, quality assurance, marketing and sales personnel, and personnel in all other areas of our operations, which strains our existing managerial, operational, financial and other resources. As a result of the scaling of our manufacturing process and the limited orders we have received since the launch of LAVIV in the fourth quarter of 2011, we are currently incurring negative margins on sales of LAVIV, and will continue to incur such margins until we are able to generate significant sales volume. As discussed below, to accommodate increased sales, we will need to add manufacturing capacity, which will require us, in the short-term, to add personnel to our current manufacturing operation and, in the long-term, to build-out our current manufacturing facility. In pursuing expansion, we must continue to monitor quality and effective controls, or we risk possible delays in approval of the facilities by the FDA for commercial manufacturing. Any delay in readiness of our expanded Exton facility could result in the loss of revenue from potential sales of LAVIV, and adversely impact market acceptance for LAVIV. If we fail to manage the growth in our systems and personnel appropriately and successfully in order to achieve our commercialization plans for LAVIV, our revenues could suffer and our business could be harmed.

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We have significant risks relating to the manufacturing and regulation of LAVIV and our other product candidates, including the following:

If we are able to increase orders for LAVIV, we will need to increase our manufacturing capacity, which will require significant expenditures and regulatory approval.

We currently have limited manufacturing capacity, although we have sufficient manufacturing capacity to fill the orders for LAVIV we have received since the launch of the product during the fourth quarter of 2011. To the extent we are successful in increasing the demand for LAVIV, we will need to add manufacturing capacity, which will require us, in the short-term, to add personnel to our current manufacturing operation and, in the long-term, to build-out our current manufacturing facility. Increasing manufacturing capacity will require additional expenditures, for which we will require external financing. In addition, our ability to increase manufacturing capacity will be subject to additional FDA review.

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.

Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.

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;

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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.

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, 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.

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, which depends on one facility, 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, 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.

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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;

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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, which we expect to commence in mid-2012 and complete in 2014.

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 our LAVIV. 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 is 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.

Any failure or delay in completing clinical trials for our product candidates, or in receiving regulatory approval for the sale of any product candidates, has the potential to materially harm our business, and may prevent us from raising necessary, additional financing that we may need in the future.

Other significant risk factors include the following:

Since our emergence from bankruptcy we have completed numerous equity financings of convertible securities, and it is likely that we will make additional equity financings in the future, which may materially and adversely affect the price of our common stock. We have a significant number of convertible securities that may result in significant dilution to our common stockholders.

Sales of substantial amounts of shares of our common stock in the public market, or the perception that those sales may occur, could cause the market price of our common stock to decline. We have used and it is likely that we will continue to use our common stock or securities convertible into or exchangeable for our common stock to fund our working capital needs or to acquire technology, product rights or businesses, or for other purposes. If we issue additional equity securities, particularly during times when our common stock is trading at relatively low price levels, the price of our common stock may be materially and adversely affected.

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Since our emergence from bankruptcy we have completed numerous equity financings of convertible preferred stock and warrants. The conversion or exercise of the preferred stock or warrants, as applicable, into common stock and the sale of such common stock into the market may cause the price of our common stock to fall. Even if such sales do not occur, the market may anticipate such sales in the future, which may cause the price of our common stock to fall.

Furthermore, our outstanding preferred stock has a mandatory conversion feature that we may trigger if the price of our common stock trades above $1.00 per share for a period of 20 days. As of March 26, 2012, if such price occurs and if we trigger the mandatory conversion feature, we would be required to issue in excess of 6 million shares of common stock. The issuance of these shares or the sale of these shares may materially reduce the price of our common stock.

We have a significant number of warrants and convertible preferred stock outstanding that contain anti-dilution and price-protection provisions that may result in the reduction of their exercise prices or conversion prices in the future.

Since October 2009, we have completed several offerings of convertible preferred stock and warrants. Many of these securities contain anti-dilution provisions, which provisions require the lowering of the conversion price or exercise price, as applicable, to the purchase price of future offerings. Furthermore, with respect to certain of the warrants issued in these offerings, if we complete an offering below the exercise price of such warrants, the number of shares issuable under the warrants will be proportionately increased such that the aggregate exercise price payable after taking into account the decrease in the exercise price, shall be equal to the aggregate exercise price prior to such adjustment. The conversion and exercise price of our convertible preferred stock and warrants has been lowered in the past (with proportional increases in the number of shares underlying the warrants as described in the preceding sentence) due to the completion of subsequent financings. If in the future we issue securities for less than the conversion or exercise price of the securities we issued in these prior financings, we may be required to further reduce the relevant conversion or exercise prices, and the number of shares underlying the warrants may be increased.

During the term that the warrants and preferred stock are outstanding, the holders of those securities are given the opportunity to profit from a rise in the market price of our common stock. In addition, certain of the warrants are not redeemable by us. We may find it more difficult to raise additional equity capital while these warrants or preferred stock are outstanding. At any time during which these warrants are likely to be exercised, we may be able to obtain additional equity capital on more favorable terms from other sources.

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, which may limit or delay our ability to become profitable.

We have incurred losses since our inception, have never generated significant revenue from commercial sales of our products, and have never been profitable. We are focused on the commercialization of LAVIV and product development, and we have expended significant resources on the launch of LAVIV, our clinical trials, personnel and research and development. We expect these costs to continue to rise in the future. We expect to continue to experience increasing operating losses and negative cash flow as we expand our operations.

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

- the commercialization of LAVIV;
- expansion of laboratory and manufacturing operations, including the hiring of manufacturing and quality control and assurance personnel;
- FDA clinical trials and regulatory approvals;

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research and development;

brand development;

personnel costs;

development of relationships with strategic business partners, including physicians who might use our future products; and

interest expense and amortization of issuance costs related to our outstanding note payables.

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 until we begin to generate significant revenue from LAVIV, which will require a significant increase in our manufacturing capacity.

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.

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. In addition, our budgeted expense levels are based in part on our expectations of future revenue that we may receive from our Agera product line, and the size of future revenue depends on the choices and demand of individuals. 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;

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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

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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.

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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 most of our key management personnel, but some of these people are employed at-will, and any of them may elect to pursue other opportunities at any time. We have no present intention of obtaining key man life insurance on any of our executive officers or key management personnel.

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

In the future, we may need to seek additional senior executives, as well as manufacturing and quality staff members. There is a high demand for highly trained executive, manufacturing and quality personnel in our industry. We do not know whether we will be able to attract, train and retain highly qualified manufacturing and quality personnel in the future, which could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

As of December 31, 2011, we had 10 issued U.S. patents, 3 pending U.S. patent applications, 30 granted foreign patents and 3 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;

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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

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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, the ability to issue blank check preferred stock, and the adoption of stockholder rights plans 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.

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Because our consolidated financial statements for the year ended December 31, 2009 reflect fresh-start accounting adjustments made on emergence from bankruptcy and because of the effects of the transactions that became effective pursuant to the Plan, financial information in our current and future financial statements will not be comparable to our financial information from prior periods.

In connection with our emergence from bankruptcy, we adopted fresh-start accounting as of September 1, 2009 in accordance with ASC 852-10. The adoption of fresh-start accounting resulted in our becoming a new entity for financial reporting purposes. As required by fresh-start accounting, our assets and liabilities have been preliminarily adjusted to fair value, and certain assets and liabilities not previously recognized in our financial statements have been recognized. In addition to fresh-start accounting, our financial statements reflect all effects of the transactions implemented by the Plan. Accordingly, the financial statements prior to September 1, 2009 are not comparable with the financial statements for periods on or after September 1, 2009. Furthermore, the estimates and assumptions used to implement fresh-start accounting are inherently subject to significant uncertainties and contingencies beyond our control. Accordingly, we cannot provide assurance that the estimates, assumptions, and values reflected in the valuations will be realized, and actual results could vary materially.

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 26, 2012, there were 96,078,253 shares of common stock issued and outstanding. All of our outstanding shares are freely transferable without restriction or further registration under the Securities Act. In addition to our common stock outstanding, as of such date, we had preferred stock outstanding that was convertible into a total of 6,882,000 shares of common stock and warrants outstanding that were exercisable for a total of 49,135,602 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.

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

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

We depend on a third-party manufacturer for our Agera product line, the loss or unavailability of which would require us to find a substitute manufacturer, if available, resulting in delays in production and additional expenses.

Our Agera skin care product line is manufactured by a third party. We are dependent on this third party to manufacture Agera s products, and the manufacturer is responsible for supplying the formula ingredients for the Agera product lines. If for any reason the manufacturer discontinues production of Agera s products at a time when we have a low volume of inventory on hand or are experiencing a high demand for the products, significant delays in production of the products and interruption of product sales may result as we seek to establish a relationship and commence production with a new manufacturer, which would negatively impact our results of operation.

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The large majority of our revenue, which relates to the Agera business segment, is to one international customer.

Our revenues, which relate solely to the Agera business segment, are highly concentrated in one large, international customer. This large customer represented 65% and 72% of 2011 and 2010 consolidated revenues, respectively. Further, this large customer represented 85% and 88% of consolidated accounts receivable, net, at December 31, 2011 and December 31, 2010, respectively. A reduction of revenue related to this large customer, due to competitor product alternatives, pricing pressures, the financial health of the large customer, or otherwise, would have a significant, negative impact on the business of Agera, and the related value thereof.

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 is noncancelable through March 31, 2013. Subsequent to December 31, 2011, we renegotiated the lease and extended it for a period of ten years until March 31, 2023.

Item 3. Legal Proceedings

None.

Item 4. Mine Safety Disclosure

N/A.

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, 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
Year Ended December 31, 2010		
First Quarter	$ 1.13	$ 0.80
Second Quarter	$ 1.04	$ 0.65
Third Quarter	$ 0.85	$ 0.53
Fourth Quarter	$ 0.60	$ 0.40

The closing price of our common stock on March 26, 2012 was $0.47 as reported on the OTCBB.

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Holders of Record

As of March 26, 2012, there were 96,078,253 shares of our common stock outstanding and held by 244 stockholders of record. As of March 26, 2012, there were 3,250 shares issued and no shares outstanding for Series A preferred stock, 4,640 shares issued and no shares outstanding for Series B preferred stock and 7,779 shares issued and 3,441 shares outstanding for Series D preferred stock.

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.

Holders of our Series D Preferred Stock are entitled to receive cumulative dividends at the rate per share (as a percentage of the stated value per share) of 6% per annum (subject to increase in certain circumstances), payable quarterly in arrears. The dividends are payable in cash, or at our option, in duly authorized, validly issued, fully paid and non-assessable shares of common stock equal to 110% of the cash dividend amount payable on the dividend payment date, or a combination thereof; provided that we may not pay the dividends in shares of common stock unless we meet certain conditions described in the Certificate of Designation, including that the resale of the shares has been registered under the Securities Act. If we pay the dividend in shares of common stock, the common stock will be valued for such purpose at 80% of the average of the volume weighted average price for the 10 consecutive trading days ending on the trading day that is immediately prior to the dividend payment date. Cash payments for Series A dividends were approximately $0.1 million for 2010 and cash payments for Series A, Series B and Series D 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.

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Recent Sales of Unregistered Securities

All information regarding the financings we completed during 2011 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 2011.

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

General

We are a cellular aesthetic and therapeutic development stage biotechnology company focused on developing novel skin and tissue rejuvenation products. Our clinical development product candidates are designed to improve the appearance of skin injured by the effects of aging, sun exposure, acne and burn scars with a patient s own, or autologous, fibroblast cells produced by our proprietary Fibrocell process. Our clinical development programs encompass both aesthetic and therapeutic indications.

Our lead product, 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.

During 2009 we completed a Phase II study for the treatment of acne scars. We announced on November 3, 2011, that the first scientific presentation of data demonstrating the efficacy of LAVIV (azficel-T) in treating moderate-to-severe depressed acne scars was presented at the American Society for Dermatologic Surgery (ASDS) annual meeting in Washington, D.C. During 2008 we completed our open-label Phase II study related to full face rejuvenation.

We also develop and market an advanced skin care product line through our Agera subsidiary, in which we acquired a 57% interest in August 2006.

Exit from Bankruptcy

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. Fibrocell now operates outside of the restraints of the bankruptcy process, free of the debts and liabilities discharged by the Plan.

Going Concern

The Company emerged from Bankruptcy in September 2009 and continues to operate as a going concern. At December 31, 2011, the Company had cash and cash equivalents of approximately $10.8 million and working capital of $2.9 million.

As of March 26, 2012, the Company had cash and cash equivalents of approximately $4.7 million and our accounts payable and accrued expenses were approximately $1.6 million. In addition, the Company has approximately $7.0 million of outstanding debt which is due in June 2012. The Company s current monthly cash run-rate is approximately $2.2 million. The Company will need to access the capital markets in the near future in order to fund future operations. There is no guarantee that any such required financing will be available on terms satisfactory to the Company or available at all. These matters create uncertainty relating to its ability to continue as a going concern. The accompanying consolidated financial statements do not reflect any adjustments relating to the recoverability and classification of assets or liabilities that might result from the outcome of these uncertainties.

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Further, if the Company raises additional cash resources in the near future, it may be raised in contemplation of or in connection with bankruptcy. In the event of a bankruptcy, it is likely that its common stock and common stock equivalents will become worthless and our creditors will receive significantly less than what is owed to them.

Through December 31, 2011, the Company has been primarily engaged in developing its initial product technology. In the course of its development activities, the Company has sustained losses and expects such losses to continue through at least 2012. During the year ended December 31, 2011, the Company financed its operations primarily through its existing cash received from external equity financings, but as discussed above it now requires additional financing. There is substantial doubt about the Company s ability to continue as a going concern.

The Company s ability to complete additional offerings is dependent on the state of the debt and/or equity markets at the time of any proposed offering, and such market s reception of the Company and the offering terms. The Company s ability to complete an offering is also dependent on the status of its Food and Drug Administration (FDA) regulatory milestones and its clinical trials. There is no assurance that capital in any form would be available to the Company, and if available, on terms and conditions that are acceptable.

As a result of the conditions discussed above, and in accordance with Generally Accepted Accounting Principles (GAAP), there exists substantial doubt about the Company s ability to continue as a going concern, and its ability to continue as a going concern is contingent, among other things, upon its ability to secure additional adequate financing or capital in the near future. If the Company does not obtain additional funding, or does not anticipate additional funding, in the near future, it will likely enter into bankruptcy and/or cease operations. Further, if it does raise additional cash resources in the near future, it may be raised in contemplation of or in connection with bankruptcy. If the Company enters into bankruptcy, it is likely that its common stock and common stock equivalents will become worthless and its creditors, including preferred stock, will receive significantly less than what is owed to them.

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 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. This value is related to research and development assets that are not subject to amortization.

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

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

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Warrant Liability: We account for our warrants in accordance with U.S. GAAP. The warrants are measured at fair value and liability-classified under Accounting Standards Codification (ASC) 815, Derivatives and Hedging, (ASC 815) because 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 calculated the fair value of the warrants using the Monte Carlo simulation valuation method due to the changes in the product status with the approval of LAVIV. Prior to December 31, 2011, the Black-Scholes option-pricing model was utilized due to the assumptions present prior to the approval of LAVIV. 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 any holder of Series A, B or D Preferred may require the Company to redeem all of its Series A, B or D Preferred in the event of a triggering event which is outside of the control of the Company.

The embedded conversion option for the Series A Preferred, Series B Preferred and 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 December 31, 2010, and will be re-measured on the Company s reporting dates. 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 Company will continue to classify the fair value of the embedded conversion option as a liability until the preferred stock is converted into common stock.

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 our competitor s stock since the Predecessor Company ceased trading as part of the bankruptcy and emerged as a new entity. 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.

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

As of September 1, 2009, the Company adopted fresh-start accounting in accordance with ASC 852-10, Reorganizations. The Company selected September 1, 2009, as the date to effectively apply fresh-start accounting based on the absence of any material contingencies at the August 27, 2009 confirmation hearing and the immaterial impact of transactions between August 27, 2009 and September 1, 2009. The adoption of fresh-start accounting resulted in the Company becoming a new entity for financial reporting purposes.

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Accordingly, the financial statements prior to September 1, 2009 are not comparable with the financial statements for periods on or after September 1, 2009. References to Successor or Successor Company refer to the Company on or after September 1, 2009, after giving effect to the cancellation of Isolagen, Inc. common stock issued prior to the Effective Date, the issuance of new Fibrocell Science, Inc. common stock in accordance with the Plan, and the application of fresh-start accounting. References to Predecessor or Predecessor Company refer to the Company prior to September 1, 2009.

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, 2011 and 2010

Revenue and Cost of Sales. Revenue and cost of sales for the years ended December 31, 2011 and 2010 were comprised of the following:

	Year ended December 31,		Increase (Decrease)	
	2011	2010	$000s	%
	(in thousands)			
Total revenue	$ 812	$ 936	$ (124)	(13.2)%
Cost of sales	464	502	(38)	(7.5)%
Gross profit	$ 348	$ 434	$ (86)	(19.8)%

Revenue decreased $0.1 million to $0.8 million for the year ended December 31, 2011 as compared to $0.9 million for the year ended December 31, 2010. Our revenue is from the operations of Agera which markets and sells a complete line of advanced skin care systems based on a wide array of proprietary formulations, trademarks and nano-peptide technology.

Costs of sales remained constant at $0.5 million for the year ended December 31, 2011 and for the year ended December 31, 2010. As a percentage of revenue, Agera s cost of sales was approximately 57% for the year ended December 31, 2011 and 54% for the year ended December 31, 2010. Cost of sales as a percentage of revenue in 2011 has increased as compared to 2010 primarily due to component costs (containers, cartons and labels).

Selling, General and Administrative Expense. Selling, general and administrative expense for the year ended December 31, 2011 and 2010 was comprised of the following:

	Year Ended December 31,		Increase (Decrease)	
	2011	2010	$000s	%
	(in thousands)			
Compensation and related expense	$ 4,687	$ 2,501	$ 2,186	87%
External services consulting	693	942	(249)	(26)%
Marketing expense	3,820	157	3,663	2,339%
License fees	805	17	788	4,681%
Facilities and related expense and other	3,206	2,899	307	11%
Total selling, general and administrative expense	$ 13,211	$ 6,516	$ 6,695	103%

Selling, general and administrative expenses increased by approximately $6.7 million, or 103%, to $13.2 million for the year ended December 31, 2011 as compared to $6.5 million for the year ended December 31, 2010. The increase primarily consists of an increase in stock compensation expense of $1.8 million, an increase in salaries of $0.4 million, an increase in marketing expense of $3.7 million in preparation of

the launch of LAVIV and an increase in license fees of $0.8 million for FDA product and establishment fees. Consulting fees decreased $0.2 million due to the hiring of key personnel offset by an increase in office expense.

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Research and Development Expense. Research and development expense for the year ended December 31, 2011 and 2010 was comprised of the following:

	Year Ended December 31,		Increase (Decrease)	
	2011	2010	$000s	%
	(in thousands)			
Compensation and related expense	$ 2,108	$ 1,600	$ 508	32%
External services consulting	1,927	2,129	(202)	(10)%
Lab costs and related expense	1,620	879	741	84%
Facilities and related expense	1,516	878	638	73%
Total research and development expense	$ 7,171	$ 5,486	$ 1,685	31%

Research and development expense increased $1.7 million to $7.2 million for the year ended December 31, 2011 as compared to $5.5 million for the year ended December 31, 2010. The increase is primarily due to an increase of $0.4 million in compensation and related expense, an increase of $0.1 million for stock compensation expense, an increase of $0.7 million for lab costs and $0.6 million for contract labor as the Company prepares for the launch and production of the product LAVIV, offset by $0.1 million decrease for consulting fees. Research and development costs are composed primarily of quality and manufacturing costs in connection with LAVIV which was recently approved by the FDA. As we begin selling LAVIV these costs will appear as cost of goods sold on the statements of operations. There are also other costs related to other potential indications for our Fibrocell Therapy, such as acne scars and burn scars. Also, research and development expense includes costs to develop manufacturing, cell collection and logistical process improvements. Research and development costs primarily include personnel and laboratory costs related to these FDA trials and certain consulting costs. The total inception (December 28, 1995) to date cost of research and development as of August 31, 2009 for the Predecessor Company was $56.3 million and total inception (September 1, 2009) to date cost of research and development as of December 31, 2011, for the Successor Company was $14.5 million.

Other income (expense). In November 2010, we received one grant totaling $0.2 million under the Qualified Therapeutic Discovery Project Grants Program. The Qualified Therapeutic Discovery Project Grants Program was included in the healthcare reform legislation, and established a one-time pool of $1 billion for grants to small biotechnology companies developing novel therapeutics which show potential to: (a) result in new therapies that either treat areas of unmet medical need, or prevent, detect, or treat chronic or acute diseases and conditions; (b) reduce long-term health care costs in the United States; or (c) significantly advance the goal of curing cancer within a the 30-year period. There are no matching funding requirements or other requirements necessary to receive the funding.

Interest expense. Interest expense remained relatively constant at $1.1 million for the years ended December 31, 2011 and 2010. Our interest expense for the years ended December 31, 2011 and 2010 is related to the 12.5% notes we issued in connection with our bankruptcy plan.

Change in Revaluation of Warrant and Derivative Liability. During the years ended December 31, 2011 and 2010, we recorded non-cash expense of $4.8 million and $0.5 million for warrant expense, respectively, in our statements of operations due to an increase in the fair value of the warrant liability. This increase in fair value was primarily due to a change in the valuation method from the Black Scholes model to the Monte Carlo simulation model. In addition, the number of shares underlying the warrants increased in 2011 due to the issuance of our Series D 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. During the year ended December 31, 2011, we recorded non-cash expense of $5.5 million for derivative revaluation expense in our statements of operations due to the change in the fair value of the derivative liability related to the Series A, B and D preferred stock financings.

Net Loss attributable to common shareholders. Net loss, excluding reorganization items, increased $18.5 million to $31.4 million for the year ended December 31, 2011, as compared to $12.9 million for the year ended December 31, 2010. The increase in expense is due to preparation for the launch and production of LAVIV.

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Liquidity and Capital Resources

The following table summarizes our cash flows from operating, investing and financing activities for the two years ended December 31, 2011 and 2010:

	Year Ended December 31,	
	2011	2010
	(in thousands)	
Statement of Cash Flows Data:		
Total cash provided by (used in):		
Operating activities	$ (16,837)	$ (9,266)
Investing activities	(1,570)	(30)
Financing activities	28,336	8,795

Operating Activities. Cash used in operating activities during the year ended December 31, 2011 amounted to $16.8 million, an increase of $7.5 million over the year ended December 31, 2010. 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 $6.6 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, 2011 amounted to $1.6 million due to the purchase of property and equipment for the lab facility in Exton, Pennsylvania in preparation of the launch of LAVIV.

Financing Activities. There was $28.3 million cash proceeds received from financing activities during the year ended December 31, 2011, as compared to $8.8 million received from financing activities during the year ended December 31, 2010. During the years ended December 31, 2011 and 2010, we raised cash of $30.4 million and $9.0 million, respectively, from the issuance of common stock, preferred stock and warrants, offset primarily by principal debt payments of $1.3 million in 2011 and dividend payments of $0.6 million and $0.1 million in 2011 and 2010, respectively.

Working Capital

As of December 31, 2011, we had cash and cash equivalents of $10.8 million and working capital of $2.9 million. As of March 26, 2012, the Company had cash and cash equivalents of approximately $4.7 million and our accounts payable and accrued expenses were approximately $1.6 million. In addition, the Company has approximately $7.0 million of outstanding debt which is due in June 2012. The Company s current monthly cash run-rate is approximately $2.2 million. The Company will need to access the capital markets in the near future in order to fund future operations. There is no guarantee that any such required financing will be available on terms satisfactory to the Company or available at all. These matters create uncertainty relating to its ability to continue as a going concern. The accompanying consolidated financial statements do not reflect any adjustments relating to the recoverability and classification of assets or liabilities that might result from the outcome of these uncertainties.

Factors Affecting Our Capital Resources

Inflation did not have a significant impact on the Company s results during the year ended December 31, 2011.

Off-Balance Sheet Transactions

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

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Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2011 (in thousands):

	Payments due by period				
	Total	2012	2013 and 2014	2015 and 2016	2017 and thereafter
Contractual Obligations					
Debt obligation	$ 6,731	$ 6,731	$	$	$
Operating lease obligations[(1)]	14,205	884	2,152	2,465	8,704
Total	$ 20,936	$ 7,615	$ 2,152	$ 2,465	$ 8,704

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

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.

N/A.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, including our principal executive officer and principal financial officer, evaluated the disclosure controls and procedures related to the recording, processing, summarization and reporting of information in the periodic reports that the Company files with the SEC. These disclosure controls and procedures have been designed to ensure that (a) material information relating to the Company, including its consolidated subsidiaries, is made known to management, including these officers, by other employees of the Company, 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, 2011, the officers (the principal executive officer and principal financial officer) concluded that the Company s disclosure controls and procedures were effective.

Management s Report on Internal Control over Financial Reporting

Our 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.

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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*, our management concluded that our internal control over financial reporting was effective as of December 31, 2011. This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. As we are 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

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.

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 the Company s Proxy Statement for the 2012 Annual Meeting of Stockholders which will be filed with the Securities and Exchange Commission no later than April 29, 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 the Company s 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 the Company s fiscal year ended December 31, 2011.

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

The information required under this Item 12 is incorporated herein by reference to the Company s 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 the Company s fiscal year ended December 31, 2011.

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

The information required under this Item 13 is incorporated herein by reference to the Company s 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 the Company s fiscal year ended December 31, 2011.

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Item 14. Principal Accountant Fees and Services

The information required under this Item 14 is incorporated herein by reference to the Company s 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 the Company s fiscal year ended December 31, 2011.

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, 2011 and 2010

Consolidated Statements of Operations for the years ended December 31, 2011 and 2010 (Successor Company), from inception (September 1, 2009) to December 31, 2011 (Successor Company) and from inception to August 31, 2009 (Predecessor Company)

Consolidated Statements of Shareholders Deficit and Comprehensive Income (Loss) from inception to August 31, 2009 (Predecessor Company) and from inception (September 1, 2009) to December 31, 2011 (Successor Company)

Consolidated Statements of Cash Flows for the years ended December 31, 2011 and 2010, from inception (September 1, 2009) to December 31, 2011 (Successor Company) and cumulative period from inception (December 28, 1995) to August 31, 2009 (Predecessor Company)

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.

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(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	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to our Form 8-K filed September 2, 2009)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to our Form 8-K filed September 2, 2009)
3.3	Certificate of Designation of Preferences, Rights and Limitations of Series A 6% Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to our Form 8-K filed October 14, 2009)
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock, dated July 16, 2010. (incorporated by reference to Exhibit 3.1 to our Form 8-K filed July 20, 2010).
3.5	Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock. (incorporated by reference to Exhibit 3.2 to our Form 8-K filed December 8, 2010).
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 12.5% Promissory Note (incorporated by reference to Exhibit 10.1 to our Form 8-K filed September 10, 2009)
4.4	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)
4.5	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)
4.6	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)
4.7	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)
4.8	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).
4.9	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).
4.10	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)
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	Consulting Agreement between the Company and Robert Langer (incorporated by reference to Exhibit 10.2 to our Form 10-Q filed November 23, 2009)

10.4	2009 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 4.5 to our Form S-8 filed March 3, 2011)
10.5	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)

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10.6	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)
10.7	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)
10.8	Employment Agreement between the Company and David Pernock (incorporated by reference to Exhibit 10.1 to our Form 8-K filed February 1, 2010)
10.9	Securities Purchase Agreement dated March 2, 2010 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed March 3, 2010)
10.10	Registration Rights Agreement dated March 2, 2010 (incorporated by reference to Exhibit 10.2 to our Form 8-K filed March 3, 2010)
10.11	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)
10.12	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)
10.13	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)
10.14	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).
10.15	Securities Purchase Agreement dated August 3, 2011 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed August 4, 2011)
10.16	Registration Rights Agreement dated August 3, 2011 (incorporated by reference to Exhibit 10.2 to our Form 8-K filed August 4, 2011)
*10.17	Amendment to Lease Agreement between Fibrocell Science, Inc. and The Hankin Group dated February 17, 2012
21	List of Subsidiaries (previously filed as an exhibit to the company s Annual Report on Form 10-K for the fiscal year ended December 31, 2006)
*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.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.

* Filed herewith.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

FIBROCELL SCIENCE, INC.

By: /s/ David Pernock

David Pernock

Chief Executive Officer

Date: March 30, 2012

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	March 30, 2012
/s/ Declan Daly Declan Daly	Chief Financial Officer, Chief Operating Officer and Director	March 30, 2012
/s/ Kelvin Moore Kelvin Moore	Director	March 30, 2012
/s/ Dr. Robert Langer Dr. Robert Langer	Director	March 30, 2012
/s/ Marc Mazur Marc Mazur	Director	March 30, 2012
/s/ Dr. George Korkos Dr. George Korkos	Director	March 30, 2012

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Fibrocell Science, Inc.

(A Development Stage Company)

Index to Consolidated Financial Statements

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Fibrocell Science, Inc. (a development stage company)

Exton, Pennsylvania

We have audited the accompanying consolidated balance sheets of Fibrocell Science, Inc. (in the development stage) as of December 31, 2011 and 2010 and the related consolidated statements of operations, shareholders equity (deficit) and comprehensive loss, and cash flows for the years ended December 31, 2011 and 2010 (Successor), and for the period from the Successor s inception of operations (September 1, 2009) through December 31, 2011 and for the period from the Predecessor s inception of operations (December 28, 1995) through August 31, 2009. We have also audited the statements of shareholders equity (deficit) for the period from December 28, 1995 (Predecessor s inception) through August 31, 2009 and for the period from the Successor s inception of operations (September 1, 2009) through December 31, 2011. 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, 2011 and 2010, and the results of its operations and its cash flows for the years then ended (Successor), and for the period from the Successor s inception of operations (September 1, 2009) through December 31, 2011 and for the period from the Predecessor s inception of operations (December 31, 1995) through August 31, 2009 and the statements of shareholders equity (deficit) for the period from December 28, 1995 (Predecessor s inception) to August 31, 2009 and for the period from the Successor s inception of operations (September 1, 2009) through December 31, 2011, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the financial statements, the Company has suffered recurring losses from operations, has a net capital deficit, and has limited cash resources that raise substantial doubt about its ability to continue as a going concern. Management s plan in regard to these matters is also described in Note 3. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ BDO USA, LLP

Houston, Texas

March 30, 2012

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Fibrocell Science, Inc.

(A Development Stage Company)

Consolidated Balance Sheets

	December 31, 2011	December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	$ 10,798,995	$ 867,738
Accounts receivable, net	215,714	229,891
Inventory, net	266,348	258,939
Prepaid expenses and other current assets	1,217,596	559,082
Total current assets	12,498,653	1,915,650
Property and equipment, net of accumulated depreciation of $165,841 and $8,085, respectively	1,433,938	21,589
Intangible assets and other assets	6,340,906	6,340,906
Total assets	$ 20,273,497	$ 8,278,145
Liabilities, Redeemable Preferred Stock, Shareholders Deficit and Noncontrolling Interest		
Current liabilities:		
Current debt	$ 6,730,861	$ 56,911
Accounts payable	1,899,045	1,096,125
Accrued expenses	926,141	789,482
Deferred revenue	55,400	
Total current liabilities	9,611,447	1,942,518
Long-term debt		7,290,881
Deferred tax liability	2,500,000	2,500,000
Warrant liability	13,087,000	8,171,518
Derivative liability	533,549	2,120,360
Other long-term liabilities	142,002	255,606
Total liabilities	25,873,998	22,280,883
Commitments		
Preferred stock series A, $0.001 par value; 9,000 shares authorized; 3,250 shares issued; 0 and 2,886 shares outstanding, respectively		1,280,150
Preferred stock series B, $0.001 par value; 9,000 shares authorized; 4,640 shares issued; 0 and 4,640 shares outstanding, respectively		
Preferred stock series B, $0.001 par value; subscription receivable		(210,000)
Preferred stock series D, $0.001 par value; 8,000 shares authorized; 7,779 and 1,645 shares issued, respectively, and 3,641 and 1,645 shares outstanding, respectively		
Fibrocell Science, Inc. shareholders deficit:		
Common stock, $0.001 par value; 250,000,000 shares authorized; 95,678,255 and 20,375,500 issued and outstanding, respectively	95,678	20,376
Common stock-subscription receivable	(550,020)	
Additional paid-in capital	43,734,339	2,437,893
Accumulated deficit during development stage	(49,349,080)	(17,981,530)
Total Fibrocell Science, Inc. shareholders deficit	(6,069,083)	(15,523,261)

Noncontrolling interest	468,582	450,373
Total deficit and noncontrolling interest	(5,600,501)	(15,072,888)
Total liabilities, preferred stock, shareholders deficit and noncontrolling interest	$ 20,273,497	$ 8,278,145

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

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Fibrocell Science, Inc.

(A Development Stage Company)

Consolidated Statements of Operations

	Successor For the year ended December 31, 2011	Successor For the year ended December 31, 2010	Successor Cumulative period from September 1, 2009 (date of inception) to December 31, 2011	Predecessor Cumulative period from December 28, 1995 (date of inception) to August 31, 2009
Revenue				
Product sales	$ 812,235	$ 936,369	$ 2,078,545	$ 4,818,994
License fees				260,000
Total revenue	812,235	936,369	2,078,545	5,078,994
Cost of sales	463,874	502,648	1,148,570	2,279,335
Gross profit	348,361	433,721	929,975	2,799,659
Selling, general and administrative expenses	13,211,486	6,515,581	22,435,423	84,805,520
Research and development expenses	7,170,520	5,486,319	14,480,035	56,269,869
Operating loss	(20,033,645)	(11,568,179)	(35,985,483)	(138,275,730)
Other income (expense)				
Interest income			1	6,989,539
Reorganization items, net		3,303	(69,174)	73,538,984
Other income		244,479	244,479	316,338
Warrant expense	(4,762,694)	(465,232)	(5,547,010)	
Derivative revaluation expense	(5,451,518)		(5,451,518)	
Interest expense	(1,061,862)	(1,045,199)	(2,354,235)	(18,790,218)
Loss from continuing operations before income taxes	(31,309,719)	(12,830,828)	(49,162,940)	(76,221,087)
Income tax benefit				190,754
Loss from continuing operations	(31,309,719)	(12,830,828)	(49,162,940)	(76,030,333)
Loss from discontinued operations	(39,622)	(48,805)	(100,540)	(41,091,311)
Net loss	(31,349,341)	(12,879,633)	(49,263,480)	(117,121,644)
Deemed dividend associated with beneficial conversion				(11,423,824)
Preferred stock dividends				(1,589,861)
Net (income) loss attributable to noncontrolling interest	(18,209)	(51,898)	(85,600)	1,799,523
Net loss attributable to Fibrocell Science, Inc. common shareholders.	$ (31,367,550)	$ (12,931,531)	$ (49,349,080)	$ (128,335,806)
Per share information:				
Loss from continuing operations-basic and diluted	$ (0.57)	$ (0.68)	$ (1.46)	$ (4.30)
				(2.32)

Loss from discontinued operations-basic and diluted				
Income attributable to noncontrolling interest				0.10
Deemed dividend associated with beneficial conversion of preferred stock				(0.65)
Preferred stock dividends				(0.09)
Net loss attributable to common shareholders per common share basic and diluted	$ (0.57)	$ (0.68)	$ (1.46)	$ (7.26)
Weighted average number of basic and diluted common shares outstanding	54,857,520	18,757,756	33,664,124	17,678,219

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

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Fibrocell Science, Inc.

(A Development Stage Company)

Consolidated Statements of Shareholders Equity (Deficit) and Comprehensive Income (Loss)

	Series A Preferred Stock		Series B Preferred Stock		Common Stock			Treasury Stock		Accumulated Other	Accumulated Deficit	Total Shareholders
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Number of Shares	Amount	Comprehensive Income	During Development Stage	Equity (Deficit)
Issuance of common stock for cash on 12/28/95	$	$			2,285,291	$ 2,285	$ (1,465)		$	$	$	$ 820
Issuance of common stock for cash on 11/7/96					11,149	11	49,989					50,000
Issuance of common stock for cash on 11/29/96					2,230	2	9,998					10,000
Issuance of common stock for cash on 12/19/96					6,690	7	29,993					30,000
Issuance of common stock for cash on 12/26/96					11,148	11	49,989					50,000
Net loss											(270,468)	(270,468)
Balance, 12/31/96 (Predecessor)	$	$			2,316,508	$ 2,316	$ 138,504		$	$	$ (270,468)	$ (129,648)
Issuance of common stock for cash on 12/27/97					21,182	21	94,979					95,000
Issuance of common stock for services on 9/1/97					11,148	11	36,249					36,260
Issuance of common stock for services on 12/28/97					287,193	287	9,968					10,255
Net loss											(52,550)	(52,550)
Balance, 12/31/97(Predecessor)	$	$			2,636,031	$ 2,635	$ 279,700		$	$	$ (323,018)	$ (40,683)

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

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Consolidated Statements of Shareholders' Equity (Deficit) and Comprehensive Income (Loss)

	Series A Preferred Stock		Series B Preferred Stock		Common Stock			Treasury Stock		Accumulated Other	Accumulated Deficit During	Total Shareholders
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Number of Shares	Amount	Comprehensive Income	Development Stage	Equity (Deficit)
Issuance of common stock for cash on 8/23/98	$	$			4,459	$ 4	$ 20,063		$	$	$	$ 20,067
Repurchase of common stock on 9/29/98								2,400	(50,280)			(50,280)
Net loss											(195,675)	(195,675)
Balance, 12/31/98 (Predecessor)	$	$			2,640,490	$ 2,639	$ 299,763	2,400	$ (50,280)	$	$ (518,693)	$ (266,571)
Issuance of common stock for cash on 9/10/99					52,506	53	149,947					150,000
Net loss											(1,306,778)	(1,306,778)
Balance, 12/31/99 (Predecessor)	$	$			2,692,996	$ 2,692	$ 449,710	2,400	$ (50,280)	$	$ (1,825,471)	$ (1,423,349)
Issuance of common stock for cash on 1/18/00					53,583	54	1,869					1,923
Issuance of common stock for services on 3/1/00					68,698	69	(44)					25
Issuance of common stock for services on 4/4/00					27,768	28	(18)					10
Net loss											(807,076)	(807,076)
Balance, 12/31/00 (Predecessor)	$	$			2,843,045	$ 2,843	$ 451,517	2,400	$ (50,280)	$	$ (2,632,547)	$ (2,228,467)

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

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Consolidated Statements of Shareholders' Equity (Deficit) and Comprehensive Income (Loss)

	Series A Preferred Stock		Series B Preferred Stock		Common Stock			Treasury Stock		Accumulated Other	Accumulated Deficit During	Total Shareholders
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Number of Shares	Amount	Comprehensive Income	Development Stage	Equity (Deficit)
Issuance of common stock for services on 7/1/01	$	$			156,960	$ 157	$ (101)		$	$	$	$ 56
Issuance of common stock for services on 7/1/01					125,000	125	(80)					45
Issuance of common stock for capitalization of accrued salaries on 8/10/01					70,000	70	328,055					328,125
Issuance of common stock for conversion of convertible debt on 8/10/01					1,750,000	1,750	1,609,596					1,611,346
Issuance of common stock for conversion of convertible shareholder notes payable on 8/10/01					208,972	209	135,458					135,667
Issuance of common stock for bridge financing on 8/10/01					300,000	300	(192)					108
Retirement of treasury stock on 8/10/01							(50,280)	(2,400)	50,280			
Issuance of common stock for net assets of Gemini on 8/10/01					3,942,400	3,942	(3,942)					
Issuance of common stock for net assets of AFH on 8/10/01					3,899,547	3,900	(3,900)					
Issuance of common stock for cash on 8/10/01					1,346,669	1,347	2,018,653					2,020,000
Transaction and fund raising expenses on 8/10/01							(48,547)					(48,547)
Issuance of common stock for services on 8/10/01					60,000	60						60
Issuance of common stock for cash on 8/28/01					26,667	27	39,973					40,000
Issuance of common stock for services on 9/30/01					314,370	314	471,241					471,555

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

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Consolidated Statements of Shareholders' Equity (Deficit) and Comprehensive Income (Loss)

	Series A Preferred Stock		Series B Preferred Stock		Common Stock			Treasury Stock		Accumulated Other	Accumulated Deficit During	Total Shareholders
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Number of Shares	Amount	Comprehensive Income	Development Stage	Equity (Deficit)
Uncompensated contribution of services 3rd quarter		$		$		$	$ 55,556		$	$	$	$ 55,556
Issuance of common stock for services on 11/1/01					145,933	146	218,754					218,900
Uncompensated contribution of services 4th quarter							100,000					100,000
Net loss											(1,652,004)	(1,652,004)
Balance, 12/31/01 (Predecessor)		$		$	15,189,563	$ 15,190	$ 5,321,761		$	$	$ (4,284,551)	$ 1,052,400
Uncompensated contribution of services 1st quarter							100,000					100,000
Issuance of preferred stock for cash on 4/26/02	905,000	905					2,817,331					2,818,236
Issuance of preferred stock for cash on 5/16/02	890,250	890					2,772,239					2,773,129
Issuance of preferred stock for cash on 5/31/02	795,000	795					2,473,380					2,474,175
Issuance of preferred stock for cash on 6/28/02	229,642	230					712,991					713,221
Uncompensated contribution of services 2nd quarter							100,000					100,000
Issuance of preferred stock for cash on 7/15/02	75,108	75					233,886					233,961
Issuance of common stock for cash on 8/1/02					38,400	38	57,562					57,600
Issuance of warrants for services on 9/06/02							103,388					103,388
Uncompensated contribution of services 3rd quarter							100,000					100,000
Uncompensated contribution of services 4th quarter							100,000					100,000
Issuance of preferred stock for dividends	143,507	144					502,517				(502,661)	
Deemed dividend associated with beneficial conversion of							10,178,944				(10,178,944)	

preferred stock									
Comprehensive income:									
Net loss								(5,433,055)	(5,433,055)
Other comprehensive income, foreign currency translation adjustment							13,875		13,875
Comprehensive loss									(5,419,180)
Balance, 12/31/02 (Predecessor)	3,038,507	$ 3,039	$ 15,227,963	$ 15,228	$ 25,573,999	$	$ 13,875	$ (20,399,211)	$ 5,206,930

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

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Consolidated Statements of Shareholders' Equity (Deficit) and Comprehensive Income (Loss)

	Series A Preferred Stock		Series B Preferred Stock		Common Stock			Treasury Stock			Accumulated	
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Number of Shares	Amount	Accumulated Other Comprehensive Income	Deficit During Development Stage	Total Shareholders Equity (Deficit)
Issuance of common stock for cash on 1/7/03		$		$	61,600	$ 62	$ 92,338		$	$	$	$ 92,400
Issuance of common stock for patent pending acquisition on 3/31/03					100,000	100	539,900					540,000
Cancellation of common stock on 3/31/03					(79,382)	(79)	(119,380)					(119,459)
Uncompensated contribution of services 1st quarter							100,000					100,000
Issuance of preferred stock for cash on 5/9/03			110,250	110			2,773,218					2,773,328
Issuance of preferred stock for cash on 5/16/03			45,500	46			1,145,704					1,145,750
Conversion of preferred stock into common stock 2nd qtr	(70,954)	(72)			147,062	147	40,626					40,701
Conversion of warrants into common stock 2nd qtr					114,598	114	(114)					
Uncompensated contribution of services 2nd quarter							100,000					100,000
Issuance of preferred stock dividends											(1,087,200)	(1,087,200)
Deemed dividend associated with beneficial conversion of preferred stock							1,244,880				(1,244,880)	
Issuance of common stock for cash 3rd qtr					202,500	202	309,798					310,000
Issuance of common stock for cash on 8/27/03					3,359,331	3,359	18,452,202					18,455,561
Conversion of preferred stock	(2,967,553)	(2,967)	(155,750)	(156)	7,188,793	7,189	(82,875)					(78,809)

into common stock 3rd qtr								
Conversion of warrants into common stock 3rd qtr			212,834	213	(213)			
Compensation expense on warrants issued to non-employees					412,812			412,812
Issuance of common stock for cash 4th qtr			136,500	137	279,363			279,500
Conversion of warrants into common stock 4th qtr			393					
Comprehensive income:								
Net loss							(11,268,294)	(11,268,294)
Other comprehensive income, foreign currency translation adjustment						360,505		360,505
Comprehensive loss								(10,907,789)
Balance, 12/31/03 (Predecessor)	$	$	26,672,192	$ 26,672	$ 50,862,258	$	$ 374,380	$ (33,999,585)	$ 17,263,725

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Consolidated Statements of Shareholders' Equity (Deficit) and Comprehensive Income (Loss)

	Series A Preferred Stock		Series B Preferred Stock		Common Stock		Additional Paid-In Capital	Treasury Stock		Accumulated Other Comprehensive Income	Accumulated Deficit During Development Stage	Total Shareholders Equity (Deficit)
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount		Number of Shares	Amount			
Conversion of warrants into common stock 1st qtr	$	$			78,526	$ 79	$ (79)		$	$	$	$
Issuance of common stock for cash in connection with exercise of stock options 1st qtr					15,000	15	94,985					95,000
Issuance of common stock for cash in connection with exercise of warrants 1st qtr					4,000	4	7,716					7,720
Compensation expense on options and warrants issued to non-employees and directors 1st qtr							1,410,498					1,410,498
Issuance of common stock in connection with exercise of warrants 2nd qtr					51,828	52	(52)					
Issuance of common stock for cash 2nd qtr					7,200,000	7,200	56,810,234					56,817,434
Compensation expense on options and warrants issued to non-employees and directors 2nd qtr							143,462					143,462
Issuance of common stock in connection with exercise of warrants 3rd qtr					7,431	7	(7)					
Issuance of common stock for cash in connection with exercise of stock options 3rd qtr					110,000	110	189,890					190,000
Issuance of common stock for cash in connection with exercise of warrants 3rd qtr					28,270	28	59,667					59,695

Compensation expense on options and warrants issued to non-employees and directors qtr				229,133					229,133
Issuance of common stock in connection with exercise of warrants qtr		27,652	28	(28)					
Compensation expense on options and warrants issued to non-employees, employees, and directors qtr				127,497					127,497
Purchase of treasury stock qtr					4,000,000	(25,974,000)			(25,974,000)
Comprehensive income:									
Net loss								(21,474,469)	(21,474,469)
Other comprehensive income, foreign currency translation adjustment							79,725		79,725
Other comprehensive income, net unrealized gain on available-for-sale investments							10,005		10,005
Comprehensive loss									(21,384,739)
Balance, 12/31/04 (Predecessor)	$	$ 34,194,899	$ 34,195	$ 109,935,174	4,000,000	$ (25,974,000)	$ 464,110	$ (55,474,054)	$ 28,985,425

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Consolidated Statements of Shareholders' Equity (Deficit) and Comprehensive Income (Loss)

	Series A Preferred Stock		Series B Preferred Stock		Common Stock		Additional Paid-In Capital	Treasury Stock		Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit During Development Stage	Total Shareholders Equity (Deficit)
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount		Number of Shares	Amount			
Issuance of common stock for cash in connection with exercise of stock options 1st qtr	$	$			25,000	$ 25	$ 74,975		$	$	$	$ 75,000
Compensation expense on options and warrants issued to non-employees 1st qtr							33,565					33,565
Conversion of warrants into common stock 2nd qtr					27,785	28	(28)					
Compensation expense on options and warrants issued to non-employees 2nd qtr							(61,762)					(61,762)
Compensation expense on options and warrants issued to non-employees 3rd qtr							(137,187)					(137,187)
Conversion of warrants into common stock 3rd qtr					12,605	12	(12)					
Compensation expense on options and warrants issued to non-employees 4th qtr							18,844					18,844
Compensation expense on acceleration of options 4th qtr							14,950					14,950
Compensation expense on restricted stock award issued to employee 4th qtr							606					606
Conversion of predecessor company shares					94							
Comprehensive loss:												
Net loss											(35,777,584)	(35,777,584)
										(1,372,600)		(1,372,600)

Other comprehensive loss, foreign currency translation adjustment									
Foreign exchange gain on substantial liquidation of foreign entity							133,851		133,851
Other comprehensive loss, net unrealized gain on available-for-sale investments							(10,005)		(10,005)
Comprehensive loss									(37,026,338)
Balance, 12/31/05 (Predecessor)	$	$ 34,260,383	$ 34,260	$ 109,879,125	4,000,000	$ (25,974,000)	$ (784,644)	$ (91,251,638)	$ (8,096,897)

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Consolidated Statements of Shareholders' Equity (Deficit) and Comprehensive Income (Loss)

	Series A Preferred Stock		Series B Preferred Stock		Common Stock			Treasury Stock					
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Number of Shares	Amount	Accumulated Other Comprehensive Income	Accumulated Deficit During Development Stage	Noncontrolling Interest	Total Shareholders Equity (Deficit)
Compensation expense on options and warrants issued to non-employees 1st qtr	$	$		$		$	42,810		$	$	$	$	42,810
Compensation expense on option awards issued to employees and directors 1st qtr							46,336						46,336
Compensation expense on restricted stock issued to employees 1st qtr					128,750	129	23,368						23,497
Compensation expense on options and warrants issued to non-employees 2nd qtr							96,177						96,177
Compensation expense on option awards issued to employees and directors 2nd qtr							407,012						407,012
Compensation expense on restricted stock to employees 2nd qtr							4,210						4,210
Cancellation of unvested restricted stock 2nd qtr					(97,400)	(97)	97						
Issuance of common stock for cash in connection with exercise of stock options 2nd qtr					10,000	10	16,490						16,500
Compensation expense on options and warrants issued to non-employees 3rd qtr							25,627						25,627
							389,458						389,458

Compensation expense on option awards issued to employees and directors 3rd qtr										
Compensation expense on restricted stock to employees 3rd qtr				3,605						3,605
Issuance of common stock for cash in connection with exercise of stock options 3rd qtr		76,000	76	156,824						156,900
Acquisition of Agera									2,182,505	2,182,505
Compensation expense on options and warrants issued to non-employees 4th qtr				34,772						34,772
Compensation expense on option awards issued to employees and directors 4th qtr				390,547						390,547
Compensation expense on restricted stock to employees 4th qtr				88						88
Cancellation of unvested restricted stock award 4th qtr		(15,002)	(15)	15						
Comprehensive loss:										
Net loss								(35,821,406)	(78,132)	(35,899,538)
Other comprehensive gain, foreign currency translation adjustment							657,182			657,182
Comprehensive loss										(35,242,356)
Balance 12/31/06 (Predecessor)	$	$ 34,362,731	$ 34,363	$ 111,516,561	4,000,000	$ (25,974,000)	$ (127,462)	$ (127,073,044)	$ 2,104,373	$ (39,519,209)

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Consolidated Statements of Shareholders' Equity (Deficit) and Comprehensive Income (Loss)

	Series A Preferred Stock		Series B Preferred Stock		Common Stock			Treasury Stock					
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Number of Shares	Amount	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit During Development Stage	Noncontrolling Interest	Total Shareholders Equity (Deficit)
Compensation expense on options and warrants issued to non-employees 1st qtr	$	$		$		$	$ 39,742		$	$	$	$	$ 39,742
Compensation expense on option awards issued to employees and directors 1st qtr							448,067						448,067
Compensation expense on restricted stock issued to employees 1st qtr							88						88
Issuance of common stock for cash in connection with exercise of stock options 1st qtr					15,000	15	23,085						23,100
Expense in connection with modification of employee stock options 1st qtr							1,178,483						1,178,483
Compensation expense on options and warrants issued to non-employees 2nd qtr													