Fibrocell Science, Inc. Form 424B3 April 13, 2011

Filed pursuant to Rule 424(b)(3) and Rule 424(c) Registration No. 333-170688 April 13, 2011

**Prospectus Supplement No. 1** 

# FIBROCELL SCIENCE, INC. 24,533,639 Common Stock

This prospectus amends the prospectus dated February 11, 2011 that related to the resale of our common stock by certain of our stockholders, or Selling Stockholders, named in the section of the original prospectus titled "Selling Security Holders." The following shares may be offered for resale under the prospectus: (a) 9,280,000 shares of common stock underlying the Series B Convertible Preferred Stock, or Series B Preferred, issued pursuant to a securities purchase agreement, or the Securities Purchase Agreement, with certain accredited investors, (b) 12,456,851 shares of common stock underlying warrants issued pursuant to the Securities Purchase Agreement, (c) 708,788 shares of common stock underlying the warrants issued to the placement agents in the offering completed pursuant to the Securities Purchase Agreement, and (d) up to 2,088,000 shares of common stock that we may issue as dividends on the Series B Preferred Stock.

Although we will pay substantially all the expenses incident to the registration of the shares, we will not receive any proceeds from the sales by the Selling Stockholders. We will, however, to the extent the warrants are exercised for cash, as opposed to being exercised on a cash-less basis as permitted in the warrants, receive proceeds from such exercises; to the extent we receive such proceeds, they will be used for working capital purposes.

Our common stock is presently quoted for trading under the symbol "FCSC" on the over the counter bulletin board, or OTCBB. On April 11, 2011, the last sales price of the common stock, as reported on the OTCBB was \$0.86 per share.

This prospectus supplement is being filed to include the information set forth in the Annual Report on Form 10-K filed on March 30, 2011, which is set forth below. This prospectus supplement should be read in conjunction with the prospectus dated February 11, 2011, which is to be delivered with this prospectus supplement.

Investing in our common stock is highly speculative and involves a high degree of risk. You should purchase these securities only if you can afford a complete loss of your investment. You should carefully consider the risks and uncertainties described under the heading "Risk Factors" beginning on page 4 of the original prospectus before making a decision to purchase our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this Prospectus Supplement No. 1 is April 13, 2011

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

#### **FORM 10-K**

- Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 þ For the fiscal year ended December 31, 2010 OR
- Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 O

## Fibrocell Science, Inc.

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

**Delaware** (State or other jurisdiction 001-31564

87-0458888

(I.R.S. Employer Identification No.)

(Commission File Number) of incorporation)

**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 Name of Each Exchange on which Registered Over the Counter Bulletin Board

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

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

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 b No o

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

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

Large accelerated filer o

Accelerated filer o

Non-accelerated filer o

Smaller reporting company b

(Do not check if a smaller reporting company)

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

The aggregate market value of common stock held by non-affiliates of the registrant was \$15.3 million as of June 30, 2010, 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, 2010. 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, 2010 and (b) all directors of the registrant as of June 30, 2010. 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 b No o

As of June 30, 2010, issuer had 19,168,831 shares issued and outstanding of common stock, par value \$0.001.

## DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the 2010 Annual Meeting of Stockholders (the Proxy Statement ), to be filed within 120 days of the end of the fiscal year ended December 31, 2010, 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.

# TABLE OF CONTENTS

	Page
PART I	
ITEM 1. BUSINESS	2
ITEM 1A. RISK FACTORS	15
ITEM 1B. UNRESOLVED STAFF COMMENTS	32
ITEM 2. PROPERTIES	32
ITEM 3. LEGAL PROCEEDINGS	32
ITEM 4. (REMOVED AND RESERVED)	
<u>PART II</u>	
ITEM 5. MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES	33
ITEM 6. SELECTED FINANCIAL DATA	34
ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	34
ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	40
ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	40
ITEM 9A. CONTROLS AND PROCEDURES	41
ITEM 9B. OTHER INFORMATION	42
PART III	
ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE	42
ITEM 11. EXECUTIVE COMPENSATION	42
ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS	42
ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE	42
ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES	42

# PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULE	43
SIGNATURE PAGE	45

#### 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, 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 the facts suggest and words of similar import, are intended words anticipate, believe, estimate. expect, intend, identify any forward-looking statements. You should not place undue reliance on these forward-looking statements. These statements reflect our current view of future events and are subject to certain risks and uncertainties as noted below. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, our actual results could differ materially from those anticipated in these forward-looking statements. Actual events, transactions and results may materially differ from the anticipated events, transactions or results described in such statements. Although we believe that our expectations are based on reasonable assumptions, we can give no assurance that our expectations will materialize. Many factors could cause actual results to differ materially from our forward looking statements including those set forth in Item 1A of this report. Other unknown, unidentified or unpredictable factors could materially and adversely impact our future results. We undertake no obligation and do not intend to update, revise or otherwise publicly release any revisions to our forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of any unanticipated events.

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 2010 mean the year ended December 31, 2010, 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. 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 an 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 most advanced indication is for the treatment of nasolabial folds/wrinkles (United States adopted name, or USAN, is azficel-T, proposed brand name laViv®) and has completed Phase III clinical studies, and the related Biologics License Application, or BLA, has been submitted to the Food and Drug Administration, or FDA. In October 2009, the FDA's Cellular, Tissue and Gene Therapies Advisory Committee reviewed this indication. On December 21, 2009, Fibrocell received a Complete Response (CR) letter from the FDA related to the BLA for azficel-T, an autologous cell therapy for the treatment of moderate to severe nasolabial folds/wrinkles in adults. A Complete Response letter is issued by the FDA s Center for Biologics Evaluation and Research ( CBER ) when the review of a file is completed and additional data are needed prior to approval. The Complete Response letter requested that Fibrocell Science provide data from a histopathological study on biopsied tissue samples from patients following injection of azficel-T. The histology study (IT-H-001) evaluated tissue treated with azficel-T as compared to tissue treated with sterile saline (placebo). The study also provided information about the skin after treatment, including evaluation of collagen and elastin fibrils, and cellular structure of the sampled tissues.

On May 13, 2010, we announced the initiation of the small histology study of azficel-T, discussed above. The study had a target enrollment of approximately 20 participants from the completed and statistically significant pivotal Phase III studies of azficel-T (IT-R-005 and IT-R-006). We announced on July 8, 2010, the completion of enrollment of and first treatment visits for participants in its histology study of azficel-T. The second treatment visits for participants enrolled in the histology study of azficel-T were completed by the end of July. The third treatment visits for participants enrolled in the histology study of azficel-T were completed by the end of August.

The Complete Response letter also requested finalized Chemistry, Manufacturing and Controls ( CMC ) information regarding the manufacture of azficel-T as follow-up to discussions that occurred during the BLA review period, as well as revised policies and procedures.

We announced on December 20, 2010, that we had submitted our complete response to the CR letter issued by the FDA regarding our BLA for azficel-T. On January 22, 2011, the FDA accepted for review our complete response submission. Even though the FDA has accepted our response for complete evaluation, there is no assurance that it will approve our product. The FDA, under the Prescription Drug User Fee Act ( PDUFA ), has a target six months review window to completely evaluate the Company s response. The PDUFA date is June 22, 2011. We announced on March 16, 2011, that we had submitted a final study report to the FDA for the completed, six-month histological study examining skin after injections of azficel-T.

During 2009 we completed a Phase II/III study for the treatment of acne scars. 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.

3

## **Going Concern**

The Successor Company emerged from Bankruptcy in September 2009 and continues to operate as a going concern. At December 31, 2010, the Successor Company had cash and cash equivalents of approximately \$0.9 million and negative working capital of less than \$0.1 million. The Successor Company has raised approximately \$6.1 million less fees as the result of the issuance of Preferred Stock Series D and warrants in the period from January 1, 2011 through March 1, 2011. The Company received \$0.2 million in subscription receivables from a July financing in mid-March 2011.

As of March 24, 2011, the Company had cash and cash equivalents of approximately \$3.4 million and current liabilities of approximately \$0.6 million. The Company is current monthly cash run-rate is approximately \$1.0 million. The Company is also planning to purchase manufacturing equipment and incur marketing expenditures within the next three months to prepare the Company for launch post a possible FDA approval. Thus, the Successor 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 Successor 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.

Further, if the Successor 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, 2010, the Successor 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 2011. During the year ended December 31, 2010, the Successor 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 Successor Company s ability to continue as a going concern.

The Successor 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 Successor Company and the offering terms. The Successor Company s ability to complete an offering is also dependent on the status of its FDA regulatory milestones and its clinical trials, and in particular, the status of its indication for the treatment of nasolabial folds/wrinkles and the potential approval of the related BLA, which cannot be predicted. 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 GAAP, there exists substantial doubt about the Successor 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 Successor Company does not obtain additional funding, or does not anticipate additional funding, in the very 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 Successor 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.

4

## Fibrocell Science s Technology Platform

We use our proprietary Fibrocell Science Process to produce an autologous living cell therapy. We refer to this autologous living cell therapy as the Fibrocell Therapy. We believe this therapy addresses the normal effects of aging or injury to the skin. Each of our product candidates is designed to use Fibrocell Therapy to treat an indicated condition. We use our Fibrocell Science 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. In the case of our dental product candidate, the biopsy is taken from the patient s palette. 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, tested by quality control and released by quality assurance prior to shipment. The number of cells and the frequency of injections may vary and will depend on the indication or application being studied.

If and when approved, we expect our product candidates will offer patients their own living fibroblast cells in a personalized therapy designed to improve the appearance of damaged skin and wrinkles; or in the case of restrictive burn scars, improve range of motion. Our product candidates are intended to be a minimally invasive alternative to surgical intervention and a viable natural alternative to other chemical, synthetic or toxic treatments. We also believe that because 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 dental papillary insufficiency, or gum recession, and potentially help patients avoid surgical intervention. 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.

## **Our Strategy**

Our business strategy is primarily focused on our approval efforts related to our nasolabial folds/wrinkles indication, for which we have submitted our response to the FDA s Complete Response letter and have a PDUFA date of June 22, 2011. Our additional objectives include achieving regulatory milestones related to our other Phase II/III Acne Scar program and potentially pursuing other clinical trials in burn scarring, vocal scarring and the dental arena, as funding permits in the future. Refer to Clinical Development Programs below for current status.

#### **Trading of Common Stock**

The Predecessor s common stock ceased trading on the NYSE Amex on May 6, 2009 and in June 2009 the NYSE Amex delisted the Predecessor s common stock from listing on the NYSE Amex. Upon the Effective Date, the outstanding common stock of the Predecessor Company was cancelled for no consideration. Consequently, the Predecessor s stockholders prior to the Effective Date no longer have any interest as stockholders of the Predecessor Company by virtue of their ownership of the Predecessor s common stock prior to the emergence from bankruptcy. On October 21, 2009, the Successor Company was available for trading on the OTC Bulletin Board under the symbol FCSC .

# **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 nasolabial folds/wrinkles 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 acne scars, restrictive burn scars and dental papillary recession. 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, 2010, 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.

5

Aesthetic Development Programs

Nasolabial Folds/Wrinkles *Phase III Trials*: In October 2006, we reached an agreement with the FDA, on the design of a Phase III pivotal study protocol for the treatment of nasolabial folds/wrinkles (lines which run from the sides of the nose to the corners of the mouth). The randomized, double-blind protocol was submitted to the FDA under the agency s Special Protocol Assessment, or SPA. Pursuant to this assessment process, the FDA has agreed that our study design for two identical trials, including subject numbers, clinical endpoints, and statistical analyses, is adequate to provide the necessary data that, depending on the outcome, could form the basis of an efficacy claim for a marketing application. The pivotal Phase III trials evaluated the efficacy and safety of our Fibrocell therapy (USAN name azficel-T) against placebo in approximately 400 subjects total with approximately 200 subjects enrolled in each trial. The injections were completed in January 2008 and the trial data results were disclosed in October 2008. The Phase III trial data results indicated statistically significant efficacy results for the treatment of nasolabial folds/wrinkles. The Phase III data analysis, including safety results, was disclosed in October 2008. We submitted the related BLA to the FDA in March 2009. In May 2009, the FDA accepted our BLA submission for filing. On October 9, 2009, the FDA s Cellular, Tissue and Gene Therapies Advisory Committee reviewed azficel-T. The committee voted 11 yes to 3 no that the data presented on azficel-T demonstrated efficacy, and 6 yes to 8 no that the data demonstrated safety, both for the proposed indication. A Complete Response letter is issued by the FDA s CBER when the review of a file is completed and additional data are needed prior to approval. On December 21, 2009, we received a Complete Response letter from the FDA related to the BLA for azficel-T. The Complete Response letter requested that we provide data from a histopathological study on biopsied tissue samples from patients following injection of azficel-T. The histology study (IT-H-001) evaluated tissue treated with azficel-T as compared to tissue treated with sterile saline (placebo). The study also provided information about the skin after treatment, including evaluation of collagen and elastin fibrils, and cellular structure of the sampled tissues.

On May 13, 2010, we announced the initiation of a small histology study (IT-H-001) of azficel-T, discussed above. The study had a target enrollment of approximately 20 participants from the completed and statistically significant pivotal Phase III studies of azficel-T (IT-R-005 and IT-R-006). We announced on July 8, 2010, the completion of enrollment of and first treatment visits for participants in our histology study of azficel-T. The second treatment visits for participants enrolled in the histology study of azficel-T were completed by the end of July. The third treatment visits for participants enrolled in the histology study of azficel-T were completed by the end of August.

The Complete Response letter also requested finalized Chemistry, Manufacturing and Controls ( CMC ) information regarding the manufacture of azficel-T as follow-up to discussions that occurred during the BLA review period, as well as revised policies and procedures regarding shipping practices, and proposed labeling.

We announced on December 20, 2010, that we had submitted our complete response to the Complete Response ( CR ) letter issued by the FDA regarding the Company s BLA for azficel-T. On January 22, 2011, the FDA accepted for review the Company s complete response submission for azficel-T. Even though the FDA has accepted the Company s response for complete evaluation, there is no assurance that it will approve our product. The FDA, under the Prescription Drug User Fee Act ( PDUFA ), has a target six months review window to completely evaluate the Company s response upon acceptance of the response. The PDUFA date is June 22, 2011. The Company announced on March 16, 2011, that it had submitted a final study report to the FDA for the completed, six-month histological study examining skin after injections of azficel-T.

The United States Adopted Names (USAN) Council adopted the USAN name, azficel-T, on October 28, 2009, and the FDA is currently evaluating a proposed brand name,  $laViv^{\circledast}$ .

<u>Full Face Rejuvenation Phase II Trial</u>: In March 2007, the Predecessor Company 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.

6

## Therapeutic Development Programs

Acne Scars Phase II/III Trial: In November 2007, the Predecessor Company commenced an acne scar Phase II/III 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, the Predecessor Company 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, the Predecessor Company developed a photo guide for use in the evaluators assessment of acne study subjects. The Predecessor Company 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 the Predecessor Company consider conducting a Phase II study in order to address certain study issues, including additional validation related to our evaluator assessment scale. As such, the Predecessor Company modified our clinical plans to initiate a single Phase II/III trial. This Phase II/III study, was powered to demonstrate efficacy, and has allowed for a closer assessment of the evaluator assessment scale and photo guide that is ongoing. The Successor Company submitted on August 9, 2010, a clinical study report for its Phase II/III study of azficel-T for the treatment of moderate to severe acne scars to the FDA. The next step is to initiate a discussion with the FDA concerning the validation of the evaluator assessment scale and agree the path forward. These steps will be subject to obtaining sufficient financial resources.

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 patients. However, the Predecessor 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 development of this program will be subject to obtaining sufficient financial resources.

Dental Study - *Phase II Trial:* In late 2003, the Predecessor Company completed a Phase I clinical trial for the

<u>Dental Study - Phase II Trial:</u> In late 2003, the Predecessor Company completed a Phase I clinical trial for the treatment of condition relating to periodontal disease, specifically to treat Interdental Papillary Insufficiency. In the second quarter of 2005, the Predecessor Company concluded the Phase II dental clinical trial with the use of azficel-T and subsequently announced that investigator and subject visual analog scale assessments demonstrated that the azficel-T was statistically superior to placebo at four months after treatment. Although results of the investigator and subject assessment demonstrated that the azficel-T was statistically superior to placebo, an analysis of objective linear measurements did not yield statistically significant results.

In 2006, the Predecessor Company commenced a Phase II open-label dental trial for the treatment of Interdental Papillary Insufficiency. This single site study included 11 subjects. All study treatment and follow up visits were completed, but full analysis of the study was previously placed on internal hold due to our financial resource constraints. The Company is also currently reviewing potential other clinical paths in the dental arena.

## **Agera Skincare Systems**

The Successor Company markets and sells a skin care product line through our majority-owned subsidiary, Agera Laboratories, Inc., which the Predecessor Company 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).

7

## **Our Target Market Opportunities**

Aesthetic Market Opportunity

Our product candidate for nasolabial folds/wrinkles and full face rejuvenation are 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 \$4.5 billion in 2009. We believe the aesthetic procedure market is driven by:

aging of the baby boomer population, which currently includes ages approximately 46 to 64; the desire of many individuals to improve their appearance;

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

According to the ASAPS, 10.0 million surgical and non-surgical cosmetic procedures were performed in 2009, as compared to 10.3 million in 2008. Also according to the ASAPS, approximately 8.5 million non-surgical procedures were performed in 2009 and 2008. 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 2009:

Procedure	Number
Botulinum toxin type A	2,557,068
Hyaluronic acid	1,313,038
Laser hair removal	1,280,031
Microdermabrasion	621,943
Chemical peel	529,285

Procedures among the 35 to 50 year old age group made up approximately 44% of all cosmetic procedures in 2009. The 51 to 64 year old age group made up 27% of all cosmetic procedures in 2009, while the 19 to 34 year old age group made up 20% of cosmetic procedures in 2009. The Botulinum toxin type A injection was the most popular treatment 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. Indications related to acne scars, restrictive burn scars and periodontal disease are on internal company hold. We are not aware of other autologous cell-based treatments for any of these therapeutic applications.

# Sales and Marketing

While our Fibrocell Therapy product candidates are still in the pre-approval phase in the United States, no marketing or sales can occur within the United States. 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, 2010, we had 10 issued U.S. patents, 3 pending U.S. patent applications, 30 granted foreign patents and no 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. In January 2003, the Predecessor Company acquired two pending U.S. patent applications. As consideration, the Predecessor Company issued 100,000 shares of its common stock and agreed to pay a royalty on revenue from commercial applications and licensing, up to a maximum of \$2.0 million.

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.

9

## 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.

If certain of our product candidates are approved, 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.

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.

There are several dermal filler products under development and/or in the FDA pipeline for approval which claim to offer certain facial aesthetic benefits. Depending on the clinical outcomes of the Fibrocell Therapy trials in aesthetics, the success or failure of gaining approval and the label granted by the FDA if and when the therapy is approved, the competition for the Fibrocell Therapy may prove to be direct competition to certain dermal fillers, laser technologies or new technologies. However, if we gain approval, we believe our Fibrocell Therapy would be a first to market autologous cellular technology that could complement other modalities of treatment and represent a significant additional market opportunity.

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 acne scars, restrictive burn scars 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.

## Domestic Regulation

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

## FDA Approval Process

To obtain approval of a new product from the FDA, we must, among other requirements, submit data demonstrating the product 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 IND for a new drug or biologic, which must become effective before human clinical trials may begin;

performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug or biologic for its intended use;

detailed information on product characterization and manufacturing process; and submission and approval of a New Drug Application, or NDA, for a drug, or a Biologics License Application, or BLA, for a biologic.

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

11

#### **Table of Contents**

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 a 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.

12

Ongoing FDA Requirements

The sponsor must submit to the FDA the results of the pre-clinical and clinical trials, together with, among other things, detailed information on the manufacturing and composition of the product, and proposed labeling, in the form of an NDA, or, in the case of a biologic, a BLA. The applicant must also submit with the NDA or BLA a substantial user fee payment, unless a waiver or reduction applies. On February 17, 2009, the US 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 folds/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 risk evaluation and mitigation strategy, or 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.

Before approving an NDA or BLA, the FDA usually will inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facilities are in compliance with the FDA s current Good Manufacturing Practices, or cGMP, requirements which govern the manufacture, holding and distribution of a

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

13

The labeling, advertising, promotion, marketing and distribution of a drug or biologic product also must be in compliance with FDA and 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. 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. The costs incurred in operating our Exton facility (except for costs related to general corporate administration) are currently classified as research and development expenses as the activities there have been devoted to the research and development of our clinical applications and the development of a commercial scale in a cost-effective production method. 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.

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, 2010 and 2009, we incurred research and development expenses of \$5.5 million and \$3.9 million, respectively.

# **Employees**

As of March 22, 2011, we employed 23 people on a full-time basis, all located in the United States, and one employee, our Chief Operating and Chief Financial Officer, who is based in Ireland and works in both Ireland and the United States. We also 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 17 in the Notes to Consolidated Financial Statements contained in Item 8 of 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.

# 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 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.

Table of Contents 27

15

#### **Table of Contents**

There exists substantial doubt regarding our ability to continue as a going concern. As of December 31, 2010 we had cash and cash equivalents of \$0.9 million and negative working capital of less than \$0.1 million. The Successor Company has raised approximately \$6.1 million less fees as the result of the issuance of Preferred Stock Series D and warrants in the period from January 1, 2011 through March 1, 2011. We received \$0.2 million in subscription receivables from a July financing in mid-March 2011.

As of March 24, 2011, we had cash and cash equivalents of approximately \$3.4 million and current liabilities of approximately \$0.6 million. Our current monthly cash run-rate is approximately \$1.0 million. The Company is also planning to purchase manufacturing equipment and incur marketing expenditures within the next three months to prepare the Company for launch post a possible FDA approval. Thus, we will be required to raise additional cash resources in the near future, or it will likely cease operations. 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.

We will need additional capital to achieve commercialization of our product candidates 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 \$7.5 million of debt as of March 25, 2011, which has a priority over common shareholders. In addition, our Series A, B and D Preferred Stock are 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, 2010, 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, 2010 may materially and adversely affect our stock price and our ability to raise new capital.

16

We could fail to obtain approval of our lead product, azficel-T, from the FDA. The FDA accepted our response to their Complete Response Letter in January 2011 and set a PDUFA date of June 22, 2011. However, the FDA may not approve our product candidate or may delay our approval. Either of these situations could significantly impact our ability to raise required capital to continue operations.

We have finished injections related to our pivotal Phase III clinical trial for our lead facial product candidate, azficel-T, and have submitted the related BLA to the FDA. In October 2009, the FDA Cellular, Tissue and Gene Therapies Advisory Committee reviewed our nasolabial folds/wrinkles product candidate. The Committee voted 11 yes to 3 no that the data presented on our product demonstrated efficacy, and 6 yes to 8 no that the data demonstrate safety; both for the proposed indication of treatment of nasolabial folds/wrinkles. The Committee s recommendations are not binding on the FDA, but the FDA will consider their recommendations during their review of our application, which could adversely affect the application. On December 21, 2009, we received a Complete Response letter from the FDA related to the BLA for azficel-T. A Complete Response letter is issued by the FDA s CBER when the review of a file is completed and additional data are needed prior to approval. The Complete Response letter requested that we provide data from a histopathological study on biopsied tissue samples from patients following injection of azficel-T. The letter also requested finalized CMC information regarding the manufacture of azficel-T as follow-up to discussions that occurred during the BLA review period, as well as revised policies and procedures. We announced on December 20, 2010, that we had submitted our complete response to the CR letter issued by the FDA regarding our BLA for azficel-T. On January 22, 2011, the FDA accepted for review our complete response submission for azficel-T. Even though the FDA has accepted our response for complete evaluation, there is no assurance that it will approve our product. The FDA, under the PDUFA, has a target six months review window to completely evaluate our response. The PDUFA date is June 22, 2011. To the extent that the data obtained from the histopathological study is negative and/or the CMC information and revised policies and procedures required by the FDA is not satisfactory, we may not obtain approval from the FDA or there may be a delay in approval.

If the FDA does not approve our product candidate or, alternatively, if there is a delay in approval, we will be required to raise additional cash resources in the near future, or it will likely cease operations. There is no guarantee that any such required financing will be available to us.

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.

17

#### **Table of Contents**

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 our Fibrocell Therapy. Future FDA regulations, as well as currently proposed regulations, may require us to change the source of the bovine-sourced materials we use in our products or to cease using bovine-sourced materials. If we are required to use alternative materials in our products, and in the event that such alternative materials are available to us, or if we choose to change the materials used in our products in the future, we would need to validate the new manufacturing process and run comparability trials with the reformulated product, which could delay our submission for regulatory approval.

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

labeling and advertising requirements, restrictions or limitations, including the inclusion of warnings, precautions, contra-indications or use limitations that could have a material impact on the future profitability of our product candidates;

testing and surveillance to further evaluate or monitor our future products and their continued compliance with regulatory standards and requirements;

submitting products for inspection; or

imposing a risk evaluation and mitigation strategy, or REMS, to ensure that the benefits of the drug outweigh the risks.

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. For further information about fresh-start accounting, see Note 5 Fresh-Start Accounting in Notes to Consolidated Financial Statements.

Protocol deviations may release the FDA from its binding acceptance of our SPA study design, which may result in the delay, or non-approval, by the FDA of the Fibrocell Therapy.

In connection with preparations for FDA Investigator Inspections related to our nasolabial folds/wrinkles Phase III studies, we identified protocol deviations related to the timing of visits and other types of deviations. The possibility exists that our special protocol assessment could no longer be binding on the FDA if the FDA considers these deviations, individually or in aggregate, to be significant. Further, future investigator audits may identify deviations unknown at this time. Accordingly, the possibility exists that although our Phase III studies yielded statistically significant results, the studies may not be acceptable to the FDA under the SPA.

18

# 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 have recently completed a pivotal Phase III clinical trial related to our lead facial aesthetic product candidate. 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. In addition, if our Phase III clinical trials related to our lead facial aesthetic product candidate is deemed to be unacceptable or deficient in any way by the FDA, we may be unable to raise additional equity or debt financing that we may require to continue our operations.

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 folds/wrinkles trial, our Phase II/III 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.

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.

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, the preferred stock has a mandatory conversion feature that we may trigger if the price of our common stock trades above \$1.00 per share. As of March 24, 2011, if such price occurs and if we trigger the mandatory conversion feature, we would be required to issue in excess of 27 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.

19

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.

In October 2009, we completed an offering of Series A Preferred Stock and warrants, and, in March 2010, we completed an offering of common stock and warrants. In November 2010, we completed an offering of Series B Preferred Stock and warrants, and, in March 2011, we completed an offering of Series D Preferred Stock and warrants. Each of the foregoing securities were subject to certain 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 the warrants, 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 securities related to the Preferred Stock Series A and warrants, the common stock and warrants issued in the March 2010 offering and the Preferred Stock Series B and warrants offering were adjusted due to the Preferred Stock Series D and warrants offering. If in the future we issue securities for less than the conversion or exercise price of the securities we issued so far, 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, losses may continue 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 product development, and we have expended significant resources on 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:

FDA clinical trials and regulatory approvals;

expansion of laboratory and manufacturing operations;

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 (a) the sale of our product candidates, which is dependent on the receipt of FDA approval for our product candidates and is dependent on our ability to successfully market and sell such product candidates, and (b) our Agera product line, which is dependent on achieving significant market penetration in its markets.

# We may be unable to successfully commercialize any of our product candidates currently under development.

Before we can commercialize any of our product candidates in the United States, we will need to:

conduct substantial additional research and development;

successfully complete lengthy and expensive pre-clinical and clinical testing, including the Phase II/III clinical trial for our acne scar product candidate;

successfully improve our manufacturing process; and

obtain FDA approvals.

Even if our product development efforts are successful, we cannot assure that we will be able to commercialize any of our product candidates currently under development. In that event, we will be unable to generate significant revenue, and our business will fail.

# We have not generated significant revenue from commercial sales of our products to date, and we do not know whether we will ever generate significant revenue.

We are focused on product development and have not generated significant revenue from commercial sales of our products to date. Prior to the fourth quarter of 2006 we offered the Fibrocell Therapy for sale in the United Kingdom. Our United Kingdom operation had been operating on a negative gross margin as we investigated means to improve manufacturing technologies for the Fibrocell Process.

We do not currently offer any products for sale that are based upon our Fibrocell Therapy, and we cannot guarantee that we will ever market any such products. We must demonstrate that our product candidates satisfy rigorous standards of safety and efficacy before the FDA and other regulatory authorities in the United States and abroad will approve the product candidates for commercial marketing. We will need to conduct significant additional research, including potentially pre-clinical testing and clinical testing before we can file additional applications with the FDA for approval of our product candidates. We must also develop, validate and obtain FDA approval of any improved manufacturing process. In addition, to compete effectively our future products must be easy to use, cost-effective and economical to manufacture on a commercial scale. We may not achieve any of these objectives, and we may never generate revenue from our product candidates.

# Our ability to effectively commercialize our product candidates depends on our ability to improve our manufacturing process and validate such future improvements.

As part of the approval process, we must pass a pre-approval inspection of our manufacturing facility before we can obtain marketing approval for our product candidates. The Complete Response letter that we received from the FDA in December 2009 requested finalized CMC information regarding the manufacture of azficel-T as follow-up to discussions that occurred during the BLA review period. We cannot guarantee that this CMC information will satisfy the FDA s requirements for approval. All of our manufacturing methods, equipment and processes for the active pharmaceutical ingredient and finished product must comply with the FDA s current Good Manufacturing Practices, or cGMP, requirements. We will also need to perform extensive audits of our suppliers, vendors and contract laboratories. The cGMP requirements govern all areas of recordkeeping, production processes and controls, personnel and quality control. To ensure that we meet these requirements, we will expend significant time, money and effort. Due to the unique nature of our Fibrocell Therapy, we cannot predict the likelihood that the FDA will approve our facility as compliant with cGMP requirements even if we believe that we have taken the steps necessary to achieve compliance.

21

The FDA, in its regulatory discretion, may require us to undergo additional clinical trials with respect to any new or improved manufacturing process we develop or utilize, in the future, if any. This could include a requirement to change the materials used in our manufacturing process. These improvements or modifications could delay or prevent approval of our product candidates. If we fail to comply with cGMP requirements, pass an FDA pre-approval inspection or obtain FDA approval of our manufacturing process, we would not receive FDA approval and would be subject to possible regulatory action. The failure to successfully implement our manufacturing process may delay or prevent our future profitability.

Even if we obtain FDA approval in the future and satisfy the FDA with regard to a validated manufacturing process, we still may be unable to commercially manufacture the Fibrocell Therapy profitably. Our manufacturing cost has been subject to fluctuation, depending, in part, on the yields obtained from our manufacturing process. There is no guarantee that future manufacturing improvements will result in a manufacturing cost low enough to effectively compete in the market. Further, we currently manufacture the Fibrocell Therapy on a limited basis (for research and development and for trial purposes only) and we have not manufactured commercial levels of the Fibrocell Therapy in the United States. Such commercial manufacturing volumes, in the future, could lead to unexpected inefficiencies and result in unprofitable performance results.

We may not be successful in our efforts to develop commercial-scale manufacturing technology and methods. In order to successfully commercialize any approved product candidates, we will be required to produce such products on a commercial scale and in a cost-effective manner. As stated in the preceding risk factor, we intend to seek FDA approval of our manufacturing process as a component of the BLA application and approval process. However, we can provide no assurance that we will be able to cost-effectively and commercially scale our operations using our current manufacturing process. If we are unable to develop suitable techniques to produce and manufacture our product candidates, our business prospects will suffer.

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.

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 72% and 64% of 2010 and 2009 consolidated revenues, respectively. Further, this large customer represented 88% and 87% of consolidated accounts receivable, net, at December 31, 2010 and December 31, 2009, 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.

If our Fibrocell Therapy is found to be unsafe or ineffective, or if our Fibrocell Therapy is perceived to be unsafe or ineffective, our business would be materially harmed.

Our product candidates utilize our Fibrocell Therapy. In addition, we expect to utilize our Fibrocell Therapy in the development of any future product candidates. If our Fibrocell Therapy is found to be, or perceived to be, unsafe or ineffective, we will not be successful in obtaining marketing approval for any product candidates then pending, and we may have to modify or cease production of any products that previously may have received regulatory approval. Negative media exposure, whether founded or unfounded, related to the safety and/or effectiveness of our Fibrocell Therapy may harm our reputation and/or competitive position.

# 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 will continue to be dependent on physicians to follow such protocols if 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.

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, if we obtain FDA approval of any of our product candidates, all of the commercial manufacturing for the U.S. market are currently expected to take 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 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.

# As a result of our limited operating history, we may not be able to correctly estimate our future operating expenses, which could lead to cash shortfalls.

We have a limited operating history and our primary business activities consist of conducting clinical trials. As such, our historical financial data is of limited value in estimating future operating expenses. Our budgeted expense levels are based in part on our expectations concerning the costs of our clinical trials, 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.

23

# 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 for the products that we may develop:

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 our Fibrocell Therapy 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.

24

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

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

administrative or judicial enforcement actions;

changes to advertising;

failure to obtain marketing approvals for our product candidates;

revocation or suspension of regulatory approvals of products;

product seizures or recalls;

court-ordered injunctions;

import detentions;

delay, interruption or suspension of product manufacturing, distribution, marketing and sales; or civil or criminal sanctions.

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

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

incurring substantial expenses, including fines, penalties, legal fees and costs to comply with the FDA s requirements;

changes in the methods of marketing and selling products;

taking FDA mandated corrective action, which may include placing advertisements or sending

letters to physicians rescinding previous advertisements or promotions; or

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

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

Physicians may prescribe pharmaceutical or biologic products for uses that are not described in a product slabeling 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.

# Legislative or regulatory reform of the healthcare system may affect our ability to sell our future products profitably.

In the United States and a number of foreign jurisdictions, there have been legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our future products profitably. For instance, there currently is no legal pathway for generic or similar versions of BLA-approved biologics, sometimes called follow-on biologics or biosimilars, but there is continuing interest by Congress on this issue and on healthcare reform in general. It is unknown what type of regulatory framework, what legal provisions, and what timeframes for issuance of regulations or guidance any final legislation on biosimilars would contain, but the future profitability of any approved biological product could be materially adversely impacted by the approval of a biosimilar product. The FDA s policies may change and additional government regulations may be enacted, which could prevent or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we might not be permitted to market our future products and our business could suffer.

### Any future products that we develop may not be commercially successful.

Even if we obtain regulatory approval for our product candidates in the United States and other countries, those products may not be accepted by the market. A number of factors may affect the rate and level of market acceptance of our products, including:

labeling requirements or limitations; market acceptance by practitioners and their patients; our ability to successfully improve our manufacturing process; the effectiveness of our sales efforts and marketing activities; and the success of competitive products.

Table of Contents 41

26

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#### **Table of Contents**

If our current or future product candidates fail to achieve market acceptance, our profitability and financial condition will suffer.

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

The human healthcare products and services industry is extremely competitive. Our competitors include major pharmaceutical, medical device and biotechnology companies. Most of these competitors have more extensive research and development, 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 future products against those of our competitors. If our future products receive marketing approval but cannot compete effectively in the marketplace, our results of operations and financial position will suffer.

# We are dependent on our key scientific 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 scientific 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 technical and managerial personnel in the future.

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

# If we are unable to effectively promote our brands and establish a competitive position in the marketplace, our business may fail.

Our Fibrocell Therapy brand names are new and unproven. We believe that the importance of brand recognition will increase over time. In order to gain brand recognition, we may increase our marketing and advertising budgets to create and maintain brand loyalty. We do not know whether these efforts will lead to greater brand recognition. If we are unable to effectively promote our brands, including our Agera product line, and establish competitive positions in the marketplace, our business results will be materially adversely affected.

# 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.

27

## Edgar Filing: Fibrocell Science, Inc. - Form 424B3

#### **Table of Contents**

As of December 31, 2010, we had 10 issued U.S. patents, 3 pending U.S. patent applications, 30 granted foreign patents and no pending international patent application. However, we may not be able to obtain additional patents relating to our technology or otherwise protect our proprietary rights. If we fail to obtain or maintain patents from our pending and future applications, we may not be able to prevent third parties from using our proprietary technology. We will be able to protect our proprietary rights from unauthorized use only to the extent that these rights are covered by valid and enforceable patents that we control or are effectively maintained by us as trade secrets. Furthermore, the degree of future protection of our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep a competitive advantage.

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

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

the inventors of the inventions covered by each of our pending patent applications might not have been the first to make such inventions;

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

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

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

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

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

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

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

28

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

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

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

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

pay monetary damages;

expend time and funding to redesign our Fibrocell Therapy so that it does not infringe others patents while still allowing us to compete in the market with a substantially similar product; obtain a license, if possible, in order to continue manufacturing or marketing the affected products or services, and pay license fees and royalties, which may be non-exclusive. This license may be non-exclusive, giving our competitors access to the same intellectual property, or the patent owner may require that we grant a cross-license to our patented technology; or stop research and commercial activities relating to the affected products or services if a license is not available on acceptable terms, if at all.

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

29

# If we are unable to keep up with rapid technological changes, our future products may become obsolete or unmarketable.

Our industry is characterized by significant and rapid technological change. Although we attempt to expand our technological capabilities in order to remain competitive, research and discoveries by others may make our future products obsolete. If we cannot compete effectively in the marketplace, our potential for profitability and financial position will suffer.

# 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.

### 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 24, 2011, there were 24,469,099 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 26,806,000 shares of common stock and warrants outstanding that were exercisable for a total of 33,701,250 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.

# Lack of effectiveness of internal controls over financial reporting could adversely affect the value of our securities.

As directed by Section 404 of the Sarbanes-Oxley Act, the SEC adopted rules requiring public companies to include a report of management on the company s internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of the company s internal control over financial reporting. Ineffective internal controls over our financial reporting have occurred in the past and may arise in the future. As a consequence, our investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our securities.

### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report, including the documents we incorporate by reference, 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 that is based on management s exercise of business judgment and assumptions made by and information currently available to management. When used in this document and other documents, releases and reports released by us, the words anticipate, believe, expect, 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. Several of these factors include, without limitation:

our ability to finance our business and continue in operations;

whether the results of our full Phase III pivotal study and our BLA filing will result in approval of our product candidate, and whether any approval will occur on a timely basis;

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;

31

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#### **Table of Contents**

our ability to decrease our manufacturing costs for our Fibrocell Therapy product candidates through the improvement of our manufacturing process, and our ability to validate any such improvements with the relevant regulatory agencies;

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; 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;

our dependence on physicians to correctly follow our established protocols for the safe administration of our Fibrocell Therapy; and

other risks referenced from time to time elsewhere in this prospectus and in our filings with the SEC.

These factors are not necessarily all of the important factors that could cause actual results of operations to differ materially from those expressed in these forward-looking statements. Other unknown or unpredictable factors also could have material adverse effects on our future results. We undertake no obligation and do not intend to update, revise or otherwise publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of any unanticipated events. We cannot assure you that projected results will be achieved.

#### **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.

# Item 3. Legal Proceedings

None.

#### Item 4. (Removed and Reserved)

Reserved.

32

#### Part II

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

#### **Market Information**

On October 21, 2009, our common stock became available for trading OTCBB under the symbol FCSC. Currently, there is only a limited, sporadic and volatile market for our stock on the OTCBB. The table below presents the high and low bid price for our common stock each quarter during the past two years and reflects inter-dealer prices, without retail markup, markdown, or commission, and may not represent actual transactions.

Quarter Ended	]	High	Low
December 31, 2009 (from October 21, 2009)	\$	2.40	\$ 0.50
March 31, 2010	\$	1.13	\$ 0.80
June 30, 2010	\$	1.04	\$ 0.65
September 30, 2010	\$	0.85	\$ 0.53
December 31, 2010	\$	0.60	\$ 0.40

The closing price of our common stock on March 24, 2011 was \$0.77.

The common stock of our predecessor company, Isolagen, Inc., traded on the NYSE Amex under the symbol ILE. The common stock ceased trading on the NYSE Amex on May 6, 2009 and in June 2009 the NYSE Amex delisted the common stock from listing on the NYSE Amex. Upon the effective date of our bankruptcy plan, the outstanding common stock of Isolagen was cancelled. Consequently, the stockholders of Isolagen prior to the effective date of the bankruptcy plan no longer have any interest as stockholders of Fibrocell by virtue of their ownership of Isolagen s common stock prior to the emergence from bankruptcy.

#### **Holders**

As of March 24, 2011, there were 24,469,099 shares of our common stock outstanding and held by 227 stockholders of record. As of March 24, 2011, there were 3,250 shares issued and 2,886 shares outstanding for Series A preferred stock, 4,640 shares issued and 2,738 shares outstanding for Series B preferred stock and 7,779 shares Series D preferred stock issued and outstanding.

#### **Dividends**

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

Holders of the Series A, Series B and 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 on January 15, April 15, July 15 and October 15, beginning on April 15, 2010, January 15, 2011 and July 15, 2011, respectively. 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 both 2010 and the first quarter 2011. No dividend cash payments have been made for the Series B or Series D as of March 24, 2011.

#### **Penny Stock**

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

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

# **Recent Sales of Unregistered Securities**

All information regarding the financings we completed during 2010 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 2010.

#### 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 an 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 most advanced indication utilizing the Fibrocell Therapy is for the treatment of nasolabial folds/wrinkles, which completed Phase III clinical studies and the related Biologics License Application ( BLA ) was accepted for filing by the Food and Drug Administration (FDA) during May 2009. On October 9, 2009 the FDA Cellular, Tissue and Gene Therapies Advisory Committee reviewed our nasolabial folds/wrinkles product candidate. The Committee voted 11 yes to 3 no that the data presented on our product demonstrated efficacy, and 6 yes to 8 no that the data demonstrated safety; both for the proposed indication of treatment of nasolabial folds/wrinkles. The committee s recommendations are not binding on the FDA, but the FDA will consider their recommendations during their review of our application. The United States Adopted Names ( USAN ) Council adopted the USAN name, azficel-T, for our product on October 28, 2009, and the FDA is currently evaluating a proposed brand name, laViv®. On December 21, 2009, Fibrocell Science received a Complete Response letter from the FDA related to the BLA for azficel-T. A Complete Response letter is issued by the FDA s Center for Biologics Evaluation and Research (CBER) when the review of a file is completed and additional data are needed prior to approval. The Complete Response letter requested that Fibrocell Science

provide data from a histopathological study on biopsied tissue samples from patients following injection of azficel-T. The letter also requested finalized Chemistry, Manufacturing and Controls (CMC) information regarding the manufacture of azficel-T as follow-up to discussions that occurred during the BLA review period, as well as revised policies and procedures regarding shipping practices, and proposed labeling. The Company announced on December 20, 2010, that it had submitted its complete response to the Complete Response (CR) letter issued by the FDA regarding the Company s BLA for azficel-T. On January 22, 2011, the FDA accepted for review the Company s complete response submission for azficel-T. Even though the FDA has accepted the Company s response for complete evaluation, there is no assurance that it will approve our product. The FDA, under the Prescription Drug User Fee Act (PDUFA), has a target six months review window to completely evaluate the Company s response upon acceptance of the response. The PDUFA date is June 22, 2011. The Company announced on March 16, 2011, that it had submitted a final study report to the FDA for the completed, six-month histological study examining skin after injections of azficel-T.

During 2009 we completed a Phase II/III study for the treatment of acne scars. 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 Successor Company emerged from Bankruptcy in September 2009 and continues to operate as a going concern. At December 31, 2010, the Successor Company had cash and cash equivalents of approximately \$0.9 million and negative working capital of less than \$0.1 million. The Successor Company has also raised approximately \$6.1 million less fees as the result of the issuance of Preferred Stock Series D and warrants in the period from January 1, 2011 through March 1, 2011. We received \$0.2 million in subscription receivables from a July financing in mid-March 2011.

As of March 24, 2011, the Company had cash and cash equivalents of approximately \$3.4 million and current liabilities of approximately \$0.6 million. The Company is current monthly cash run-rate is approximately \$1.0 million. The Company is also planning to purchase manufacturing equipment and incur marketing expenditures within the next three months to prepare the Company for launch post a possible FDA approval. Thus, the Successor 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 Successor 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.

Further, if the Successor 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, 2010, the Successor 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 2011. During the year ended December 31, 2010, the Successor Company financed its operations primarily through its existing cash, but as discussed above it now requires additional financing. There is substantial doubt about the Successor Company s ability to continue as a going concern.

The Successor 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 Successor Company and the offering terms. The Successor Company s ability to complete an offering is also dependent on the status of its FDA regulatory milestones and its clinical trials, and in particular, the status of its indication for the treatment of nasolabial folds/wrinkles and the potential approval of the related BLA, which cannot be predicted. 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 GAAP, there exists substantial doubt about the Successor 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 Successor 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 Successor 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 accounting principles generally accepted in the United States of America. 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 Successor Company s primary study that was recognized upon emergence from bankruptcy (see Note 5). Intangibles are tested for recoverability whenever events or changes in circumstances indicate the carrying amount may not be recoverable. An impairment loss, if any, would be measured as the excess of the carrying value over the fair value determined by discounted cash flows.

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

Warrant Liability: We account for our warrants in accordance with U.S. GAAP. The warrants are measured at fair value and liability-classified under 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. The fair value of the warrants 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. 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 Successor 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 Successor 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 Successor s consolidated balance sheet as of December 31, 2010 and will be re-measured on the Successor 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 Successor 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 and non-employees using the fair value based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. We use a Black-Scholes options-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.

Emergence from Voluntary Reorganization Under Chapter 11 Proceedings and Reorganization Plan Fibrocell emerged from Chapter 11 on September 3, 2009. See Note 2 in the accompanying Consolidated Financial Statements.

## **Basis of Presentation**

As of September 1, 2009, the Successor Company adopted fresh-start accounting in accordance with ASC 852-10, Reorganizations. The Successor 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 Successor Company becoming a new entity for financial reporting purposes.

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. See Note 5 Fresh Start Accounting in the notes to these Consolidated Financial Statements for further details.

For discussions on the results of operations, the Successor Company has combined the results of operations for the eight months ended August 31, 2009, with the results of operations for the four months ended December 31, 2009. The combined periods have been compared to the year-ended December 31, 2010. The Successor Company believes that the combined financial results provide management and investors a more meaningful analysis of the Company s performance and trends for comparative purposes.

The following discussion should be read in conjunction with the Consolidated Financial Statements and the accompanying Notes to the Consolidated Financial Statements in Part 1, Item 1 of this report.

# Results of Operations Comparison of Years Ending December 31, 2010 and 2009

REVENUES. Revenue remained constant at \$0.9 million for the year ended December 31, 2010 and for the year ended December 31, 2009. Our revenue from continuing operations is from the operations of Agera which we acquired on August 10, 2006. Agera markets and sells a complete line of advanced skin care systems based on a wide array of proprietary formulations, trademarks and non-peptide technology.

COST OF SALES. Costs of sales decreased \$0.1 million to \$0.5 million for the year ended December 31, 2010 as compared to \$0.6 million for the year ended December 31, 2009. Our cost of sales relates to the operation of Agera. As a percentage of revenue, Agera cost of sales were approximately 55% for the year ended December 31, 2010 and 70% for the year ended December 31, 2009. Cost of sales as a percentage of revenue in 2010 has decreased as compared to 2009 primarily due to the recording of a reserve for slow moving and obsolete inventory in 2009. SELLING, GENERAL AND ADMINISTRATIVE EXPENSES. Selling, general and administrative expenses increased by approximately \$0.4 million, or 6%, to \$6.5 million for the year ended December 31, 2010 as compared to \$6.1 million for the year ended December 31, 2009. The increase primarily relates to a \$0.3 million increase related to general and administrative expenses associated with consultants for financing and marketing as well as office expenses, \$0.3 million increase related to legal expenses, \$0.1 million increase in marketing, offset by a \$0.3 million decrease in payroll related expenses. Legal expenses for the year ended December 31, 2009 were \$0.2 million due to a \$0.3 million reimbursement received from our insurance carrier related to defense costs associated with our class action and derivative matters. Had we not received this reimbursement, legal expenses would have been \$0.5 million for both years ended December 31, 2010 and December 31, 2009.

RESEARCH AND DEVELOPMENT. Research and development expenses increased by approximately \$1.6 million, or 40%, to \$5.5 million for the year ended December 31, 2010 as compared to \$3.9 million for the year ended December 31, 2009. The increase primarily relates to a \$0.7 million increase in payroll related expenses, \$0.5 million increase in consulting fees and \$0.2 million increase in laboratory costs associated with clinical and manufacturing activities in our Exton, Pennsylvania location. Research and development costs are composed primarily of costs related to our efforts to gain FDA approval for our Fibrocell Therapy for specific dermal applications in the United States, as well as 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, 2010, for the Successor Company was \$7.3 million.

The FDA approval process is extremely complicated and is dependent upon our study protocols and the results of our studies. In the event that the FDA requires additional studies for our product candidate or requires changes in our study protocols or in the event that the results of the studies are not consistent with our expectations, the process will be more expensive and time consuming. Due to the complexities of the FDA approval process, we are unable to predict what the cost of obtaining approval for our dermal product candidate will be.

Table of Contents 58

38

REORGANIZATION ITEMS, NET. On June 15, 2009, Isolagen, Inc. and its wholly-owned, U.S. subsidiary Isolagen Technologies, Inc., filed voluntary petitions for relief under Chapter 11 of the federal bankruptcy laws in the United States Bankruptcy Court for the District of Delaware, as more fully discussed under Bankruptcy, Debt and Going Concern. A reorganization gain, net of reorganization costs, of less than \$0.1 million and \$73.5 million was recorded for the year ended December 31, 2010 and December 31, 2009, respectively, which was comprised primarily of legal fees and the unamortized debt acquisition costs, and gain of discharge of liabilities.

OTHER INCOME, NET. 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 decreased \$1.4 million to \$1.1 million for the year ended December 31, 2010, as compared to \$2.5 million for the year ended December 31, 2009. Our interest expense for the year ended December 31, 2010 is related to the 12.5% notes we issued in connection with our bankruptcy plan. We have been accreting the interest to principal at the rate of 15%. Our interest expense for the year ended December 31, 2009 is related to our \$90.0 million, 3.5% convertible subordinated notes, as well as the related amortization of deferred debt issuance costs of \$0.1 million and interest expense related to the secured bridge loan and DIP financing until the emergence out of bankruptcy. With the emergence out of bankruptcy, the 3.5% convertible subordinated notes were exchanged for \$6.0 million of debt and 3,960,000 shares of the new common stock. There is also interest expense related to the 12.5% notes for the year end December 31, 2009.

NONCONTROLLING INTEREST. The noncontrolling interest income was approximately \$0.1 million for the year ended December 31, 2010, as compared to noncontrolling interest income of \$0.2 million for the year ended December 31, 2009. The decrease in noncontrolling interest income of \$0.1 million is due to Agera s decrease in net income in 2010 as compared to 2009.

NET INCOME/(LOSS). Net loss, excluding reorganization items, was relatively constant at \$12.9 million for the year ended December 31, 2010 as compared to a net loss of \$12.8 million for the year ended December 31, 2009. Net income of \$60.7 million for the year ended December 31, 2009, included reorganization items of \$73.5 million as a result of the emergence out of bankruptcy and discharge of debt and unsecured liabilities.

### **Liquidity and Capital Resources**

Net cash provided by (used in) operating, investing and financing activities for the two years ended December 31, 2010 and 2009 were as follows:

	Year E	Year Ended December 31,			
	2010	2010 20		009	
		(in millions)			
Cash flows from operating activities	\$	(9.3)	\$	(9.0)	
Cash flows from investing activities					
Cash flows from financing activities		8.8		7.5	

OPERATING ACTIVITIES. Cash used in operating activities during the year ended December 31, 2010 amounted to \$9.3 million, an increase of \$0.3 million over the year ended December 31, 2009. 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 \$0.7 million, offset by operating cash inflows from changes in operating assets and liabilities. The change in operating assets and liabilities is primarily due to a large increase in accounts payable at December 31, 2010 as compared to December 31, 2009.

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#### **Table of Contents**

Our negative operating cash flows in 2010 were funded from cash on hand at December 31, 2009, which were primarily the result of previously completed debt and equity offerings, as well as funds received for the issuance of preferred stock and common stock in 2010.

INVESTING ACTIVITIES. Minimal or no cash was used in investing activities during the year ended December 31, 2010 and during the year ended December 31, 2009.

FINANCING ACTIVITIES. There were \$8.8 million cash proceeds from financing activities during the year ended December 31, 2010, as compared to \$7.5 million received from financing activities during the year ended December 31, 2009. During 2010, we raised cash from the issuance of preferred stock, common stock and warrants. Working Capital

As of December 31, 2010, we had cash and cash equivalents of \$0.9 million and negative working capital of less than \$0.1 million. The Successor Company has raised approximately \$6.1 million less fees as the result of the issuance of Series D Preferred Stock and warrants in the period from January 1, 2011 through March 1, 2011. As of March 24, 2011, the Company had cash and cash equivalents of approximately \$3.4 million and current liabilities of approximately \$0.6 million. The Company is also planning to purchase manufacturing equipment and incur marketing expenditures within the next three months to prepare the Company for launch post a possible FDA approval. Thus, the Successor 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 Successor 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.

#### **Debt**

The Successor Company s outstanding long-term debt at December 31, 2010 and December 31, 2009 consists of \$7.3 million and \$6 million, respectively, of 12.5% Unsecured Promissory Notes (New Notes). Unpaid interest has been accreted to the principal at a rate of 15%. The New Notes have the following features: (1) 12.5% interest payable quarterly in cash or, at the Successor Company s option, 15% payable in kind by capitalizing such unpaid amount and adding it to the principal as of the date it was due; (2) maturing June 1, 2012; (3) at any time prior to the maturity date, the Successor Company may redeem any portion of the outstanding principal of the New Notes in Cash at 125% of the stated face value of the New Notes. There is a mandatory redemption feature that requires the Successor Company to redeem all outstanding new notes if: (1) the Successor Company successfully completes a capital campaign raising in excess of \$10 million; or (2) the Successor Company is acquired by, or sell a majority stake to, an outside party.

#### Factors Affecting Our Capital Resources

Inflation did not have a significant impact on the Company s results during the year ended December 31, 2010.

#### **Off-Balance Sheet Transactions**

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

### 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. None.

40

#### 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, 2010, 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 is assets that could have a material effect on the financial statements.

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

Based on our evaluation under the framework in *Internal Control* Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2010. 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.

41

#### Item 9B. Other Information

On January 28, 2011, we completed a private placement of securities in which we sold to certain accredited investors in the aggregate: (i) 1,414 shares of Series D Convertible Preferred Stock, with a par value of \$0.001 per share and a stated value of \$1,000 per share ( Series D Preferred ), and (ii) warrants to purchase 2,828,000 shares of Company common stock ( Common Stock ) at an exercise price of \$0.50 per share.

The aggregate purchase price paid by the Purchasers for the Series D Preferred and the warrants was \$1,414,000 (representing \$1,000 for each share of Series D Preferred together with warrants). We intend to use the proceeds for working capital purposes.

The placement agents for the offering received cash compensation of \$113,120 and warrants to purchase 226,240 shares of Common Stock at an exercise price of \$0.50 per share.

#### 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 2011 Annual Meeting of Stockholders which will be filed with the Securities and Exchange Commission no later than May 2, 2011 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 by this Item 11 will be included in the Company s Proxy Statement for the 2011 Annual Meeting of Stockholders which will be filed with the Securities and Exchange Commission no later than May 2, 2011 and is incorporated into this Item 11 by reference.

**Item 12.** Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters The information required by this Item 12 will be included in the Company s Proxy Statement for the 2011 Annual Meeting of Stockholders which will be filed with the Securities and Exchange Commission no later than May 2, 2011 and is incorporated into this Item 12 by reference.

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

The information required by this Item 13 will be included in the Company s Proxy Statement for the 2011 Annual Meeting of Stockholders which will be filed with the Securities and Exchange Commission no later than May 2, 2011 and is incorporated into this Item 13 by reference.

# Item 14. Principal Accountant Fees and Services

The information required by this Item 14 will be included in the Company s Proxy Statement for the 2011 Annual Meeting of Stockholders which will be filed with the Securities and Exchange Commission no later than May 2, 2011 and is incorporated into this Item 14 by reference.

42

#### **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, 2010 (Successor Company) and 2009 (Successor Company)

Consolidated Statements of Operations for the year ended December 31, 2010 (Successor Company), four months ended December 31, 2009 (Successor Company), from inception (September 1, 2009) to December 31, 2010 (Successor Company), eight months ended August 31, 2009 (Predecessor

Company) and from inception to August 31, 2009 (Predecessor Company)

Consolidated Statements of Shareholders Equity (Deficit) and Comprehensive Income (Loss) from inception to August 31, 2009 (Predecessor Company) and from inception (September 1, 2009) to December 31, 2010 (Successor Company)

Consolidated Statements of Cash Flows for the year ended December 31, 2010, four months ended December 31, 2009, from inception (September 1, 2009) to December 31, 2010 (Successor Company), eight months ended August 31, 2009 (Predecessor Company) and cumulative period from inception 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.

(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)

43

<b>EXHIBIT</b>	
NO.	IDENTIFICATION OF EXHIBIT
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
4.6	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
4.7	(incorporated by reference to Exhibit 4.1 to our Form 8-K filed July 20, 2010) Form of Placement Agent Warrant issued in July 2010 Series B preferred stock offering
4.7	(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
0	(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).
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
10.5	Form S-8 filed March 3, 2011)
10.5	Lease Agreement between Isolagen, Inc and The Hankin Group dates April 7, 2005 (previously filed as an exhibit to the company s Form 8-K, filed on April 12, 2005)
10.6	Purchase Option Agreement between Isolagen, Inc and 405 Eagleview Associates dated April 7,
10.0	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 10.1 to
10.11	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
10.12	filed October 14, 2009) Securities Purchase Agreement between the Company and Series B Preferred Stock Purchasers
10.12	(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)

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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).
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

<sup>\*</sup> Filed herewith.

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### **Table of Contents**

### **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, 2011

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	Chief Executive Officer and Chairman of the Board of Directors	March 30, 2011
David Pernock		
/s/ Declan Daly	Chief Financial Officer, Chief Operating Officer and Director	March 30, 2011
Declan Daly	Birector	
/s/ Kelvin Moore	Director	March 30, 2011
Kelvin Moore		
/s/ Dr. Robert Langer	Director	March 30, 2011
Dr. Robert Langer		
/s/ Marc Mazur	Director	March 30, 2011
Marc Mazur		
/s/ Dr. George Korkos	Director	March 30, 2011
Dr. George Korkos		
	45	

# Fibrocell Science, Inc. (A Development Stage Company) Index to Consolidated Financial Statements

	PAGE
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2010 and 2009	F-3
Consolidated Statements of Operations for the year ended December 31, 2010 (Successor Company), four months ended December 31, 2009 (Successor Company), from inception (September 1, 2009) to December 31, 2010 (Successor Company), eight months ended August 31, 2009 (Predecessor	
Company) and from inception to August 31, 2009 (Predecessor Company)	F-4
Consolidated Statements of Shareholders Deficit and Comprehensive Income (Loss) From Inception (December 28, 1995) to August 31, 2009 (Predecessor Company) and four months ended December 31, 2009 (Successor Company) and year ended December 31, 2010 (Successor Company)	F-5
Consolidated Statements of Cash Flows for the year ended December 31, 2010 (Successor Company), four months ended December 31, 2009 (Successor Company), cumulative period from inception (September 1, 2009) to December 31, 2010 (Successor Company), eight months ended August 31, 2009 (Predecessor Company) and cumulative period from inception (December 28, 1995) to	
August 31, 2009 (Predecessor Company)	F-17
Notes to Consolidated Financial Statements	F-19

F1

#### 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, 2010 and 2009 and the related consolidated statements of operations, shareholders equity (deficit) and comprehensive loss, and cash flows for the year ended December 31, 2010 (Successor), for the period from January 1 to August 31, 2009 (Predecessor as described in Note 1 of the notes to the consolidated financial statements ) and for the period from the Successor s inception of operations (September 1, 2009) through December 31, 2009. We have also audited the statements of shareholders equity (deficit) for the period from December 28, 1995 (Predecessor s inception) to December 31, 2008. 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. Our audit 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, 2010 and 2009, and the results of its operations and its cash flows for the year ended December 31, 2010 (Successor), for the period from January 1 to August 31, 2009 (Predecessor) and for the period from the Successor s inception of operations (September 1, 2009) through December 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, 2009, 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, 2011

F2

# Fibrocell Science, Inc. (A Development Stage Company) Consolidated Balance Sheets

	Do	ecember 31, 2010	De	ecember 31, 2009
Assets				
Current assets:				
Cash and cash equivalents	\$	867,738	\$	1,362,488
Accounts receivable, net		229,891		269,759
Inventory, net		258,939		226,032
Prepaid expenses and other current assets		559,082		525,024
Total current assets		1,915,650		2,383,303
Property and equipment, net of accumulated depreciation of \$8,085 and \$0,				
respectively		21,589		
Other assets		250		250
Intangible assets		6,340,656		6,340,656
Total assets	\$	8,278,145	\$	8,724,209
Liabilities, Redeemable Preferred Stock, Shareholders Deficit and Noncontrolling Interest Current liabilities:				
Current debt	\$	56,911	\$	47,795
Accounts payable		1,096,125		245,023
Accrued expenses		789,482		544,260
Total current liabilities		1,942,518		837,078
Long-term debt		7,290,881		6,000,060
Deferred tax liability		2,500,000		2,500,000
Warrant liability		8,171,518		635,276
Derivative liability		2,120,360		
Other long-term liabilities		255,606		369,210
Total liabilities		22,280,883		10,341,624
Commitments and contingencies				
Preferred stock series A, \$0.001 par value; 9,000 shares authorized; 3,250 shares issued and 2,886 shares outstanding Preferred stock series B, \$0.001 par value; 9,000 shares authorized; 4,640 shares issued and outstanding		1,280,150		2,511,070
Preferred stock series B, \$0.001 par value; subscription receivable Preferred stock series D, \$0.001 par value; 8,000 shares authorized; 1,645 shares issued and outstanding		(210,000)		

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Fibrocell Science, Inc. shareholders deficit: Successor common stock, \$0.001 par value: 250.000.000 shares authorized:

Successor common stock, \$0.001 par value; 250,000,000 snares authorized;		
20,375,500 issued and outstanding	20,376	14,692
Additional paid-in capital	2,437,893	508,347
Accumulated deficit during development stage	(17,981,530)	(5,049,999)
Total Fibrocell Science, Inc. shareholders deficit	(15,523,261)	(4,526,960)
Noncontrolling interest	450,373	398,475
Total deficit and noncontrolling interest	(15,072,888)	(4,128,485)
Total liabilities, preferred stock, shareholders deficit and noncontrolling interest	\$ 8,278,145	\$ 8,724,209

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

F3

# Fibrocell Science, Inc. (A Development Stage Company) Consolidated Statements of Operations

	Successor	Successor	Successor Cumulative period from September 1,	Predecessor	Predecessor Cumulative period from December 28,
	For the year ended December 31, 2010	For the four months ended December 31,	2009 (date of inception) to December 31, 2010	For the eight months ended August 31, 2009	1995 (date of inception) to August 31, 2009
Revenue Product sales License fees	\$ 936,369	\$ 329,941	\$ 1,266,310	\$ 538,620	\$ 4,818,994 260,000
Total revenue Cost of sales	936,369 502,648	329,941 182,048	1,266,310 684,696	538,620 424,139	5,078,994 2,279,335
Gross profit Selling, general and	433,721	147,893	581,614	114,481	2,799,659
administrative expenses Research and	6,515,581	2,708,356	9,223,937	3,427,374	84,805,520
development expenses	5,486,319	1,823,196	7,309,515	2,107,718	56,269,869
Operating loss Other income (expense)	(11,568,179)	(4,383,659)	(15,951,838)	(5,420,611)	(138,275,730)
Interest income Reorganization items,		1	1	248	6,989,539
net Other income (expense) Werent expense	3,303 244,479 (465,232)	(72,477)	(69,174) 244,479 (784,216)	73,538,984 (6,243)	73,538,984 316,338
Warrant expense Interest expense	(465,232) (1,045,199)	(319,084) (247,174)	(784,316) (1,292,373)	(2,232,138)	(18,790,218)
Income (loss) from continuing operations before income taxes Income tax benefit	(12,830,828)	(5,022,393)	(17,853,221)	65,880,240	(76,221,087) 190,754
Income (loss) from continuing operations	(12,830,828)	(5,022,393)	(17,853,221)	65,880,240	(76,030,333)
Income (loss) from discontinued operations	(48,805)	(12,113)	(60,918)	46,923	(41,091,311)
Net income (loss)	(12,879,633)	(5,034,506)	(17,914,139)	65,927,163	(117,121,644)

Deemed dividend associated with beneficial conversion										(11,423,824)
Preferred stock dividends Net (income)/loss attributable to										(1,589,861)
noncontrolling interest		(51,898)		(15,493)		(67,391)		(205,632)		1,799,523
Net income (loss) attributable to Fibrocell Science, Inc.	ф	(10.001.501)	Φ.	(5 0 40 000)	Φ.	(17.001.520)	Ф	(5.701.501	Φ.	(120, 225, 200)
common shareholders	\$	(12,931,531)	\$	(5,049,999)	\$	(17,981,530)	\$	65,721,531	\$	(128,335,806)
Per share information: Income (loss) from continuing operations-basic and										
diluted Loss from discontinued operations-basic and	\$	(0.68)	\$	(0.35)	\$	(1.01)	\$	1.72	\$	(4.30)
diluted										(2.32)
Income attributable to noncontrolling interest										0.10
Deemed dividend associated with										
beneficial conversion of preferred stock										(0.65)
Preferred stock dividends										(0.09)
Net income (loss) attributable to common shareholders per common share basic and diluted	\$	(0.68)	\$	(0.35)	\$	(1.01)	\$	1.72	\$	(7.26)
Weighted average number of basic and diluted common shares										,
outstanding		18,757,756		14,380,381		17,681,500		38,230,886		17,678,219

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

F4

## Fibrocell Science, Inc. (A Development Stage Company) Consolidated Statements of Shareholders Equity (Deficit) and Comprehensive Income (Loss)

#### Accumulated

	Series	Series					Accumulated	u
	A Preferred	В				Accum Treasury	nulate <b>D</b> eficit	Total
	Stock Number Nu	Stock umber	Common Number	Stock		Stock Otumber	ther During	Shareholders
	of	of	of		Paid-In	of Compr	ehe <b>heiwe</b> lopmen	t Equity
	Sha Aesno 6	<b>hta Aes</b> noun	t Shares	Amount	Capital S	Sha <b>Aas</b> nou <b>Im</b> tc	come Stage	(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)	•
							, , ,	,
Balance,								
12/31/97(Predecesso	or) \$	\$	2,636,031	\$ 2,635	\$ 279,700	\$ \$	\$ (323,018)	\$ (40,683)
The	accompanyii	ng notes ar				dated financ	ial statements.	
	- 1		-	-				

	G	• ~							Accumulated	
	I	ries So A err <b>e</b> tre	В					Accumi	ulate <b>D</b> eficit	Total
	Numb	ock S eiNum	ber	Common Number	Stock		Number	iry Stock Oth	er During	Shareholders
	of Sha <b>k</b> r	of <b>esoSilma</b> 4		of t Shares	Amount	Paid-In Capital	of Shares	Comprel AmountInco	h <b>eDsiwe</b> lopment me Stage	Equity (Deficit)
Issuance of common stock for ca on 8/23/98 Repurchase common stock on	sh	\$	\$	4,459	\$ 4	\$ 20,063		\$ \$	\$	\$ 20,067
9/29/98 Net loss							2,400	(50,280)	(195,675)	(50,280) (195,675)
Balance, 12/31/98 (Predecessor Issuance of	-	\$	\$	2,640,490	\$ 2,639	\$ 299,763	2,400	\$ (50,280) \$	\$ (518,693)	\$ (266,571)
common stock for ca on 9/10/99 Net loss	sh			52,506	53	149,947			(1,306,778)	150,000 (1,306,778)
Balance, 12/31/99 (Predecesso Issuance of	-	\$	\$	2,692,996	\$ 2,692	\$ 449,710	2,400	\$ (50,280) \$	\$ (1,825,471)	\$ (1,423,349)
stock for ca on 1/18/00 Issuance of common				53,583	54	1,869				1,923
stock for services on 3/1/00 Issuance of common stock for				68,698	69	(44)	)			25
services on 4/4/00 Net loss				27,768	28	(18)	)		(807,076)	10 (807,076)
Balance, 12/31/00		\$	\$	2,843,045	\$ 2,843	\$ 451,517	2,400	\$ (50,280) \$	\$ (2,632,547)	\$ (2,228,467)

(Predecessor)

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

F6

	6		<b>G</b> •							Aco	cumula	ted	
	3	Series A	Series B						Ac	cumul	<b>Defi</b> cit	1	Total
	5	Stock	Preferred Stock umber	Common	Sto	ck	Additional	Treasui Number	ry Stock	Other	During	Shar	eholders
	of	f	umber of <b>ht</b> ar <b>ke</b> nount	Number of Shares	Am	ount	Paid-In Capital	of Shares	Con Amount	npr <b>Elec</b> Incom	_		quity eficit)
Issuance of common sto for services	ock						•						·
7/1/01 Issuance of common sto for services		\$	\$	156,960	\$	157	\$ (101)		\$	\$	\$	\$	56
7/1/01 Issuance of common stor for capitalization of accrued	ock			125,000		125	(80)						45
salaries on 8/10/01 Issuance of common sto for conversi of convertib	on			70,000		70	328,055						328,125
debt on 8/10/01 Issuance of common sto for conversi of convertib shareholder	on ole			1,750,000	1	,750	1,609,596					1,	611,346
notes payab on 8/10/01 Issuance of common sto for bridge	ock			208,972		209	135,458						135,667
financing or 8/10/01 Retirement of treasury stoo	of			300,000		300	(192)						108
on 8/10/01 Issuance of common sto for net asset of Gemini o	ts			3,942,400	3	3,942	(50,280) (3,942)	(2,400)	50,280				

8/10/01				
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.

F7

Accumulated

79

## **Table of Contents**

			Series							A	ccumulated		
	Series	s A	B Preferred	I				A Treasui	ccumulate y	ed	Deficit		Total
	Preferred Number		x Stock Number	Common	Stock	A		al Stock Number	Other		During	Sh	areholders
	of Shares			Number of	Amount		Paid-In	of Co	omprehens in <b>l</b> ncome	iDe	evelopment Stage		Equity (Deficit)
Uncompensated contribution of services 3rd quarter Issuance of common stock		\$	\$	e Saures	\$	\$	_		\$	\$	Suige	\$	
for services on 11/1/01 Uncompensated contribution of services 4th				145,933	146		218,75	54					218,900
quarter Net loss							100,00	00			(1,652,004)	)	100,000 (1,652,004)
Balance, 12/31/01 (Predecessor) Uncompensated contribution of		\$	\$	15,189,563	\$ 15,190	\$	5,321,76	51 \$	\$	\$	(4,284,551	) \$	1,052,400
services 1st quarter Issuance of preferred stock							100,00	00					100,000
for cash on 4/26/02 Issuance of preferred stock	905,000	90	05				2,817,33	31					2,818,236
for cash on 5/16/02 Issuance of preferred stock	890,250	89	90				2,772,23	39					2,773,129
for cash on 5/31/02 Issuance of preferred stock	795,000	79	95				2,473,38	80					2,474,175
for cash on 6/28/02 Uncompensated contribution of services 2nd	229,642	2	30				712,99 100,00						713,221 100,000

			•	Ū		,			
quarter Issuance of preferred stock for cash on 7/15/02 Issuance of common stock	75,108	75				233,886			233,961
for cash on 8/1/02 Issuance of warrants for				38,400	38	57,562			57,600
services on 9/06/02 Uncompensated contribution of						103,388			103,388
services 3rd quarter Uncompensated contribution of						100,000			100,000
services 4th quarter Issuance of preferred stock						100,000			100,000
for dividends Deemed dividend associated with beneficial	143,507	144				502,517		(502,661)	
conversion of preferred stock Comprehensive						10,178,944		(10,178,944)	
income: Net loss Other comprehensive income, foreign currency								(5,433,055)	(5,433,055)
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

F8

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

Accumulated

## **Table of Contents**

	Series	s A	Serie	es B				A Treasury	Accumulated	l Deficit	Tot
	Preferred	d Stock	Preferred Number		Common	Stock	Additional			During	Shareh
	Number of Shares	Amount	of	Amount	Number of t Shares	Amount	Paid-In	of Co	-	<b>R</b> evelopment Stage	Equ (Defi
e of n stock 1 on							-				
e of n stock ent		\$		\$	61,600	\$ 62	\$ 92,338	8 \$	\$ \$	\$	\$ 9
tion on					100,000	100	539,900	)			54
ation of n stock /03 pensated ution of					(79,382)						(11
s 1st							100,000	)			10
ed stock n on e of			110,250	) 110			2,773,218	3			2,77
ed stock 1 on			45,500	) 46			1,145,704	4			$1,1^{2}$
sion of ed stock mmon 2nd qtr sion of s into	(70,954)	(72)	ı		147,062	147	40,626	5			2
n 2nd qtr pensated ution of					114,598	114	(114	ł)			
e of							100,000	)			10
ed stock ds							1,244,880	)		(1,087,200) (1,244,880)	

d										
d ted with ial sion of ed stock e of										
n stock  n '9 qtr  e of  n stock  on					202,500	202	309,798			31
sion of					3,359,331	3,359	18,452,202			18,45
nmon  qtr sion of s into	(2,967,553)	(2,967)	(155,750)	(156)	7,188,793	7,189	(82,875)			(1
n  qtr  nsation on s issued					212,834	213	(213)			
ployees e of							412,812			41
n stock  1 4 qtr sion of s into					136,500	137	279,363			21
n I qtr ehensive :					393					
s hensive , foreign y									(11,268,294)	(11,26
ion ient								360,505		36
ehensive										(10,90

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

essor)

26,672,192 \$26,672 \$50,862,258 \$ \$374,380 \$(33,999,585) \$ 17,20

F9

Accumulated

## **Table of Contents**

	Sorio	s Series						r	Accumulated	
	$\mathbf{A}$	B Bedeferred						Accumulated	Deficit	Total
	Stock	Stock umber	Common	Stock	Additional	Treasur Number	y Stock	Other	During	Sharehold
	Number of		Number of		Paid-In	of		Comprehensid	<b>e</b> evelopment	Equity
		ih <b>dnes</b> oun	t Shares	Amount	Capital	Shares	Amount	Income	Stage	(Deficit
version of ants into non stock	s <b>t</b>									
non stock	\$	\$	78,526	\$ 79	\$ (79)		\$	\$ 5	\$	\$
nce of non stock t in	for									
ection with cise of stoc ons <sup>s</sup> I qtr			15,000	15	94,985					95,
ince of non stock i	for		13,000	15	77,703					<i>70</i> ,
ection with	h		4,000	4	7,716					7,
ants <sup>s</sup> I qtr pensation nse on			4,000	4	/,/10					΄,
ns and ants issued employees										
lirectors <sup>s</sup> ł	ł				1,410,498					1,410,
nce of non stock i ection with cise of					•					·
ants <sup>121</sup> qtr ince of non stock t			51,828	52	(52)					
non stock in the pensation nse on and ants issued employees	l to		7,200,000	7,200	56,810,234					56,817,
lirectors 2	<u>d</u>				142 460					1.42
			7,431	7	143,462 (7)					143,

	Eaga	ar Filing: I	Fibroceii Scie	rice, inc F	-01111 424B3			
nce of								
non stock in								
ection with cise of								
ants <sup>1</sup> 9 qtr								
ince of								
non stock for								
in								
ection with								
rise of stock								
ns <sup>13</sup> qtr	110,000	110	189,890					190,
nce of								
non stock for								
in								
ection with								
cise of								
ants <sup>13</sup> qtr	28,270	28	59,667					59,
pensation								
nse on								
ns and								
ants issued to								
employees lirectors <sup>rg</sup>								
lirectors ' <del>3</del>			220 133					229,
nce of			229,133					۷۷۶,
non stock in								
ection with								
rise of								
ants 4 qtr	27,652	28	(28)					
pensation	,							
nse on								
ns and								
ants issued to								
employees,								
oyees, and								
tors 4 qtr			127,497					127,
nase of								
ury stock 4				4 000 000	(27.074.000)			(2.7.07.4
1				4,000,000	(25,974,000)			(25,974,
prehensive								
ne:							(21,474,469)	(21.474
OSS r							(41,474,405)	(21,474,
prehensive								
ne, foreign								
ncy								
lation								ĺ
tment						79,725		79,
4								

Table of Contents 85

orehensive ne, net 10,005

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alized gain

able-for-sale stments

prehensive

(21,384,

nce, 12/31/04

lecessor)

\$ 34,194,899 \$34,195 \$109,935,174 4,000,000 \$(25,974,000) \$464,110 \$(55,474,054) \$28,985. The accompanying notes are an integral part of these consolidated financial statements.

F10

	c .									Accumulated	
	A Prefer		rred	Commen	Stool	A 4444 amal	Т	grave S4 a al-	Accumulated	Deficit	Tota
1	Stoc Numbel of	k Sto Numb of	er	Common Number of	Stock	Additional Paid-In	Number of	sury Stock	Other Comprehensive	During Development	Shareho Equi
ce of on stock f		Shrine	sount	Shares	Amount	Capital	Shares	Amount	Income (Loss)	Stage	(Defic
n ction with se of stock	k										
s sqtr ensation se on s and its issued			\$	25,000	\$ 25	\$ 74,975		\$	\$	\$	\$ 7.
nployees	4					33,565					3.
its into on stock	<b>12</b> d			27,785	28	(28)					
ensation se on s and its issued nployees											
ensation se on s and its issued						(61,762)					(6
nployees	rg					(137,187)					(13
its into on stock	r <b>g</b> l			12,605	12	(12)					
ensation se on s and its issued nployees											
r = 7255						18,844 14,950					18 1

ensation									
se on									
ration of									
s 4 qtr									
ensation									
se on									
ted stock									
issued to									
yee 4 qtr				60	06				
rsion of									
essor		0							
my shares		94	4						
rehensive									
ss								(35,777,584)	(35,77
ehensive									
oreign									
су									
ition									
ment							(1,372,600)		(1,372
n exchange									
n									
ntial									
ation of									
n entity							133,851		133
ehensive									
et									
ized gain									
ble-for-sale									
ments							(10,005)		(1
rehensive									(37,020
									(07,0=
e, 12/31/05									
cessor)	\$ \$	34,260,383	3 \$ 34,260	\$ 109,879,12	25 4,000,000	\$ (25,974,000)	\$ (784,644)	\$ (91,251,638)	\$ (8,09)

F11

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

## **Table of Contents**

										A	ccumulated	d	
	Series Series A B efern <b>ed</b> eferre								Accumu	lated	Deficit		
S	Stock Stock nbeNumber		mon S	Stock	A	Additional	Treasu Number	ry Stock	Othe	er	During		Sh
0	of of Ames&huanesou	Numbe ant Share		Amount		Paid-In Capital	of Shares	Amount			evelopmen Stage	t Noncontr Intere	
ıed													
ees <sup>s</sup> I	\$ \$		S	\$	\$	42,810		\$	\$	\$		\$	\$
ls													
nd µtr on						46,336							
ock													
1 qtr on		128	,750	129		23,368							
ıed													
ees 12d on						96,177							
ls													
nd qtr on						407,012							
ock s 12d						4,210							
of													
ock		(97	,400)	(97)	)	97							

ck					
vith tock r on	10,000	10	16,490		
ned					
ees ng			25,627		
on Jo					
ls nd					
tr n			389,458		
ck rg					
			3,605		
k					
rith ock	76,000	76	156,824		
f	70,000	, 0	150,02		2,182
1					
ed					
es 4			34,772		
l					
5					
d r n			390,547		
ck Up					
	(15,002)	(15)	88 15		

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\$ 34,362,731 \$34,363 \$111,516,561 4,000,000 \$(25,974,000) \$(127,462) \$(127,073,044) \$2,104,373 \$( The accompanying notes are an integral part of these consolidated financial statements.

F12

## **Table of Contents**

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	a .	g .								Ac	cumulated	l	
F	A	Series B <b>Ed</b> eferre	d						Accumulat	ed	Deficit		
		Stock	Common	Stock	A	Additional	Treasur Number	y Stock	Other		During		Sh
190	of	of	Number of			Paid-In	of		Comprehens Income	sivĐe	velopment	tNoncontrolli	ng
S.	h <i>a</i> knesos	d <b>raines</b> ou	nt Shares	Amount		Capital	Shares	Amount			Stage	Interest	(
ued													
rees s	§1 \$	\$		\$	\$	39,742	\$	3	\$	\$		\$	\$
on						•							
ds													
and qtr on						448,067							
ock													
<sup>s</sup> qtr						88							
ock													
with stock													
tr			15,000	15		23,085							
with n of ock													
ıtr on						1,178,483							
ued													
rees r	<b>2</b> d												
on						39,981 462,363							
1.													

and qtr on			
ock			
ற <sup>l</sup> qtr on			88
ds			
and qtr on			478,795
ock			
<sup>13</sup> qtr			88
ock se of qtr	492,613	493	893,811
ock			
t of ts <sup>13</sup>	6,767,647	6,767	13,745,400
ock			
with stock tr on	1,666	2	3,164
rds			
and qtr on			378,827
ock			
<del>4</del> qtr			88
sive			

(35,573,114)

846,388

(246,347) (3

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\$ 41,639,657 \$41,640 \$129,208,631 4,000,000 \$(25,974,000) \$718,926 \$(162,646,158) \$1,858,026 \$(35,974,000) \$1,858,000 \$1,858,000 \$1,858,000 \$1,858,000 \$1,858,000 \$1,858,000 \$1,858,000 \$1,858,000 \$1,858,000 \$1,858,000 \$1,858,000 \$1,858,000 \$1,858,000 \$1,858,000 \$1,858,000 \$1,858,000 \$1,858,000 \$1

F13

## **Table of Contents**

											Accumulated	I
	Series Serie A B efern <b>ed</b> efern									Accumulated	Deficit	
5	Stock Stock nbeNumber	<b>C</b>	Commoi	1 Stocl	k	Ac	lditional		sury Stock	Other	During	
O	of of	Nun	nber of				Paid-In	Number of		Income		Noncontrollin
Sha	<b>Anes/SinAnes</b> o	unt Si	nares	Amo	ount	(	Capital	Shares	Amount	(Loss)	Stage	Interest
ted to s §1												
	\$ \$			\$		\$	44,849		\$	\$	\$	\$
ion to												
							151,305					
h f K												
ζ.							1,262,815					
			(165	)	(1)		-,,,					
ted												
to ngd												
							62,697					
ion to												
•							193,754					
ted to												
r <b>g</b> l							166,687					
ion to												
ątr							171,012					
ted							(86,719)					

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to 44th

ion o (ptr 166,196)

an of ge attial (2,152,569)

attial (1,433,643)

\$ 41,639,492 \$41,639 \$131,341,227 4,000,000 \$(25,974,000) \$ \$(194,057,337) \$ 177,350 The accompanying notes are an integral part of these consolidated financial statements.

80

F14

#### **Table of Contents**

sive

	S	eries	Series							A	Accumulated		
		A	B Edeferre	d					A	ccumulat	edDeficit		
	S	tock	Stock umber	Common	Stock	A	Additional	Treasi	ury Stock	Other	During		
	O		of	Number of			Paid-In	Number of	Co	mprehed Income	<b>Sèwe</b> lopmen <b>t</b>	Noncontrolli	ng
	Sha	nenSi	h <b>etnes</b> ou	nt Shares	Amount		Capital	Shares	Amount		Stage	Interest	(
ion vested ted to													
rees <sup>s</sup> fion option ed to and	-	\$	\$		\$	\$	1,746		\$	\$ \$		\$	\$
qtr of deb							138,798						
n stoc	K			37,564	38		343,962						
ion option ed to and													
nd qtr of deb							112,616						
9 ion option ed to and month				1,143,324	1,143		10,468,857						
09 expensellation ssued t	se n						35,382						
2 moi	nths						294,912						
sive													

97 Table of Contents

65,721,531

205,632

sive								(
1/09 or) n of common	42,820,380	\$ 42,820	\$ 142,737,500	4,000,000	\$ (25,974,000) \$	\$ (128,335,806)	\$ 382,982	\$ (1
esh start of	(42,820,380)	(42,820)	(150,426,331)	(4,000,000)	25,974,000			(12
d deficit dated cehensive						128,335,806		12
/09 r)			(7,688,831)			.,,	382,982	
n shares stock in with from								
nom	11,400,000	11,400	5,460,600					
/09	11,400,000	11,400	(2,228,231)				382,982	
shares of ock in with the								
ng common at. 28,	2,666,666	2,667	1,797,333					
ion shares	25,501	25	58,627					
it ion option	600,000	600	167,400					
ed to ion			326,838					
option ed to rees			386,380					

sive loss:

(5,049,999) 15,493

sive loss

31/09

\$ 14,692,167 \$ 14,692 \$ 508,347 \$ \$ (5,049,999) \$ 398,475 \$ The accompanying notes are an integral part of these consolidated financial statements.

F15

## Accumulated

	Series Series				. Teedinalated						
	A	B				Accumulat	edDeficit				
		edeferred		G. 1		<b>Freasury</b>	<b>.</b>				
	Stock Numbelvi	Stock	Common	Stock		StockOther umber	During		Total		
	of		Number of		Paid-In		<b>siwe</b> lopmen	Noncontrolling	Equity		
	Shamenos	hainesoun	t Shares	Amount	Capital S	hatneso(Inoss)	Stage	Interest	(Deficit)		
ssuance of 5.1 million shares of common stock March 2010, net of	in										
ssuance costs of \$338,10 Warrant fair value associated with common		\$	5,076,664	\$ 5,077	\$ 3,464,323	\$ \$ \$		\$ \$	3,469,400		
shares issued in  March 2010	•				(2,890,711)	)			(2,890,711)		
Compensation expense of the compensation is compensation expense of the compensation is compensation and the compensation expense of the compe	on										
nanagement 1Q10 Compensation expense o	on				18,000				18,000		
option awards issued to lirectors/employees-1Q1 Compensation expense o					324,377				324,377		
option awards issued to non-employees-1Q10					18,391				18,391		
Compensation expense of shares issued to	on				40.000				40.000		
management 2Q10 Compensation expense o	on				18,000				18,000		
option awards issued to directors/employees-2Q1 Compensation expense o					222,011				222,011		
option awards issued to non-employees-2Q10					33,206				33,206		
Compensation expense of shares issued to	on				10,000				10,000		
nanagement 3Q10 Compensation expense option awards issued to	on				18,000				18,000		
directors/employees-3Q1 Compensation expense o					183,231				183,231		
option awards issued to non-employees-3Q10					7,724				7,724		
Compensation expense on the compensation of th	on										
management 4Q10					18,000 104,094				18,000 104,094		

option awards issued to						
directors/employees-4Q10						
Compensation expense on						
option awards issued to						
non-employees-4Q10			27,507			27,507
Preferred Stock Series A	60.6.66 <b>=</b>	60 <b>=</b>	262.202			264.000
conversion	606,667	607	363,393			364,000
Comprehensive loss:						
Net loss				(12,931,531)	51,898	(12,879,633)

Balance 12/31/10

Comprehensive loss

Compensation expense on

Successor) \$ \$ 20,375,498 \$ 20,376 \$ 2,437,893 \$ \$ \$ (17,981,530) \$ 450,373 \$ (15,072,888)

(12,879,633)

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

F16

# Fibrocell Science, Inc. (A Development Stage Company) Consolidated Statements of Cash Flows

	Successor	Successor	Successor Cumulative period from	Predecessor	Predecessor
	Twelve months ended  December 31, 2010	Four months ended December 31, 2009	September 1,  2009 (date of inception) to December 31, 2010	Eight months ended August 31, 2009	Cumulative period from December 31, 1995 (date of inception) to August 31, 2009
Cash flows from operating activities:					
Net (loss) income Adjustments to reconcile net (loss) income to net cash used in operating activities:	\$ (12,931,531)	\$ (5,049,999)	\$ (17,981,530)	\$ 65,721,531	\$ (115,322,121)
Reorganization items, net Expense related to equity awards and issuance of		72,477	72,477	(74,648,976)	(74,648,976)
stock Warrant expense Uncompensated	992,541 465,232	881,218 319,084	1,873,759 784,316	583,453	10,608,999
contribution of services Depreciation and					755,556
amortization Provision for doubtful	8,085		8,085		9,091,990
accounts Provision for excessive	(7,818)	(46,619)	(54,437)	501	337,810
and/or obsolete inventory Amortization of debt issue	(60,366)	11,664	(48,702)	169,085	259,427
costs Amortization of debt				985,237	4,107,067
discounts on investments Loss on disposal or					(508,983)
impairment of property and equipment Foreign exchange gain on					17,668,477
substantial liquidation of foreign entity Net (loss) income attributable to	(5,072)	(2,614)	(7,686)	30,012	(2,256,408)
non-controlling interest	51,898	15,493	67,391	205,632	(1,799,523)

Change in operating assets and liabilities, excluding effects of acquisition:  Decrease (increase) in					
accounts receivable	47,686	23,544	71,230	91,666	(91,496)
Decrease (increase) in other receivables	(4,033)	4,740	707	23,632	218,978
Decrease (increase) in inventory	27,459	30,923	58,382	29,543	(455,282)
Decrease (increase) in prepaid expenses	42,799	(244,905)	(202,106)	628,197	34,341
Decrease (increase) in other assets		4,120	4,120	(112,441)	71,000
Increase (decrease) in accounts payable Increase (decrease) in	851,102	107,622	958,724	(230,592)	57,648
accrued expenses, liabilities subject to compromise and other					
liabilities Increase (decrease) in	1,256,140	(425,794)	830,346	1,868,162	3,311,552
deferred revenue				(7,522)	(50,096)
Net cash used in operating activities	(9,265,878)	(4,299,046)	(13,564,924)	(4,662,880)	(148,610,040)
Cash flows from investing activities: Acquisition of Agera, net					
of cash acquired Purchase of property and					(2,016,520)
equipment Proceeds from the sale of property and equipment,	(29,674)		(29,674)		(25,515,170)
net of selling costs Purchase of investments Proceeds from sales and					6,542,434 (152,998,313)
maturities of investments					153,507,000
Net cash used in investing activities	(29,674)		(29,674)		(20,480,569)
Cash flows from financing activities: Proceeds from convertible					
debt Offering costs associated with the issuance of					91,450,000
convertible debt Proceeds from notes payable to shareholders,					(3,746,193) 135,667

net Proceeds from the issuance of redeemable preferred stock series A, net Proceeds from the issuance		2,870,000	2,870,000		12,931,800
of redeemable preferred stock series B, net Proceeds from the issuance of redeemable preferred	4,019,570		4,019,570		
stock series D, net Proceeds from the issuance	1,509,400		1,509,400		
of common stock, net Costs associated with secured loan and	3,469,400	1,800,000	5,269,400		93,753,857
debtor-in-possession loan				(360,872)	(360,872)
Proceeds from secured loan				500,471	500,471
Proceeds from debtor-in-possession loan				2,750,000	2,750,000
Payments on insurance	(62,692)	(21,001)	(05.574)		
loan Cash dividends paid on	(63,683)	(21,891)	(85,574)	(63,983)	(79,319)
preferred stock	(139,750)		(139,750)		(1,087,200)
Cash paid for fractional shares of preferred stock					(38,108)
Merger and acquisition expenses					(48,547)
Repurchase of common					(40,547)
stock					(26,024,280)
Net cash provided by					
financing activities	8,794,937	4,648,109	13,443,046	2,825,616	170,137,276
Effect of exchange rate					
changes on cash balances	5,865	3,149	9,014	(6,760)	(36,391)
		<b>7</b> .4 -			
		F17			

	Successor	Successor	Successor Cumulative period from	Predecessor	Predecessor
	Twelve months	Four months	September 1, 2009 (date of		Cumulative period from December 31,
	ended December 31, 2010	ended December 31, 2009	inception) to December 31, 2010	Eight months ended August 31, 2009	1995 (date of inception) to August 31, 2009
Net increase (decrease) in cash and cash equivalents Cash and cash equivalents, beginning of period	(494,750)	352,212	(142,538)	(1,844,024)	1,010,276
	1,362,488	1,010,276	1,010,276	2,854,300	
Cash and cash equivalents, end of period	\$ 867,738	\$ 1,362,488	\$ 867,738	\$ 1,010,276	\$ 1,010,276
Supplemental disclosures of cash flow information: Predecessor cash paid for interest	\$	\$	\$	\$	\$ 12,715,283
Successor cash paid for dividends	139,750		139,750		
Non-cash investing and financing activities: Predecessor deemed dividend associated with beneficial conversion of preferred stock	\$	\$	\$	\$	\$ 11,423,824
Predecessor preferred stock dividend					1,589,861
Successor accrued preferred stock dividend	191,417	42,740	191,417		
Predecessor uncompensated contribution of services					755,556
					540,000

Predecessor common stock issued for intangible assets					
Predecessor common stock issued in connection with conversion of debt				10,814,000	10,814,000
Predecessor equipment acquired through capital lease					167,154
Successor/Predecessor financing of insurance premiums	97,065	81,517	178,582		87,623
Successor issuance of notes payable				6,000,060	6,000,060
Successor common stock issued in connection with reorganization				5,472,000	5,472,000
Successor intangible assets				6,340,656	6,340,656
Successor deferred tax liability in connection with fresh-start				2,500,000	2,500,000
Elimination of Predecessor common stock and fresh start adjustment				14,780,320	14,780,320
Successor subscription receivable	210,000	316,192	210,000		
Successor accrued warrant liability	7,071,010	316,192	7,387,202		
Successor conversion of preferred stock into common stock	364,000		364,000		
Successor accrued derivative liability	2,120,360		2,120,360		

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

F18

# Fibrocell Science, Inc. (A Development Stage Company) Notes to Consolidated Financial Statements

#### **Note 1 Business and Organization**

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

The Company is an aesthetic and therapeutic company focused on developing novel skin and tissue rejuvenation products. The Company s clinical development product candidates are designed to improve the appearance of skin injured by the effects of aging, sun exposure, acne and burns with a patient s own, or autologous, fibroblast cells produced in the Company s proprietary Fibrocell Process. The Company also markets an advanced skin care line with broad application in core target markets through its Agera subsidiary.

In October 2006, the Predecessor Company reached an agreement with the U.S. Food and Drug Administration (FDA) on the design of a Phase III pivotal study protocol for the treatment of nasolabial folds/wrinkles. The randomized, double-blind protocol was submitted to the FDA under the agency s Special Protocol Assessment (SPA) regulations. Pursuant to this assessment process, the FDA has agreed that the Predecessor Company s study design for two identical trials, including patient numbers, clinical endpoints, and statistical analyses, is acceptable to the FDA to form the basis of an efficacy claim for a marketing application. The randomized, double-blind, pivotal Phase III trials will evaluate the efficacy and safety of our product against placebo in approximately 400 patients with approximately 200 patients enrolled in each trial. The Predecessor Company completed enrollment of the study and commenced injection of subjects in early 2007. All injections were completed in January 2008 and top line results from this trial were publically announced in August 2008. The data analysis, including safety data, was publically released in October 2008. The related Biologics License Application (BLA) was submitted to the FDA in March 2009. In May 2009, the Predecessor Company announced that the FDA had completed its initial review of the Company s BLA related to its nasolabial folds/wrinkles product candidate and that the FDA had accepted (or filed) the BLA for full review.

On October 9, 2009, the FDA Cellular, Tissue and Gene Therapies Advisory Committee reviewed the Company s nasolabial folds/wrinkles product candidate. The Committee voted 11 yes to 3 no that the data presented on our product demonstrated efficacy, and 6 yes to 8 no that the data demonstrated safety; both for the proposed indication of treatment of nasolabial folds/wrinkles. The Committee's recommendations are not binding on the FDA, but the FDA will consider their recommendations during their review of our application. The United States Adopted Names (USAN) Council adopted the USAN name, azficel-T, for our nasolabial folds/wrinkles product candidate on October 28, 2009, and the FDA is currently evaluating a proposed brand name, laViv®.

On December 21, 2009, Fibrocell received a Complete Response letter from the FDA related to the BLA for azficel-T, an autologous cell therapy for the treatment of moderate to severe nasolabial folds/wrinkles in adults. A Complete Response letter is issued by the FDA s Center for Biologics Evaluation and Research (CBER) when the review of a file is completed and additional data are needed prior to approval. The Complete Response letter requested that Fibrocell Science provide data from a histopathological study on biopsied tissue samples from patients following injection of azficel-T. The histology study (IT-H-001) will evaluate tissue treated with azficel-T as compared to tissue treated with sterile saline (placebo). The study will also provide information about the skin after treatment, including evaluation of collagen and elastin fibrils, and cellular structure of the sampled tissues. The Company submitted a proposed protocol concerning a histopathological study on biopsied samples to the FDA and to the Company s Investigational Review Board (IRB). The IRB has approved the protocol and the Company received the comments from the FDA on the protocol in May 2010.

Table of Contents

107

On May 13, 2010, the Company announced the initiation of the small histology study of azficel-T, discussed above. The study had a target enrollment of approximately 20 participants from the completed and statistically significant pivotal Phase III studies of azficel-T (IT-R-005 and IT-R-006). The Company announced on July 8, 2010, the completion of enrollment of and first treatment visits for participants in its histology study of azficel-T. The second treatment visits for participants enrolled in the histology study of azficel-T were completed by the end of July. The third treatment visits for participants enrolled in the histology study of azficel-T were completed by the end of August. The Complete Response letter also requested finalized Chemistry, Manufacturing and Controls (CMC) information regarding the manufacture of azficel-T as follow-up to discussions that occurred during the BLA review period, as well as revised policies and procedures.

The Company announced on December 20, 2010, that it had submitted its complete response to the Complete Response ( CR ) letter issued by the FDA regarding the Company s BLA for azficel-T. On January 22, 2011, the FDA accepted for review the Company s complete response submission. Even though the FDA has accepted the Company s response for complete evaluation, there is no assurance that it will approve our product. The FDA, under the Prescription Drug User Fee Act ( PDUFA ), has a target six months review window to completely evaluate the Company s response. The PDUFA date is June 22, 2011.

Trading of Common Stock

The Predecessor s common stock ceased trading on the NYSE Amex on May 6, 2009 and in June 2009 the NYSE Amex delisted the Predecessor s common stock from listing on the NYSE Amex. Upon the Effective Date, the outstanding common stock of the Predecessor Company was cancelled for no consideration. Consequently, the Predecessor s stockholders prior to the Effective Date no longer have any interest as stockholders of the Predecessor Company by virtue of their ownership of the Predecessor s common stock prior to the emergence from bankruptcy. On October 21, 2009, the Successor Company was available for trading on the OTC Bulletin Board under the symbol FCSC .

#### **Note 2 Basis of Presentation**

Basis of Presentation

In June 2009, the Financial Accounting Standards Board (FASB) issued Accounting Standards Codification 105 (ASC), Generally Accepted Accounting Principles, which became the single source of authoritative nongovernmental U.S. generally accepted accounting principles (GAAP), superseding existing FASB, American Institute of Certified Public Accountants (AICPA), Emerging Issues Task Force (EITF), and related accounting literature. This pronouncement reorganizes the thousands of GAAP pronouncements into roughly 90 accounting topics and displays them using a consistent structure. Also included is relevant Securities and Exchange Commission guidance organized using the same topical structure in separate sections and will be effective for financial statements issued for reporting periods that end after September 15, 2009. This will have an impact on our financial disclosures since all future references to authoritative accounting literature will be references in accordance with ASC 105.

Financial Reporting by Entities in Reorganization under the Bankruptcy Code

On June 15, 2009 Isolagen, Inc. ( the Predecessor ) and Isolagen s wholly owned subsidiary, Isolagen Technologies, Inc. ( Isolagen Tech ) (Isolagen and Isolagen Tech are referred as the Debtors ), each filed a voluntary petition for reorganization under Chapter 11 of the United States Bankruptcy Code (the Bankruptcy Code ) in the United States Bankruptcy Court for the District of Delaware in Wilmington (the Bankruptcy Court ) under Case Nos. 09-12072 and 09-12073, respectively.

F20

On August 27, 2009 (the Confirmation Date ), the Bankruptcy Court entered an order (the Confirmation Order ) confirming the Debtors 
Joint First Amended Plan of Reorganization dated July 30, 2009, as supplemented by the Plan Supplement dated August 21, 2009 (as so modified and supplemented, the Plan ). The ( Effective Date ) of the Plan was September 3, 2009. Isolagen and Isolagen Tech emerged from bankruptcy as the reorganized debtors, Fibrocell Science, Inc. ( Fibrocell or the Company or the Successor ) and Fibrocell Technologies, Inc. ( Fibrocell Tech ), respectively (collectively, the Reorganized Debtors ), and the bankruptcy cases remain pending only to reconcile the claims asserted against the Debtors. Fibrocell now operates outside of the restraints of the bankruptcy process, free of the debts and liabilities discharged by the Plan.

Overall, ASC 852-10, Financial Reporting by Entities in Reorganization under the Bankruptcy Code, (ASC 852) applies to the Company s financial statements for the periods that the Company operated under the provisions of Chapter 11. ASC 852 does not change the application of generally accepted accounting principles in the preparation of financial statements. However, for periods including and subsequent to the filing of the Chapter 11 petition, ASC 852 does require that the financial statements distinguish transactions and events that are directly associated with the reorganization from the ongoing operations of the business. Accordingly, certain revenues, expenses, gains, and losses that were realized or incurred during the Chapter 11 proceedings have been classified as reorganization items, net on the accompanying consolidated statements of operations.

As of September 1, 2009, the Successor Company adopted fresh-start accounting in accordance with ASC 852-10. The Successor Company selected September 1, 2009, as the date to effectively apply fresh-start accounting based on the absence of any material contingencies at the September 3, 2009 effective date and the immaterial impact of transactions between September 1, 2009 and September 3, 2009. The adoption of fresh-start accounting resulted in the Successor Company becoming a new entity for financial reporting purposes. The Successor Company is a development stage company in accordance with ASC 915, Development Stage Entities. As such, the cumulative to date totals commenced on September 1, 2009 for the Successor Company.

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. See Note 5 Fresh-Start Accounting in the notes to these Consolidated Financial Statements for further details.

For discussions on the results of operations, the Successor Company has combined the results of operations for the eight months ended August 31, 2009, with the results of operations for the four months ended December 31, 2009. The combined periods have been compared to the year ended December 31, 2010. The Successor Company believes that the combined financial results provide management and investors a more meaningful analysis of the Successor Company s performance and trends for comparative purposes.

# **Note 3 Going Concern**

The Successor Company emerged from Bankruptcy in September 2009 and continues to operate as a going concern. At December 31, 2010, the Successor Company had cash and cash equivalents of approximately \$0.9 million and negative working capital of less than \$0.1 million. The Successor Company has raised approximately \$6.1 million less fees as the result of the issuance of Series D Preferred Stock and warrants in the period from January 1, 2011 through March 1, 2011. The Company received \$0.2 million in subscription receivables from a July financing in mid-March 2011.

F21

As of March 24, 2011, the Company had cash and cash equivalents of approximately \$3.4 million and current liabilities of approximately \$0.6 million. The Company s current monthly cash run-rate is approximately \$1.0 million. The Company is also planning to purchase manufacturing equipment and incur marketing expenditures within the next three months to prepare the Company for launch post a possible FDA approval. Thus, the Successor 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 Successor 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.

Further, if the Successor 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, 2010, the Successor 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 2011. During the year ended December 31, 2010, the Successor Company financed its operations primarily through its existing cash received from external financings, but as discussed above it now requires additional financing. There is substantial doubt about the Successor Company s ability to continue as a going concern.

The Successor 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 Successor Company and the offering terms. The Successor Company s ability to complete an offering is also dependent on the status of its FDA regulatory milestones and its clinical trials, and in particular, the status of its indication for the treatment of nasolabial folds/wrinkles and the potential approval of the related BLA, which cannot be predicted. 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 GAAP, there exists substantial doubt about the Successor 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 Successor 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 Successor 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.

# **Note 4 Summary of Significant Accounting Policies**

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts in the consolidated financial statements and notes. In addition, management s assessment of the Successor Company s ability to continue as a going concern involves the estimation of the amount and timing of future cash inflows and outflows. Actual results may differ materially from those estimates. *Cash and Cash Equivalents* 

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

F22

## Concentration of Credit Risk

As of December 31, 2010, the Successor Company maintains the majority of its cash primarily with one major U.S. domestic bank. All of our non-interest bearing cash balances were fully insured at December 31, 2010 due to a temporary federal program in effect from December 31, 2010 through December 31, 2012. Under the program, there is no limit to the amount of insurance for eligible accounts. Beginning 2013, insurance coverage will revert to \$250,000 per depositor at each financial institution, and our non-interest bearing cash balances may again exceed federally insured limits. The terms of these deposits are on demand to minimize risk. The Successor Company has not incurred losses related to these deposits. Cash and cash equivalents of approximately \$0.1 million, related to Agera and the Successor Company s Swiss subsidiary, is maintained in two separate financial institutions. The Successor Company invests these funds primarily in demand deposit accounts.

# Allowance for Doubtful Accounts

The Successor Company maintains an allowance for doubtful accounts related to its accounts receivable that have been deemed to have a high risk of collectability. Management reviews its accounts receivable on a monthly basis to determine if any receivables will potentially be uncollectible. One foreign customer represents 88% and 87% of accounts receivable, net, at December 31, 2010 and 2009, respectively. Management analyzes historical collection trends and changes in its customer payment patterns, customer concentration, and creditworthiness when evaluating the adequacy of its allowance for doubtful accounts. In its overall allowance for doubtful accounts, the Successor Company includes any receivable balances that are determined to be uncollectible. Based on the information available, management believes the allowance for doubtful accounts is adequate; however, actual write-offs might exceed the recorded allowance.

The allowance for doubtful accounts was \$29,280 and \$37,098 at December 31, 2010 and 2009, respectively. *Inventory* 

Agera purchases the large majority of its inventory from one contract manufacturer. Agera accounts for its inventory on the first-in-first-out method. At December 31, 2010, Agera s inventory of \$0.3 million consisted of \$0.2 million of raw materials and \$0.1 million of finished goods. At December 31, 2009, Agera s inventory of \$0.2 million consisted of \$0.2 million of raw materials and less than \$0.1 million of finished goods.

# Property and equipment

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

# Intangible assets

Intangible assets are research and development assets related to the Successor Company s primary study that was recognized upon emergence from bankruptcy (see Note 5). Intangibles are tested for recoverability whenever events or changes in circumstances indicate the carrying amount may not be recoverable. An impairment loss, if any, would be measured as the excess of the carrying value over the fair value determined by discounted cash flows. There was no impairment of the intangible assets as of December 31, 2010.

## Revenue recognition

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

F23

Revenue from the sale of Agera's products is recognized upon transfer of title, which is upon shipment of the product to the customer. The Successor Company believes that the requirements of ASC 605 are met when the ordered product is shipped, as the risk of loss transfers to our customer at that time, the fee is fixed and determinable and collection is reasonably assured. Any advanced payments are deferred until shipment.

Shipping and handling costs

Agera charges its customers for shipping and handling costs. Such charges to customers are presented net of the costs of shipping and handling, as selling, general and administrative expense, and are not significant to the consolidated statements of operations.

Advertising cost

Agera advertising costs are expensed as incurred and include the costs of public relations and certain marketing related activities. These costs are included in selling, general and administrative expenses in the accompanying consolidated statements of operations.

Research and development expenses

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

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

Other Income, Net

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. Warrant Liability

The warrants for the Successor Company are measured at fair value and liability-classified under ASC 815, Derivatives and Hedging, (ASC 815) because the warrants contain down-round protection and therefore, do not meet the scope exception for treatment as a derivative under ASC 815. Since down-round protection is not an input into the calculation of the fair value of the warrants, the warrants cannot be considered indexed to the Company s own stock which is a requirement for the scope exception as outlined under ASC 815. The fair value of the warrants 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 Successor Company 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.

F24

## 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 and D Preferred may require the Successor 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 Successor 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 Successor s consolidated balance sheet as of December 31, 2010 and will be re-measured on the Successor 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 Successor 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

The Successor Company accounts for stock-based awards to employees and non-employees using the fair value based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. The Successor Company uses a Black-Scholes options-pricing model to determine the fair value of each option grant as of the date of grant for expense incurred. The Black-Scholes model requires inputs for risk-free interest rate, dividend yield, volatility and expected lives of the options. Expected volatility is based on historical volatility of the Company s 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. The Successor Company estimates future forfeitures of options based upon expected forfeiture rates.

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

In the event the Company is charged interest or penalties related to income tax matters, the Company would record such interest as interest expense and would record such penalties as other expense in the consolidated statements of operations. No such charges have been incurred by the Company. As of December 31, 2010 and December 31, 2009, the Successor Company had no accrued interest related to uncertain tax positions.

At December 31, 2010 and December 31, 2009, the Company has provided a full valuation allowance for the net deferred tax assets, the large majority of which relates to the future benefit of loss carryovers. In addition, as a result of fresh-start accounting, the Successor Company may be limited by section 382 of the Internal Revenue Service Code. The tax years 2007 through 2010 remain open to examination by the major taxing jurisdictions to which we are subject. The deferred tax liability at December 31, 2010 and December 31, 2009, relates to the intangible assets recognized upon fresh-start accounting.

F25

## Earnings (loss) per share data

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

The Predecessor and Successor Company s potentially dilutive securities consist of potential common shares related to stock options, warrants, restricted stock and convertible preferred stock. Diluted EPS includes the impact of potentially dilutive securities except in periods in which there is a loss because the inclusion of the potential common shares would be anti-dilutive. The Company does not present diluted earnings per share for periods in which it incurred net losses as the effect is anti-dilutive. There were no potentially dilutive securities for the eight months ended August 31, 2009, due to the cancellation of the convertible notes and the cancellation of all the outstanding stock option plans and the last known market price was less than exercise price.

# Fair Value of Financial Instruments

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

The fair value of the reorganization value which applies in fresh-start accounting was estimated by applying the income approach and a market approach. This fair value measurement is based on significant inputs that are not observable in the market and, therefore, represents a Level 3 measurement as defined in ASC 820, Fair Value Measurements.

## Adoption of Standards

In January 2010, the FASB issued Accounting Standards Update ( ASU ) 2010-06, Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements ( ASU 2010-06), which amends the existing fair value measurement and disclosure guidance currently included in ASC Topic 820, Fair Value Measurements and Disclosures, to require additional disclosures regarding fair value measurements. Specifically, ASU 2010-06 requires entities to disclose the amounts of significant transfers between Level 1 and Level 2 of the fair value hierarchy and the reasons for these transfers, the reasons for any transfer in or out of Level 3 and information in the reconciliation of recurring Level 3 measurements about purchases, sales, issuances and settlements on a gross basis. In addition, ASU 2010-06 also clarifies the requirement for entities to disclose information about both the valuation techniques and inputs used in estimating Level 2 and Level 3 fair value measurements. ASU 2010-06 is effective for interim and annual reporting periods beginning after December 15, 2009, except for additional disclosures related to Level 3 fair value measurements, which are effective for fiscal years beginning after December 15, 2010. The adoption of ASU 2010-06 did not impact the Company s consolidated financial statements or results of operations.

In September 2009, the FASB issued ASU 2009-13, Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements (ASU 2009-13), which requires companies to allocate revenue in arrangements involving multiple deliverables based on the estimated selling price of each deliverable when such deliverables are not sold separately either by the company or other vendors. ASU 2009-13 eliminates the requirement that all undelivered elements must have objective and reliable evidence of fair value before a company can recognize the portion of the overall arrangement fee that is attributable to items that already have been delivered. As a result, the new guidance may allow some companies to recognize revenue on transactions that involve multiple deliverables earlier than under current requirements. ASU 2009-13 is effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption is permitted at the beginning of a company s fiscal year. The Company expects to adopt ASU 2009-13 on January 1, 2011 and does not expect ASU 2009-13 to have a material impact on its consolidated financial statements.

## **Note 5 Fresh-Start Accounting**

On September 1, 2009, the Successor Company adopted fresh-start accounting upon the emergence of bankruptcy in accordance with ASC 852-10, Reorganization. Fresh-start accounting results in the Company becoming a new entity for financial reporting purposes. Accordingly, the Company s consolidated financial statements for periods prior to September 1, 2009 are not comparable to consolidated financial statements presented on or after September 1, 2009. The Company selected September 1, 2009, as the date to apply fresh-start accounting based on the absence of any material contingencies at the September 3, 2009 effective date and the immaterial impact of transactions between September 1, 2009 and September 3, 2009.

Under ASC 852-10, the Successor Company must determine a value to be assigned to the equity of the emerging company as of the date of the adoption of fresh-start accounting. The Successor Company obtained an independent appraisal to value the equity and it served as the fair market value of the emerging Company s equity. Fresh-start accounting reflects the value of the Successor Company as determined in the confirmed Plan. Under fresh-start accounting, the Successor Company s assets values are remeasured and allocated in conformity with ASC 805-20, Business Combinations, Identifiable Assets and Liabilities, and Any Noncontrolling Interest. Fresh-start accounting also requires that all liabilities should be stated at fair value. The portion of the reorganization value which was attributed to identified intangible assets was \$6,340,656. This value is related to research and development assets that are not subject to amortization. In accordance with ASC 805-20, this amount is reported as intangibles in the consolidated balance sheets, and is not being amortized.

# Note 6 Liabilities Subject to Compromise and Reorganization Items

Liabilities subject to compromise refers to pre-petition obligations that were impacted by the Chapter 11 reorganization process. For further information regarding the discharge of liabilities subject to compromise, see Note 5- Fresh-Start Accounting in the notes of these Financial Statements. As of December 31, 2010, there were no liabilities subject to compromise.

The Company incurred certain professional fees and other expenses directly associated with the bankruptcy proceedings. In addition, the Company has made adjustments to the carrying value of certain prepetition liabilities. Such costs and adjustments are classified as reorganization items, net and are presented separately in the unaudited consolidated statements of operations. For the year ended December 31, 2010, for the four months ended December 31, 2009 and for the eight months ended December 31, 2009, the following have been incurred:

	Ye	ar ended ember 31,	Fo	Successor Four months ended December 31,		Predecessor Eight months ended
	Dec	2010	ЪС	2009	A	ugust 31, 2009
Professional fees expense Debt issuance costs related to DIP facility Other debt issuance costs Gain (loss) on discharge of liabilities subject to	\$	(13,150)	\$	(13,825)	\$	(533,271) (295,757) (280,964)
compromise		16,453		(58,652)		74,648,976
Total reorganization items, net	\$	3,303	\$	(72,477)	\$	73,538,984

F27

The \$74.6 million gain from discharge of liabilities subject to compromise is the result of the settlement of 3.5% Subordinated Notes in exchange for \$6.0 million in Notes Payable and 3,960,000 shares of the Successor company, Debtor-in-Possession Credit Facility and Prepetition Secured Loan in exchange for 7,320,000 shares of the Successor Company s common stock and unsecured claims in exchange for 120,000 shares. On the Effective Date, all stock option plans of the Predecessor Company were cancelled.

Cash paid for reorganization items during the year ended December 31, 2010 and December 31, 2009 was less than \$0.1 million and \$0.6 million, respectively. Professional fees include financial, legal and valuation services directly associated with the reorganization process.

# Note 7 Agera Laboratories, Inc.

On August 10, 2006, the Predecessor Company acquired 57% of the outstanding common shares of Agera. Agera is a skincare company that has proprietary rights to a scientifically-based advanced line of skincare products. Agera markets its product primarily in the United States and Europe. The results of Agera s operations and cash flows have been included in the consolidated financial statements from the date of the acquisition. The assets and liabilities of Agera have been included in the consolidated balance sheets since the date of the acquisition.

### **Note 8 Fair Value Measurements**

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

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

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

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

The following fair value hierarchy table presents information about each major category of the Company s financial assets and liability measured at fair value on a recurring basis as of December 31, 2010 and 2009:

	Quoted prices in	Fair value meas Significant other	urement using Significant unobservable	
	active markets	observable inputs (Level	inputs	
	(Level 1)	2)	(Level 3)	Total
At December 31, 2010				
Cash and cash equivalents	\$ 867,738	\$	\$	\$ 867,738
<b>Liabilities</b> Warrant liability Derivative liability	\$	\$	\$ 8,171,518 2,120,360	\$ 8,171,518 2,120,360
Total	\$	\$	\$ 10,291,878	\$ 10,291,878

F28

		Fair value meas	urement using	
		Significant	Significant	
	Quoted			
	prices in active	other	unobservable	
	markets	observable inputs (Level	inputs	
	(Level 1)	2)	(Level 3)	Total
At December 31, 2009	(201011)	-)	(20,010)	10001
Cash and cash equivalents	\$ 1,362,488	\$	\$	\$ 1,362,488
Liabilities				
Warrant liability	\$	\$	\$ 635,276	\$ 635,276

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

	Warrant Liability
Balance at January 1, 2009	\$
Issuance of additional warrants	316,192
Change in fair value of warrant liability	319,084
Polomos et Posomkon 21, 2000	(25.27)
Balance at December 31, 2009	635,276
Issuance of additional warrants	7,071,010
Change in fair value of warrant liability	465,232
Balance at December 31, 2010	\$ 8,171,518

The fair value of the warrant liability is based on Level 3 inputs. For this liability, the Company developed its own assumptions that do not have observable inputs or available market data to support the fair value. See note 15 for further discussion of the warrant liability.

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

	Derivative Liability
Balance at December 31, 2009 Record fair value of derivative liability	\$ 2,120,360
Balance at December 31, 2010	\$ 2,120,360

The fair value of the derivative liability is based on Level 3 inputs. For this liability, the Company developed its own assumptions that do not have observable inputs or available market data to support the fair value. See note 14 for further discussion of the derivative liability.

## **Note 9 Property and Equipment**

As of December 31, 2010 and 2009, property and equipment consisted of the following:

	ember 31, 2010	December 31, 2009
Lab equipment Computer equipment and software	\$ 18,685 10,989	\$
Less: Accumulated depreciation and amortization	29,674 (8,085)	
Property and equipment, net	\$ 21,589	\$

Depreciation expense was \$8,085 for the year ending December 31, 2010.

# **Note 10 Accrued Expenses**

Accrued expenses consist of the following:

	December 31 2010	December 31, 2009
Accrued professional fees	\$ 413,384	4 \$ 147,410
Accrued compensation	7,076	6 7,208
Accrued interest		246,578
Dividend on preferred stock payable	191,417	7 42,740
Accrued other	177,603	5 100,324
Accrued expenses	\$ 789,482	2 \$ 544,260

#### Note 11 Debt

The Successor Company s outstanding long-term debt at December 31, 2010 and December 31, 2009 consists of \$7.3 million and \$6 million, respectively, of 12.5% Unsecured Promissory Notes (New Notes). Unpaid interest has been accreted to the principal at a rate of 15%. The New Notes have the following features: (1) 12.5% interest payable quarterly in cash or, at the Successor Company s option, 15% payable in kind by capitalizing such unpaid amount and adding it to the principal as of the date it was due; (2) maturing June 1, 2012; (3) at any time prior to the maturity date, the Successor Company may redeem any portion of the outstanding principal of the New Notes in Cash at 125% of the stated face value of the New Notes. There is a mandatory redemption feature that requires the Successor Company to redeem all outstanding new notes if: (1) the Successor Company successfully completes a capital campaign raising in excess of \$10 million; or (2) the Successor Company is acquired by, or sell a majority stake to, an outside party. The current debt of \$57K is due in 2011 and the promissory note is due June 2012. Total debt is comprised of the following:

	December 31, 2010			December 31, 2009		
Current debt	\$	56,911	\$	47,795		
Total Current Debt Promissory Note		56,911 7,290,881		47,795 6,000,060		
Total debt	\$	7,347,792	\$	6,047,855		

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# **Note 12 Income Taxes**

Fibrocell Science, Inc. and Fibrocell Technologies, Inc. file a consolidated U.S. Federal income tax return. During the third quarter of 2006, the Company acquired a 57% interest in Agera (see Note 7 — Agera Laboratories, Inc. ). Agera files a separate U.S. Federal income tax return. The Company s foreign subsidiaries, which comprise loss from discontinued operations, file income tax returns in their respective jurisdictions. The geographic source of loss from continuing operations is the United States.

F30

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

	Year ended December 31, 2010	Four months ended December 31, 2009	Predecessor Eight Months ended August 31, 2009
U.S. Federal:			
Current	\$	\$	\$
Deferred			
U.S. State:			
Current			
Deferred			
	\$	\$	\$

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

	Y	Successor  Zear ended ecember 31, 2010	Successor Four months ended December 31, 2009			Predecessor ight months ended August 31, 2009
Tax expense/(benefit) at U.S. federal statutory rate Increase/(decrease) in domestic valuation allowance State income taxes/(benefit) before valuation allowance, net	\$	(4,490,789) 5,077,136	\$	(1,757,838) 2,303,065	\$	23,058,084 (30,209,991)
of federal benefit Deferred tax impact of reorganization		(789,894)		(357,619) (172,395)		4,690,990 2,261,359
Other	\$	203,547	\$	(15,213)	\$	199,558

The components of the Successor Company s net deferred tax liabilities at December 31, 2010 and 2009 are as follows:

	De	cember 31, 2010	De	ecember 31, 2009
Deferred tax liabilities: Intangible assets	\$	2,500,000	\$	2,500,000
Total deferred tax liabilities	\$	2,500,000	\$	2,500,000
Deferred tax assets: Loss carryforwards Property and equipment	\$	38,003,210 1,460,890	\$	32,942,543 1,559,631

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Accrued expenses and other Stock compensation	1,285,007 930,103	1,551,822 548,078
Total deferred tax assets Less: valuation allowance	41,679,210 (41,679,210)	36,602,074 (36,602,074)
Total deferred tax assets	\$	\$
Net deferred tax liabilities	\$ 2,500,000	\$ 2,500,000

F31

As of December 31, 2010, the Company had generated U.S. net operating loss carryforwards of approximately \$81.6 million which expire from 2026 to 2030 and net loss carryforwards in certain non-US jurisdictions of approximately \$24.4 million. The U.S. net operating loss carryforwards were reduced by approximately \$74 million as a result of the Company s emergence from bankruptcy (see Note 6 Liabilities Subject to Compromise and Reorganization Items ). The net operating loss carryforwards are available to reduce future taxable income. However, a, change in ownership, as defined by federal income tax regulations, could significantly limit the Company s ability to utilize its U.S. net operating loss carryforwards. Additionally, because federal tax laws limit the time during which the net operating loss carryforwards may be applied against future taxes, if the Company fails to generate taxable income prior to the expiration dates it may not be able to fully utilize the net operating loss carryforwards to reduce future income taxes. As the Company has had cumulative losses and there is no assurance of future taxable income, valuation allowances have been recorded to fully offset the deferred tax asset at December 31, 2010 and 2009. The valuation allowance increased by \$5.1 million during 2010, due to the impact from the current year net loss, and decreased by \$27.3 million during 2009, due primarily to the impact from the Company s reorganization described above and net loss in that period.

# Note 13 Commitments and Contingencies

Legal Proceedings

As of December 31, 2010, there were no legal proceedings.

**Employment Agreements** 

On February 1, 2010, the Company entered into an employment agreement with Mr. Pernock pursuant to which Mr. Pernock agreed to serve as Chief Executive Officer of the Company for an initial term ending February 1, 2013, which may be renewed for an additional one-year term by mutual agreement. The agreement provides for an annual salary of \$450,000. Mr. Pernock is entitled to receive an annual bonus each year, payable subsequent to the issuance of the Company s final audited financial statements, but in no case later than 120 days after the end of its most recently completed fiscal year. The final determination on the amount of the annual bonus will be made by the Board of Directors (or the Compensation Committee of the Board of Directors, if such committee has been formed), based on criteria established by the Board of Directors (or the Compensation Committee of the Board of Directors, if such committee has been formed). The targeted amount of the annual bonus shall be 60% of Mr. Pernock s base salary, although the actual bonus may be higher or lower.

Under the agreement, Mr. Pernock was granted a ten-year option to purchase 1,650,000 shares at an exercise price per share equal to the closing price of the Company's common stock on the date of execution of the agreement, or February 1, 2010. The options vest as follows: (i) 250,000 shares upon execution of the agreement; (ii) 100,000 shares upon the closing of a strategic partnership or licensing deal with a major partner that enables the Company to significantly improve and/or accelerate its capabilities in such areas as research, production, marketing and/or sales and enable the Company to reach or exceed its major business milestones within the Company's strategic and operational plans, provided Mr. Pernock is the CEO on the closing date of such partnership or licensing deal (the determination of whether any partnership or licensing deal meets the foregoing criteria will be made in good faith by the Board upon the closing of such partnership or licensing deal); and (iii) 1,300,000 shares in equal 1/36th installments (or 36,111 shares per installment) monthly over a three-year period, provided Executive is the CEO on each vesting date. The vesting of all options set forth above shall accelerate upon a change in control as defined in the agreement, provided Mr. Pernock is employed by the Company within 60 days prior to the date of such change in control.

F32

If Mr. Pernock s employment is terminated at the Company s election at any time, for reasons other than death, disability, cause (as defined in the agreement) or a voluntary resignation, or by Mr. Pernock for good reason (as defined in the agreement), Mr. Pernock shall be entitled to receive severance payments equal to twelve months of Mr. Pernock s base salary and of the premiums associated with continuation of Mr. Pernock s benefits pursuant to COBRA to the extent that he is eligible for them following the termination of his employment; provided that if anytime within eighteen months after a change in control either (i) Mr. Pernock is terminated, at the Company s election at any time, for reasons other than death, disability, cause or voluntary resignation, or (ii) Mr. Pernock terminates the agreement for good reason, Mr. Pernock shall be entitled to receive severance payments equal to: (1) two years of Mr. Pernock s base salary, (2) Mr. Pernock s most recent annual bonus payment, and (3) the premiums associated with continuation of Mr. Pernock s benefits pursuant to COBRA to the extent that he is eligible for them following the termination of his employment for a period of one year after termination. All severance payments shall be made in a lump sum within ten business days of Mr. Pernock s execution and delivery of a general release of the Company, its parents, subsidiaries and affiliates and each of its officers, directors, employees, agents, successors and assigns in a form acceptable to the Company. If severance payments are being made, Mr. Pernock has agreed not to compete with the Company until twelve months after the termination of his employment.

On August 24, 2010, the Company entered into an amended and restated employment agreement with Mr. Declan Daly, which replaced and terminated his prior employment agreement with the Company, pursuant to which Mr. Daly agreed to serve as Chief Operating Officer and Chief Financial Officer of the Company for an initial term ending August 24, 2013, which may be renewed for an additional one-year term by mutual agreement. The agreement provides for an annual salary of \$300,000. Mr. Daly is entitled to receive an annual bonus each year, payable subsequent to the issuance of the Company s final audited financial statements, but in no case later than 120 days after the end of its most recently completed fiscal year. The final determination on the amount of the annual bonus will be made by the Board of Directors (or the Compensation Committee of the Board of Directors, if such committee has been formed), based on criteria established by the Board of Directors (or the Compensation Committee of the Board of Directors, if such committee has been formed). The targeted amount of the annual bonus shall be 50% of Mr. Daly s base salary, although the actual bonus may be higher or lower.

Under the agreement, Mr. Daly was granted a ten-year option to purchase 400,000 shares at an exercise price per share equal to the closing price of the Company s common stock on the date of execution of the agreement, or \$0.55 per share. The options vest as follows: (i) 40,000 shares upon execution of the agreement; and (ii) 360,000 shares in equal 1/36th installments (or 10,000 shares per installment) monthly over a three-year period, provided Mr. Daly is the COO or CFO on each vesting date. The vesting of all options set forth above shall accelerate upon a change in control as defined in the agreement, provided Mr. Daly is employed by the Company within 60 days prior to the date of such change in control.

Mr. Daly is entitled to receive a one-time bonus in the amount of \$50,000 (the Milestone Bonus ) upon the FDA s approval of the Company s Biologics License Application filing, provided that Mr. Daly is the CFO or COO at the time of said event.

If Mr. Daly s employment is terminated at the Company s election at any time, for reasons other than death, disability, cause (as defined in the agreement) or a voluntary resignation, or by Mr. Daly for good reason (as defined in the agreement), Mr. Daly shall be entitled to receive severance payments equal to twelve months of Mr. Daly s base salary and of the premiums associated with continuation of Mr. Daly s benefits pursuant to COBRA to the extent that he is eligible for them following the termination of his employment; provided that if anytime within eighteen months after a change in control either (i) Mr. Daly is terminated, at the Company s election at any time, for reasons other than death, disability, cause or voluntary resignation, or (ii) Mr. Daly terminates the agreement for good reason, Mr. Daly shall be entitled to receive severance payments equal to: (1) two years of Mr. Daly s base salary, (2) Mr. Daly s most recent annual bonus payment, and (3) the premiums associated with continuation of Mr. Daly s benefits pursuant to COBRA to the extent that he is eligible for them following the termination of his employment for a period of one year after termination. All severance payments shall be made in a lump sum within ten business days of Mr. Daly s execution and delivery of a general release of the Company, its parents, subsidiaries and affiliates and each of its officers, directors, employees, agents, successors and assigns in a form acceptable to the Company. If severance payments are

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being made, Mr. Daly has agreed not to compete with the Company until twelve months after the termination of his employment.

F33

## **Consulting Agreements**

In June 2010, we entered into two consulting agreements with two individuals. We issued the two consultants options to purchase 150,000 shares each. The options have an expiration date five years from the date of issuance and an exercise price of \$0.93 per share.

In September 2010, we entered into a consulting agreement with one individual and issued the consultant options to purchase 120,000 shares. The options have an expiration date five years from the date of issuance and an exercise price of \$0.59 per share.

Effective upon our exit from bankruptcy on September 3, 2009, we entered into a consultant agreement, pursuant to which Dr. Langer agreed to provide consulting services to us, including serving as a scientific advisor. The agreement has a one year term, provided that either party may terminate the agreement on 30 days notice. The agreement provides Dr. Langer annual compensation of \$50,000.

In October 2009, we entered into two consulting agreements with two individuals. We issued the two consultants options to purchase 200,000 shares and 150,000 shares, respectively. The options have an expiration date five years from the date of issuance and an exercise price of \$0.75 per share.

In December 2009, we entered into a consulting agreement with one individual and issued the consultant options to purchase 100,000 shares. The options have an expiration date five years from the date of issuance and an exercise price of \$1.25 per share.

#### Leases

The Company has entered into a lease for office, warehouse and laboratory facilities in Exton, Pennsylvania under a third party non-cancelable operating lease through 2013. Future minimum lease commitments at December 31, 2010 are as follows:

# **Year Ending**

December 31,		_
	December	31,

2011	\$ 1,194,350
2012	1,194,350
2013	298,588

Total \$ 2,687,288

For each of the years ended December 31, 2010 and 2009, rental expense totaled \$1.4 million.

In April 2005, the Company entered into a non-cancelable three year operating lease for approximately 86,500 square feet in Exton, Pennsylvania. This facility houses members of the senior management team, quality and manufacturing personnel, and the corporate finance department. The Company began constructing a production line in a portion of this facility in anticipation of eventual FDA approval. The facility was completed during September 2005. This production line is expected to be utilized for the production of clinical supplies. During 2007, the Company extended the lease through March 31, 2013. Lease expense is recognized on a straight-line basis through March 31, 2013. The Exton, Pennsylvania minimum lease payments are included in the future minimum lease commitments table above through March 31, 2013.

# **Note 14 Equity**

Redeemable Preferred stock

As of December 31, 2010 the number of Redeemable Preferred stock ( Preferred ) outstanding, with a par value of \$0.001 per share and a stated value of \$1,000 per share is as follows:

Preferred stock Series A	2,886
Preferred stock Series B	4,640
Preferred stock Series D	1,645

Total 9,171

Terms of Redeemable Preferred stock

Dividends; Rank; Liquidation

Holders of the Preferred stock Series A ( Series A Preferred ), Preferred stock Series B ( Series B Preferred ) and Preferred stock Series D ( Series D Preferred ) 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 on January 15, April 15, July 15 and October 15. 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.

The Series A Preferred, Series B Preferred and Series D Preferred ranks senior to all shares of Company common stock (Common Stock). The Series D Preferred ranks junior to the Company s Series A Preferred and Series B Preferred.

Upon our liquidation, dissolution or winding-up, whether voluntary or involuntary, the holders of the Series A Preferred, Series B Preferred and Series D Preferred shall be entitled to receive out of our assets, whether capital or surplus, an amount equal to the stated value of the common stock, plus any accrued and unpaid dividends thereon and any other fees or liquidated damages then due and owing thereon under the Certificate of Designation, for each share of Series A Preferred, Series B Preferred and Series D Preferred before any distribution or payment shall be made to the holders of any junior securities, and if our assets are insufficient to pay in full such amounts, then the entire assets to be distributed to the holders of the Series A Preferred, Series B Preferred and Series D Preferred shall be ratably distributed among the holders in accordance with the respective amounts that would be payable on such shares if all amounts payable thereon were paid in full.

Conversion; Conversion Price; Forced Conversion; Optional Redemption

Each share of Series A Preferred, Series B Preferred and Series D Preferred is convertible into a number of shares of common stock equal to (1) the stated value of the share (\$1,000), divided by (2) \$0.50 (as a result of the December 2010 Series D Preferred financing), subject to adjustment as discussed below. We refer to this price as the Conversion Price.

With certain exceptions, if, at any time while the Series A Preferred, Series B Preferred and Series D Preferred is outstanding, we sell or grant any option to purchase or sell or grant any right to reprice, or otherwise dispose of or issue (or announce any sale, grant or any option to purchase or other disposition), any common stock or common stock equivalents at an effective price per share that is lower than the then Conversion Price, then the Conversion Price will be reduced to equal the lower price (down-round provision). The Conversion Price is also subject to proportional adjustment in the event of any stock split, stock dividend, reclassification or similar event with respect to the common stock.

Commencing six months from the date of the agreement pursuant to which we issued the Series A Preferred, Series B Preferred and Series D Preferred, if the volume weighted average price for each of any 20 consecutive trading days exceeds 200% of the then effective Conversion Price and various other equity conditions are satisfied (including that the resale of the shares underlying the Series A Preferred, Series B Preferred and Series D Preferred, has been registered under the Securities Act), upon 30 days notice, the Series A Preferred, Series B Preferred and Series D Preferred plus all accrued and unpaid dividends will automatically convert into shares of common stock.

F35

Voting

Commencing two years from the date of the agreement pursuant to which we issued the Series A Preferred, Series B Preferred and Series D Preferred, upon 30 days notice and provided various other equity conditions are satisfied (including that the resale of the shares underlying the Series A Preferred, Series B Preferred and Series D Preferred has been registered under the Securities Act), we may redeem some or all of the then outstanding Series A Preferred, Series B Preferred and Series D Preferred for cash in an amount equal to the 150% of the stated value of the Series A Preferred, Series B Preferred and Series D Preferred.

The holders of the Series A Preferred, Series B Preferred and Series D Preferred have no voting rights except with respect to specified matters affecting the rights of the Series A Preferred, Series B Preferred and Series D Preferred. *Negative Covenants* 

As long as any shares of Series A Preferred, Series B Preferred and Series D Preferred are outstanding, we may not, directly or indirectly: (a) amend our charter documents in any manner that materially and adversely affects any rights of the holders of the Series A Preferred, Series B Preferred and Series D Preferred; (b) pay cash dividends or distributions on our junior securities (including the common stock); or (c) enter into any transaction with any affiliate of ours which would be required to be disclosed in any public filing, unless such transaction is made on an arm s-length basis and expressly approved by a majority of our disinterested directors. *Triggering Events* 

In the event of a Triggering Event (as defined in the Certificate of Designation and described below), any holder of Series A Preferred, Series B Preferred and Series D Preferred may require us to redeem all of its Series A Preferred, Series B Preferred and Series D Preferred, at a redemption price equal to the greater of (a) 130% of the stated value and (b) the product of (i) the volume weighted average price on the trading day immediately preceding the date of the Triggering Event and (ii) the stated value divided by the then Conversion Price, plus all accrued but unpaid dividends thereon and all liquidated damages and other costs, expenses or amounts due in respect of the Series A Preferred, Series B Preferred and Series D Preferred. Triggering Events include, among other things, bankruptcy related events, change of control transactions (as defined in the Certificate of Designation), and various types of failures to perform under, and breaches of, the transaction documents.

# Preferred Stock Series A

In October 2009, the Successor Company completed an offering of Series A Preferred, Class A Warrants and Class B Warrants (the October 2009 Offering). Each of the foregoing securities were subject to the down-round protection, which provisions require the lowering of the conversion price or exercise price, as applicable, to the purchase price in the recent December 2010 Series D Preferred offering, or \$0.50, and with respect to the warrants, the number of shares issuable under the warrants issued in the October 2009 Offering were proportionately increased such that the aggregate exercise price payable, after taking into consideration the decrease in exercise price, is now equal to the aggregate exercise price prior to such adjustment. 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 Preferred may require the Successor Company to redeem all of its Series A Preferred in the event of a triggering event which is outside of the control of the Successor Company. After giving effect to this anti-dilution provision, as of December 31, 2010, there will be 5,772,000 shares of Common Stock underlying the Series A Preferred, Class A warrants to purchase 1,624,996 shares of Common Stock at an exercise price of \$0.50 per share, Class B warrants to purchase 650,000 shares of Common Stock at an exercise price of \$0.50 per share and co-placement warrants to purchase 650,000 shares of Common Stock at an exercise price of \$0.50 per share.

Holders of the Series A Preferred are entitled to receive cumulative dividends at the rate per share of 6% per annum, payable quarterly in arrears on January 15, April 15, July 15 and October 15, beginning on April 15, 2010. As of December 31, 2010, \$92,404 was accrued for dividends payable.

F36

# Preferred Stock Series B

In 2010, the Successor Company completed an offering of Series B Preferred and warrants (the Warrants). Each of the foregoing securities were subject to the down-round protection, which provisions require the lowering of the conversion price or exercise price, as applicable, to the purchase price in the recent December 2010 Series D offering, or \$0.50, and with respect to the warrants, the number of shares issuable under the warrants issued in the 2010 Offerings were proportionately increased such that the aggregate exercise price payable, after taking into consideration the decrease in exercise price, is now equal to the aggregate exercise price prior to such adjustment. 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 B Preferred may require the Successor Company to redeem all of its Series B Preferred in the event of a triggering event which is outside of the control of the Successor Company.

The Successor Company records accrued dividends at a rate of 6% per annum on the Series B Preferred. The Successor Company records accrued dividends at a rate of 6% per annum on the Series B Preferred. As of December 31, 2010, \$96,581 is accrued for dividends payable.

The details of the 2010 Preferred Stock Series B financing are as follows:

In the third and fourth quarter of 2010, the Company entered into a Securities Purchase Agreement (the Purchase Agreement ) with certain accredited investors (the Purchasers), pursuant to which the Company agreed to sell to the Purchasers in the aggregate: (i) 4,640 shares of Series B Preferred, with a par value of \$0.001 per share and a stated value of \$1,000 per share Series B Preferred, and (ii) the Warrants to purchase 7,733,334 shares of Common Stock at an exercise price of \$0.8054 per share. As of December 31, 2010, the Company had not received \$210,000 in subscription proceeds representing 210 shares Series B Preferred and Warrants to purchase 350,000 shares. Upon receipt of these subscription proceeds, the Company will issue the foregoing securities. The aggregate purchase price for the third and fourth quarter 2010 Series B Preferred financing paid by the Purchasers for the Series B Preferred and the Warrants was \$4,430,000 (representing \$1,000 for each share of Series B Preferred together with the Warrants and adjusted for subscription receivable of \$210,000). The Company used the proceeds for working capital purposes.

Viriathus Capital LLC and John Carris Investments LLC were co-placement agents for the Transaction, and received, in the aggregate, cash compensation of \$354,400 and warrants to purchase 590,657 (adjusted for subscription receivable of \$210,000) shares of Common Stock at an exercise price of \$0.60 per share. As a result of the December 2010 Series D Preferred Stock transaction the shares and warrants were repriced to \$0.50 per share. After giving effect to this anti-dilution provision, as of December 31, 2010, there will be 9,280,000 shares of Common Stock underlying the Series B Preferred, warrants to purchase 12,456,853 shares of Common Stock at an exercise price of \$0.50 per share and co-placement warrants to purchase 708,789 shares of Common Stock at an exercise price of \$0.50 per share.

## Preferred Stock Series D

On December 15, 17 and 27, 2010, the Successor Company completed a private placement of securities of Series D Preferred and warrants. Each of the foregoing securities were subject to the down-round protection and if at any time while the Series D Preferred is outstanding, we sell or grant any option to purchase or sell or grant any right to reprice, or otherwise dispose of or issue (or announce any sale, grant or any option to purchase or other disposition), any common stock or common stock equivalents at an effective price per share that is lower than the then Conversion Price, then the Conversion Price will be reduced to equal the lower price. 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 D Preferred may require the Successor Company to redeem all of its Series D Preferred in the event of a triggering event which is outside of the control of the Successor Company.

Table of Contents

132

The Successor Company records accrued dividends at a rate of 6% per annum on the Series D Preferred. The Successor Company records accrued dividends at a rate of 6% per annum on the Series D Preferred. As of December 31, 2010, \$2,432 is accrued for dividends payable.

The details of the 2010 Series D Preferred financing are as follows:

1,645 shares of Series D Preferred, with a par value of \$0.001 per share and a stated value of \$1,000 per share and (ii) warrants to purchase 3,290,000 shares of Common Stock at an exercise price of \$0.50 per share.

The aggregate purchase price paid by the Purchasers for the Series D Preferred and the Warrants was \$1,645,000 (representing \$1,000 for each share of Series D Preferred together with Warrants).

The placement agents for the Transactions received cash compensation of \$131,600 and warrants to purchase 263,200 shares of Common Stock at an exercise price of \$0.50 per share (assuming all subscription proceeds are received in the Transactions).

Conversion option of Redeemable Preferred stock

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 Successor s consolidated balance sheet as of December 31, 2010 and will be re-measured on the Successor 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 Successor 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.

The embedded conversion option for the Series A Preferred, Series B Preferred and Series D Preferred was valued at \$2,120,360 at December 31, 2010 at fair value using the Black-Scholes option pricing model. The fair market value of the derivative liability was computed using the Black-Scholes option-pricing model with the following weighted average assumptions:

> December 31, 2010

Expected life (years) 1.6 years Interest rate 1.6%

Dividend yield

Volatility 63%

Common Stock Offering

On March 2, 2010, the Company entered into a Securities Purchase Agreement with certain accredited investors, pursuant to which the Company sold to the Purchasers in the aggregate 5,076,664 shares of common stock at a purchase price of \$0.75 per share. Each Purchaser also received a warrant to purchase the same number of shares of Common Stock acquired in the offering at an exercise price of \$0.98 per share.

The aggregate purchase price paid by the Purchasers for the common stock and the warrants was \$3,807,500. The Company used the proceeds for working capital purposes.

Viriathus Capital LLC and John Carris Investments LLC were co-placement agents for the transaction, and received cash compensation of \$304,600 and warrants to purchase 406,133 shares of common stock at an exercise price of \$0.75 per share upon the closing.

F38

Each of the foregoing securities were subject to the down-round protection and if at any time while the Common Stock is outstanding, we sell or grant any option to purchase or sell or grant any right to reprice, or otherwise dispose of or issue (or announce any sale, grant or any option to purchase or other disposition), any common stock or common stock equivalents at an effective price per share that is lower than the then Conversion Price, then the Conversion Price will be reduced to equal the lower price. As of result of the December 2010 Series D Preferred Stock transaction the Warrants were repriced to \$0.50 per share. After giving effect to this anti-dilution provision, as of December 31, 2010, there will be Warrants to purchase 9,950,261 shares of Common Stock at an exercise price of \$0.50 per share and co-placement warrants to purchase 609,200 shares of Common Stock at an exercise price of \$0.50 per share.

### **Note 15 Warrants**

Preferred Stock Series A Class A and B Warrants and Placement Agent Warrants

As disclosed above in Note 9, the Successor Company issued Class A warrants, Class B warrants and placement agent warrants in connection with the October 2009 preferred stock transaction. The warrants are liability classified since they have down-round price protection and they are re-measured on the Company s reporting dates. As a result of the December 2010 Series D convertible preferred stock financing and the down-round provision, the Class A warrants, Class B warrants and placement agent warrants were reissued to purchase approximately 3.9 million shares of Common Stock at an exercise price of \$0.50 per share.

Preferred Stock Series B Warrants and Co-placement Agent Warrants

In connection with the Series B Convertible Preferred Stock transaction, the Successor Company issued warrants and co-placement agent warrants. The warrants are liability classified since they have down-round price protection and they are re-measured on the Company s reporting dates. As a result of the December 2010 Series D convertible preferred stock financing and the down-round provision, the Series B warrants and co-placement agent warrants were reissued to purchase approximately 13.2 million shares of Common Stock at an exercise price of \$0.50 per share. *Preferred Stock Series D Warrants and Co-placement Agent Warrants* 

In connection with the Series D Convertible Preferred Stock transaction, the Successor Company issued 3,290,000 warrants at an exercise price of \$0.50 per share and 263,200 placement agent warrants at an exercise price of \$0.50 per share. The warrants are liability classified since they have down-round price protection and they are re-measured on the Company s reporting dates. The weighted average fair market value of the warrants, at the date of issuance, granted to the accredited investors and co-placement agents, based on the Black-Scholes valuation model, is estimated to be \$0.31 per warrant.

Common Stock Warrants and Co-placement Agent Warrants

In connection with the March 2, 2010 financing, the Successor Company issued 5,076,664 warrants at an exercise price of \$0.98 per share to the accredited investors and 406,133 warrants at an exercise price of \$0.75 to the co-placement agents upon closing. The warrants are liability classified since they have down-round price protection and they are re-measured on the Company s reporting dates. The warrants were exercisable immediately after grant and expire five years thereafter. The fair market value of the warrants, at the date of issuance, granted to the accredited investors and co-placement agents, based on the Black-Scholes valuation model, is estimated to be \$0.52 per warrant and \$0.58 per warrant, respectively. As a result of the Convertible Preferred Stock Series B financing and the down-round provision, the Common Stock warrants and placement agent warrants were reissued to purchase 10.6 million shares of Common Stock at an exercise price of \$0.50 per share.

F39

The Successor Company recognizes these warrants as a liability at the fair value on each reporting date due to the down-round price protection provision. The Company measured the fair value of these warrants as of December 31, 2010, and recorded warrant expense of \$2.0 million resulting from the increase in the liability associated with the fair value of the warrants for the three months ended December 31, 2010. The Company computed the value of the warrants using the Black-Scholes method. The fair value of the warrants will continue to be classified as a liability until such time as the warrants are exercised, expire or an amendment of the warrant agreements renders these warrants to be no longer classified as a liability. The warrants are exercisable upon issuance and expire on the fifth anniversary of issuance. There were no warrants exercised in 2010.

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

	December 31,	December 31,		
	2010	2009		
Expected life (years)	4.7 years	4.8 years		
Interest rate	1.8%	2.7%		
Dividend yield				
Volatility	63%	66%		

Roll forward of Successor Company warrant liability from December 31, 2009 through December 31, 2010:

	D	ecember 31, 2009	Additions	Revaluation	Ι	December 31, 2010
Preferred stock class A warrants	\$	275,378	\$	\$ 120,711	\$	396,089
Preferred stock class B warrants		207,611		188,478		396,089
Preferred stock co-placement warrants		152,287		6,150		158,437
Common stock warrants			2,654,752	(123,604)		2,531,148
Common stock placement warrants			235,958	(80,990)		154,968
Preferred stock series B warrants			2,837,394	522,678		3,360,072
Preferred stock series B co-placement						
warrants			249,778	(58,784)		190,994
Preferred stock series D warrants			1,011,553	(100,717)		910,836
Preferred stock series D co-placement						
warrants			81,575	(8,690)		72,885
Total	\$	635,276	\$ 7,071,010	\$ 465,232	\$	8,171,518

Warrant liability is comprised of the following as of December 31, 2010:

	Successor			
	Number of	Fair Value of	December 31,	
	Warrants	Warrants	2010	
Preferred stock class A warrants	1,624,996	\$ 0.24	\$ 396,089	
Preferred stock class B warrants	1,624,996	0.24	396,089	
Preferred stock co-placement warrants	650,000	0.24	158,437	
Common stock warrants	9,950,261	0.25	2,531,148	
Common stock placement warrants	609,200	0.25	154,968	
Preferred stock series B warrants	12,456,853	0.27	3,360,072	
Preferred stock series B co-placement warrants	708,789	0.27	190,994	
Preferred stock series D warrants	3,290,000	0.28	910,836	
Preferred stock series D co-placement warrants	263,200	0.28	72,885	

Total 31,178,295 \$ 0.26 \$ 8,171,518

Warrant liability is comprised of the following as of December 31, 2009:

			Successor	•		
	Fair Value					
	Number of		of	Ba	lance as of	
				De	cember 31,	
	Warrants	Warrants		2009		
Preferred stock class A warrants	501,543	\$	0.55	\$	275,378	
Preferred stock class B warrants	416,667		0.50		207,611	
Preferred stock co-placement warrants	250,000		0.61		152,287	
Total	1,168,210			\$	635,276	

F40

## **Note 16 Equity-based Compensation**

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

	Successor Twelve months December 31, 2010		~	Successor		edecessor Eight
			Four months December		months	
				31, 2009		August 31, 2009
Stock option compensation expense for employees and						
directors	\$	833,713	\$	326,838	\$	581,707
Restricted stock expense		72,000		168,000		
Equity awards for nonemployees issued for services		86,828		386,380		1,746
Total stock-based compensation expense	\$	992,541	\$	881,218	\$	583,453

# Successor Company

Our board of directors adopted the 2009 Equity Incentive Plan (the Plan ) effective September 3, 2009. The Plan is intended to further align the interests of the Successor Company and its stockholders with its employees, including its officers, non-employee directors, consultants and advisors by providing incentives for such persons to exert maximum efforts for the success of the Successor Company. The Plan allows for the issuance of up to 4,000,000 shares of the Successor Company s common stock. Subsequent to December 31, 2010, the board of directors of the Company amended the 2009 Equity Incentive Plan to increase the number of shares available for issuance under the Plan to 15,000,000 shares of common stock. The types of awards that may be granted under the Plan include options (both nonqualified stock options and incentive stock options), stock appreciation rights, stock awards, stock units, and other stock-based awards. Notwithstanding the foregoing, to the extent the Successor Company is unable to obtain shareholder approval of the Plan within one year of the effective date, any incentive stock options issued pursuant to the Plan shall automatically be considered nonqualified stock options, and to the extent a holder of an incentive stock option exercises his or her incentive stock option prior to such shareholder approval date, such exercised option shall automatically be considered to have been a nonqualified stock option. The term of each award is determined by the Board at the time each award is granted, provided that the terms of options may not exceed ten years. On February 23, 2010, modifications were made to all fiscal year 2009 grants for directors and employees. The modifications provided for all options granted under the 2009 Plan in fiscal year 2009 to extend to a ten year term and allowed Directors to extend the exercise period after departure to one year. As a result of the modifications, the Successor Company recognized incremental compensation cost of approximately \$149,000 in the first quarter of 2010.

F41

During the year ended December 31, 2010, the weighted average fair market value using the Black-Scholes option-pricing model of the options granted was \$0.53 for this period. During the period September 2009 through December 2009, the weighted average fair market value using the Black-Scholes option-pricing model of the options granted was \$0.33 for this period. The fair market value of the stock options at the date of grant was estimated using the Black-Scholes option-pricing model with the following weighted average assumptions:

	Year Ended	Four Months Ended
	December 31, 2010	December 31, 2009
Expected life	5.1 years	2.7 years
Interest rate	2.0%	1.4%
Di Dividend yield		
Volatility	64%	67%

There were no stock options exercised during the year ended December 31, 2010 and the period September 2009 through December 2009.

A summary of option activity for the year ended December 31, 2010 is as follows:

Options	Shares	Av Ex	eighted verage vercise Price	Weighted Average Remaining Contractual Term	Int	gregate crinsic alue
Outstanding at January 1, 2010	2,807,000	\$	0.77	7.35	\$	0.38
Granted Exercised Forfeited	2,870,000		0.95			
Outstanding at December 31, 2010	5,677,000	\$	0.86	7.46	\$	
Options exercisable at December 31, 2010	3,627,384	\$	0.84	7.16	\$	

The following table summarizes the Successor Company s non-vested stock options:

	Non-vested Options			
		We	ighted-	
	Number of	Average Fair		
	Shares	7	<b>Value</b>	
Non-vested at January 1, 2010	677,000	\$	0.36	
Granted	2,870,000		0.53	
Vested	(1,497,384)		0.49	
Forfeited				
Non-vested at December 31, 2010	2,049,616	\$	0.50	

The total fair value of shares vested during the twelve months ended December 31, 2010 was \$0.8 million. As of December 31, 2010, there was \$0.7 million of total unrecognized compensation cost, related to non-vested stock

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options which vest over time. That cost is expected to be recognized over a weighted-average period of two years. As of December 31, 2010, there was \$0.3 million of total unrecognized compensation expense related to performance-based, non-vested employee and consultant stock options. That cost will be recognized when the performance criteria within the respective performance-based option grants become probable of achievement.

F42

#### Restricted stock

The following table summarizes the Successor s restricted stock activity for the year ended December 31, 2010:

	Non-vested Options			
		Weighted-		
	Number of	Average Fair		
	Shares	V	alue	
Non-vested at January 1, 2010	300,000	\$	0.48	
Granted				
Vested	(150,000)		0.48	
Forfeited				
Non-vested at December 31, 2010	150,000	\$	0.48	

As of December 31, 2010, there was less than \$0.1 million of total unrecognized compensation cost related to non-vested restricted stock that is expected to be recognized over a weighted-average period less than 1 year. *Predecessor Company* 

Prior to September 3, 2009, the Effective Date, the Predecessor Company maintained stock-based incentive compensation plans for employees and directors of the Company. On the Effective Date, the following stock option plans were terminated (and any and all awards granted under such plans were terminated and will no longer be of any force or effect): (1) the 2001 Stock Option and Appreciation Rights Plan, (2) the 2003 Stock Option and Appreciation Rights Plan. As a result of the cancellation of the stock options, the Predecessor Company recorded additional stock compensation expense of \$0.3 million for the unrecognized stock compensation expense.

# Note 17 Segment Information and Geographical information

The Successor Company has two reportable segments: Fibrocell Therapy and Agera. The Fibrocell Therapy segment specializes in the development and commercialization of autologous cellular therapies for soft tissue regeneration. The Agera segment maintains proprietary rights to a scientifically-based advanced line of skincare products. There is no intersegment revenue. The following table provides operating financial information for the continuing operations of the Successor Company s two reportable segments:

		Successor Fibrocell		Segment		Successor	
Year Ended December 31, 2010		herapy	Agera		Consolidated		
Total operating revenue	\$	<b>P</b> J	\$	936,369	\$	936,369	
Segment income (loss) from continuing operations	\$ (12,840,598)		\$	9,770	\$ (12,830,828)		
Supplemental information related to continuing operations							
Depreciation and amortization expense	\$	8,085	\$		\$	8,085	
Total assets, including assets from discontinued operations as of							
December 31, 2010		7,681,502		596,643		8,278,145	
Property and equipment, net	21,589					21,589	
Intangible assets, net	6,340,656				6,340,656		
An intercompany receivable as of December 31, 2010, of \$0.9 mil	lion, d	ue from the	Agei	ra segment t	to the l	Fibrocell	

An intercompany receivable as of December 31, 2010, of \$0.9 million, due from the Agera segment to the Fibrocell Therapy segment, is eliminated in consolidation. This intercompany receivable is primarily due to the intercompany

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management fee charge to Agera by Fibrocell Technologies, Inc., as well as Agera working capital needs provided by Fibrocell Technologies, Inc., and has been excluded from total assets of the Fibrocell Therapy segment in the above table. There is no intersegment revenue. Total assets on the consolidated balance sheet at December 31, 2010 are approximately \$8.3 million, which includes assets of discontinued operations of less than \$0.1 million.

F43

	Successor	Segment	Successor  Consolidated \$ 329,941	
Four Months Ended December 31, 2009 Total operating revenue	Fibrocell Therapy \$	<b>Agera</b> \$ 329,941		
Segment income (loss) from continuing operations	\$ (5,026,024)	\$ 3,631	\$ (5,022,393)	
Supplemental information related to continuing operations				
Depreciation and amortization expense	\$	\$	\$	
Total assets, including assets from discontinued operations as of December 31, 2009  Property and equipment, net	8,092,816	631,393	8,724,209	
Intangible assets, net	6,340,656		6,340,656	
	Predecessor	Segment	Predecessor	
Eight Months Ended August 31, 2009	Isolagen Therapy	Agera	Consolidated	
Total operating revenue	\$	\$ 538,620	\$ 538,620	
Segment income from continuing operations	\$ 65,498,934	\$ 381,306	\$ 65,880,240	

An intercompany receivable as of December 31, 2009, of \$1.0 million, due from the Agera segment to the Fibrocell Therapy segment, is eliminated in consolidation. This intercompany receivable is primarily due to the intercompany management fee charge to Agera by Fibrocell Technologies, Inc., as well as Agera working capital needs provided by Fibrocell Technologies, Inc., and has been excluded from total assets of the Fibrocell Therapy segment in the above table. There is no intersegment revenue. Total assets on the consolidated balance sheet at December 31, 2009 are approximately \$8.7 million, which includes assets of discontinued operations of less than \$0.1 million. Geographical information concerning the Company s revenue is as follows:

		Successor Year ended December 31,	F	Successor our months ended ecember 31,	Predecessor Eight months ended	
	2010			2009	August 31, 2009	
United States	\$	237,286	\$	68,526	\$	187,289
United Kingdom		669,921		251,615		308,244
Other		29,162		9,800		43,087
	\$	936,369	\$	329,941	\$	538,620

During 2010, revenue from one foreign customer and one domestic customer represented 72% and 17% of consolidated revenue, respectively. During the four months ended December 31, 2009, revenue from one foreign customer and one domestic customer represented 79% and 15% of consolidated revenue, respectively. During the

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eight months ended August 31, 2009, revenue from one foreign customer and one domestic customer represented 57% and 23% of consolidated revenue, respectively.

As of December 31, 2010 and December 31, 2009, one foreign customer represented 88% and 87%, respectively, of accounts receivable, net.

F44

## **Note 18 Subsequent Events**

On January 14, 2011, the board of directors of the Company amended the 2009 Equity Incentive Plan (the Plan ) to increase the number of shares available for issuance under the Plan to 15,000,000 shares of common stock. On January 14, 2011, the board of directors agreed to provide: (i) Mr. David Pernock, Chief Executive Officer and President, with an option to purchase 2,100,000 shares of Company common stock; (ii) Mr. Declan Daly, Chief Financial Officer, with an option to purchase 1,065,000 shares of Company common stock; and (iii) Messrs. Kelvin Moore, Robert Langer, Marc Mazur, and George Korkos, each a director of the Company, with an option to purchase 200,000 shares of Company common stock. Each of the foregoing options has: (i) a ten-year term, (ii) an exercise price equal to the closing price of the Company s common stock on the date of grant, and (iii) vests 50% on the date of grant; 25% on the one-year anniversary of the date of grant; and 25% on the two-year anniversary of the date of grant; provided in each case that the grantee is providing service to the Company on the vesting date.

On January 21, 2011, the Company completed a private placement of securities in which the Company sold to certain accredited investors in the aggregate: (i) 1,234 shares of Series D Convertible Preferred Stock, with a par value of \$0.001 per share and a stated value of \$1,000 per share (Series D Preferred), and (ii) warrants to purchase 2,468,000 shares of Company common stock (Common Stock) at an exercise price of \$0.50 per share.

The aggregate purchase price paid by the Purchasers for the Series D Preferred and the Warrants was \$1,234,000 (representing \$1,000 for each share of Series D Preferred together with warrants). The Company intends to use the proceeds for working capital purposes.

The placement agents for the offering received cash compensation of \$98,720 and warrants to purchase 197,440 shares of Common Stock at an exercise price of \$0.50 per share.

On January 28, 2011, the Company completed a private placement of securities in which the Company sold to certain accredited investors in the aggregate: (i) 1,414 shares of Series D at a stated value of \$1,000 per share, and (ii) warrants to purchase 2,828,000 shares of Common Stock at an exercise price of \$0.50 per share.

The aggregate purchase price paid by the Purchasers for the Series D Preferred and the warrants was \$1,414,000 (representing \$1,000 for each share of Series D Preferred together with warrants). The Company intends to use the proceeds for working capital purposes.

The placement agents for the offering received cash compensation of \$113,120 and warrants to purchase 226,240 shares of Common Stock at an exercise price of \$0.50 per share.

On February 9, 2011, the Company completed a private placement of securities in which the Company sold to certain accredited investors in the aggregate: (i) 3,436 shares of Series D at a stated value of \$1,000 per share, and (ii) warrants to purchase 6,872,000 shares of Common Stock at an exercise price of \$0.50 per share.

The aggregate purchase price paid by the Purchasers for the Series D Preferred and the warrants was \$3,436,000 (representing \$1,000 for each share of Series D Preferred together with warrants). The Company intends to use the proceeds for working capital purposes.

The placement agents for the offering received cash compensation of \$274,880 and warrants to purchase 549,760 shares of Common Stock at an exercise price of \$0.50 per share.

F45

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### **Table of Contents**

On March 1, 2011, the Company completed a private placement of securities in which the Company sold to certain accredited investors in the aggregate: (i) 50 shares of Series D at a stated value of \$1,000 per share, and (ii) warrants to purchase 100,000 shares of Common Stock at an exercise price of \$0.50 per share.

The aggregate purchase price paid by the Purchasers for the Series D Preferred and the warrants was \$50,000 (representing \$1,000 for each share of Series D Preferred together with warrants). The Company intends to use the proceeds for working capital purposes.

The placement agents for the offering received cash compensation of \$4,000 and warrants to purchase 8,000 shares of Common Stock at an exercise price of \$0.50 per share.

As of March 24, 2011, investors in the Series B preferred stock had converted 1,902 preferred shares into 3,804,000 common shares.

F46

Exhibit 23.1

# **Consent of Independent Registered Public Accounting Firm**

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (File No. 333-172776) of Fibrocell Science, Inc.(formerly known as Isolagen, Inc.) of our report dated March 30, 2011, relating to the consolidated financial statements appearing in the Company's Annual Report on Form 10-K for the year ended December 31, 2010. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP

Houston, Texas March 30, 2011

Exhibit 31.1

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

- I, David Pernock, Chief Executive Officer of Fibrocell Science, Inc., certify that:
- 1. I have reviewed this Annual Report on Form 10-K of Fibrocell Science, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be
    designed under our supervision, to ensure that material information relating to the registrant, including its
    consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in
    which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant s internal control over financial reporting that occurred during the registrant s most recent fiscal quarter (the registrant s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant s internal control over financial reporting; and
- 5. The registrant s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant s auditors and the audit committee of the registrant s board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant s ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal control over financial reporting.

Dated: March 30, 2011

By: /s/ David Pernock

David Pernock, Chief Executive Officer

Exhibit 31.2

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

- I, Declan Daly, Chief Financial Officer of Fibrocell Science, Inc., certify that:
- 1. I have reviewed this Annual Report on Form 10-K of Fibrocell Science, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be
    designed under our supervision, to ensure that material information relating to the registrant, including its
    consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in
    which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant s internal control over financial reporting that occurred during the registrant s most recent fiscal quarter (the registrant s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant s internal control over financial reporting; and
- 5. The registrant s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant s auditors and the audit committee of the registrant s board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant s ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal control over financial reporting.

Dated: March 30, 2011

By: /s/ Declan Daly

Declan Daly, Chief Financial Officer

Exhibit 32.1

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

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

- i. the Annual Report on Form 10-K of the Company for the year ended December 31, 2010, as filed with the Securities and Exchange Commission on the date hereof (the Report ) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Commission Act of 1934; and
- ii. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 30, 2011

By: /s/ David Pernock

David Pernock Chief Executive Officer Fibrocell Science, Inc.

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

Exhibit 32.2

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

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

- i. the Annual Report on Form 10-K of the Company for the year ended December 31, 2010, as filed with the Securities and Exchange Commission on the date hereof (the Report ) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Commission Act of 1934; and
- ii. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 30, 2011

By: /s/ Declan Daly

Declan Daly Chief Financial Officer Fibrocell Science, Inc.

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