

Fibrocell Science, Inc.  
Form S-1/A  
January 29, 2010

**Table of Contents**

As filed with the Securities and Exchange Commission on January 29, 2010 Registration No. 333-163386

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549  
Amendment No. 1 to  
FORM S-1  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933  
FIBROCELL SCIENCE, INC.  
(Exact name of registrant as specified in its charter)**

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| <b>Delaware</b><br>(State or other jurisdiction of<br>incorporation or organization) | <b>2834</b><br>(Primary Standard Industrial<br>Classification Code Number)<br>405 Eagleview Boulevard<br>Exton, Pennsylvania 19341<br>(484) 713-6000<br>(Address, including zip code, and telephone number, including<br>area code, of registrant's principal executive offices)<br>Declan Daly<br>405 Eagleview Boulevard<br>Exton, Pennsylvania 19341<br>(484) 713-6000<br>(Name, address, including zip code, and telephone number,<br>including area code, of agent for service)<br>Copies to:<br>Cavas S. Pavri, Esq.<br>Cozen O'Connor<br>1900 Market Street<br>Philadelphia, PA 19103<br>Professional Corporation<br>(215) 665-5542<br>Facsimile: (215) 701-2478 | <b>87-0458888</b><br>(I.R.S. Employer Identification<br>Number) |
|--|---|---|

APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
 (Do not check if a smaller reporting company)

**Calculation of Registration Fee**

| <b>Title of each Class of Security being Registered</b> | <b>Amount being Registered (1)</b> | <b>Proposed Maximum Offering Price Per Security(2)</b> | <b>Proposed Maximum Aggregate Offering Price(2)</b> | <b>Amount of Registration Fee</b> |
|---|------------------------------------|--|---|-----------------------------------|
| Common Stock, \$0.001 par value (3)                     | 2,750,002                          | \$0.80   | \$2,200,002   | \$123                             |
| Common Stock, \$0.001 par value (4)                     | 1,168,208                          | \$0.80   | \$934,566   | \$53                              |
| Total   |                                    |  | \$3,134,568   | \$176 (5)                         |

(1) All of the shares are offered by the Selling Stockholders. Accordingly, this registration statement includes an indeterminate number of additional shares of common stock issuable for no additional consideration pursuant to any stock dividend, stock split, recapitalization or other similar transaction effected without the receipt of consideration, which results in an increase in the number of outstanding shares of our common stock. In the event of a

stock split, stock dividend or similar transaction involving our common stock, in order to prevent dilution, the number of shares registered shall be automatically increased to cover the additional shares in accordance with Rule 416(a) under the Securities Act of 1933.

- (2) Estimated solely for purposes of determining the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, using the average of the bid and asked prices as reported on the OTC Bulletin Board on November 23, 2009, which was \$0.80 per share.
- (3) Represents 110% of the shares issuable on conversion of Series A Preferred Stock at a conversion rate equal to (1) the stated value of the

share (\$1,000),  
divided by (2)  
\$1.30, subject to  
adjustment.

(4) Represents  
shares  
underlying  
certain warrants  
issued in  
connection with  
the Series A  
Preferred Stock.

(5) Previously paid.

**THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE SECURITIES ACT OF 1933 OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(a), MAY DETERMINE.**

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**Table of Contents**

This information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION, DATED JANUARY 29, 2010

**PROSPECTUS  
FIBROCELL SCIENCE, INC.  
3,918,210 Common Stock**

This prospectus relates to the resale of our common stock by certain of our stockholders, or Selling Stockholders, named in the section of this prospectus titled **Selling Security Holders**. The following shares may be offered for resale under this prospectus: (a) 2,750,002 shares of common stock representing 110% of the shares underlying the Series A convertible preferred stock, or Series A Preferred, we issued in October 2009; (b) 501,542 shares of common stock underlying Class A warrants issued in the Series A Preferred offering; (c) 416,666 shares of common stock underlying Class B warrants issued in the Series A Preferred offering; and (d) 250,000 shares of common stock underlying warrants issued to the placement agent in the Series A Preferred offering.

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, receive proceeds if the warrants are exercised; 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 January 28, 2010, the last sales price of the common stock, as reported on the OTCBB was \$0.80 per share.

**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 this 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 is \_\_\_\_\_, 2010

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**TABLE OF CONTENTS**

|  | <b>Page</b> |
|--|-------------|
| <u>Prospectus Summary</u>  | 1           |
| <u>Risk Factors</u>  | 4           |
| <u>Special Note Regarding Forward-Looking Statements</u>                                 | 20          |
| <u>Use of Proceeds</u>   | 21          |
| <u>Market Price of and Dividends on Our Common Stock and Related Stockholder Matters</u> | 21          |
| <u>Description of Our Business</u>   | 23          |
| <u>Management</u>  | 36          |
| <u>Related Party Transactions</u>  | 39          |
| <u>Principal Stockholders</u>  | 40          |
| <u>Description of Securities</u>   | 42          |
| <u>Shares Eligible for Future Sale</u>   | 47          |
| <u>Selling Security Holders</u>  | 49          |
| <u>Plan of Distribution</u>  | 51          |
| <u>Incorporation by Reference</u>  | 53          |
| <u>Legal Matters</u>   | 53          |
| <u>Experts</u>   | 53          |
| <u>Where You Can Find More Information</u>   | 53          |
| EX-5   |             |
| EX-23.1  |             |

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**Table of Contents**

**PROSPECTUS SUMMARY**

*This summary highlights information set forth in greater detail elsewhere in this prospectus. It may not contain all the information that may be important to you. You should read this entire prospectus carefully, including the sections entitled Risk Factors beginning on page 4, Management's Discussion and Analysis of Financial Condition and Results of Operations, and our historical financial statements and related notes incorporated by reference into this prospectus. Unless the context requires otherwise, references to the Company, Fibrocell, we, our, and us, refer to Fibrocell Science, Inc. and its subsidiaries.*

**Our Company**

We are an aesthetic and therapeutic development stage 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 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. In December 2009, we received a Complete Response letter from the FDA related to the BLA. 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 we 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. During 2009 we completed one of two Phase II/III studies 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 Laboratories, Inc. 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.

Our officers and directors as of the effective date were all deemed to have resigned and a new board of directors was appointed. As of the effective date, our initial board of directors consisted of: David Pernock, Paul Hopper and Kelvin Moore. Dr. Robert Langer was appointed to the Board in late September 2009. Declan Daly remained as chief operating officer and chief financial officer of the reorganized company, and in November 2009, he was appointed to the Board of Directors. Mr. Daly is also currently acting as interim chief executive officer.

Pursuant to the Plan, all of our equity interests, including without limitation our common stock, options and warrants outstanding as of the effective date were cancelled. On the effective date, we completed an exit financing of common stock in the amount of \$2 million, after which the equity holders of our company were:

§ 7,320,000 shares, to our pre-bankruptcy lenders and the lenders that provided us our debtor-in-possession facility, collectively;

§ 3,960,000 shares, to the holders of our 3.5% convertible subordinated notes;

§ 600,000 shares, to our management as of the effective date, which was our chief operating officer;

§ 120,000 shares, to the holders of our general unsecured claims; and

§ 2,666,666 shares, to the purchasers of shares in the \$2 million exit financing (our pre-bankruptcy lenders, the lenders that provided us our debtor-in-possession facility and the holders of our 3.5% convertible subordinated notes were permitted to participate in our exit financing).



**Table of Contents**

In the Plan, in addition to the common stock set forth above, each holder of Isolagen's 3.5% convertible subordinated notes, due November 2024, in the approximate non-converted aggregate principal amount of \$81 million, received, in full and final satisfaction, settlement, release and discharge of and in exchange for any and all claims arising out of the 3.5% convertible subordinated notes, its *pro rata* share of an unsecured note in the principal amount of \$6 million, or the New Notes. The New Notes have the following features:

§ 12.5% interest payable quarterly in cash or, at our option, 15% payable in kind by capitalizing such unpaid amount and adding it to the principal as of the date it was due;

§ mature June 1, 2012;

§ at any time prior to the maturity date, we 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; provided that we will be obligated to redeem all outstanding New Notes upon the following events: (a) we or our subsidiary, Fibrocell Technologies, Inc. (formerly, Isolagen Technologies, Inc.) successfully complete a capital campaign raising in excess of \$10,000,000; or (b) we or our subsidiary, Fibrocell Technologies, Inc., are acquired by, or sell a majority stake to, an outside party;

§ the New Notes contain customary representations, warranties and covenants, including a covenant that we and our subsidiary, Fibrocell Technologies, Inc., shall be prohibited from the incurrence of additional debt without obtaining the consent of 66 2/3% of the New Note holders.

**Our Contact Information**

Our corporate headquarters is located at 405 Eagleview Boulevard, Exton, Pennsylvania 19341. Our phone number is (484) 713-6000. Our corporate website is [www.fibrocellscience.com](http://www.fibrocellscience.com). Information contained on our website or any other website does not constitute part of this prospectus.

**Risks Related to Our Business**

Our business is subject to a number of risks, which you should be aware of before making an investment decision. These risks are discussed more fully in the section of this prospectus titled Risk Factors.

**Securities Being Offered**

The Selling Stockholders named in this prospectus may offer for resale the following securities:

§ up to 2,750,002 shares of common stock representing 110% of the shares underlying the Series A Preferred we issued in October 2009;

§ up to 501,542 shares of common stock underlying Class A warrants issued in the Series A Preferred offering;

§ up to 416,666 shares of common stock underlying Class B warrants issued in the Series A Preferred offering; and

§ up to 250,000 shares of common stock underlying warrants issued to the placement agent in the Series A Preferred offering.

**Table of Contents**

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. However, we may receive proceeds of up to \$1,950,000 from the exercise of the outstanding warrants; if such proceeds are received by us, they will be used for working capital purposes.

**Table of Contents**

**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 prospectus. 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.**

There exists substantial doubt regarding our ability to continue as a going concern. As of September 30, 2009, we had cash and cash equivalents of \$1.1 million and working capital of \$1.3 million (including our cash and cash equivalents). We believe our existing capital resources are adequate to finance our operations through approximately mid-February 2010. Beyond our efforts to obtain immediate financing, which may not occur, we are incurring losses from operations, have limited capital resources, and do not have access to a line of credit or other debt facility.

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 \$6 million of debt, which has a priority over common shareholders.

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 prior to mid-February 2010, 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, 2008, 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, 2008 may materially and adversely affect our stock price and our ability to raise new capital.

**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. We have finished injections related to our pivotal Phase III clinical trial for our lead facial

**Table of Contents**

product candidate and have submitted the related BLA to the FDA. In October 2009, the FDA Cellular, Tissue and Gene Therapies Advisory Committee reviewed our nasolabial fold/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 fold 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 effect the application. Our other product candidates will require additional clinical trials. The commencement and completion of clinical trials for any of our product candidates could be delayed or prevented by a variety of factors, including:

delays in obtaining regulatory approvals to commence a study;

delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;

delays or failures in obtaining approval of our clinical trial protocol from an institutional review board, or IRB, to conduct a clinical trial at a prospective study site;

delays in the enrollment of subjects;

manufacturing difficulties;

failure of our clinical trials and clinical investigators to be in compliance with the FDA's Good Clinical Practices, or GCP;

failure of our third-party contract research organizations, clinical site organizations and other clinical trial managers, to satisfy their contractual duties, comply with regulations or meet expected deadlines;

lack of efficacy during clinical trials; or

unforeseen safety issues.

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

We utilize bovine-sourced materials to manufacture 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;

**Table of Contents**

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 three and nine month periods ended September 30, 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 under Item 1 of Part I of our quarterly report on Form 10-Q for the quarterly period ended September 30, 2009, which is incorporated by reference into this prospectus.

**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 fold/wrinkle 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.

**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 anyway 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



**Table of Contents**

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/wrinkle 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.

**We may issue additional equity securities and thereby materially and adversely affect the price of our common stock.**

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.

**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.

**Table of Contents**

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 you 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. We have never gone through a FDA pre-approval regulatory inspection of our manufacturing facility, and we cannot guarantee that we will satisfy the 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.



**Table of Contents**

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 69% and 60% of our consolidated revenues for the three and nine month periods ended September 30, 2009, respectively. Further, this large customer represented 79% of consolidated accounts receivable, net, at September 30, 2009. 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

**Table of Contents**

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 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.

**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:

**Table of Contents**

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, and, our predecessor company was publicly threatened with claims related to our product in the United Kingdom.**

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. In particular, our predecessor company received negative publicity and negative correspondence from patients in the United Kingdom that had previously received our treatment. 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.

**Table of Contents**

If we are the subject of any future product liability claims our business could be adversely affected, and if these claims are in excess of insurance coverage, if any, that we may possess, our financial position will suffer.

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

Even if we obtain regulatory approval for some or all 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

**Table of Contents**

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

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

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

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

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

**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:

**Table of Contents**

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.

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 effectively to 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.**

**Table of Contents**

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

obtain and protect commercially valuable patents or the rights to patents both domestically and abroad;

operate without infringing upon the proprietary rights of others; and

prevent others from successfully challenging or infringing our proprietary rights.

As of November 23, 2009, we had 9 issued U.S. patents, 4 pending U.S. patent applications, 28 granted foreign patents and 3 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;

**Table of Contents**

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

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

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

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

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

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

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

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

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

pay monetary damages;

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

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



**Table of Contents**

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.

**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.

**Our acquisitions of companies or technologies may result in disruptions in business and diversion of management attention.**

We have made and may in the future make acquisitions of complementary companies, products or technologies. Any acquisitions will require the assimilation of the operations, products and personnel of the acquired businesses and the training and motivation of these individuals. Acquisitions may disrupt our operations and divert management's attention from day-to-day operations, which could impair our relationships with current employees, customers and strategic partners. We may also have to, or we may choose to, incur debt or issue equity securities to pay for any future acquisitions. The issuance of equity securities for an acquisition could be substantially dilutive to our security holders. In addition, our results of operations may suffer because of acquisition-related costs or amortization or impairment costs for acquired goodwill and other intangible assets. If management is unable to fully integrate acquired businesses, products, technologies or personnel with existing operations, we may not receive the intended benefits of the acquisitions.

**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 may, 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.

**Table of Contents**

In May 2006, our Board of Directors declared a dividend of one right for each share of our common stock to purchase our newly created Series C participating preferred stock in connection with the adoption of a stockholder rights plan. These rights may have certain anti-takeover effects. For example, the rights may cause substantial dilution to a person or group that attempts to acquire us in a manner which causes the rights to become exercisable. As such, the rights may have the effect of rendering more difficult or discouraging an acquisition of our company which is deemed undesirable by our board of directors.

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. As of January 28, 2010, there were 14,692,166 shares of common stock issued and outstanding. All of our outstanding shares are freely transferable without restriction or further registration under the Securities Act.

**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. In addition, the independent registered public accounting firm auditing the company's financial statements has been required to and may be required in the future to attest to and report on 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.

**While the warrants are outstanding, it may be more difficult to raise additional equity capital.**

**Table of Contents**

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

**Table of Contents**

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus, 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, estimate, expect, intend, the facts suggest and words of similar import, are intended to identify any forward-looking statements. You should not place undue reliance on these forward-looking statements. These statements reflect our current view of future events and are subject to certain risks and uncertainties as noted below. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, our actual results could differ materially from those anticipated in these forward-looking statements. Actual events, transactions and results may materially differ from the anticipated events, transactions or results described in such statements. Although we believe that our expectations are based on reasonable assumptions, we can give no assurance that our expectations will materialize. Many factors could cause actual results to differ materially from our forward looking statements. 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;
- § 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;

**Table of Contents**

§ 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.

**USE OF PROCEEDS**

This prospectus relates to the resale of shares of our common stock to be issued to persons who convert their Series A Preferred or exercise their warrants. We will not receive any proceeds from the sale of shares of common stock in this offering. However, we will receive proceeds from the exercise of any warrants, up to a maximum amount of \$1,950,000, and we will use any such proceeds for working capital purposes.

**MARKET PRICE OF AND DIVIDENDS ON OUR COMMON STOCK  
 AND RELATED STOCKHOLDER MATTERS**

**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.

|  | <b>December 31,<br/>2009</b> |            |
|--|------------------------------|------------|
|  | <b>High</b>                  | <b>Low</b> |
| Fourth Quarter (from October 21, 2009) | 2.40                         | 0.50       |

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.

As of January 28, 2010, there were 14,692,166 shares of our common stock outstanding and held by 173 stockholders of record. As of January 28, 2010, there were 3,250 shares of Series A Preferred issued and outstanding.

On January 28, 2010 the last sale price of our common stock as reported on the OTCBB was \$0.80 per share.

**Table of Contents**

***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.

Holder of the Series A 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, beginning on April 15, 2010. 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. 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.

Shares of common stock issued as dividends on the Series A Preferred are not being registered under this prospectus. Such shares are deemed to be restricted securities under Rule 144 of the Securities Act and may only be sold in compliance with Rule 144.

***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 suitability 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.

**Table of Contents****DESCRIPTION OF OUR BUSINESS****Overview**

We are an aesthetic and therapeutic development stage 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 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. In December 2009, we received a Complete Response letter from the FDA related to the BLA. 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 we 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. During 2009 we completed one of two Phase II/III studies 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 Laboratories, Inc. 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.

Our officers and directors as of the effective date were all deemed to have resigned and a new board of directors was appointed. As of the effective date, our initial board of directors consisted of: David Pernock, Paul Hopper and Kelvin Moore. Dr. Robert Langer was appointed to the Board in late September 2009. Declan Daly remained as chief operating officer and chief financial officer of the reorganized company, and in November 2009, he was appointed to the Board of Directors. Mr. Daly is also currently acting as interim chief executive officer.

Pursuant to the Plan, all our equity interests, including without limitation our common stock, options and warrants outstanding as of the effective date were cancelled. On the effective date, we completed an exit financing of common stock in the amount of \$2 million, after which the equity holders of our company were:

§ 7,320,000 shares, to our pre-bankruptcy lenders and the lenders that provided us our debtor-in-possession facility, collectively;

§ 3,960,000 shares, to the holders of our 3.5% convertible subordinated notes;

§ 600,000 shares, to our management as of the effective date, which was our chief operating officer;

§ 120,000 shares, to the holders of our general unsecured claims; and

§ 2,666,666 shares, to the purchasers of shares in the \$2 million exit financing (our pre-bankruptcy lenders, the lenders that provided us our debtor-in-possession facility and the holders of our 3.5% convertible subordinated notes were permitted to participate in our exit financing).

In the Plan, in addition to the common stock set forth above, each holder of Isolagen's 3.5% convertible subordinated notes, due November 2024, in the approximate non-converted aggregate principal amount of \$81 million, received, in full and final satisfaction, settlement, release and discharge of and in exchange for any and all claims arising out of the 3.5% convertible subordinated notes, its *pro rata* share of an unsecured note in the principal amount of \$6 million, or the New Notes. The New Notes have the following features:

§ 12.5% interest payable quarterly in cash or, at our option, 15% payable in kind by capitalizing

**Table of Contents**

such unpaid amount and adding it to the principal as of the date it was due;

§ mature June 1, 2012;

§ at any time prior to the maturity date, we 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; provided that we will be obligated to redeem all outstanding New Notes upon the following events: (a) we or our subsidiary, Fibrocell Technologies, Inc. (formerly, Isolagen Technologies, Inc.) successfully complete a capital campaign raising in excess of \$10,000,000; or (b) we or our subsidiary, Fibrocell Technologies, Inc., are acquired by, or sell a majority stake to, an outside party;

§ the New Notes contain customary representations, warranties and covenants, including a covenant that we and our subsidiary, Fibrocell Technologies, Inc., shall be prohibited from the incurrence of additional debt without obtaining the consent of 66 2/3% of the New Note holders.

***Going Concern***

At September 30, 2009, we had cash and cash equivalents of \$1.1 million and working capital of \$1.3 million. We believe that our existing capital resources are adequate to sustain our operation through approximately mid-February 2010, under our current operating plan. As such, we require additional cash resources prior to or during approximately mid-February 2010, or we will likely enter into bankruptcy and/or cease operations. We currently have no commitments for any such additional funding and there is no assurance that we will receive any such additional funding.

As of September 30, 2009, we had \$6 million of debt, consisting of the New Notes. Through September 30, 2009, we have been primarily engaged in developing our initial product technology. In the course of our development activities, we have sustained losses and expect such losses to continue through at least 2010. In fiscal 2009 we financed our operations primarily through our existing cash, but as discussed above we now require additional financing. There is substantial doubt about our ability to continue as a going concern.

We will require additional capital to continue our operations past approximately mid-February 2010. There is no assurance that we will be able to obtain any such additional capital as we need to finance these efforts, through asset sales, equity or debt financing, or any combination thereof, on satisfactory terms or at all. Additionally, no assurance can be given that any such financing, if obtained, will be adequate to meet our ultimate capital needs and to support our growth. If adequate capital cannot be obtained on a timely basis and on satisfactory terms, our operations would be materially negatively impacted. If we do not obtain additional funding, or do not anticipate additional funding, prior to or during approximately mid-February 2010, we will likely enter into bankruptcy and/or cease operations. Further, if we do raise additional cash resources prior to mid-February 2010, it may be raised in contemplation of or in connection with bankruptcy.

Our ability to complete additional offerings is dependent on the state of the debt and/or equity markets at the time of any proposed offering, and such market's reception of us and the offering terms. Our ability to complete an offering is also dependent on the status of our FDA regulatory milestones and our clinical trials, and in particular, the status of our indication for the treatment of nasolabial folds, which cannot be predicted. There is no assurance that capital in any form would be available to us, and if available, on terms and conditions that are acceptable.

As a result of the conditions discussed above, and in accordance with generally accepted accounting principles in the United States, there exists substantial doubt about our ability to continue as a going concern, and our ability to continue as a going concern is contingent, among other things, upon our ability to secure additional adequate financing or capital prior to or during approximately mid-February 2010. If we enter into bankruptcy, it is likely that our common stock and common stock equivalents will become worthless and our lenders and creditors will receive significantly less than what is owed to them.

***Fibrocell's Technology Platform***



**Table of Contents**

We use our proprietary Fibrocell 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 the Fibrocell Therapy to treat an indicated condition. We use our Fibrocell 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 palate. 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 currently primarily focused on our approval efforts related to our nasolabial fold/wrinkle indication, for which we have submitted a BLA in March 2009 and attended the FDA's Cellular, Tissue and Gene Therapies Advisory Committee meeting in October 2009. Our additional objectives include achieving regulatory milestones related to our other Phase II/III Acne Scar program, as funding permits in the future (refer to the section Clinical Development Programs below).

***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. Currently, we have suspended activity on all of our trials, although we have continued our efforts related to obtaining FDA approval for our lead product candidate, azficel-T, for the treatment of nasolabial folds/wrinkles.

Our aesthetics development programs include product candidates to treat targeted areas or 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 the section Risk Factors for a discussion of certain of our risk factors related to our clinical development programs, as well as other risk factors related to our business.

***Aesthetic Development Programs***

**Wrinkles/Nasolabial Folds - Phase III Trials:** In October 2006, our predecessor company, Isolagen, Inc., reached an agreement with the FDA on the design of a Phase III pivotal study protocol for the treatment of nasolabial folds (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,

**Table of Contents**

could form the basis of an efficacy claim for a marketing application. The pivotal Phase III trials evaluated the efficacy and safety of our nasolabial fold wrinkles product candidate, 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. 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. We are continuing to work with the FDA following the Advisory Committee meeting. The FDA is currently evaluating the United States Adopted Name, azficel-T, and a proposed brand name, Laviv. In December 2009, we received a Complete Response letter from the FDA related to the BLA. 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 we 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.

**Full Face Rejuvenation Phase II Trial:** In March 2007 we commenced an open label (unblinded) trial of approximately 50 subjects. Injections of Fibrocell Therapy began to be administered in July 2007. This trial was designed to further evaluate the safety and use of Fibrocell Therapy 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.

**Therapeutic Development Programs**

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

In connection with this acne scar program, we developed a photo guide for use in the evaluators' assessment of acne study subjects. We had originally designed the acne scar clinical program as two randomized, double-blind, Phase III, placebo-controlled trials. However, our evaluator assessment scale and photo guide have not previously been utilized in a clinical trial. In November 2007, the FDA recommended that we consider conducting a Phase II study in order to address certain study issues, including additional validation related to our evaluator assessment scale. As such, we modified our clinical plans to initiate a single Phase II/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. We expect to initiate a subsequent, additional Phase III trial, subject to sufficient financial resources. We believe that the two trials may have the potential to form the basis of a licensure submission to the FDA.

**Restrictive Burn Scars Phase II Trial:** In January 2007, we met with the FDA to discuss our clinical program for the use of Fibrocell Therapy for restrictive burn scar patients. This Phase II trial would evaluate the use of our Fibrocell Therapy to improve range of motion, function and flexibility, among other parameters, in existing restrictive burn scars in approximately 20 patients. However, we have delayed the screening and enrollment in this trial until such time as we raise sufficient additional financing.

Dental Study Phase II Trial: In late 2003, we 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, we concluded the Phase II dental clinical trial with the use of Fibrocell Therapy and subsequently announced that investigator and subject visual analog scale assessments demonstrated that the Fibrocell Therapy was statistically superior to placebo at four months after treatment. Although results of the investigator and subject

**Table of Contents**

assessment demonstrated that the Fibrocell Therapy was statistically superior to placebo, an analysis of objective linear measurements did not yield statistically significant results.

***Agera Skincare Systems***

We market and sell a skin care product line through our majority-owned subsidiary, Agera Laboratories, Inc., which we 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 markets its products in both the United States and Europe (primarily the United Kingdom).

**Our Target Market Opportunities*****Aesthetic Market Opportunity***

Our Fibrocell product candidates for wrinkles/nasolabial folds 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 \$4.6 billion in 2008. We believe the aesthetic procedure market is driven by:

§ the aging of the baby boomer population, which currently includes ages approximately 45 to 63;

§ the desire of many individuals to improve their appearance;

§ the 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

§ the broadening base of the practitioners performing cosmetic procedures beyond dermatologists and plastic surgeons to non-traditional providers.

According to the ASAPS, over 10.2 million surgical and non-surgical cosmetic procedures were performed in 2008, as compared to 11.7 million in 2007. Also according to the ASAPS, approximately 8.5 million non-surgical procedures were performed in 2008 and approximately 9.6 million non-surgical procedures were performed in 2007. 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 2008:

| <b>Procedure</b>       | <b>Number</b> |
|------------------------|---------------|
| Botox injection        | 2,464,123     |
| Laser hair removal     | 1,280,964     |
| Hyaluronic acids       | 1,262,848     |
| Chemical peel          | 591,808       |
| Laser skin resurfacing | 570,880       |

Procedures among the 35 to 50 year old age group made up approximately 45% of all non-surgical cosmetic procedures in 2008. The 51 to 64 year old age group made up 26% of all non-surgical cosmetic procedures in 2008, while the 19 to 34 year old age group made up 22% of all non-surgical cosmetic procedures in 2008. Botox injection was the most popular treatment among the 35 to 50 year old age group.

***Therapeutic Market Opportunities***

**Table of Contents**

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. We are not aware of other autologous cell-based treatments for any of these therapeutic applications.

*Acne Scars.* Acne is the most common skin disorder in the United States. The term acne includes conditions ranging from clogged pores to outbreaks of severe lesions. According to the American Academy of Dermatology and the National Institute of Health, nearly 80% of people aged 11 to 30 have acne outbreaks at some point, and approximately 95% of these patients will have some degree of scarring depending on the severity and duration of the condition. Over time, as facial tone declines and facial fat stores are depleted, the scars typically become more noticeable. Current treatments for acne scarring are dermabrasion, laser resurfacing, surgical excision, and certain temporary fillers. We believe this market represents a significant opportunity for our acne scar product candidate.

*Burns and Burn Scars.* According to a Kalorama Information study on burns (Wound Care Volume II: Burns, Kalorama Information, August 2005), an estimated 2.5 million Americans seek medical care each year for burns and approximately 100,000 are hospitalized. Approximately 50% of patients with deep second degree, third and fourth degree burns develop restrictive scarring which are often painful, and reduce flexibility and functionality of the area affected. We believe this market represents a significant opportunity for our non-surgical treatment of existing restrictive burn scars. We also believe additional market opportunity exists for the use of our product candidate prior to the formation of a restrictive scar to promote healing in the acute phase of burn wound healing.

***Agera Skincare Market Opportunities***

The independent research firm, Kalorama Information, estimated that from 2005 to 2010, over 70 million people in the United States alone will receive cosmetic facial procedures for which they will pay over \$60 billion. Based on a Kline & Company, Inc. study, *The U.S. Professional Skin Care Market 2003*, the 2008 U.S. professional skin care market was estimated at \$742 million. This Kline & Company, Inc study describes the market as comprised of the following sub-markets: Salons and spas (59%), Retail stores (22%) and Medical care (19%). The doctor dispensing market is primarily focused in the Dermatology and Plastic Surgeon segments but we believe is gaining interest with a broader audience of physician specialties, including the medical spa environment.

**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. We believe that our Agera products have the potential to complement our Fibrocell Therapy product candidates in the future.

**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 November 23, 2009, we had 9 issued U.S. patents, 4 pending U.S. patent applications, 28 granted foreign patents and 3 pending international patent applications. Our issued patents and patent applications primarily cover the method of using autologous cell fibroblasts for the repair of skin and soft tissue defects and the use of autologous fibroblast cells for tissue regeneration. Our subsidiary, Agera Laboratories, has a number of trade names, trademarks, exclusive proprietary rights to product formulations and specified peptides that are used in the Agera skincare products.

**Table of Contents**

In January 2003, we acquired two pending U.S. patent applications. As consideration, we issued 100,000 shares of our common stock and agreed to pay a royalty on revenue from commercial applications and licensing, up to a maximum of \$2.0 million.

Our success depends in part on our ability to maintain our proprietary position through effective patent claims and their enforcement against our competitors, and through the protection of our trade secrets. Although we believe our patents and patent applications provide a competitive advantage, the patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. We do not know whether any of our patent applications or those patent applications which we have acquired will result in the issuance of any patents. Our issued patents, those that may be issued in the future or those acquired by us, may be challenged, invalidated or circumvented, and the rights granted under any issued patent may not provide us with proprietary protection or competitive advantages against competitors with similar technology. In particular, we do not know if competitors will be able to design variations on our treatment methods to circumvent our current and anticipated patent claims. Furthermore, competitors may independently develop similar technologies or duplicate any technology developed by us. Because of the extensive time required for the development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized or marketed, any related patent claim may expire or remain in force for only a short period following commercialization, thereby reducing the advantage of the patent.

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

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

We have collaborated and may collaborate in the future with other entities on research, development and commercialization activities. Disputes may arise about inventorship and corresponding rights in know-how and inventions resulting from the joint creation or use of intellectual property by us and our subsidiaries, collaborators, partners, licensors and consultants. As a result, we may not be able to maintain our proprietary position.

**Competition**

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

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.

**Table of Contents**

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 that 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 like Genzyme, Integra Life Sciences, Johnson & Johnson, C.R. Bard, LifeCell, Organogenesis, Intercytex, and others.

The market for skincare products is quite competitive with low barriers to entry. We believe Agera's dominant competitors in this market include companies like Obagi Medical Products, Inc., Skin Medica, Murad, Inc., Dermalogica, Pevonia Botanica and others.

**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 FFDC, 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 FFDC, 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 subjected to administrative or judicial enforcement action, the government may refuse to approve our marketing applications or to allow us to manufacture or market our products or product candidates, and we may be criminally prosecuted. The FDA also has the authority to suspend or revoke previously granted marketing authorizations, or seek a product withdrawal or recall (or order a recall of a biologic or a human cellular or tissue-based product under certain circumstances) 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's safety and efficacy as well as detailed information on the manufacture and composition of the product candidate. In most cases, this entails extensive laboratory tests and pre-clinical and clinical trials. This

**Table of Contents**

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 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 and must also satisfy all regulatory requirements for HCT/Ps.

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

- § completion of pre-clinical laboratory tests or trials and formulation studies;
- § submission to the FDA of an Investigational New Drug, or IND, application for a new drug or biologic, which must become effective before human clinical trials may begin;
- § performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug or biologic for its intended use;
- § detailed information on product characterization and manufacturing process; and
  
- § submission and approval of a New Drug Application, or NDA, for a drug, or a Biologics License Application, or BLA, for a biologic.

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

The sponsor typically conducts human clinical trials in three sequential phases, which may overlap. These phases generally include the following:



**Table of Contents**

§ Phase I: The product is usually first introduced into healthy humans or, on occasion, into patients, and is tested for safety, dosage tolerance, absorption, distribution, excretion and metabolism.

§ Phase II: The product is introduced into a limited subject population to:

assess its efficacy in specific, targeted indications;

assess dosage tolerance and optimal dosage; and

identify possible adverse effects and safety risks.

§ Phase III: These are commonly referred to as pivotal studies. If a product is found to have an acceptable safety profile and to be potentially effective in Phase II clinical trials, new clinical trials will be initiated to further demonstrate clinical efficacy, optimal dosage and safety within an expanded and diverse subject population at geographically-dispersed clinical study sites.

§ If the FDA does ultimately approve the product, it may require post-marketing testing, including potentially expensive Phase IV studies, to confirm or further evaluate its safety and effectiveness.

Before proceeding with a study, sponsors may seek a written agreement from the FDA regarding the design, size, and conduct of a clinical trial. This is known as a Special Protocol Assessment, or SPA. Among other things, SPAs can cover clinical studies for pivotal trials whose data will form the primary basis to establish a product's efficacy. SPAs thus help establish up-front agreement with the FDA about the adequacy of a clinical trial design to support a regulatory approval, but the agreement is not binding if new circumstances arise. Even if the FDA agrees to an SPA, the agreement may be changed by the sponsor or the FDA on written agreement by both parties, or a senior FDA official determines that a substantial scientific issue essential to determining the safety or effectiveness of the product was identified after the testing began. There is no guarantee that a study will ultimately be adequate to support an approval even if the study is subject to an SPA. The FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement.

Clinical trials must meet requirements for Institutional Review Board, or IRB, oversight, patient informed consent and the FDA's Good Clinical Practices. Prior to commencement of each clinical trial, the sponsor must submit to the FDA a clinical plan, or protocol, accompanied by the approval of the committee responsible for overseeing clinical trials at the clinical trial sites. The FDA or the IRB at each institution at which a clinical trial is being performed may order the temporary or permanent discontinuation of a clinical trial at any time if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial subjects. Data safety monitoring committees, who monitor certain studies to protect the welfare of study subjects, may also require that a clinical study be discontinued or modified.

The sponsor must submit to the FDA the results of the pre-clinical and clinical trials, together with, among other things, detailed information on the manufacturing and composition of the product, and proposed labeling, in the form of an NDA, or, in the case of a biologic, a BLA. The applicant must also submit with the NDA or BLA a substantial user fee payment, unless a waiver or reduction applies. We believe that a waiver reduction applies to Fibrocell related to our BLA submission for the nasolabial folds/wrinkles indication. For fiscal year 2009 this fee is \$1,247,200. 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. 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 for priority applications and 10 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

**Table of Contents**

of amendments. The FDA may refer the BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved, but the FDA is not bound by the recommendation of an advisory committee.

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

*Ongoing FDA Requirements*

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

The labeling, advertising, promotion, marketing and distribution of a drug or biologic product also must be in compliance with FDA and 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



**Table of Contents**

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

**Table of Contents**

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 and 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, 2008 and 2007, our predecessor company incurred research and development expenses of \$10.2 million and \$13.3 million, respectively.

**Employees**

As of November 23, 2009, we employed 12 people on a full-time basis, all located in the United States, and one employee, our chief executive 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 employee. 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 our business segments and geographic areas of operation is included in Note 15 in the Notes to Consolidated Financial Statements contained in Item 8 of our Form 10-K for the fiscal year ended December 31, 2008, which is incorporated herein by reference.

**Table of Contents****MANAGEMENT**

The following table sets forth the names and ages of all of our directors and executive officers as of January 28, 2010. Our officers are appointed by, and serve at the pleasure of, the Board of Directors.

| <b>Name</b>      | <b>Age</b> | <b>Title</b>  |
|------------------|------------|---|
| Declan<br>Daly   | 47         | Chief Executive Officer, Chief Operating Officer, and Chief Financial Officer |
| David<br>Pernock | 55         | Director  |
| Paul<br>Hopper   | 53         | Director  |
| Kelvin<br>Moore  | 60         | Director  |
| Robert<br>Langer | 61         | Director  |

Biographical information with respect to our directors and executive officers is provided below. There are no family relationships between any of our executive officers or directors.

*Declan Daly.* Mr. Daly has served as Fibrocell's Chief Executive Officer, Chief Operating Officer and Chief Financial Officer since September 2009, and as a director of Fibrocell since November 2009. Mr. Daly served as Isolagen's Chief Executive Officer and President from January 2008 until September 3, 2009, as Chief Financial Officer from June 2006 until March 2008, and as Chief Operating Officer from June 2007 until January 2008. Mr. Daly was elected to the Board of Directors of Isolagen in June 2008. Mr. Daly served as Executive Vice President and Chief Financial Officer of Inamed Corp. from November 2004 until March 2006, prior to which he served as Inamed's Senior Vice President since September 2002 and as the Corporate Controller and Principal Accounting Officer since March 2002. He was previously Vice President of Finance & Administration for Inamed International Corp. from 1998 to 2002. From 1996 to 1998, Mr. Daly was a Senior Manager with BDO Simpson Xavier, Chartered Accountants or BDO, in Dublin. Prior to joining BDO, he worked with PricewaterhouseCoopers in Dublin and London. Mr. Daly holds a B.A. in Management Science and Industrial Systems Studies from Trinity College, Dublin and he is also a Fellow of the Institute of Chartered Accountants in Ireland.

*David Pernock.* Mr. Pernock has served as a chairman of the board of Fibrocell since September 2009. From December 1993 until November 2009, Mr. Pernock held various positions at GlaxoSmithKline, eventually serving as Senior Vice President of Pharmaceuticals, Vaccines (Biologics), Oncology, Acute Care, and HIV Divisions. Mr. Pernock is a director of Martek Biosciences Corporation. Mr. Pernock holds a B.S. in Business Administration from Arizona State University.

*Paul Hopper.* Mr. Hopper has served as a director of Fibrocell since September 2009. Mr. Hopper has served as Managing Director of Cappello Group, Inc, an investment bank based in Los Angeles, since November 2005. From September 2003 to February 2005, Mr. Hopper served as Managing Director of Australian Cancer Technology Ltd, an oncology biotechnology company. Mr. Hopper is also a Director of Somnomed Ltd, Viralytics Ltd, and pSivida Corp.

*Kelvin Moore.* Mr. Moore has served as a director of Fibrocell since September 2009. Since March 2009, Mr. Moore has served as the consultant sales director for the UK based Seaborne Group developing their business in building constructions from converting shipping sea containers. Since July 2008, Mr. Moore has been a director of Acorn Cultural Developments Limited which is developing a social networking site. Between June 2004 and May 2008, Mr. Moore was a senior advisor with exit strategy planning dealing with the sale of businesses. Mr. Moore holds a London University Degree in Geography and Pure Mathematics.



## **Table of Contents**

*Robert Langer.* Dr. Langer has served as a director of Fibrocell since September 2009. Dr. Langer was named an Institute Professor at Massachusetts Institute of Technology in 2006 and has been on the faculty of Massachusetts Institute of Technology since 1978. Dr. Langer is also a Director of Alseres Pharmaceuticals, Inc. and Echo Therapeutics, Inc. Dr. Langer received his Bachelor's Degree from Cornell University in 1970 and his Sc.D. from the Massachusetts Institute of Technology in 1974, both in Chemical Engineering.

In connection with our emergence from bankruptcy, our plan of reorganization provided that our directors prior to our emergence from bankruptcy were all deemed to have resigned, and a new board of directors was appointed as of the effective date of our emergence from bankruptcy. Pursuant to the plan of reorganization, the new board of directors was determined by the lenders that provided us debtor-in-possession while we were in bankruptcy and the investors that provided us exit financing. The members of our board of directors that were designated in our plan of reorganization are David Pernock, Paul Hopper and Kelvin Moore.

No director is related to any other director or executive officer of our company or our subsidiaries, and, subject to the above paragraph, there are no arrangements or understandings between a director and any other person pursuant to which such person was elected as director.

Our Certificate of Incorporation, as amended, provides that the Board of Directors be divided into three classes. Each director serves a term of three years. At each annual meeting, the stockholders elect directors for a full term or the remainder thereof, as the case may be, to succeed those whose terms have expired. Each director holds office for the term for which elected or until his or her successor is duly elected.

No director or officer of our company has, during the last five years: (i) been convicted of any criminal proceeding (excluding traffic violations or similar misdemeanors) or (ii) been a party to a civil proceeding of a judicial or administrative body of competent jurisdiction and as a result of such proceeding was or is subject to a judgment, decree or final order enjoining future violations of, or prohibiting or mandating activities subject to, United States federal or state securities laws or finding any violations with respect to such laws.

### **Board Committees**

We do not currently have an audit committee, compensation committee or nominating committee. Our full board currently performs the duties and responsibilities of such committees.

### **Equity Incentive Plan**

We currently have an outstanding equity incentive plan, the Fibrocell Science, Inc. 2009 Equity Incentive Plan, or Incentive Plan, that permits us to grant awards in the form of incentive stock options, as defined in Section 422 of the Internal Revenue Code, or Code, as well as options which do not so qualify, called non-qualified stock options, stock units, stock awards, stock appreciation rights, and other stock-based awards. The purpose of the plan is to promote the interests of Fibrocell, and to motivate, attract and retain the services of the people upon whose efforts and contributions our success depends.

The three outstanding stock option plans we had prior to our reorganization, (a) our 2001 Stock Option and Appreciation Rights Plan reserving 5,000,000 shares of common stock for the issuance of options to employees, directors and consultants, (b) our 2003 Stock Option and Appreciation Rights Plan reserving 2,250,000 shares of common stock for the issuance of options to employees, directors and consultants, and (c) our 2005 Equity Incentive Plan reserving 2,100,000 shares of common stock for the issuance of options to employees, directors and consultants, terminated as of the effective date of our reorganization and all outstanding options issued pursuant to the plans were cancelled.

### **Management Agreements**

Effective upon our exit from bankruptcy on September 3, 2009, we entered into an employment agreement, pursuant to which Mr. Daly agreed to serve as our chief operating officer until December 31, 2011, subject to the automatic renewal of the agreement for an additional one-year term unless we notify Mr. Daly prior to the expiration



**Table of Contents**

of the agreement of our intention not to renew the agreement. Notwithstanding the foregoing, if a change of control occurs during the term of the agreement, we may not terminate the agreement for a period of two years after such change of control. The agreement provides Mr. Daly with an annual base salary of \$300,000, which will be periodically reviewed and may be increased at the Board's discretion. Mr. Daly received a one-time signing bonus payment in the amount of \$100,000. Mr. Daly is entitled to receive an annual bonus, payable each year subsequent to the issuance of final audited financial statements, but in no case later than 120 days after the end of our most recently completed fiscal year. The final determination on the amount of the annual bonus will be made by the Compensation Committee of the Board of Directors, based primarily on criteria mutually agreed upon with Mr. Daly. The targeted amount of the annual bonus shall be 50% of Mr. Daly's base salary. The actual annual bonus for any given period may be higher or lower than 50%. For any fiscal year in which Mr. Daly is employed for less than the full year (other than for 2009), he shall receive a bonus which is prorated based on the number of full months in the year which are worked. Mr. Daly is entitled to a bonus of \$50,000 if we are able to complete a capital raise or series of capital raises in excess of \$6.0 million, provided Mr. Daly is our chief operating officer at such time. Mr. Daly is entitled to a bonus of \$50,000 if our BLA is approved by the FDA, provided Mr. Daly is our chief operating officer at such time.

If we terminate the employment agreement without cause or if Mr. Daly dies or become disabled, we will continue to pay Mr. Daly (or his heirs) his base salary at such time for the longer of the remainder of the term of the employment agreement or 12 months from the date of termination. If we terminate the employment agreement without cause following a change of control or if Mr. Daly terminates the employment agreement for good reason, we must pay Mr. Daly, within 30 days of termination, a cash payment equal to the amounts payable for the greater of the remainder of the term of the employment agreement or 12 months from the date of termination.

Pursuant to the employment agreement and as provided in our bankruptcy reorganization plan, Mr. Daly received a grant of 600,000 shares of common stock, of which 300,000 shares vested immediately and 150,000 shares vest on each successive one-year anniversary; provided that if we do not renew the employment agreement at the end of the term or in the event of a change of control, any unvested shares will automatically vest. We have agreed to make a tax gross-up payment with respect to the equity grant.

Mr. Daly has agreed that during his employment and for a period of 12 months after termination or expiration of his employment agreement he will not compete with us, solicit our employees, or attempt to divert or take away our customers and clients.

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 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.

**Table of Contents**

**RELATED PARTY TRANSACTIONS**

**Review and Approval Policies and Procedures for Related Party Transactions**

Pursuant to Board policy, our executive officers and directors, and principal stockholders, including their immediate family members and affiliates, are not permitted to enter into a related party transaction with us without the prior consent of our audit committee, or other independent committee of our board of directors in the case it is inappropriate for our audit committee to review such transaction due to a conflict of interest. Any request for us to enter into a transaction with an executive officer, director, principal stockholder, or any of such persons' immediate family members or affiliates, in which the amount involved exceeds \$120,000 must first be presented to our audit committee for review, consideration and approval. All of our directors, executive officers and employees are required to report to our audit committee any such related party transaction. In approving or rejecting the proposed agreement, our audit committee shall consider the relevant facts and circumstances available and deemed relevant to the audit committee. Our audit committee shall approve only those agreements that, in light of known circumstances, are in, or are not inconsistent with, our best interests, as our audit committee determines in the good faith exercise of its discretion. We do not currently have an audit committee and our full board currently performs the duties and responsibilities of the audit committee.

**Table of Contents****PRINCIPAL STOCKHOLDERS**

The following table sets forth information regarding the beneficial ownership of our common stock as of January 28, 2010 by:

each person known by us to be the beneficial owner of more than 5% of our outstanding shares of common stock;

each of our named executive officers and directors; and

all of our officers and directors as a group.

Unless otherwise indicated, we believe that all persons named in the table have sole voting and investment power with respect to all shares of common stock beneficially owned by them. Unless otherwise indicated, the address for our named executive officers and directors is c/o Fibrocell Science Inc., 405 Eagleview Boulevard, Exton, Pennsylvania 19341.

| <b>Name of Beneficial Owner</b>                             | <b>Common stock<br/>Beneficially<br/>Owned(1)</b> | <b>Percent<br/>of<br/>Class(2)</b> |
|---|---|------------------------------------|
| Declan Daly   | 650,000 (3)                                       | 4.4%                               |
| David Pernock   | 300,000 (4)                                       | 2.0%                               |
| Paul Hopper   | 200,000 (5)                                       | 1.3%                               |
| Kelvin Moore  | 200,000 (5)                                       | 1.3%                               |
| Robert Langer   | 200,000 (5)                                       | 1.3%                               |
| Nicholas L. Teti (6)  |   |                                    |
| Todd Greenspan (6)  |   |                                    |
| Sandra Calman (6)   |   |                                    |
| All Executive Officers and Directors as a Group (5 persons) | 1,550,000 (7)                                     | 9.9%                               |
| <b>Five percent or more of shareholders</b>                 |   |                                    |
| MOG Capital, LLC (8)  | 1,051,757 (8)                                     | 6.7%                               |

(1) Beneficial ownership is determined in accordance with Rule 13d-3 under the Exchange Act. Unless otherwise noted, all listed shares of common stock are owned of record by each person or entity named as beneficial owner and that person or entity has sole voting and

dispositive power with respect to the shares of common stock owned by each of them. As to each person or entity named as beneficial owners, that person's or entity's percentage of ownership is determined based on the assumption that any options or convertible securities held by such person or entity which are exercisable or convertible within 60 days of the date of this report have been exercised or converted, as the case may be.

- (2) Based upon 14,692,166 shares of common stock outstanding as of January 28, 2010.
- (3) Includes 50,000 shares underlying an option exercisable at \$0.75 per share.
- (4) Consists of 300,000 shares underlying an option exercisable at \$0.75 per share. In addition to the shares included

in the table,  
Mr. Pernock  
holds an option  
to purchase  
150,000 shares at  
\$0.75 per share,  
which is  
exercisable in  
September 2010.

- (5) Consists of  
200,000 shares  
underlying an  
option  
exercisable at  
\$0.75 per share.

**Table of Contents**

- (6) Messrs. Teti and Greenspan ceased providing services to the company on the effective date of the bankruptcy in September 2009. Dr. Calman ceased providing services to the company in January 2009.
  
- (7) Includes 950,000 shares underlying options.
  
- (8) Includes 769,231 shares of common stock issuable upon conversion of Series A Preferred, 154,321 shares of common stock issuable upon exercise of Class A warrants and 128,205 shares of common stock issuable upon exercise of Class B warrants. Jason Adler, in his capacity as managing member of MOG Capital, LLC has voting and dispositive power over the securities held by MOG Capital, LLC. Mr. Adler disclaims beneficial

ownership of  
such securities.  
MOG Capital,  
LLC s address is  
2 Rector Street,  
3<sup>rd</sup> Floor, New  
York, NY 10006.

**Table of Contents**

**DESCRIPTION OF SECURITIES**

**General**

We are authorized to issue 250,000,000 shares of common stock and 5,000,000 shares of preferred stock. As of January 28, 2010, we had 14,692,166 shares of common stock outstanding and 3,250 shares of Series A Preferred outstanding. In addition, as of such date we had:

§ 2,807,000 shares of common stock issuable upon the exercise of options issued pursuant to our current stock option plan and outside our stock option plan;

§ 2,193,000 shares of common stock available for issuance upon the exercise of options available for future grant under our stock option plan;

§ 2,500,002 shares of common stock issuable upon the conversion of the Series A Preferred; and

§ 501,542 shares of common stock issuance upon exercise of the Class A warrants, 416,666 shares of common stock issuance upon exercise of the Class B warrants and 250,000 shares of common stock issuance upon exercise of the warrants issued to the placement agents for our Series A Preferred offering.

**Common Stock**

Subject to preferences that may be applicable to any preferred stock outstanding at the time, the holders of our common stock are entitled to receive dividends out of legally available assets at such times and in such amounts as our Board of Directors may from time to time determine. Each stockholder is entitled to one vote for each share of common stock held on all matters submitted to a vote of stockholders. Cumulative voting for the election of directors is not authorized.

Our common stock is not subject to conversion or redemption and holders of our common stock are not entitled to preemptive rights. Upon the liquidation, dissolution or winding up of our company, the remaining assets legally available for distribution to stockholders, after payment of claims or creditors and payment of liquidation preferences, if any, on outstanding preferred stock, are distributable ratably among the holders of our common stock and any participating preferred stock outstanding at that time. Each outstanding share of common stock is fully paid and nonassessable.

**Preferred Stock**

Our Board of Directors has the authority, without action by our stockholders, to designate and issue preferred stock in one or more series. Our Board of Directors may also designate the rights, preferences and privileges of each series of preferred stock, any or all of which may be greater than the rights of the common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock on the rights of holders of the common stock until our Board of Directors determines the specific rights of the holders of the preferred stock. However, these effects might include: (a) restricting dividends on the common stock; (b) diluting the voting power of the common stock; (c) impairing the liquidation rights of the common stock; and (d) delaying or preventing a change in control of our company without further action by our stockholders.

As of the date of this prospectus, we have authorized two classes of preferred stock, Series A Convertible Preferred Stock, or Series A Preferred and Series C Junior Participating Preferred Stock, or Series C Preferred. As of January 28, 2010, there were 3,250 shares of Series A Preferred outstanding and no shares of Series C Preferred outstanding.

***Series A Preferred***

The Series A Preferred shares were issued in October 2009 pursuant to an agreement between us and certain accredited investors. To designate and establish the shares of Series A Preferred, our board approved, and on



**Table of Contents**

October 8, 2009, we filed with the Delaware Secretary of State, a Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock, or Certificate of Designation.

**Dividends; Rank; Liquidation**

Holder of the Series A 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, beginning on April 15, 2010. 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. 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.

Shares of common stock issued as dividends on the Series A Preferred are not being registered under this prospectus. Such shares are deemed to be restricted securities under Rule 144 of the Securities Act and may only be sold in compliance with Rule 144.

The Series A Preferred ranks senior to all shares of common stock.

Upon our liquidation, dissolution or winding-up, whether voluntary or involuntary, the holders of the Series A 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 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 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 is convertible into a number of shares of common stock equal to (1) the stated value of the share (\$1,000), divided by (2) \$1.30, 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 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 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, 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 has been registered under the Securities Act), upon 30 days notice, the Series A Preferred plus all accrued and unpaid dividends will automatically convert into shares of common stock.

Commencing two years from the date of the agreement pursuant to which we issued the Series A 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 has been registered under the Securities Act), we may redeem some or all of the then outstanding Series A Preferred for cash in an amount equal to the 150% of the stated value of the Series A Preferred.

**Voting**

## **Table of Contents**

The holders of the Series A Preferred have no voting rights except with respect to specified matters affecting the rights of the Series A Preferred.

### **Negative Covenants**

As long as any shares of Series A 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; (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 may require us to redeem all of its Series A 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. 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.

### ***Series C Preferred***

In 2006, our Board of Directors declared a dividend distribution of one right for each outstanding share of common stock to stockholders of record at the close of business on May 22, 2006, the record date. Each right entitles the registered holder to purchase from us a unit consisting of one ten-thousandth of a share of Series C Preferred at a purchase price of \$35.00 per unit, subject to adjustment. The rights are not exercisable until the distribution date and will expire at 5:00 P.M. (New York City time) on May 12, 2016, unless such date is extended or the rights are earlier redeemed or exchanged by us. The distribution date occurs upon the earlier of:

ten business days following a public announcement that a person or group of affiliated or associated persons has acquired beneficial ownership of 15% or more of our outstanding common stock (20%, in the case of certain institutional investors) other than as a result of repurchases of stock by us or certain inadvertent actions by institutional or certain other stockholders; or

ten business days (or such later date as the Board shall determine) following the commencement of a tender offer or exchange offer that would result in a person or group becoming an acquiring person.

## **Warrants**

We issued Class A warrants to purchase 501,542 shares of common stock and Class B warrants to purchase 416,666 shares of common stock to the investors that purchased our Series A Preferred pursuant to the agreement in which we issued the Series A Preferred. In addition, we issued warrants to purchase 250,000 shares of common stock to the placement agents for the Series A Preferred. Each of the warrants is exercisable upon issuance and has a five-year term. The initial exercise price of the Class A warrants is \$1.62 per share, the initial exercise price of the Class B warrants is \$1.95 per share, and the initial exercise price of the warrants issued to the placement agents is \$1.30 per share.

With certain exceptions, if, at any time while the warrants are 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

**Table of Contents**

share that is lower than the then exercise price of the relevant warrant, then the exercise price of such warrant will be reduced to equal the lower price.

**Registration Rights**

In connection with the Series A Preferred purchase agreement, we also entered into a Registration Rights Agreements with the purchasers of the Series A Preferred, which requires us to register the resale of the 110% of the shares of common stock underlying the Series A Preferred and the shares of common stock underlying the Class A warrants, Class B warrants and placement agent warrant. We are required to file the registration statement within 45 days of the date of execution of the purchase agreement and the registration statement must be declared effective within 90 days of the date of the agreement (or 120 days if the registration statement is fully reviewed by the SEC), or we will be required to pay liquidated damages as set forth in the agreement.

**12.5% Notes**

In our bankruptcy reorganization plan, each holder of Isolagen's 3.5% convertible subordinated notes, due November 2024, in the approximate non-converted aggregate principal amount of \$81 million, received, in full and final satisfaction, settlement, release and discharge of and in exchange for any and all claims arising out of the 3.5% convertible subordinated notes, its *pro rata* share of an unsecured note in the principal amount of \$6 million, or the New Notes. The New Notes have the following features:

§ 12.5% interest payable quarterly in cash or, at our option, 15% payable in kind by capitalizing such unpaid amount and adding it to the principal as of the date it was due;

§ mature June 1, 2012;

§ at any time prior to the maturity date, we 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; provided that we will be obligated to redeem all outstanding New Notes upon the following events: (a) we or our subsidiary, Fibrocell Technologies, Inc. (formerly, Isolagen Technologies, Inc.) successfully complete a capital campaign raising in excess of \$10,000,000; or (b) we or our subsidiary, Fibrocell Technologies, Inc., are acquired by, or sell a majority stake to, an outside party;

§ the New Notes contain customary representations, warranties and covenants, including a covenant that we and our subsidiary, Fibrocell Technologies, Inc., shall be prohibited from the incurrence of additional debt without obtaining the consent of 66 2/3% of the New Note holders.

**Anti-Takeover Effects of Provisions of Delaware Law**

Provisions of Delaware law and our Certificate of Incorporation, as amended, and Bylaws could make the acquisition of our company through a tender offer, a proxy contest or other means more difficult and could make the removal of incumbent officers and directors more difficult. We expect these provisions to discourage coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of our company to first negotiate with our Board of Directors. We believe that the benefits provided by our ability to negotiate with the proponent of an unfriendly or unsolicited proposal outweigh the disadvantages of discouraging these proposals. We believe the negotiation of an unfriendly or unsolicited proposal could result in an improvement of its terms.

**Anti-Takeover Effects of Provisions of Our Charter Documents**

Our Certificate of Incorporation, as amended, provides for our Board of Directors to be divided into three classes serving staggered terms. Approximately one-third of the Board of Directors will be elected each year. The provision for a classified board could prevent a party who acquires control of a majority of the outstanding voting stock from obtaining control of the Board of Directors until the second annual stockholders' meeting following the

**Table of Contents**

date the acquirer obtains the controlling stock interest. The classified board provision could discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company and could increase the likelihood that incumbent directors will retain their positions.

Our Bylaws do not permit stockholders to call a special meeting of stockholders. Our Bylaws provide that special meetings of the stockholders may be called only by a majority of the members of our Board of Directors, our Chairman of the Board of Directors, our Chief Executive Officer or our President. Our Bylaws require that all stockholder actions be taken by a vote of the stockholders at an annual or special meeting, and do not permit our stockholders to act by written consent without a meeting. Our Bylaws provide for an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to the Board of Directors. At an annual meeting, stockholders may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the Board of Directors. Stockholders may also consider a proposal or nomination by a person who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given to our Secretary timely written notice, in proper form, of his, her or its intention to bring that business before the meeting. The Bylaws do not give our Board of Directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting of the stockholders. However, our Bylaws may have the effect of precluding the conduct of business at a meeting if the proper procedures are not followed. These provisions may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.

**Listing**

Our common stock is listed on the OTCBB under the symbol FCSC.

**Transfer Agent**

The transfer agent for our common stock is American Stock Transfer & Trust Company located at 59 Maiden Lane, New York, New York 11038.

**Table of Contents**

**SHARES ELIGIBLE FOR FUTURE SALE**

As of January 28, 2010, there were approximately 14,692,166 shares of our common stock outstanding.

Future sales of a substantial number of shares of our common stock in the public market could adversely affect market prices prevailing from time to time. Under the terms of this prospectus, the shares of common stock underlying the Series A Preferred and the warrants may be resold without restriction or further registration under the Securities Act, except that any shares offered by our affiliates, as that term is defined under the Securities Act, may generally only be sold in compliance with Rule 144 under the Securities Act.

**Shares Covered by this Prospectus**

The following shares may be offered for resale under this prospectus:

§ 2,750,002 shares of common stock representing 110% of the shares underlying the Series A convertible preferred stock, or Series A Preferred, we issued in October 2009;

§ 501,542 shares of common stock underlying the Class A warrants;

§ 416,666 shares of common stock underlying Class B warrants; and

§ 250,000 shares of common stock underlying the placement agent warrants.

All of the shares being registered in this offering may be resold by the investors without restriction under the Securities Act.

**Rule 144**

The SEC adopted amendments to Rule 144 which became effective on February 15, 2008, and apply to securities acquired both before and after that date. Under these amendments, a person who has beneficially owned restricted shares of our common stock for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the three months preceding, a sale and (ii) we are subject to the Exchange Act periodic reporting requirements for at least three months before the sale.

Of the 14,692,166 shares of our common stock issued and outstanding as of January 28, 2010, a total of 600,000 shares are deemed control securities, within the meaning of Rule 144. Absent registration under the Securities Act, the sale of such shares is subject to Rule 144, as promulgated under the Securities Act. Similarly, any shares we issue as dividends on the Series A Preferred are deemed restricted securities under Rule 144 and may only be sold in compliance with Rule 144. The remainder of our outstanding shares may be sold without limitation or restriction.

**Sales under Rule 144 by Affiliates**

Persons who have beneficially owned restricted shares of our common stock for at least six months but who are our affiliates at the time of, or at any time during the three months preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

(a) 1% of the number of shares of common stock then outstanding, which will equal 146,666 shares as of the date of this prospectus; or

**Table of Contents**

(b) if the common stock is listed on a national securities exchange, the average weekly trading volume of the common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

However, since our shares are quoted on the OTCBB, our stockholders will not be able to rely on the market-based volume limitation described in the second bullet above. If, in the future, our securities are listed on an exchange, then our stockholders would be able to rely on the market-based volume limitation. Unless and until our stock is so listed or quoted, our stockholders can only rely on the percentage based volume limitation described in the first bullet above.

Such sales by affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144. The selling stockholders will not be governed by the foregoing restrictions when selling their shares pursuant to this prospectus.

**Sales Under Rule 144 by Non-Affiliates**

Under Rule 144, a person who is not deemed to have been one of our affiliates at the time of or at any time during the three months preceding a sale, and who has beneficially owned their shares proposed to be sold for at least six months, including the holding period of any prior owner other than an affiliate, is entitled to sell their shares without complying with the manner of sale and volume limitation or notice provisions of Rule 144. We must be current in our public reporting if the non-affiliate is seeking to sell under Rule 144 after holding his shares between six months and one year. After one year, non-affiliates do not have to comply with any other Rule 144 requirements.

The possibility that substantial amounts of our common stock may be sold under Rule 144 into the public market may adversely affect prevailing market prices for the common stock and could impair our ability to raise capital in the future through the sale of equity securities.

**Table of Contents****SELLING SECURITY HOLDERS**

The following table presents information regarding the Selling Stockholders. The percentage of outstanding shares beneficially owned is based on 14,692,166 shares of common stock issued and outstanding on January 28, 2010. Beneficial ownership is determined in accordance with Rule 13d-3 under the Exchange Act. As to each person or entity named as beneficial owners, that person's or entity's percentage of ownership is determined based on the assumption that any warrants or convertible securities (such as the Series A Preferred) held by such person or entity which are exercisable or convertible within 60 days of the date of this report have been exercised or converted, as the case may be.

The Series A Preferred and warrants each provide that at no time may a holder convert the Series A Preferred or exercise the warrants if the number of shares of common stock to be issued pursuant to such conversion or exercise would exceed, when aggregated with all other shares of common stock owned by such holder at such time, the number of shares of common stock which would result in such holder beneficially owning (as determined in accordance with Section 13(d) of the Exchange Act and the rules thereunder) in excess of 9.99% of the then issued and outstanding shares of our common stock; provided, however, that upon the holder providing us with 61 days notice that such holder would like to waive this provision then this provision will be of no force or effect; provided, further, that this provision will be of no force or effect during the 61 days immediately preceding the expiration of the Series A Preferred or warrant.

Except as may be otherwise described below, to the best of our knowledge, the named Selling Stockholder beneficially owns and has sole voting and investment authority as to all of the shares set forth opposite his name, none of the selling stockholders is known to us to be a registered broker-dealer or an affiliate of a registered broker-dealer, and none of the Selling Stockholders has not held any position or office, or has had any material relationship with us or any of our affiliates within the past three years. Each of the Selling Stockholders has acquired his, her or its shares solely for investment and not with a view to or for resale or distribution of such securities.

Information with respect to beneficial ownership is based upon information provided to us by the Selling Stockholders. For purposes of presentation, we have assumed that the Selling Stockholders will sell all shares offered hereby, including the shares issuable on the exercise of warrants or conversion of their Series A Preferred.

| Name of Selling<br>Stockholders | No. of<br>Shares<br>Issuable  | No. of<br>Shares<br>Issuable   | No. of<br>Shares<br>Issuable   | No. of<br>Shares<br>Issuable   | Approximate<br>Percentage<br>of<br>Issued<br>and<br>Outstanding<br>Number of<br>Shares       | Number of<br>Registered<br>and To Be<br>Sold In<br>This<br>Offering                          | Number of<br>Shares<br>Beneficially<br>Owned<br>Prior<br>to the<br>Offering                  | Number of<br>Shares<br>Beneficially<br>Owned<br>Prior<br>to the<br>Offering                  | Number of<br>Shares<br>Beneficially<br>Owned<br>Prior<br>to the<br>Offering                  | Number of<br>Shares<br>Beneficially<br>Owned<br>Prior<br>to the<br>Offering                  | Number of<br>Shares<br>Beneficially<br>Owned<br>Prior<br>to the<br>Offering                  | Number of<br>Shares<br>Beneficially<br>Owned<br>Prior<br>to the<br>Offering                  | Number of<br>Shares<br>Beneficially<br>Owned<br>Prior<br>to the<br>Offering                  |
|---------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|
|                                 | Upon<br>Conversion<br>of Series<br>A<br>Preferred<br>Owned<br>Prior<br>to the<br>Offering | Upon<br>Exercise<br>of<br>the Class<br>A<br>Warrants<br>Owned<br>Prior to<br>the<br>Offering | Upon<br>Exercise<br>of<br>the Class<br>B<br>Warrants<br>Owned<br>Prior to<br>the<br>Offering | Upon<br>Exercise<br>of<br>the Class<br>B<br>Warrants<br>Owned<br>Prior to<br>the<br>Offering | Upon<br>Exercise<br>of<br>the Class<br>B<br>Warrants<br>Owned<br>Prior to<br>the<br>Offering | Upon<br>Exercise<br>of<br>the Class<br>B<br>Warrants<br>Owned<br>Prior to<br>the<br>Offering | Upon<br>Exercise<br>of<br>the Class<br>B<br>Warrants<br>Owned<br>Prior to<br>the<br>Offering | Upon<br>Exercise<br>of<br>the Class<br>B<br>Warrants<br>Owned<br>Prior to<br>the<br>Offering | Upon<br>Exercise<br>of<br>the Class<br>B<br>Warrants<br>Owned<br>Prior to<br>the<br>Offering | Upon<br>Exercise<br>of<br>the Class<br>B<br>Warrants<br>Owned<br>Prior to<br>the<br>Offering | Upon<br>Exercise<br>of<br>the Class<br>B<br>Warrants<br>Owned<br>Prior to<br>the<br>Offering | Upon<br>Exercise<br>of<br>the Class<br>B<br>Warrants<br>Owned<br>Prior to<br>the<br>Offering | Upon<br>Exercise<br>of<br>the Class<br>B<br>Warrants<br>Owned<br>Prior to<br>the<br>Offering |
| Basu Biosciences,<br>LLC (2)    | 76,923  | 15,432   | 12,821   |  | *  | 105,176  |  |  |  |  |  |  |  |

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|   |         |         |         |       |           |         |                          |
|---|---------|---------|---------|-------|-----------|---------|--------------------------|
| MOG Capital,<br>LLC (3)                 | 769,231 | 154,321 | 128,205 | 6.69% | 1,051,757 |         |                          |
| Ravinder Holder                         | 38,462  | 7,716   | 6,410   | *     | 52,588    |         |                          |
| Straus Healthcare<br>Partners, L.P. (4) | 262,308 | 52,623  | 43,718  | 2.39% | 358,649   | 143,623 | *                        |
| Straus-GEPT<br>Partners,<br>L.P. (4)    | 280,000 | 56,173  | 46,667  | 2.54% | 382,840   | 153,106 | 1.0%                     |
| Straus Partners,<br>L.P. (4)            | 419,231 | 84,105  | 69,872  | 3.76% | 573,208   | 229,505 | 1.5%                     |
| Bao Ruo Wang                            | 144,231 | 28,935  | 24,038  | 1.33% | 197,204   | 87,725  | *                        |
| Chen Zhang                              | 144,231 | 28,935  | 24,038  | 1.33% | 197,204   | 87,725  | *                        |
| William Zuo                             | 144,231 | 28,935  | 24,038  | 1.33% | 197,204   | 87,725  | *                        |
| Tao Zhou                                | 144,231 | 28,935  | 24,038  | 1.33% | 197,204   | 87,725  | *                        |
| Margery M. Scotti                       | 76,923  | 15,432  | 12,821  | *     | 105,176   |         |                          |
| George Carris (6)                       |         |         |         |       | 125,000   | *       | 125,000 500,000 (5) 3.3% |
| David Batista (7)                       |         |         |         |       | 62,500    | *       | 62,500 500,000 (5) 3.3%  |
| David Walter<br>Boral (8)               |         |         |         |       | 62,500    | *       | 62,500                   |

49



**Table of Contents**

- \* Stockholder owns less than 1%
  
- (1) The Selling Stockholders and any broker-dealers or agents that are involved in selling these shares are deemed to be underwriters within the meaning of the Securities Act for such sales. An underwriter is a person who has purchased shares from an issuer with a view towards distributing the shares to the public. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be considered to be underwriting commissions or discounts under the Securities Act.
  
- (2) Shekhar Basu, in his capacity as managing member of Basu Biosciences,

LLC has voting and dispositive power over the securities held by Basu Biosciences, LLC.

- (3) MOG Capital, LLC is a registered broker dealer. The registrable securities were acquired in the ordinary course of business and not as compensation for investment banking services. Accordingly, the selling security holder is an underwriter within the meaning of Section 2(a)(11) of the Securities Act under the interpretations of the SEC. Jason Adler, in his capacity as managing member of MOG Capital, LLC has voting and dispositive power over the securities held by MOG Capital, LLC. Mr. Adler disclaims beneficial ownership of such securities.

(4)

Ravinder  
Holder, general  
partner of each  
of the selling  
stockholders,  
holds voting and  
dispositive  
power over the  
securities held  
by the selling  
stockholders.

- (5) Consists of an option to purchase 500,000 shares of common stock at \$0.75 per share.
- (6) The shares being registered underlie warrants we agreed to issue to our placement agent in connection with the Series A Preferred offering. Mr. Carris is an affiliate of the placement agent.
- (7) The shares being registered underlie warrants we agreed to issue to our placement agent in connection with the Series A Preferred offering. Mr. Batista is an affiliate of the placement agent.

(8)

The shares being registered underlie warrants we agreed to issue to our placement agent in connection with the Series A Preferred offering. Mr. Boral is an affiliate of the placement agent.

We may require the Selling Stockholders to suspend the sales of the securities offered by this prospectus upon the occurrence of any event that makes any statement in this prospectus or the related registration statement untrue in any material respect or that requires the changing of statements in these documents in order to make statements in those documents not misleading.

**Table of Contents**

**PLAN OF DISTRIBUTION**

Each Selling Stockholder of the common stock and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their shares of common stock covered hereby on the principal trading market or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. A Selling Stockholder may use any one or more of the following methods when selling shares:

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;

in transactions through broker-dealers that agree with the Selling Stockholders to sell a specified number of such shares at a stipulated price per share;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;

a combination of any such methods of sale; or

any other method permitted pursuant to applicable law.

The Selling Stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the Selling Stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

In connection with the sale of the common stock or interests therein, the Selling Stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The Selling Stockholders may also sell shares of the common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The Selling Stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The Selling Stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by



**Table of Contents**

them may be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Stockholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the Common Stock. In no event shall any broker-dealer receive fees, commissions and markups which, in the aggregate, would exceed 8%.

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the shares. The Company has agreed to indemnify the Selling Stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

Because Selling Stockholders may be deemed to be underwriters within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act including Rule 172 thereunder. The Selling Stockholders have advised us that there is no underwriter or coordinating broker acting in connection with the proposed sale of the resale shares by the Selling Stockholders.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the shares may be resold by the Selling Stockholders without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, without the requirement for the Company to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect or (ii) all of the shares have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale shares of Common Stock covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of the common stock by the Selling Stockholders or any other person. We will make copies of this prospectus available to the Selling Stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

**Table of Contents**

**INCORPORATION BY REFERENCE**

The SEC allows us to incorporate by reference information in this prospectus that we have filed with it. This means that we can disclose important information to you by referring you to another document already on file with the SEC. The information incorporated by reference is an important part of this prospectus, except for any information that is superseded by information that is included directly in this prospectus.

We incorporate by reference into this prospectus the following documents:

- § our annual report on Form 10-K for the year ended December 31, 2008, filed with the SEC on April 15, 2009, and our annual report on Form 10-K/A for the year ended December 31, 2008, filed with the SEC on April 30, 2009;
- § our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2009, June 30, 2009, and September 30, 2009; and
- § our Current Reports on Form 8-K, filed with the SEC on January 15, 2009; February 4, 2009; March 17, 2009; March 20, 2009; May 6, 2009; June 16, 2009; June 19, 2009; July 10, 2009; September 2, 2009; September 10, 2009; October 1, 2009; October 14, 2009; and October 26, 2009.

Subsequent events had been evaluated by the Successor Company through November 23, 2009, which was the date the financial statements for the quarter ended September 30, 2009 were available to be issued. In conjunction with this registration statement, subsequent events have been evaluated through January 28, 2010, which was the date the registration statement was available to be issued. There were no changes to the previously disclosed information.

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, upon written or oral request, a copy of the reports and documents that have been incorporated by reference in this prospectus, at no cost. Any such request may be made by writing or telephoning us at the following address or phone number:

Fibrocell Science, Inc.  
405 Eagleview Boulevard  
Exton, Pennsylvania 19341  
(484) 713-6000  
Attention: Corporate Secretary

These documents can also be requested through, and are available in, the Investors section of our website, which is located at [www.fibrocellscience.com](http://www.fibrocellscience.com), or as described under Where You Can Find More Information below. The information and other content contained on or linked from our internet website are not part of this prospectus.

**LEGAL MATTERS**

The validity of the common stock offered by this prospectus has been passed upon for us by Cozen O Connor, Philadelphia, Pennsylvania.

**EXPERTS**

The consolidated financial statements as of December 31, 2008 and 2007 and for each of the two years in the period ended December 31, 2008 incorporated by reference in this prospectus and in the Registration Statement have been so incorporated in reliance on the report of BDO Seidman, LLP, an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

**WHERE YOU CAN FIND MORE INFORMATION**

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the common stock offered in this offering. This prospectus does not contain all of the information set forth in the registration statement. For further information with respect to us and the common stock offered in this offering, we



**Table of Contents**

refer you to the registration statement and to the attached exhibits. With respect to each such document filed as an exhibit to the registration statement, we refer you to the exhibit for a more complete description of the matters involved.

You may inspect our registration statement and the attached exhibits and schedules without charge at the public reference facilities maintained by the SEC at 100 F Street, N.E., Washington, D.C. 20549. You may obtain copies of all or any part of our registration statement from the SEC upon payment of prescribed fees. You may obtain information on the operation of the public reference room by calling the SEC at 1-800-SEC-0330.

Our SEC filings, including the registration statement and the exhibits filed with the registration statement, are also available from the SEC's website at [www.sec.gov](http://www.sec.gov), which contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC.

**Table of Contents**

**PART II**  
**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 13. Other Expenses of Issuance and Distribution**

The following table sets forth the costs and expenses, other than underwriting discounts, payable by the registrant in connection with the sale of the shares of common stock being registered. All amounts are estimates except the fees payable to the SEC.

|                              |           |
|------------------------------|-----------|
| SEC Registration Fee         | \$ 224    |
| Accounting Fees and Expenses | \$ 5,000  |
| Legal Fees and Expenses      | \$ 10,000 |
| Miscellaneous                | \$ 3,000  |
| Total                        | \$ 18,224 |

**Item 14. Indemnification of Directors and Officers**

Fibrocell's Certificate of Incorporation and Bylaws authorize it to indemnify directors, officers, employees and agents of Fibrocell against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement, actually and reasonably incurred in connection with any action, suit or proceeding, if the party to be indemnified acted in good faith and in a manner that he reasonably believed to be in or not opposed to the best interests of Fibrocell, and, with respect to any criminal action or proceeding, such party had no reasonable cause to believe his conduct was unlawful. The Certificate of Incorporation and the Bylaws of Fibrocell also authorize it to indemnify directors, officers, employees and agents of Fibrocell who are or were a party to or threatened to be a party to, any threatened, pending, or completed action or suit by or in the right of Fibrocell to procure a judgment in its favor by reason of the fact that he was a director, officer, employee or agent of Fibrocell or of another entity at the request of Fibrocell, against expenses (including reasonable attorneys' fees) actually and reasonably incurred by him in connection with the defense or settlement of such action or suit if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of Fibrocell, except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged liable to Fibrocell unless and to the extent that the court in which such suit or action was brought shall determine on application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses as the court deems proper.

The Bylaws also permit Fibrocell to enter into indemnity agreements with individual directors, officers, employees, and other agents. Fibrocell reserves the right to enter into such agreements with its directors and executive officers effective upon the closing of this offering. These agreements, together with the Bylaws and Certificate of Incorporation, may require Fibrocell, among other things, to indemnify directors or officers against certain liabilities that may arise by reason of their status or service as directors (other than liabilities resulting from willful misconduct of a culpable nature), to advance expenses to them as they are incurred, provided that they undertake to repay the amount advanced if it is ultimately determined by a court that they are not entitled to indemnification, and to obtain and maintain directors' and officers' insurance if available on reasonable terms.

Fibrocell's Certificate of Incorporation provides that directors shall have no personal liability to Fibrocell or its stockholders for monetary damages for breach of fiduciary duty as a director, except (i) for any breach of a director's duty of loyalty to Fibrocell or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under section 174 of the General Corporation Law of Delaware as it may from time to time be amended or any successor provision thereto, or (iv) for any transaction from which a director derived an improper personal benefit.

Fibrocell currently has directors' and officers' liability insurance. Delaware General Corporation Law, Section 145, and the Certificate of Incorporation and Bylaws of Fibrocell provide for the indemnification of officers, directors and other corporate agents in terms sufficiently broad to indemnify such persons, under certain circumstances, for liabilities (including reimbursement of expenses incurred) arising under the Securities Act. Insofar as indemnification

for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons pursuant to the foregoing provisions, or

II-1

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**Table of Contents**

otherwise, Fibrocell has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

**Item 15. Recent Sales of Unregistered Securities**

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.

Pursuant to the Plan, all Isolagen equity interests, including without limitation its common stock, options and warrants outstanding as of the effective date were cancelled. On the effective date, Fibrocell completed an exit financing of common stock in the amount of \$2 million. Fibrocell issued the following shares of common stock pursuant to the Plan:

- § 7,320,000 shares, to its pre-bankruptcy lenders and the lenders that provided its debtor-in-possession facility, collectively;
- § 3,960,000 shares, to the holders of the 3.5% convertible subordinated notes issued by Isolagen;
- § 600,000 shares, to its management as of the effective date, which was its chief operating officer;
- § 120,000 shares, to the holders of its general unsecured claims; and
- § 2,666,666 shares, to the purchasers of shares in the exit financing (its pre-bankruptcy lenders, the lenders that provided the debtor-in-possession facility and the holders of the 3.5% convertible subordinated notes were permitted to participate in the exit financing).

The common stock issued pursuant to the Plan was issued pursuant to Section 1145 of the United States Bankruptcy Code, which exempts the issuance of securities from the registration requirements of the Securities Act of 1933, as amended ( Securities Act ).

A condition precedent to Fibrocell's exit from bankruptcy was that it execute an investment banking agreement with John Carris Investments LLC and Viriathus Capital LLC. In connection with this agreement, Fibrocell was required to pay a retainer, which consisted in part of the issuance of options to purchase an aggregate of 1,000,000 shares of common stock at \$0.75 per share. These securities were issued pursuant to the exemption from registration permitted under Section 4(2) of the Securities Act.

The Series A Preferred and the warrants, the underlying common stock of which is being registered for resale in this registration statement, were sold in a transaction exempt from registration under the Securities Act, in reliance on Section 4(2) thereof and Rule 506 of Regulation D thereunder. Each purchaser represented that it was an accredited investor as defined in Regulation D.

In October 2009, Fibrocell entered into two consulting agreements with two individuals. Fibrocell 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. The options were issued in a transaction exempt from registration under the Securities Act of 1933, in reliance on Section 4(2) thereof.

**Item 16. Exhibits and Financial Statement Schedules****Exhibit  
Number****Description**

- |     |   |
|-----|---|
| 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) |
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**Table of Contents**

| <b>Exhibit<br/>Number</b> | <b>Description</b>  |
|---------------------------|---|
| 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)  |
| 4.1                       | Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to our Form 10-Q filed November 23, 2009)  |
| 4.2                       | Form of Class A/B Common Stock Purchase Warrant (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)  |
| 4.6                       | Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.2 to our Form 10-Q filed November 23, 2009)   |
| 4.7                       | Registration Rights Agreement between the Company and the Series A Preferred Stock Purchasers, dated October 13, 2009 (incorporated by reference to Exhibit 10.2 to our Form 8-K filed October 14, 2009)              |
| *5                        | Opinion of Cozen O Connor   |
| 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                      | Employment Agreement between the Company and Declan Daly (incorporated by reference to Exhibit 10.1 to our Form 10-Q filed November 23, 2009)   |
| 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 (incorporated by reference to Exhibit 10.3 to our Form 10-Q filed November 23, 2009)   |
| 10.5                      | Lease Agreement between Isolagen Technologies, Inc. and Beltway 8 Service Center Investors Ltd. dated February 16, 2005 (previously filed as an exhibit to the company's Form 8-K, filed on February 23, 2005)        |
| 10.6                      | Purchase Option Agreement between Isolagen, Inc and 405 Eagleview Associates dated April 7, 2005 (previously filed as an exhibit to the company's Form 8-K, filed on April 12, 2005)                                  |
| 10.7                      | Intellectual Property Purchase Agreement between Isolagen Technologies, Inc., Gregory M. Keller, and PacGen Partners (previously filed as an exhibit to the company's amended Form S-1, as filed on October 24, 2003) |

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 Seidman, LLP

23.2 Consent of Cozen O'Connor (included in Exhibit 5)

24.1 Power of Attorney (included on signature page)

\* Filed herewith.

**Item 17. Undertakings**

The undersigned registrant hereby undertakes:

1. To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

i. To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;

II-3

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**Table of Contents**

ii. To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement.

iii. To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

Provided however, That:

A. Paragraphs (1)(i), (1)(ii) and (1)(iii) of this section do not apply if the registration statement is on Form S-3 or Form F-3 and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

2. That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

3. To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

4. That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

i. If the registrant is relying on Rule 430B:

A. Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

B. Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; or

ii. If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will,



**Table of Contents**

as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

5. That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities: The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

i. Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

ii. Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

iii. The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

iv. Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

6. The undersigned registrant hereby undertakes to deliver or cause to be delivered with the prospectus, to each person to whom the prospectus is sent or given, the latest annual report to security holders that is incorporated by reference in the prospectus and furnished pursuant to and meeting the requirements of Rule 14a-3 or Rule 14c-3 under the Securities Exchange Act of 1934; and, where interim financial information required to be presented by Article 3 of Regulation S-X are not set forth in the prospectus, to deliver, or cause to be delivered to each person to whom the prospectus is sent or given, the latest quarterly report that is specifically incorporated by reference in the prospectus to provide such interim financial information.

7. Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Exton, Commonwealth of Pennsylvania, on January 29, 2010.

FIBROCELL SCIENCE, INC.

By: /s/ Declan Daly

Name:

**Declan Daly**

Title: **Chief Executive Officer, Chief  
Financial Officer, Chief Operating  
Officer & Controller**

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated:

| <b>Signature</b> | <b>Title</b>   | <b>Date</b>      |
|------------------|--|------------------|
| /s/ Declan Daly  | Director, Chief Executive Officer, Chief<br>Financial Officer, Chief Operating<br>Officer and Controller | January 29, 2010 |
| Declan Daly      |  |                  |
| *                | Chairman of the Board  | January 29, 2010 |
| David Pernock    |  |                  |
| *                | Director   | January 29, 2010 |
| Paul Hopper      |  |                  |
| *                | Director   | January 29, 2010 |
| Kelvin Moore     |  |                  |
| *                | Director   | January 29, 2010 |
| Robert Langer    |  |                  |

\*By: /s/ Declan Daly  
Declan Daly  
Attorney-in-fact

**Table of Contents**

**EXHIBIT INDEX**

| <b>Exhibit<br/>Number</b> | <b>Description</b>   |
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  - 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)
  - 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)
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  - 23.2 Consent of Cozen O'Connor (included in Exhibit 5)
- \* Filed herewith.

II-7