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

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**FORM 10-K**

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2005

or

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

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**Isolgen, Inc.**

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

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

**405 Eagleview Boulevard**  
**Exton, Pennsylvania 19341**  
(Address of principal executive offices, including zip code)

**(484) 713-6000**  
(Issuer's telephone number, including area code)

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

Title of Each Class	Name of Each Exchange on which Registered
Common Stock, \$.001 par value	American Stock Exchange

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

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

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

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

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

Large accelerated filer     Accelerated filer     Non-accelerated filer

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

As of June 30, 2005, the aggregate market value of the issuer's common stock held by non-affiliates of the issuer based upon the price at which such common stock was sold on the American Stock Exchange as of such date was \$121,253,211.

As of March 9, 2006, issuer had 34,389,133 shares issued and 30,389,133 shares outstanding of common stock, par value \$0.001.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Proxy Statement for the 2006 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed within 120 days of the end of the fiscal year ended December 31, 2005, are incorporated by reference in Part III hereof. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part hereof.

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## TABLE OF CONTENTS

	<b>Page</b>
<b>PART I</b>	
<a href="#"><u>ITEM 1. BUSINESS</u></a>	3
<a href="#"><u>ITEM 1A. RISK FACTORS</u></a>	20
<a href="#"><u>ITEM 1B. UNRESOLVED STAFF COMMENTS</u></a>	35
<a href="#"><u>ITEM 2. PROPERTIES</u></a>	36
<a href="#"><u>ITEM 3. LEGAL PROCEEDINGS</u></a>	36
<a href="#"><u>ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS</u></a>	38
<b>PART II</b>	
<a href="#"><u>ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS</u></a>	39
<a href="#"><u>ITEM 6. SELECTED FINANCIAL DATA</u></a>	40
<a href="#"><u>ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u></a>	41
<a href="#"><u>ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u></a>	55
<a href="#"><u>ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u></a>	56
<a href="#"><u>ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u></a>	56
<a href="#"><u>ITEM 9A. CONTROLS AND PROCEDURES</u></a>	56
<a href="#"><u>ITEM 9B. OTHER INFORMATION</u></a>	60
<b>PART III</b>	
<a href="#"><u>ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT</u></a>	61
<a href="#"><u>ITEM 11. EXECUTIVE COMPENSATION</u></a>	61
<a href="#"><u>ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u></a>	61
<a href="#"><u>ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS</u></a>	61
<a href="#"><u>ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES</u></a>	61
<b>PART IV</b>	
<a href="#"><u>ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES</u></a>	62

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## Forward-Looking Information

This report 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 Isolagen 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 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 and other health-related markets;
- whether our clinical human trials relating to autologous cellular therapy applications for the treatment of dermal defects or gingival recession 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;
- whether the FDA accepts our proposed protocol relating to our dermal Phase III study as the basis for a confirmatory study;
- whether the results of such confirmatory study, together with the data from the previous dermal Phase III study, will support a successful BLA filing;
- our ability to provide and deliver any autologous cellular therapies that we may develop, on a basis that is cost competitive with other therapies, drugs and treatments that may be provided by our competitors;
- our ability to finance our business;
- our ability to improve our current pricing model;
- our ability to decrease our cost of goods sold through the improvement and/or automation of our manufacturing process, which we believe will eliminate several of the steps and materials involved in our current system and will lead to significant cost reductions in both skilled labor and materials and will enable scalable mass production;
- whether we can successfully transfer the technology relating to process improvements into our UK operations;
- our ability to reduce our need for fetal bovine calf serum by improved use of less expensive media combinations and different media alternatives;
- a stable currency rate environment in the world, and specifically the countries we are doing business in or plan to do business in;

- our ability to meet requisite regulations or receive regulatory approvals in the United States, Europe, Asia and the Americas, and our ability to retain the licenses that we have obtained and 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;
- continued availability of supplies at satisfactory prices;
- no new entrance of competitive products or further penetration of existing products in our markets;
- no adverse publicity related to our products or the Company itself;
- no adverse claims relating to our intellectual property;
- the adoption of new, or changes in, accounting principles; and/or legal proceedings;
- our ability to maintain compliance with the AMEX requirements for continued listing of our common stock;
- the costs inherent with complying with new statutes and regulations applicable to public reporting companies, such as the Sarbanes-Oxley Act of 2002;
- our ability to efficiently integrate future acquisitions, if any;
- our ability to successfully integrate other new lines of business that we may enter in the future, if any; and
- other risks referenced from time to time elsewhere in this report 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.

## Part I

### Item 1. Business

#### Overview

We specialize in the development and commercialization of autologous cellular therapies for soft tissue regeneration. Autologous cellular therapy is the process whereby a patient's own cells are extracted, allowed to multiply and then injected into the patient. Our two product candidates, which are directed at the aesthetic and dental markets, utilize our proprietary Isolagen Process. Based on our accumulated clinical experience, we believe that our Isolagen Process can utilize a patient's own cells to create safe and effective therapies to address a number of conditions brought on by aging. Our product candidates are designed to be minimally invasive and non-surgical.

We are developing our lead product candidate for the correction and reduction of the normal effects of aging, such as wrinkles and creases. In March 2004, we announced positive results of our first Phase III exploratory clinical trial for our lead product candidate. In July 2004, we announced the commencement of a pivotal Phase III trial, which was being conducted in two different geographic and demographic populations in the United States as two identical studies for the treatment of facial wrinkles. These studies, which were concluded during the second half of 2005, were randomized, double blind and placebo-controlled and were conducted at various sites in the United States. The studies, which were conducted simultaneously, each had in excess of 100 subjects split evenly between the treatment group and the placebo group.

We announced on August 1, 2005 the results of our pivotal Phase III dermal studies. The dermal studies met three of the four primary endpoints and achieved statistical significance when combined. The studies' primary endpoints were based on blinded physician visual assessment using a six-point scale with a two-point positive move required to meet the endpoint and subject assessment using a visual analog scale. Trial B of the study proved to be clinically and statistically significant with both the subject and physician assessment achieving positive results. Trial A results were mixed with only a positive assessment from the subjects. In addition, there was a wide variance in results from site to site with a range of response rates from 73.3% to 7.6%, where a "response" represents the improvement of at least two points, on a six point scale, based on a visual assessment performed by the physician. We believe that this range of outcomes suggests that results are dependent on, among other things, injection technique. We conducted a post hoc statistical analysis and a thorough review of the results of the Phase III studies that suggested trial results were negatively impacted by two factors in addition to injection technique. First, our statistical analysis included all subjects who were randomized to the study. The statistical analysis did not exclude subjects who received neither our product nor placebo; these subjects were deemed to have failed the study. Second, our study population included a number of subjects with a baseline assessment of two (of their wrinkles) on the six-point scale. A two point improvement for these subjects would have required an assessment of zero on the six-point scale. After consultation with our clinical advisors familiar with utilizing the six-point scale, we believe subjects with an initial assessment of two on the scale should have been excluded from participation in the studies because of investigator reluctance to make a final assessment of zero (equivalent to no wrinkles) at the endpoint. Our future protocols will exclude subjects with a baseline assessment of two.

We used the information derived from our post hoc statistical analysis and the input of our clinical advisors to develop a Phase III confirmatory study. During the fourth quarter of 2005, we submitted a protocol to the Food and Drug Administration (FDA) for a 200 subject confirmatory study the results of which we intend to submit together with our previous studies to support a Biological License Approval (BLA) filing in 2007. We are diligently working with the FDA to secure Special Protocol Assessment (SPA) approval of this new Phase III confirmatory study and to resolve a number of issues relating to the commencement of the confirmatory study. As part of this process, we believe we have made significant

progress in addressing the FDA's requests for information regarding Chemistry Manufacturing Controls (CMC) data and process validation. We intend to conduct the confirmatory study from our Exton, Pennsylvania facility. We completed the construction of the Exton manufacturing facility during the fourth quarter of 2005 and this facility is now validated for trial commencement.

During the fourth quarter of 2005, we commenced preparations for our confirmatory study, including identifying and recruiting investigator sites and submission of the protocol to the FDA. We recently conducted an investigator meeting during which we provided injection and assessment training to participants. We expect to complete training and site initiation by the end of the first quarter of 2006. This study will be conducted from our Exton facility.

We completed a Phase I clinical trial for our second product candidate, for the treatment of periodontal disease, in late 2003. In the second quarter of 2004, we initiated a Phase II clinical trial for the cosmetic, or "black triangle," application of this product candidate. This Phase II clinical trial concluded during the second quarter of 2005. The analysis of the investigator and subject visual analog scale assessment demonstrated that the Isolagen Process was statistically superior to placebo at four months after treatment. Although results of the investigator and subject assessment demonstrated that the Isolagen Process was statistically superior to placebo, an analysis of objective linear measurements did not yield statistically significant results despite a positive change observed as a result of treatment with the Isolagen Process. Clinical advisors believe that current measurement techniques are not precise enough to accurately record the positive change. We are investigating alternative measurement techniques to assess change in future trials.

We believe our company is still considered to be a "development stage" enterprise since the focus of our efforts has been and will continue to be the development, testing and approval of the aesthetic applications and research into other applications of our process. Since 2002, however, we have made the Isolagen Process available to physicians primarily in the United Kingdom as a means of developing our marketing, sales and manufacturing processes. Revenue from the sale of these treatments was approximately \$8.75 million in 2005, which was less than our original projection although this level of sales represents over a 100% increase in revenue over the prior year. We believe our revenue was adversely affected by the following factors:

- Our 2005 sales remained heavily concentrated in United Kingdom. We envisioned a much greater geographical reach.
- Our marketing efforts in the United Kingdom were curtailed by marketing restrictions.
- We were unable to effectively and efficiently implement manufacturing process and technology improvements in the United Kingdom which led to a high variable cost base and negative margins during the period of implementation of these improvements. As a result, we dedicated less resources toward market development.
- At the time of our initial projections, we assumed a positive BLA submission during 2005. As a result of our trial results and our inability to file the BLA, we dedicated less resources than we previously anticipated towards market development.

Our corporate headquarters is located at 405 Eagleview Boulevard, Exton, Pennsylvania 19341. Our phone number is (484) 713-6000, and the address of our web site is [www.Isolagen.com](http://www.Isolagen.com). Information appearing at our web site is not a part of this Annual Report on Form 10-K. Our web site includes links to our Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments to those reports (SEC Reports). The SEC Reports are available without charge as soon as reasonably practicable following the time that they are filed with or furnished to the SEC. Our fiscal year begins on January 1, and ends on December 31, and any references herein to "Fiscal 2005"

mean the year ended December 31, 2005, and references to other “Fiscal” years mean the year ending December 31, of the year indicated.

Unless the context required otherwise, all references to “Isolagen,” “the Company,” “us,” “we,” and “our” refer to Isolagen, Inc. together with its consolidated subsidiaries.

### **The Structure of Skin and Conditions that Affect Appearance**

The skin is the body’s largest organ and is comprised of layers called the epidermis and dermis. The epidermis is the outer layer, and serves as a protective barrier for the body. It contains cells that determine pigmentation, or skin color. The underlying layer of skin, the dermis, contains hair follicles and large and small blood vessels that are found at various depths below the epidermis. Fibroblasts are found in the dermis and are responsible for creating collagen and elastin, which provide strength and flexibility to the skin.

Many factors, such as age, sun damage, acne or other injury to the skin and the human body’s diminished ability to repair and renew itself over time, can result in aesthetically unpleasant changes in the skin’s appearance. As the number of fibroblasts decreases over time the mechanical strength of skin changes as less collagen and elastin are produced, resulting in wrinkles and looseness in the skin. As people age or experience some of these skin conditions, they may seek aesthetic treatments to improve their appearance.

### **Our Target Market Opportunity**

#### *Aesthetic Market Opportunity*

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 \$4.2 billion in 2005. We believe the aesthetic procedure market is driven by:

- aging of the “baby boomer” population, currently ages 42 to 60, representing approximately 28% of the U.S. population;
- increasing desire of many individuals to improve their appearance;
- impact of managed care and reimbursement policies on physician economics, which has motivated physicians to establish or expand the menu of elective, private-pay aesthetic procedures that they offer; and
- broadening base of the practitioners performing cosmetic procedures beyond dermatologists and plastic surgeons to non-traditional providers.

Our lead product candidate is directed primarily at the aesthetic market. According to the ASAPS, 11.4 million surgical and non-surgical cosmetic procedures were performed in 2005, as compared to 11.9 million in 2004. Also according to the ASAPS, nearly 9.3 non-surgical procedures were performed in 2005, as compared to 9.7 million non-surgical procedures in 2004. 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 2005:

<u>Procedure</u>	<u>Number</u>
Botox injection	3,294,782
Laser hair removal	1,566,909
Hyaluronic acids	1,194,222
Microdermabrasion	1,023,931
Chemical peel	556,172

Procedures among the 35 to 50 year old age group made up 47% of all non-surgical cosmetic procedures in 2005. The 51 to 64 year old age group made up 24% of all non-surgical cosmetic procedures in 2005, while the 19 to 34 year old age group made up 22% of the non-surgical cosmetic procedures. Botox injection was the most popular treatment among the 35 to 50 and 51 to 64 year old age groups.

#### *Dental Market Opportunity*

In addition to the aesthetic market, we believe there is a dental market opportunity for an effective therapy for regenerating tissue because a majority of the population will experience periodontal disease at some point in their lives. According to the Department of Labor, Bureau of Labor Statistics, there were over 150,000 active privately practicing dentists in the United States in 2004.

Gum and bone erosion in the mouth increase with age. The single greatest cause of bone and tooth loss in the mouth is periodontal disease. Although modern dentistry's ability to conserve teeth has improved, the ability to preserve bone and soft tissue, or gum, remains a challenge. As the periodontal pockets deepen due to the presence of bacteria at the attachment of the gum to the tooth and/or jaw bone, the amount of bacteria trapped in these pockets increases, leading to inflammation and gum and bone loss around the tooth. Therapeutic options that decrease the depth of the pockets make the patient's daily home care more effective and reduce the chance of further gum and bone loss.

Papillary recession, also known as "black triangles," can be associated with the progression of periodontal disease, and involves the recession of the triangular section of gum tissue between two teeth. We are not aware of any documented effective treatment for this condition. If not treated, this recession can lead to tooth loss. Currently, the loss of tissue associated with severe periodontal disease can only be treated through surgical procedures. These surgical procedures are expensive and painful, can potentially result in complications and have variable outcomes.



## Limitations of Existing Dermal Therapies

There are many alternatives to reduce the signs of aging in the face, such as injectables, surface treatments, laser therapies and surgery. There have been a number of minimally invasive products developed over the years, including injectables of various collagen formulations derived from animal and human sources, hyaluronic acid from animal and synthetic sources, plastic beads and calcium hydroxyapatite. Other available therapies include paralysis of the underlying superficial musculature with Botulinum toxin, commonly known as “Botox,” and transplantation of autologous fat. These products are associated with clinical problems that vary from product to product, including:

- *Short duration of effect.* Many of these products last for a short time, as they are reabsorbed by the body over a three to six month period. The need for repeated treatments to maintain an improved appearance may make these options inconvenient and more costly over time for patients.
- *Significant pain associated with the injection.* All of these products are administered through injections directly into the facial tissue. Some competing procedures can be very painful for the patient and require the use of a thicker needle for the injection. For some of these products, physicians will have to anesthetize the area or administer a nerve block in order to complete the procedure. This is both inconvenient for the patient and adds extra time to the procedure for the physician.
- *Irregular correction and lumpiness.* Some of these products may eventually cause uneven contours following the injection. Patients may feel unnatural lumps under their skin and experience discomfort where the material has been injected. In some cases, this effect dissipates as the material is reabsorbed by the body over time. In other cases, the effect is permanent.
- *Immunological reactions.* Many of these products are derived from animal sources, such as cow or sheep, or other foreign substances not naturally found in the human body. As a result, the body may react negatively to the material resulting in an allergic reaction. In some cases, the patient must undergo an allergy test to determine whether or not the treatment is suitable for the patient. This may be inconvenient for both the patient and the physician because it requires an additional visit to the physician’s office.

## Our Solution

We have designed our proprietary Isolagen Process to address many of the drawbacks of existing treatment alternatives while providing an effective treatment outcome for patients. Some of the advantages of our Isolagen Process are as follows:

- *Natural mechanism of action.* Our Isolagen Process produces a living cell therapy that is designed to replace the fibroblasts that have deteriorated over time as the patient ages. We believe that the fibroblasts created by our Isolagen Process and injected into the patient’s dermis continue to multiply and lead to the production of collagen and elastin. These fibroblast cells are subject to the normal physiological controls of tissue and, therefore, can potentially return the tissue to a more youthful appearance without over-correction or deformity.
- *Long duration of effect.* Fibroblast cells remain viable for many years and, therefore, the effects are likely to last longer. Some patients treated with our Isolagen Process have exhibited positive results for longer than one year. We believe our Isolagen Process will produce long-lasting effects though we do not have adequate clinical data to support this belief.
- *Minimal pain associated with the injection.* We believe that patients experience minimal pain with our Isolagen Process because the injected material is less viscous and causes less irritation than

other synthetic filler products. A thin needle is used, and anesthesia is generally not required for the injection.

- *No immunological reaction.* Our Isolagen Process uses the patient's own cells. As a result, the therapy should not cause a negative immunological response.
- *Broad applications.* Our dermal product candidate may be applicable to virtually every area of the face. We are also exploring the use of our Isolagen Process for the treatment of periodontal disease, vocal cord injury, acne scars and bum scars.

There are some disadvantages of our Isolagen Process compared to alternative injectable therapies. Our Isolagen Process takes approximately six weeks to produce the first injection. Furthermore, the visible effects of our Isolagen Process are not as rapid as some injectable products, but rather improve over time. The treatment is also administered through up to three injections during separate visits to the physician's office.

#### *Our Isolagen Process*

Our proprietary Isolagen Process begins when the patient's physician obtains a punch biopsy from behind the patient's ear with the use of a local anesthetic. We use this location both because it has had limited exposure to the sun and so the procedure does not leave a visible scar. In the case of our dermal product candidate, a biopsy is taken from the patient's gum. The biopsy is then packed in a vial in a special shipping container that we provide to the physician and is shipped overnight to our laboratory. Upon arrival at our laboratory, the biopsy is initiated into culture. The fibroblasts within the biopsy are allowed to multiply over a period of approximately four to six weeks in a series of cell factories. The fibroblasts are then harvested and put into a special transport vial. After completion of a series of quality control tests, the cells are released and shipped to the physician's office overnight. Injections are supplied and administered to the patient at approximately two week intervals. A patient may elect to cryogenically store his or her fibroblasts at our facilities to be used for future treatments.

Since 2002 we have made our Isolagen Process available to physicians in the United Kingdom. We have been using the commercialization of our process in this market as a means of researching and developing manufacturing technologies that are more efficient and economical. In addition, we have a number of process development and manufacturing improvement initiatives underway in our U.S. facilities. We believe these efforts will improve our manufacturing process and to allow us to produce our product on a profitable basis in the future. There can be no assurance that our efforts to develop and commercialize such manufacturing technologies will be successful.

#### **Clinical Trials**

Commencing in 1995, a predecessor of our Isolagen Process was used to correct facial defects, such as wrinkles, depressions and scars. From 1995 to 1999, approximately 200 physicians utilized this process on approximately 1,000 patients, for a total of approximately 4,000 injections. The physicians who used this process during this period did not document any significant adverse reactions.

In May 1996, the FDA, in response to the increasing use of cellular therapy to treat serious illness, released draft regulation for public comment to regulate cellular therapy. In May 1998, this regulation was passed, and in 1999, the FDA notified us that the Isolagen Process would require FDA approval as a regulated biologic product. In October 1999, we filed an investigational new drug application, or IND, which was accepted by the FDA. In November 1999, our IND was placed on clinical hold while we established a cGMP facility and standard operating procedures, including quality control release criteria. The clinical hold was released in May 2002. From June 2002, we assembled our management and scientific team and improved our Isolagen Process. These improvements included the introduction of an improved

transport medium to extend cell viability, the standardization of the injection technique and the standardization of our manufacturing and laboratory techniques. We commenced clinical trials in January 2003 upon completion of our previously leased Houston, Texas facility (refer to Part I, Item II, Properties for a discussion of our current property locations).

#### *Our Dermal Product Candidate*

*Phase II Clinical Trial.* In January 2003, we commenced a Phase II clinical trial involving two sites. The double-blind placebo-controlled clinical trial consisted of 40 subjects and four dose regimens. The Phase II clinical trial results suggested that the two larger doses were more effective than either the lowest dose or the placebo. Based on these results, we were able to determine that the largest dose was the most effective dose in this clinical trial, confirming previous clinical experience prior to 1999. We then utilized this target dose in our subsequent Phase III exploratory clinical trial.

The Phase II study was also used to determine the efficacy of the product candidate using two different scales; the 5-point ordinal photoguide scale, which was designated as the “primary” scale, and the visual analog scale. Results did not show a statistically different effect in the treatment and placebo groups using the 5-point ordinal scale. In contrast, after four months, subjects that used the target dosage experienced a statistically significant change using the visual analog scale. The difference between the results may have been due to the failure of the 5-point scale to capture efficacy data from subjects whose baseline value was thought to be more severe than five. Based on the results obtained in the Phase II program, the study design for the Phase III exploratory clinical trial was revised to include a 7-point photoguide scale with a two point shift to indicate efficacy. Also, the inclusion criteria for the study was modified to only include subjects with defects that were ranked as three or more. The 7-point scale was subsequently validated by comparison to the FDA-recommended 6-point photoguide used in related studies by other companies.

*Phase III Exploratory Clinical Trial.* In July 2003, a Phase III exploratory clinical trial for the treatment of wrinkles and scars was conducted at ten sites and included 158 subjects in the “Intent-To-Treat” group. It was a double-blind clinical trial with 75% of the subjects receiving the therapeutic dosage and the remaining 25% receiving a placebo. On March 3, 2004, we announced positive results of our four-month clinical endpoint. Of the evaluable population, 77% of treatment group subjects were responders, whereas 36% of the placebo group were responders ( $p < 0.0001$ ). In this statistically significant result, response was determined by a change of two or more points on a 7-point photoguide scale four months following the first injection. Although the primary endpoint for this study was four-months, evaluations continued for six, nine and twelve-months after first injection. The Isolagen treatment was offered to placebo subjects after a six-month evaluation. On July 28, 2004, we announced a positive response in 82% of the Isolagen treated subjects who were evaluated at six months. The therapeutic effect of the Isolagen Process compared to placebo was demonstrated at six months (82.2% vs. 38.2%, Fisher’s exact,  $p\text{-value} < 0.0001$ ). Results of a 12-month follow-up assessment on only the Isolagen treated group demonstrated the therapeutic effect was maintained with a response rate of 82.4% in those subjects who were evaluated at 12 months. A p-value is a statistical measure of the probability of drawing an erroneous conclusion from an experimental result. A p-value of less than or equal to 0.05 is generally considered to signify a statistically significant result, which means a result is unlikely to occur by chance. There were no serious adverse events related to the Isolagen Process. There was some mild edema and bruising observed at the injection site in both the placebo and treatment groups, which resolved spontaneously. The FDA expressed issues concerning the design of this study and stated that additional studies would be necessary to support BLA approval.

*Pivotal Phase III Clinical Trials.* We commenced two pivotal Phase III clinical trials in July 2004. The injection phase of both Phase III studies was completed in December 2004. We announced on August 1, 2005 that the results of the Phase III dermal studies would not support a BLA filing. These pivotal trials

were randomized, double blind and placebo-controlled and were being conducted at various sites in the United States. The trials, which were conducted simultaneously, each had in excess of 100 subjects split evenly between the treatment group and the placebo group. Efficacy was measured by a two-point improvement on the six-point scale, as evaluated by an independent assessor at four, six, nine and twelve months. The dermal studies met three of the four primary endpoints and achieved statistical significance when combined. The studies' primary endpoints were based on blinded physician visual assessment using a six-point scale with a two point change required to meet the endpoint and subject assessment using a visual analog scale ("VAS"). Trial B of the study proved to be clinically and statistically significant with both the subject and physician assessment achieving positive results. Trial A results were mixed with only a positive assessment from the subjects. In addition, there was a wide variance in results from site to site with a range of response rates from 73.3% to 7.6%, where a "response" represents an improvement of at least two points, on a six point scale, based on a visual assessment performed by the physician. In response to the results of these pivotal Phase III trials, we commenced preparations for a 200 subject confirmatory clinical trial with a six month endpoint during the fourth quarter of 2005.

*Phase III Confirmatory Study.* We conducted a post hoc statistical analysis and a thorough review of the results of the Pivotal Phase III study that suggested trial results were negatively impacted by a number of factors. First, our statistical analysis included all subjects who were randomized to the study. The statistical analysis did not exclude subjects who received neither our product nor placebo; these subjects were deemed to have failed the study. Second, our study population included a number of subjects with a baseline assessment of two (of their wrinkles) on the six-point scale. A two point improvement for these subjects would have required an assessment of zero on the six-point scale. After consultation with our clinical advisors familiar with utilizing the six-point scale, we believe subjects with an initial assessment of two on the scale should have been excluded from participation in the studies because of investigator reluctance to make a final assessment of zero (equivalent to no wrinkles) at the endpoint. Our future protocols will exclude subjects with a baseline assessment of two.

We used the information derived from our post hoc statistical analysis and the input of our clinical advisors to develop a Phase III confirmatory study. During the fourth quarter of 2005, we submitted a protocol to the FDA for a 200 subject confirmatory study the results of which we intend to submit together with the results of Study B to support a BLA filing in 2007. We are diligently working with the FDA to secure SPA approval of this new Phase III confirmatory study and to resolve a number of issues relating to the commencement of the confirmatory study. As part of this process, we believe we have made significant progress in addressing the FDA's requests for information regarding CMC data and process validation. We intend to conduct the confirmatory study from our Exton, Pennsylvania facility. We completed the construction of the Exton manufacturing facility during the fourth quarter of 2005 and this facility is now validated for trial commencement.

During the fourth quarter of 2005, we commenced preparations for our confirmatory study, including identifying and recruiting investigator sites and submission of the protocol to the FDA. We recently conducted an investigator meeting during which we provided injection and assessment training to participants. We expect to complete training and site initiation by the end of the first quarter of 2006. This study will be conducted from our Exton facility.

*Retrospective Study.* In 2002, we conducted a retrospective study of 354 of the approximately 1,000 patients who were treated with a predecessor of our Isolagen Process prior to filing our IND in 1999. No serious adverse events were reported by any of the 354 patients studied. In fact, less than 10% of those patients reported any adverse events. The majority of the adverse events that were reported were mild edema and bruising at the injection site.

*UK International Registry.* We collected patient response data from 59 patients randomly chosen from a total of the approximately 400 patients treated as of November 2003 in the United Kingdom with

our dermal product. This data was analyzed by an independent clinical research organization. The sampling reflects a cross section of all treated patients at all stages of treatment as of November 2003 rather than a summary of patients at some fixed time point.

The results indicated that 73% of sampled patients tested demonstrated positive results within the first four months after the first injection. All of the patients who were treated with our dermal product showed positive results both at six months and one year after first injection. Very few adverse events, consisting of mild edema and bruising at the injection site, were reported, which resolved spontaneously.

#### *Our Dental Product Candidate*

*Phase I Clinical Trial.* In January 2003, we commenced a Phase I clinical trial of our dental product candidate for the treatment of gum recession and deep periodontal pockets. The trial was a 12-month double-blind, internal and placebo controlled clinical trial of 21 subjects conducted at the University of Texas Health Science Center Dental Branch. In February 2004, we reported that subjects demonstrated significant improvement at a majority of the treatment sites by reducing deep periodontal pocket areas, whereas placebo treated sites showed only a nominal improvement. For pockets equal to or greater than 5 millimeters in depth, a 2.4 millimeter improvement was seen in the treatment group as compared to a 0.3 millimeter improvement in the placebo group. In May 2004, we announced the completion of our analysis of the data from this clinical trial. The clinical trial included areas with gum recession between teeth, showing improvement at 20 of 21 treated sites, with deterioration of the gum height recorded at 14 of 21 placebo sites. Furthermore, no adverse events were related to treatment with our dental product candidate.

*Phase II Clinical Trial.* In May 2004 we announced the initiation of a Phase II randomized, double-blind, placebo-controlled clinical study to determine the safety and efficacy of Isolagen injections for the treatment of interdental papillary insufficiency. This Phase II clinical trial concluded during the second quarter of 2005. The analysis of the investigator and subject visual analog scale assessment demonstrated that the Isolagen Process was statistically superior to placebo at four months after treatment. Although results of the investigator and subject assessment demonstrate that the Isolagen Process was statistically superior to placebo, an analysis of objective linear measurements did not yield statistically significant results despite a positive change observed as a result of treatment with the Isolagen Process. Clinical advisors believe that current measurement techniques are not precise enough to accurately record the positive change.

*Phase II Clinical Trial.* We anticipate that a new Phase II clinical trial will begin by the end of the first quarter of 2006. This will include subjects from the previous clinical trial who had both Isolagen Process and placebo treatments. The trial will be a 15 subject open-label trial (a non-placebo trial whereby all subjects are treated with the Isolagen Process) for the treatment of interdental papillary insufficiency. Subjects will receive a higher dose of Isolagen Process to lesions previously treated with placebo, as compared to the previous Phase II trial. In addition, areas previously treated with the Isolagen Process will receive additional injections of the Isolagen Process. We believe that this increased dose exposure should improve the results over those seen previously. In addition, we are utilizing a new photographic technique which we believe will allow us to accurately measure a positive change.

#### *Other Clinical Trials*

*Phase I Vocal Cord Clinical Trial.* We currently have an active IND for vocal cord scarring and we submitted a protocol amendment during 2005. We are currently screening subjects to participate in this trial. This trial will study 5 subjects with unilateral or bilateral vocal fold scars who will be treated with Isolagen Process injections into the vocal fold. Their ability to speak will be measured at baseline and for improvement at various endpoints. Safety will be followed over the 12 month period of the trial. If the trial shows improvement in speaking quality, additional trials will be anticipated.

We are also exploring additional product candidates including the treatment of acne scars, burn scars and acute burns. We anticipate that a preclinical study for acute burns will commence prior to the end of the first quarter of 2006.

### **Our Strategy**

Our goal is to become a leading provider of solutions for soft tissue regeneration. We intend to achieve our goal by:

- *Leveraging our expertise in autologous cellular therapies to expand into other applications.* We believe that our Isolagen Process is applicable to both aesthetic and medical conditions and can provide meaningful benefits to patients. We plan to pursue additional applications for acne and burn scars and repairing vocal cords. We are also exploring additional opportunities to use our product candidates and technology.
- *Optimizing our manufacturing processes to achieve cost reductions and scalability.* We are researching and developing manufacturing technologies to yield future significant cost reductions and allow us to implement a platform that enables scalable mass production.
- *Expanding our international presence.* We believe the size of the international market is comparable to the United States market, and we are focused on increasing our market penetration abroad and building global brand-recognition. We currently sell our dermal product primarily in the United Kingdom. We plan to ultimately expand sales of our product to other parts of Europe, Asia and the Americas following FDA approval of our product in the United States.
- *Capitalizing on strong direct to consumer response.* In the United Kingdom, we have received interest from physicians and patients who have learned about our dermal product through independent news coverage or word of mouth. We may in the future decide to enter into a strategic partnership with a company that has a strong direct to consumer capability.

### **Sales and Marketing**

While our product candidates are still in the pre-approval phase in the United States, no marketing or sales can occur within the United States. From our experience in the United Kingdom, we have learned that our business is consumer-focused and we must create demand and drive patients to physicians. We believe this is accomplished utilizing direct-to-consumer marketing, public relations and advertising. To prepare physicians in the United Kingdom, we hold seminars on our Isolagen Process and conduct demonstrations of proper biopsy and injection techniques. We may elect to enter into a strategic partnership with a company that has a strong direct-to-consumer capability in order to expand our market coverage.

In addition to the United States, we plan to commercialize our future products in other countries. In August 2001, we formed Isolagen Europe Limited, our subsidiary organized under the laws of the United Kingdom, for the purpose of marketing our dermal product to patients in Europe. In August 2003, we received a license from Australia's Therapeutic Goods Administration, or TGA, to begin the manufacture of autologous fibroblast cells. We commenced limited commercialization in the United Kingdom and Australia in late 2003. We are also investigating commercialization opportunities in other foreign countries.

We focused our initial commercialization activities in the United Kingdom in order to establish and develop our processing, sales and marketing capabilities. This consisted of introducing our dermal product to selected leading medical practitioners, primarily plastic surgeons and dermatologists, who could offer the treatment to their patients. Training sessions were given in order to train a broader group of physicians, such as general practitioners. In our United Kingdom facility we are using our

commercialization activities to study and implement methods by which the processing of cells and the production of injections can be performed on higher volume and more efficient bases.

During this initial phase, our dermal product garnered additional public exposure through independent articles in health and beauty journals. During 2005, we increased our public relations and advertising expenditures to increase public awareness through print advertising and other multimedia forums.

The Isologen Process is administered to each patient using our recommended regimen of up to six injections. Due to the short shelf life, each injection is cultured on an as needed basis and shipped prior to the individual injection being administered by the physician. We believe each injection has stand alone value to the patient. We invoice the attending physician upon that physician submitting his or her patient's tissue sample to us; as a result of which the contractual arrangement is between us and the medical professional. The amount invoiced varies directly with the number of injections requested. Generally, orders are paid in advance by the physician prior to the first injection. There is no performance provision under any arrangement with any physician, and there is no right to refund or returns for unused injections.

We also offer a service whereby it stores a patient's cells for later use in the preparation of injections. The fees charged for this service is recognized as revenue ratably over the length of the storage agreement. Revenue related to this service was approximately \$0.3 million in 2005 and was less than \$0.1 million prior to 2005. We also offer a service whereby it processes a patient's cells to expand the cells to the mass necessary to prepare an injection, but then store the expanded cells for later use in the preparation of injections. Revenue related to this service has been less than \$0.1 million inception to date.

As a result of the increased exposure beginning in 2004, we experienced continued demand for our dermal product in 2005, and revenue for 2005 was \$8.75 million as compared to revenue of \$4.18 million in 2004.

### **Intellectual Property**

We believe that patents, trademarks, copyrights and other proprietary rights are important to our business. We also rely on trade secrets, know-how, continuing technological innovations and licensing opportunities 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 foreign countries.

As of December 31, 2005, we had 6 issued U.S. patents, 9 pending U.S. patent applications, 27 foreign patents and 50 pending foreign patent applications. Our issued patents and patent applications primarily cover the method of using autologous cell fibroblasts for the repair of skin and soft tissue defects and the use of autologous fibroblast cells for tissue regeneration. We are in the process of pursuing several other patent applications.

In January 2003, 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. 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, such as for our core products.

We 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 injections and Botulinum toxin injections, and other dermal fillers. Indirect competition comes from facial care treatment products. Items catering to the growing demand for therapeutic skin care products include facial scrubs, anti-aging treatments, tonics, astringents and skin-restoration formulas.

Many of our competitors are large, well-established pharmaceutical, chemical, cosmetic or health care companies with considerably greater financial, marketing, sales and technical resources than those available to us. Additionally, many of our present and potential competitors have research and development capabilities that may allow them to develop new or improved products that may compete with



our product lines. Our products could be rendered obsolete or made uneconomical by the development of new products to treat the conditions addressed by our products, technological advances affecting the cost of production, or marketing or pricing actions by one or more of our competitors. Our dermal product competes for a share of the existing market with numerous products that have become standard treatments recommended or prescribed by dermatologists and administered by plastic surgeons and aesthetic dermatologists.

There are several dermal filler products under development and/or in the FDA pipeline for approval which claim to offer equivalent or greater facial aesthetic benefits than our products and, if approved, the companies producing such products could charge less to doctors for their products.

### **Government Regulation**

Our 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, export, marketing and distribution, among other things, of pharmaceutical products under various federal laws including the Federal Food, Drug and Cosmetic Act, or FDCA, and under comparable laws by the states and in most foreign countries.

#### *Domestic Regulation*

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

#### *FDA Approval Process*

To obtain approval of a new product from the FDA, we must, among other requirements, submit data demonstrating the product's safety and efficacy as well as detailed information on the manufacture and composition of the product candidate. In most cases, this entails extensive laboratory tests and pre-clinical and clinical trials. This testing and the preparation of necessary applications and processing of those applications by the FDA are expensive and typically take many years to complete. The FDA may deny our applications or may not act quickly or favorably in reviewing these applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approvals that could delay or preclude us from marketing any products we may develop. The FDA also may require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approvals that could restrict the commercial applications of these products. Regulatory authorities may withdraw product approvals if we fail to comply with regulatory standards or if we encounter problems following initial marketing. With respect to patented products or technologies, delays imposed by the governmental approval process may materially reduce the period during which we will have the exclusive right to exploit the products or technologies.

The FDA does not apply a single regulatory scheme to human tissues and the products derived from human tissue. On a case-by-case basis, the FDA may choose to regulate such products as transplanted human tissue, medical devices or biologics. A fundamental difference in the treatment of products under these classifications is that the FDA generally permits human tissue for transplantation to be commercially

distributed without marketing approval. In contrast, products that require manufacturing or processing are regulated as medical devices or biologics and require FDA approval.

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

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

Pre-clinical tests include laboratory evaluation of product chemistry formulation and stability, as well as 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. The results of 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, that may overlap. These phases generally include the following:

- Phase I: The product is usually first introduced into healthy humans or, on occasion, into patients, and is tested for safety, dosage tolerance, absorption, distribution, excretion and metabolism.
- Phase II: The product is introduced into a limited subject population to:
  - assess its efficacy in specific, targeted indications;
  - assess dosage tolerance and optimal dosage; and
  - identify possible adverse effects and safety risks.
- Phase III: These are commonly referred to as pivotal studies. If a product is found to have an acceptable safety profile and to be potentially effective in Phase II clinical trials, new clinical trials will be initiated to further demonstrate clinical efficacy, optimal dosage and safety within an expanded and diverse subject population at geographically-dispersed clinical study sites.
- If the FDA does ultimately approve the product, it may require post-marketing testing, including potentially expensive Phase IV studies, to monitor its safety and effectiveness.

Clinical trials must meet requirements for Institutional Review Board, or IRB, oversight, 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 and 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.

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, in the form of an NDA, or, in the case of a biologic, a BLA. The FDA has advised us it is regulating our Isologen Process as a biologic. Therefore, we expect to submit BLAs to obtain approval of our product candidates. Once the submission has been accepted for filing, the FDA has 12 months to review the application and respond to the applicant. The review process is often significantly extended by FDA requests for additional information or clarification. 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 several 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 monitor the safety and effectiveness 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.

#### *Ongoing FDA Requirements*

Before approving an NDA or BLA, the FDA 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 biologics also must comply with the FDA's 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 full 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. 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, a requirement that future advertising and promotional materials be pre-cleared by the FDA 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.

#### *International Regulation*

The regulation of our products 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 products. Certain other countries classify our products 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 products, creating uncertainty as to what standards we may be required to meet. Previously, management made inquiry to the Medicines Control Agency with respect to our proposed use of our Isolagen Process in cosmetic applications in the United Kingdom. Based on the written responses received from the Medicines Control Agency, we believe that the proposed use of our Isolagen Process in cosmetic applications in the United Kingdom does not currently require regulatory approval. However, the European Union has introduced new legislation, Directive 2004/23/EC relating to human tissue and cells for human application, which was to be effective April 7, 2006. Our operations in the United Kingdom do not currently comply with the Directive. The European Commission has not yet developed or adopted required technical guidelines

relating to this Directive. We believe that implementation of the Directive is unlikely until these guidelines are developed and adopted both by the European Commission and by the member states of the European Union.

Our marketing communications are governed by the United Kingdom advertising rules, based on voluntary code and statutory provisions. In June 2004, the Medicines and Healthcare products Regulatory Agency (MHRA) informed Isolagen that they had received inquiries about the advertising material that described the Isolagen product. Accordingly, the MHRA requested copies of all the material used to advertise and/or promote Isolagen within the United Kingdom to determine if any action was required. Based on our discussions with the agency, we agreed to modify our advertising and promotional materials to address agency concerns, including clarifying the regulatory status of the product in the United Kingdom. It is possible that further questions could be forthcoming from the agency requiring further revisions to promotional material. Such revisions could negatively impact our ability to promote the product.

### **Manufacturing**

We currently have two manufacturing facilities, one located in London, England and one located in Exton, Pennsylvania. We use our London facility for commercial production to supply United Kingdom and other non-US markets. Our London facility is engaged in the commercialization of our process (for which we earned revenue from the sale of Isolagen Process) and as a means to improve our manufacturing process. Therefore, we classify as cost of sales those costs (except for costs related to marketing, sales and general corporate administration) incurred in operating our London facility. The costs incurred in operating our Exton facility (except for costs related to general corporate administration) are currently classified as research and development expenses.

All component parts used in our manufacturing process are readily available with short lead times, and all machinery is maintained and calibrated. We have made improvements in our manufacturing processes, including performing all cellular manufacturing processes within a class 10,000 clean room and implementation of our laboratory information management system, or LIMS. LIMS is a server-based software system incorporating a handheld computer with a bar-code scanner, connected by firewall protected telemetry for tracking all equipment, patient samples, consumables and processing steps.

### **Research and Development**

In addition to our clinical development activities, our research and development activities include improving our manufacturing processes and reducing costs. Fibroblasts are a general support cell for the tissue and, in addition to their direct production of collagen and elastin, produce endocrine factors, which we believe may assist in the growth or repair of surrounding tissues, such as the epidermis. We believe this effect is responsible for some of the positive results that physicians have observed when treating patients with severe scarring. We continue to explore additional opportunities for our Isolagen Process for other applications, such as vocal cord injury, acne scarring, acute burns and burn scarring. We expense research and development costs as they are incurred. For the years ended December 31, 2005, 2004 and 2003, we incurred research and development expenses of \$11.4 million, \$5.1 million and \$3.3 million, respectively.

### **Employees**

As of March 1, 2006, we employed 141 people on a full-time basis, including 13 in Houston, Texas, 26 in Exton, Pennsylvania, 92 in London, England, 9 in Neuchâtel, Switzerland and 1 in Sydney, Australia. We anticipate hiring additional employees in the areas of executive management, sales and marketing, quality assurance, manufacturing and research and development as the need arises. None of our employees are covered by a collective bargaining agreement, and we consider our relationship with our employees to be

good. We may also employ consultants and temporary labor on an as needed basis to supplement existing staff.

### **Segment Information**

Financial information concerning the Company's business segments and geographic areas of operation is included in Note 11 in the Notes to Consolidated Financial Statements contained in Item 8 of this Form 10-K.

### **Corporate History**

On August 10, 2001, our company, then known as American Financial Holding, Inc., acquired Isolagen Technologies through the merger of our wholly-owned subsidiary, Isolagen Acquisition Corp., and an affiliated entity, Gemini IX, Inc., with and into Isolagen Technologies. As a result of the merger, Isolagen Technologies became our wholly owned subsidiary. On November 13, 2001, we changed our name to Isolagen, Inc.

### **Item 1A. Risk Factors**

Potential investors should carefully consider the following risk factors prior to making any investment decisions regarding our securities.

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

Before we can commercialize our Isolagen Process or 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 confirmatory pivotal Phase III clinical trial for our lead product candidate;
- successfully improve and/or automate our manufacturing process; and
- obtain U.S. Food and Drug Administration, or FDA, approvals.

Commercialization of our Isolagen Process involves a high degree of risk and may take several years. Favorable results in pre-clinical or earlier stage clinical trials do not ensure that the results of later stage and pivotal trials will also be favorable or adequate to demonstrate the safety or efficacy of the product candidate or to obtain FDA approval. Our product development efforts may fail for many reasons, including:

- failures in pre-clinical studies;
- insufficient clinical trial data to support the safety or efficacy of our product candidates;
- failure to successfully implement improved and/or automated manufacturing systems; or
- failure to obtain the required FDA approvals.

Even if our product development efforts are successful, we cannot assure you that we will be able to commercialize our Isolagen Process or 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. We have incurred operating losses since our inception. Our revenue for the years ended December 31, 2005 2004 and 2003 was \$8.75 million, \$4.18 million and \$0.45 million, respectively. Our net loss for the years ended December 31, 2005, 2004 and 2003 was \$35.8 million, \$21.5 million and \$11.3 million, respectively. As of December 31, 2005, we had an accumulated development stage net loss attributable to common shareholders of \$91.3 million.

We currently have no product candidates for sale in the United States, and we cannot guarantee that we will ever have marketable products in the United States. 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 products for commercial marketing. We will need to conduct significant additional research, preclinical testing and clinical testing before we can file applications with the FDA for approval of our product candidates. We must also develop, validate and obtain FDA approval of any improved and/or automated 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.

We expect to continue to incur losses as we research, develop and seek regulatory approvals for our product candidates. 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.

**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 to design and implement. Clinical trials are required and the marketing and manufacturing of our product candidates are subject to rigorous testing procedures. We have commenced initial preparations related to our confirmatory pivotal Phase III clinical trial for our lead product candidate. Our other product candidates will require additional clinical trials. The commencement and completion of clinical trials for our Isolagen Process or 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 in the enrollment of subjects;
- 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. Significant delays in clinical trials will impede our ability to commercialize our product candidates and generate revenue, and could significantly increase our development costs.

Even if marketing approval from the FDA is received, 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 monitor our future products and their continued compliance with regulatory requirements;
- submitting products for inspection and, if any inspection reveals that the product is not in compliance, prohibiting the sale of all products;
- suspending manufacturing; or
- withdrawing marketing clearance.

**Our ability to effectively commercialize our dermal product and our product candidates depends on our ability to improve our manufacturing process and to satisfactorily validate the cellular expansion and harvesting process.**

We must obtain FDA approval of our validated manufacturing process before we can commercially manufacture our product candidates in the United States. In addition, we must pass a pre-approval inspection of our manufacturing facility before we can obtain marketing approval for our product candidates. We intend to seek FDA approval of our cellular expansion manufacturing process as a component of the BLA application and approval process. In order to obtain approval, all of our manufacturing methods, equipment and processes 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 Isologen Process, 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.

Large-scale improvements in capacity and operating margins depend on the successful implementation of improved manufacturing processes. We hope to eliminate several of the steps and materials involved in our current system, which we expect will lead to significant cost reductions in both skilled labor and materials and will enable scalable mass production in the future. However, the commercial viability of improved manufacturing processes under consideration are uncertain, and we do not know whether we will be successful in implementing such improved manufacturing processes, validating the safety and efficacy of these processes, obtaining the required scalability, achieving cost savings or obtaining FDA approval of these processes. Our previous and current clinical trials are conducted using a manual process, rather than a more automated manufacturing process.

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 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.



**Our inability to comply with regulatory requirements in the United Kingdom will limit or delay our ability to attain profitability.**

We began limited commercialization of our dermal product in the United Kingdom in late 2003. Our facility in the United Kingdom was primarily designed to demonstrate the efficacy of our Isolagen Process, and has limited capacity. In light of the European Directive 2004/23/EC, we may be required to expend significant additional funds to make our UK operations compliant. This includes the addition of personnel, introduction of systems enhancements, and possibly the establishment of new facilities. Our inability to meet the regulatory requirements in the United Kingdom may limit our ability to supply product and to maximize this market opportunity. In order to implement the changes in the facility needed to comply with the new Directive, it may be necessary for Isolagen to decrease capacity, or stop production from the United Kingdom facility.

**Our dermal product and our product candidates are all derived from our Isolagen Process. If our Isolagen Process is found to be unsafe or ineffective, our business would be materially harmed.**

Our dermal product that is sold in the United Kingdom and our dermal candidate undergoing clinical testing in the United States, and our dental product, are all derived from our proprietary Isolagen Process. In addition, we expect to utilize our Isolagen Process in the development of any future products we market. If these current or future products are found to be unsafe or ineffective, we may have to modify or cease production of the products. As our dermal product and all of our product candidates utilize or will utilize our Isolagen Process, any defects with this technology would severely harm our business operations, since all of our primary revenue sources would be negatively affected by the defects.

**Our ability to expand our operations to support the full-scale commercialization of our Isolagen Process is dependent on our ability to establish new manufacturing facilities.**

None of our facilities were designed or have the capacity to support the full-scale commercialization of all of our product candidates. Our manufacturing facility in the United Kingdom was designed primarily to enable us to demonstrate the efficacy of our Isolagen Process, and to provide a platform for the future development of our manufacturing processes and our information and other support systems. While we have expanded our capacity at that facility, the limited size of that facility represents an inherent limitation of our capacity. The UK facility may not be able to meet the ongoing demand for our dermal product in the United Kingdom, even if our efforts to improve the manufacturing process are effectively and timely implemented. The failure to timely establish full-scale commercial manufacturing facilities may delay or prevent our future profitability.

We plan to operate a single manufacturing facility in the United States. As a result, if we obtain FDA approval of our lead product candidate, all of the commercial manufacturing for the U.S. market will 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 in the United States, which would adversely impact our business.

**Our recent issuance of notes or of other indebtedness in the future may impact our financial condition and results of operations.**

In November 2004, we completed a note offering in which we issued \$90.0 million of indebtedness pursuant to an indenture. We may incur additional indebtedness in the future, and the indenture does not restrict our future incurrence of indebtedness. Our level of indebtedness will have several significant effects on our future operations, including the following:

- we will be required to use a portion of our cash for the payment of any principal or interest due on our outstanding indebtedness, including the recently issued notes;

- our outstanding indebtedness and leverage will increase the impact of negative changes in general economic and industry conditions, as well as competitive pressures; and
- the level of our outstanding debt may affect our ability to obtain additional financing for working capital, capital expenditures or general corporate purposes.

General economic conditions, industry cycles and financial, business and other factors affecting our operations, many of which are beyond our control, may affect our future performance. As a result, these and other factors may affect our ability to make principal and interest payments on our indebtedness. If we cannot generate sufficient cash flow from operations in the future to service our debt, we may, among other things:

- seek additional financing in the debt or equity markets;
- refinance or restructure all or a portion of our indebtedness;
- sell selected assets;
- reduce or delay planned capital expenditures; or
- reduce or delay planned research and development expenditures.

These measures might not be sufficient to enable us to service our indebtedness. In addition, any financing, refinancing or sale of assets might not be available, or available on economically favorable terms.

**We may need to raise substantial additional capital to fund our operations in the future, and we do not have any future commitments for capital.**

We believe our cash resources will be sufficient to fund our planned operations for at least 18 months from December 31, 2005. We are focused on research and development, are incurring losses from operations, have limited capital resources, and do not have access to a line of credit or other debt facility. We may need additional capital in the future to execute our business strategy, and if we are unsuccessful in raising such additional capital we may be 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 interests of our stockholders would be subordinated to the interests of our debt holders and any interest payments would reduce the amount of cash available to operate and grow our business. If we raise additional capital through the sale of equity securities, the ownership of our current stockholders would be diluted. 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 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. If we terminate or delay regulatory approval, curtail or delay manufacturing improvements or delay the expansion of our sales and marketing capabilities, our business may fail.

**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 because of the emerging nature of the markets in which we compete, 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 future revenue. However, the size of future revenue depends on the choices and demand of individuals, which are difficult to forecast accurately. We may be unable to adjust our operations in a timely manner to compensate for any unexpected shortfall in revenue. Accordingly, a significant shortfall in demand for our products could have an immediate and material adverse effect on our business, results of operations and financial condition.

Further, our fixed manufacturing costs and business development and marketing expenses will increase significantly as we expand our operations. To the extent that expenses precede or are not rapidly followed by increased revenue, our business, results of operations and financial condition may be materially adversely affected.

**Clinical trials may fail to demonstrate the safety and efficacy of our product candidates, which could prevent or significantly delay regulatory approval.**

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 are conducting a confirmatory pivotal Phase III clinical trial related to our lead dermal 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 these trials or future clinical trials are unsuccessful, our business and reputation would be harmed and our stock price would be adversely affected.

All of our product candidates are prone to the risks of failure inherent in biologic development. 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 show desired safety and efficacy traits despite having 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. Preclinical and clinical data can be interpreted in different ways. Accordingly, FDA officials could interpret such data in different ways than we do, which could delay, limit or prevent regulatory approval. The FDA, other regulatory authorities, our Institutional Review Boards or we may suspend or terminate clinical trials at any time. Any failure or significant delay in completing clinical trials for our product candidates, or in receiving regulatory approval for the sale of any products resulting from our product candidates, may severely harm our business and reputation.

**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:

- the level of demand for our Isolagen Process and future 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;
- the amount and timing of capital expenditures and other costs relating to the expansion of our operations;
- government regulation and legal developments regarding our Isolagen Process in the United States and in the foreign countries in which we operate; 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.

**Losses may continue to increase from current levels and we will continue to experience negative cash flow as we expand our operations, which may limit or delay our ability to become profitable.**

We have expended significant resources on hiring of personnel, research and development, advertising and expansion, and we expect these costs to continue or rise in the future. As a result, we have incurred losses since our inception and expect to experience operating losses and negative cash flow as we expand our operations. We have had limited revenue to date and losses from operations, therefore, 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;
- promotional and marketing activities;
- brand development;
- personnel costs;
- development of relationships with strategic business partners, including physicians who might use our future products; and
- interest expense related to the notes we recently offered.

If we cannot adequately manage our costs and expenses, we will continue to experience operating losses and negative cash flow. In particular, the costs to improve our manufacturing process and to obtain regulatory approvals has been and will be considerable and the failure to improve our manufacturing process, or to obtain, or delays in obtaining, any regulatory approvals could materially adversely affect our business performance and financial results.

**We are party to securities and derivative litigation that distracts our management, is expensive to conduct and seeks a damage award against us.**

We and certain of our current and former officers have been named as defendants in several putative shareholder class action lawsuits in the United States District Court for the Southern District of Texas and the United States District Court for the Eastern District of Pennsylvania. The complaints purport to seek unspecified damages on behalf of an alleged class of persons who purchased our common stock between March 3, 2004 and August 1, 2005. The complaints allege that we and our officers violated Section 10(b) and Rule 10b-5 of the Exchange Act by making certain false statements and omissions to the investing public regarding our business operations, management, and intrinsic value of our publicly traded securities. The complaints also allege liability against the individual defendants under Section 20(a) of the Exchange Act. In addition, two stockholders have filed derivative actions in the state court in Texas seeking recovery on behalf of Isolagen against certain of our current and former officers and directors, alleging, among other things, breach of fiduciary duties and other wrongful conduct by those individual defendants. While we have directors and officers liability insurance, it is uncertain whether the insurance will be sufficient to cover all damages, if any, that we may be required to pay. In addition, the securities and

derivative lawsuits may distract the attention of our management, and are expensive to conduct. We have and may continue to incur substantial legal and other professional service costs in connection with the stockholder lawsuits. The amount of any future costs in this respect cannot be determined at this time.

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

Even if we obtain regulatory approval for our product candidates, we will continue to be subject to extensive requirements 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, record keeping, approval, advertising and promotion of our future products. 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:

- fines;
- changes to advertising;
- failure to obtain marketing approvals for our product candidates;
- revocation or suspension of regulatory approvals of products;
- product seizures or recalls;
- 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 manufacture. 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, the FDA and the FTC issue correspondence alleging that some advertising or promotional practices are false, misleading or deceptive. The FDA may impose a wide array of sanctions on companies for such advertising practices, which could result in any of the following:

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

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.

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 law, 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.

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

In both 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. 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.

**We conduct business in foreign markets, and we are subject to a variety of regulations in those foreign markets that could have a material adverse effect on our business in a particular market or in general.**

We presently have foreign operations in the United Kingdom. In addition, we intend to expand our operations into other foreign markets. We are already subject to a variety of regulations in foreign markets, and as we expand our operations, we will become subject to even more foreign regulations. Our failure to comply, or assertions that we fail to comply, with these regulations could have a material adverse effect on our business in a particular market or in general. To the extent we decide to commence or expand operations in additional countries, government regulations in those countries may prevent or delay entry into, or expansion of operations in, those markets. Government regulations in international markets could delay or prevent the introduction, or require the reformulation or withdrawal, of some of our future products.

**Our foreign operations are exposed to risks associated with exchange rate fluctuations, trade restrictions and political, economic and social instability.**

We are subject to the risks of doing business abroad, including:

- unexpected changes in regulatory requirements;
- export and import restrictions, tariffs and other trade barriers;
- difficulties in staffing and managing foreign operations;
- longer payment cycles and problems in collecting accounts receivable;
- potential adverse tax consequences;
- exchange rate fluctuations;
- increased risks of piracy and limits on our ability to enforce our intellectual property rights;
- limits on repatriation of funds; and
- political risks that may limit or disrupt international sales.

A foreign government may impose trade or foreign exchange restrictions or increased tariffs, which could adversely affect our operations. Our operations in some markets also may be adversely affected by political, economic and social instability in foreign countries, including terrorism. As we continue to focus on expanding our existing international operations, these and other risks associated with international operations may increase.

Any limitations or interruptions in our foreign operations could have a material adverse effect on our business. In addition, for financial reporting purposes, results of operations of our foreign subsidiaries are translated from local currency into U.S. dollars based on average monthly exchange rates. We currently do not hedge our foreign currency transactions and are therefore subject to the risk of changes in exchange rates.

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

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

- labeling requirements or limitations;
- market acceptance by practitioners and their patients;
- our ability to successfully improve and/or automate our manufacturing process to allow us to more cost-effectively produce our future products, thereby reducing the price at which we can offer our future products;
- 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.

**Difficulties managing growth could adversely affect our business, operating results and financial condition.**

If we achieve growth in our operations in the next few years, such growth could place a strain on our management, and our administrative, operational and financial infrastructure. We would need to hire additional management, financial, sales and marketing personnel to manage our operations. In addition, our ability to manage our future operations and growth would require the continued improvement of operational, financial and management controls, reporting systems and procedures. If we are unable to manage our growth effectively or if we are unable to attract additional highly qualified personnel, our business, operating results and financial condition may be materially adversely affected.

**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 will need to attract, train and retain additional highly qualified senior executives and technical and managerial personnel in the future.**

We are in the process of seeking 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 brand and establish a leading position in the marketplace, our business may fail.**

Our brand name is new and unproven. We believe that the importance of brand recognition will increase over time. In order to gain brand recognition, we may increase our marketing and advertising budgets to create and maintain brand loyalty. We do not know whether these efforts will lead to greater brand recognition. If we are unable to effectively promote our brand and establish a leading position in the marketplace, our operations will suffer.

**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. If we are unable to obtain and maintain protection for our intellectual property and proprietary technology, the value of our technology and future products will be adversely affected, and we will not be able to protect our technology from unauthorized use by third parties.**

Our long-term success largely depends on our ability to market technologically competitive future products and to protect those technological creations. In order to do so we must:

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

As of December 31, 2005, we had 6 issued U.S. patents, 9 pending U.S. patent applications, 27 foreign patents and 50 pending foreign patent applications. If we fail to obtain or maintain these protections, we may not be able to prevent third parties from using our proprietary rights. 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 or are effectively maintained as trade secrets.

The patent situation in the markets in which we compete is highly uncertain and involves complex legal and scientific questions. It may be difficult to obtain additional patents relating to our technology.



Furthermore, any changes in, or unexpected interpretations of, the patent laws may adversely affect our ability to enforce our patent position.

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;
- because the information contained in patent applications is generally not publicly available, we might not have been the first to file patent applications for these inventions or similar technology;
- the future and pending applications we will file or have filed, or to which we will or do have exclusive rights, may not result in issued patents or may take longer than we expect to result in issued patents;
- the claims of any patents that are issued may not provide meaningful protection;
- our issued patents may not provide a basis for commercially viable products or may not be valid or enforceable;
- we might not be able to develop additional proprietary technologies that are patentable;
- the patents licensed or issued to us may not provide a competitive advantage;
- patents issued to other companies, universities or research institutions may harm our ability to do business;
- other companies, universities or research institutions may independently develop 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.

**We have obtained some of our rights from third parties. If our agreements with these parties do not appear as we anticipate our business may be adversely affected.**

The rights to some of our patent applications were obtained in a purchase agreement with a third party. If this purchase agreement is found invalid or there are otherwise disputes regarding the invention and corresponding ownership rights in the invention, we may not be able to market future products covered by the license. We may enter into collaboration and cooperation agreements with third parties from time to time to develop new technologies. We may not be able to use and claim proprietary rights to the technology resulting from collaboration and cooperation agreements, which may adversely affect our business.

**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 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.

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 Isolagen Process 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 in order to continue manufacturing or marketing the affected products or services, and pay license fees and royalties. This license may be non-exclusive, giving our competitors access to the same intellectual property, or the patent owner may require that we grant a cross-license to our patented technology; or
- stop research and commercial activities relating to the affected products or services if a license is not available on acceptable terms, if at all.

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

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

**We may not be successful in our efforts to develop commercial-scale manufacturing technology and methods.**

Primarily through internal research, we are seeking to develop a commercially viable design and production process for our future products, as well as new areas of application for our Isolagen Process. If we are unable to develop suitable techniques to produce and manufacture our technology for the commercial market or additional areas of application for our Isolagen Process, our business prospects will suffer.

**We may be liable for product liability claims not covered by insurance.**

Physicians that use our dermal product, or any of our future products, and patients who have been treated by our dermal product, or any of our future products, may bring product liability claims against us. While we have taken, and continue to take, what we believe are appropriate precautions, we may be unable to avoid significant liability exposure. We currently intend to obtain and keep in force product liability insurance. However, we may be unable to obtain insurance in the future, or we may be unable to do so on acceptable terms. Any insurance we obtain may not provide adequate coverage against any asserted claims. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- diversion of management's time and attention;
- expenditure of large amounts of cash on legal fees, expenses and payment of damages;
- decreased demand for our products or any of our future products and services; or
- injury to our reputation.

**If we are 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 may 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 stockholders. 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. As of the date of this report, we are not party to any agreements, written or oral, for the acquisition of any company, product or technology.

**Our business, which depends on a small number of facilities, 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 operations in three main facilities located in Exton, Pennsylvania, Houston, Texas and London, England. We also purchased land and two buildings located in Switzerland in April 2005. The majority of this acquisition is currently under construction and is not considered fully operational. Our facilities 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 facilities. 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.

**Our stock price has been volatile and could experience substantial declines.**

The market price of our common stock has experienced, and may continue to experience, significant volatility. During 2005, the per share closing price of our common stock ranged from \$1.05 to \$8.05 per share. During 2004, the per share closing price of our common stock ranged from \$5.40 to \$12.04 per share. The value of our common stock may decline regardless of our operating performance or prospects. Factors affecting our market price include, but are not limited to:

- the success or failure of our product development efforts, especially those related to obtaining regulatory approvals domestically and internationally;
- the implementation of improved and/or automated manufacturing processes;
- technological innovations developed by us or our competitors;
- variations in our operating results and the extent to which we achieve our key business targets;
- differences between our reported results and those expected by investors and securities analysts;

- market reaction to any acquisitions or joint ventures announced by us or our competitors; and
- developments with respect to the class and derivative action litigation of which we are currently defendants.

In addition, in recent years, the stock market in general, and the market for life sciences companies in particular, have experienced significant price and volume fluctuations. This volatility has affected the market prices of securities issued by many companies, often for reasons unrelated to their operating performance, and it may adversely affect the price of our common stock. In the past, securities class action litigation has often been instituted following periods of volatility in the market price of a company's securities. The current class and derivative action suits or a future securities class action suit against us could result in potential liabilities, substantial costs and the diversion of management's attention and resources, regardless of whether we win or lose.

**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.

The use of a staggered Board of Directors and the ability to issue "blank check" preferred stock are traditional anti-takeover measures. These provisions in our charter documents make it difficult for a majority stockholder to gain control of the Board of Directors and of our company. These provisions may be beneficial to our management and our Board of Directors in a hostile tender offer and may have an adverse impact on stockholders who may want to participate in such a tender offer, or who may want to replace some or all of the members of our Board of Directors.

**Provisions in our bylaws provide for indemnification of officers and directors, which could require us to direct funds away from our business and future products.**

Our bylaws provide for the indemnification of our officers and directors. We may 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. In addition, these factors could make it more difficult for us to raise funds through future offerings of common stock. As of December 31, 2005, there are 34,260,383 shares of common stock issued and 30,260,383 outstanding. All of our outstanding shares are freely transferable without restriction or further registration under the Securities Act.

**There is a limited public trading market for our common stock.**

There is a limited 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.

**As a public company, our business is subject to numerous reporting requirements that are currently and continuously evolving and could substantially increase our operating expenses and divert management's attention from the operation of our business.**

The Sarbanes-Oxley Act of 2002, which became law in July 2002, has required changes in some of our corporate governance, securities disclosure and compliance practices. In response to the requirements of that Act, the SEC and the American Stock Exchange have promulgated new rules and listing standards covering a variety of subjects. Compliance with these new rules and listing standards has significantly increased our legal and financial and accounting costs, and we expect these increased costs to continue. In addition, the requirements have taxed a significant amount of management's and the Board of Directors' time and resources. Likewise, these developments may make it more difficult for us to attract and retain qualified members of our board of directors, particularly independent directors, or qualified executive officers.

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 controls 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 controls over financial reporting. In addition, the public accounting firm auditing the company's financial statements must attest to and report on management's assessment of the effectiveness of the company's internal controls over financial reporting. This requirement is applicable to our current annual report on Form 10-K and for all future annual reports.

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

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.

**Item 1B. Unresolved Staff Comments**

None.

## **Item 2. Properties**

Our principal executive office and U.S. manufacturing facility is located in Exton, Pennsylvania. This facility is leased and occupies approximately 86,500 square feet. This lease is noncancelable through March 31, 2008. Pursuant to the lease agreement, if we do not provide written notice of cancellation by March 31, 2007, the lease term will then expire on March 31, 2013. The Exton facility primarily houses our executive staff, our clinical operations staff, including clinical supplies manufacturing staff, and corporate accounting and finance.

Our research and development facility is located in Houston, Texas. This facility occupies a total of approximately 14,800 square feet. The facility is leased and this lease expires April 30, 2008.

Our commercial manufacturing facility and cellular laboratory is located in London, England. Our London, England facility consists of approximately 11,800 square feet under a lease that expires in March 2010. Effective January 1, 2005, we also leased approximately 3,600 square feet of office space in London for our selling and administrative personnel. This lease expires April 30, 2007.

In October 2005, we terminated our Sydney, Australia facility lease which consisted of approximately 7,100 square feet. We expect to service any future Australian product demand from our London facility.

In April 2005, we acquired a two-building, 100,000 square foot corporate campus in Bevaix, Canton of Neuchâtel, Switzerland for \$10 million. The \$10 million purchase price was paid using cash on hand from the proceeds of our 2004 issuances of common stock and 3.5% convertible subordinated notes. Our initial estimate of the total cost of acquisition and renovation of the facility, including the purchase of required equipment, was \$25 million. We have spent approximately \$1.8 million to date on the first phase of the renovation. At the present time, management is re-assessing the need for a second manufacturing facility in Europe. Until such an assessment is made, we do not expect to incur any material additional expenditures for renovation. We received a financing offer of approximately \$14 million for the purchase and renovation. In addition, we obtained a financial incentive package of government grants and a number of years of tax-free status. However, we do not intend to avail ourselves of the foregoing financial arrangements.

## **Item 3. Legal Proceedings**

### *Federal Securities Litigation*

The Company and certain of its current and former officers and directors are defendants in class action cases pending in the United States District Court for the Southern District of Texas and the United States District Court for the Eastern District of Pennsylvania.

On August 18, 2005, Elliot Liff brought an action styled, C.A. No. H-05-2887, *Elliot Liff v. Isolagen, Inc. et al.*, in the United States District Court for the Southern District of Texas. In this action, the Plaintiff purports to bring a federal securities fraud class action on behalf of purchasers of the publicly traded securities of Isolagen between March 3, 2004 and August 1, 2005, including purchasers of Isolagen stock issued in connection with and traceable to Isolagen's June 2004 common stock offering. The action asserts that the defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 by making certain false statements and omissions to the investing public regarding the Company's business operations, management, and intrinsic value of Isolagen's publicly traded securities. The Complaint also alleges liability against the individual defendants under Section 20(a) of the Exchange Act.

On September 6, 2005, Michael Cumiskey brought an action styled C.A. No. 05-cv-03105, *Michael Cumiskey v. Isolagen, Inc. et al.*, in the United States District Court for the Southern District of Texas. On September 16, 2005, Ronald Gargiulo brought an action styled, C.A. No. 05-cv-4983, *Ronald A. Gargiulo v. Isolagen, Inc. et al.*, in the United States District Court for the Eastern District of Pennsylvania.

On September 23, 2005, Gregory J. Newman brought an action styled, C.A. No. 05-cv-5090, *Gregory J. Newman v. Frank M. DeLape, et al.*, in the United States District Court for the Eastern District of Pennsylvania. These actions make allegations against the defendants substantially similar to those made in the *Liff* action. Together, the *Liff*, *Cummiskey*, *Gargiulo* and *Newman* actions comprise the “Federal Securities Actions.”

The *Liff* and *Cummiskey* actions were consolidated on October 7, 2005. The *Gargiulo* and *Newman* actions were consolidated on November 29, 2005. On November 18, 2005, the Company filed a motion with the Judicial Panel on Multidistrict Litigation (the “MDL Motion”) to transfer the Federal Securities Actions and the *Keene* derivative case (described below) to the United States District Court for the Eastern District of Pennsylvania. The *Liff* and *Cummiskey* actions were stayed on November 23, 2005, pending resolution of the MDL Motion. The *Gargiulo* and *Newman* actions were stayed on December 7, 2005, pending resolution of the MDL Motion. The MDL Motion was heard on January 7, 2006 and a ruling was issued on February 23, 2006. The ruling transferred the actions pending in the Southern District of Texas to the Eastern District of Pennsylvania. The Company anticipates that a Lead Plaintiff and Lead Counsel will be selected and an amended complaint will be filed in the near future.

#### *Derivative Actions*

The Company is the nominal defendant in derivative actions (the “Derivative Actions”) pending in State District Court in Harris County, Texas, the United States District Court for the Southern District of Texas, and the Court of Common Pleas of Chester County, Pennsylvania.

On September 28, 2005, Carmine Vitale filed an action styled, Cause No.2005-61840, *Carmine Vitale v. Frank DeLape, et al.* in the 55<sup>th</sup> Judicial District Court of Harris County, Texas and in February 2006 Mr. Carmine filed an amended complaint. In this action, the plaintiff purports to bring a shareholder derivative action on behalf of the Company against certain of the Company’s current and former officers and directors. The Plaintiff alleges that the individual defendants breached their fiduciary duties to the Company and engaged in other wrongful conduct. Certain individual defendants are accused of improper trading in Isolagen stock. The plaintiff did not make a demand on the Board of Isolagen prior to bringing the action and plaintiff alleges that a demand was excused under the law as futile.

On December 2, 2005, the Company filed its answer and special exceptions pursuant to Rule 91 of the Texas Rules of Civil Procedure based on pleading defects inherent in the *Vitale* complaint. The plaintiff filed an amended complaint on February 15, 2006.

On October 8, 2005, Richard Keene, filed an action styled, C.A. No. H-05-3441, *Richard Keene v. Frank M. DeLape et al.*, in the United States District Court for the Southern District of Texas. This action makes substantially similar allegations as the original complaint in the *Vitale* action. The plaintiff also alleges that his failure to make a demand on the Board prior to filing the action is excused as futile.

The Company has sought to transfer the *Keene* action to the United States District Court for the Eastern District of Pennsylvania as part of the MDL Motion. On January 21, 2006, the court stayed the *Keene* action pending resolution of the MDL Motion.

On October 31, 2005, William Thomas Fordyce filed an action styled, C.A. No. GD-05-08432, *William Thomas Fordyce v. Frank M. DeLape, et al.*, in the Court of Common Pleas of Chester County, Pennsylvania. This action makes substantially similar allegations as the original complaint in the *Vitale* action. The plaintiff also alleges that his failure to make a demand on the Board prior to filing the action is excused as futile.

On January 20, 2006, the Company filed its preliminary objections to the complaint. The Company filed a memorandum of law in support of its objections on February 23, 2006.

*Other*

We are involved in various other legal matters that are being defended and handled in the ordinary course of business. Although it is not possible to predict the outcome of these matters, management believes that the results will not have a material impact on the Company's financial statements.

**Item 4. Submission of Matters to a Vote of Security Holders**

No matters were submitted to a vote of security holders during the fourth quarter of 2005.



## Part II

### Item 5. Market For Registrant's Common Equity and Related Stockholder Matters

#### Market Information

Since December 11, 2002, our common stock has been traded on the American Stock Exchange under the symbol "ILE." Prior to December 11, 2002, our common stock was quoted on the OTC Bulletin Board under the symbol "ISLG." The market for our common stock is limited and volatile. The following table sets forth the high and low sales prices, as applicable, for our common stock for each of the periods indicated as reported by the AMEX.

	December 31, 2005		December 31, 2004	
	High	Low	High	Low
First Quarter	\$8.05	\$6.26	\$11.79	\$5.40
Second Quarter	6.50	3.35	12.04	8.40
Third Quarter	5.59	1.49	10.24	7.09
Fourth Quarter	1.90	1.05	9.89	6.65

#### Holdings

As of March 1, 2006, we had 460 stockholders of record of our common stock.

#### Dividends

We have never paid any cash dividends on our common stock. We anticipate that we will retain future earnings, if any, to support operations and to finance the growth and development of our business. Therefore, we do not expect to pay cash dividends in the foreseeable future.

#### Recent Sales of Unregistered Securities

None.

**Item 6. Selected Financial Data**

Our selected historical consolidated financial information presented as of December 31, 2005, 2004, 2003, 2002 and 2001 and for each of the five years ended December 31, 2005 was derived from our audited consolidated financial statements.

This information should be read in conjunction with the historical consolidated financial statements and related notes included herein, and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	<b>For the Year Ended December 31,</b>				
	<b>2005</b>	<b>2004</b>	<b>2003</b>	<b>2002</b>	<b>2001</b>
<b>Consolidated Statement of Operations Data</b>					
Revenue	\$ 8,753,684	\$ 4,179,247	\$ 445,689	\$ 50,991	\$ 25,482
License fees	—	—	—	40,000	80,000
Total revenue	8,753,684	4,179,247	445,689	90,991	105,482
Cost of sales	9,249,615	5,491,008	2,197,222	481,153	17,891
Selling, general and administrative expenses	23,012,458	15,127,365	6,311,774	3,764,187	723,690
Research and development	11,440,322	5,057,149	3,301,341	1,519,819	933,907
Operating loss	(34,948,711)	(21,496,275)	(11,364,648)	(5,674,168)	(1,570,006)
Other income (expense)					
Interest income	2,820,388	566,526	40,691	208,692	17
Other income	285,451	91,956	55,663	32,421	—
Interest expense	(3,934,712)	(636,676)	—	—	(82,015)
Net loss	(35,777,584)	(21,474,469)	(11,268,294)	(5,433,055)	(1,652,004)
Deemed dividend associated with beneficial conversion of preferred stock	—	—	(1,244,880)	(10,178,944)	—
Preferred stock dividends	—	—	(1,087,200)	(502,661)	—
Net loss attributable to common shareholders	\$ (35,777,584)	\$ (21,474,469)	\$ (13,600,374)	\$ (16,114,660)	\$ (1,652,004)
Per share information					
Net loss—basic and diluted	\$ (1.18)	\$ (0.71)	\$ (0.58)	\$ (0.36)	\$ (0.22)
Deemed dividend associated with beneficial conversion of preferred stock	—	—	(0.06)	(0.67)	—
Preferred stock dividends	—	—	(0.06)	(0.03)	—
Net loss attributable to common shareholders	\$ (1.18)	\$ (0.71)	\$ (0.70)	\$ (1.06)	\$ (0.22)
Weighted Average Shares outstanding	30,245,283	30,116,827	19,297,865	15,205,554	7,618,947
<b>Consolidated Balance Sheet Data</b>					
Cash and cash equivalents, restricted cash and available-for-sale investments	67,013,659	\$ 116,139,016	\$ 15,935,558	\$ 4,244,640	\$ 1,380,824
Working capital	61,130,870	111,061,724	14,367,768	2,811,160	870,377
Total assets	90,179,922	128,121,138	19,644,465	7,257,664	1,563,914
Total liabilities	98,276,819	99,135,713	2,380,740	2,050,734	511,514
Total shareholders equity (deficit)	(8,096,897)	28,985,425	17,263,725	5,206,930	1,052,400

## **Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

### **General**

We specialize in the development and commercialization of autologous cellular therapies for soft tissue regeneration. Our two product candidates, which are directed at the aesthetic and dental markets, utilize our proprietary Isolagen Process. Our ability to operate profitably under our current business plan is largely contingent upon our success in obtaining regulatory approval to sell our products and upon our successful development of markets for our products and development of profitable manufacturing processes. We may be required to obtain additional capital in the future to support these efforts or expand our operations. No assurance can be given that we will be able to obtain such regulatory approvals, successfully develop the markets for our products or develop profitable manufacturing methods, or obtain such additional capital as we might need, either through equity or debt financing, 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 satisfactory terms, our operations could be negatively impacted.

If we achieve growth in our operations in the next few years, such growth could place a strain on our management, administrative, operational and financial infrastructure. We may find it necessary to hire additional management, financial, sales and marketing personnel to manage our expanding operations. In addition, our ability to manage future operations and growth may require the continued improvement of operational, financial and management controls, reporting systems and procedures. If we are unable to manage this growth effectively and successfully, our business, operating results and financial condition may be materially adversely affected.

The focus of our efforts has been and will continue to be the development, testing and approval of the Isolagen Process, and research into other applications, as a result of which we are still considered to be a "development stage" enterprise. We have, since 2002, made the Isolagen Process available to physicians primarily in the United Kingdom as a means of developing our marketing, sales and manufacturing processes. Revenue from the sale of treatments was approximately \$8.75 million for the year ended December 31, 2005. Although our revenue has increased more than 100% as compared to the prior year, we continue to generate negative gross margins, as discussed under "Results of Operations—Comparison of Years Ending December 31, 2005 and 2004."

At December 31, 2005, we had cash, cash equivalents, restricted cash and available-for-sale investments of \$67.0 million, as compared to \$116.1 million at December 31, 2004. The causes of our decrease in cash, cash equivalents and available-for-sale investments are discussed under "Liquidity and Capital Resources." We believe our existing capital resources are adequate to finance our operations until June 30, 2007; however, our long-term viability is dependent upon successful operation of our business, which includes our ability to improve and/or automate our manufacturing process, the approval of our products and the ability to raise additional debt and equity to meet our business objectives.

### **Recent Developments**

We are developing our lead product candidate for the correction and reduction of the normal effects of aging, such as wrinkles and nasolabial folds. In March 2004, we announced positive results of our first Phase III exploratory clinical trial for our lead product candidate. In July 2004, we announced the commencement of two pivotal Phase III trials, which were being conducted in two different geographic and demographic populations in the United States as two identical trials for the treatment of facial wrinkles. These trials, which were concluded during the second half of 2005, were randomized, double blind and placebo-controlled and were conducted at various sites in the United States. The trials, which were conducted simultaneously, each had in excess of 100 subjects split evenly between the treatment group and the placebo group.

We announced on August 1, 2005 the results of our pivotal Phase III dermal studies. The dermal studies met three of the four primary endpoints and achieved statistical significance when combined. The studies' primary endpoints were based on blinded physician visual assessment using a six-point scale with a two-point positive move required to meet the endpoint and subject assessment using a visual analog scale. Trial B of the study proved to be clinically and statistically significant with both the subject and physician assessment achieving positive results. Trial A results were mixed with only a positive assessment from the subjects. In addition, there was a wide variance in results from site to site with a range of response rates from 73.3% to 7.6%, where a "response" represents the improvement of at least two points, on a six point scale, based on a visual assessment performed by the physician. We believe that this range of outcomes suggests that results are dependent on, among other things, injection technique. We conducted a post hoc statistical analysis and a thorough review of the results of the Phase III studies that suggested trial results were negatively impacted by two factors in addition to injection technique. First, our statistical analysis included all subjects who were randomized to the study. The statistical analysis did not exclude subjects who received neither our product nor placebo; these subjects were deemed to have failed the study. Second, our study population included a number of subjects with a baseline assessment of two (of their wrinkles) on the six-point scale. A two point improvement for these subjects would have required an assessment of zero on the six-point scale. After consultation with our clinical advisors familiar with utilizing the six-point scale, we believe subjects with an initial assessment of two on the scale should have been excluded from participation in the studies because of investigator reluctance to make a final assessment of zero (equivalent to no wrinkles) at the endpoint. Our future protocols will exclude subjects with a baseline assessment of two.

We used the information derived from our post hoc statistical analysis and the input of our clinical advisors to develop a Phase III confirmatory study. During the fourth quarter of 2005, we submitted a protocol to the FDA for a 200 subject confirmatory study the results of which we intend to submit together with our previous studies to support a Biological License Approval (BLA) filing in 2007. We are diligently working with the FDA to secure Special Protocol Assessment (SPA) approval of this new Phase III confirmatory study and to resolve a number of issues relating to the commencement of the confirmatory study. As part of this process, we believe we have made significant progress in addressing the FDA's requests for information regarding Chemistry Manufacturing Controls (CMC) data and process validation. We intend to conduct the confirmatory study from our Exton, Pennsylvania facility. We completed the construction of the Exton manufacturing facility during the fourth quarter of 2005 and this facility is now validated for trial commencement.

During the fourth quarter of 2005, we commenced preparations for our confirmatory study, including identifying and recruiting investigator sites and submission of the protocol to the FDA. We recently conducted an investigator meeting during which we provided injection and assessment training to participants. We expect to complete training and site initiation by the end of the first quarter of 2006. This study will be conducted from our Exton facility.

We completed a Phase I clinical trial for our second product candidate, for the treatment of periodontal disease, in late 2003. In the second quarter of 2004, we initiated a Phase II clinical trial for the cosmetic, or "black triangle," application of this product candidate. This Phase II clinical trial concluded during the second quarter of 2005. The analysis of the investigator and subject visual analog scale assessment demonstrated that the Isolagen Process was statistically superior to placebo at four months after treatment. Although results of the investigator and subject assessment demonstrated that the Isolagen Process was statistically superior to placebo, an analysis of objective linear measurements did not yield statistically significant results despite a positive change observed as a result of treatment with the Isolagen Process. Clinical advisors believe that current measurement techniques are not precise enough to accurately record the positive change. We are investigating alternative measurement techniques to assess change in future trials.

On October 3, 2005, we announced that the Board of Directors had appointed Susan Ciallella to the position of Interim Chief Executive Officer. Ms. Ciallella's appointment followed the resignation of Frank DeLape from the post of interim CEO. On October 27, 2005, Mr. DeLape resigned from the Board of Directors and entered into a Separation Agreement with the Company. See Note 8 of Notes to Consolidated Financial Statements

For a discussion of pending litigation, including the class action and derivative action matters for which we are defendants, see Note 8 of Notes to Consolidated Financial Statements and Part I, Item 3, Legal Proceedings, set forth elsewhere in this Report.

### **Critical Accounting Policies**

The following discussion and analysis of financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in conformity with accounting principles generally accepted in the United States of America. Our significant accounting policies are more fully described in Note 2 of Notes to the Consolidated Financial Statements. However, certain accounting policies and estimates are particularly important to the understanding of our financial position and results of operations and require the application of significant judgment by our management or can be materially affected by changes from period to period in economic factors or conditions that are outside the control of management. As a result they are subject to an inherent degree of uncertainty. In applying these policies, our management uses their judgment to determine the appropriate assumptions to be used in the determination of certain estimates. Those estimates are based on our historical operations, our future business plans and projected financial results, the terms of existing contracts, our observance of trends in the industry, information provided by our customers and information available from other outside sources, as appropriate. The following discusses our significant accounting policies and estimates.

*Revenue Recognition:* We recognize revenue over the period the service is performed in accordance with SEC Staff Accounting Bulletin No. 104, "Revenue Recognition in Financial Statements" ("SAB 104"). In general, SAB 104 requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services rendered, (3) the fee is fixed and determinable and (4) collectibility is reasonably assured.

The Isolagen Process is administered to each patient using our recommended regimen of up to six injections. Due to the short shelf life, each injection is cultured on an as needed basis and shipped prior to the individual injection being administered by the physician. We believe each injection has stand alone value to the patient. We invoice the attending physician upon that physician submitting his or her patient's tissue sample to us; as a result of which the contractual arrangement is between us and the medical professional. The amount invoiced varies directly with the number of injections requested. Generally, orders are paid in advance by the physician prior to the first injection. There is no performance provision under any arrangement with any physician, and there is no right to refund or returns for unused injections.

As a result, we believe that the requirements of SAB 104 are met as each injection is shipped, as the risk of loss transfers to the physician at that time, the fee is fixed and determinable and collection is reasonably assured. Advance payments are deferred until shipment. The amount of the revenue deferred represents the fair value of the remaining undelivered injections measured in accordance with Emerging Issues Task Force Issue ("EITF") 00-21, "Accounting for Revenue Arrangements with Multiple Deliverables," which addresses the issue of accounting for arrangements that involve the delivery of multiple products or services. Should the physician discontinue the regimen prematurely all remaining deferred revenue is recognized.

Revenue from licenses and other upfront fees are recognized on a ratable basis over the term of the respective agreement. We also offer a service whereby we store a patient's cells for later use in the preparation of injections. In accordance with EITF 00-21, the fees charged for this service is recognized as revenue ratably over the length of the storage agreement.

*Cost of Sales, Selling, General and Administrative Expenses and Research and Development Expenses:* The primary purpose of our Houston, Texas and to a large degree our Exton, Pennsylvania facility is to conduct research on the development, testing and approval of the Isolagen Process. Our London facility was engaged in the commercialization of our process (for which they earned revenue from the sale of Isolagen Process injections) as a means aimed at improving manufacturing technologies that are more automated and therefore would be used to produce commercial quantities of injections on a profitable basis in the future. Therefore, we classify as cost of sales the costs (except for costs related to marketing, sales and general corporate administration) incurred in operating our London facility and our previous Australian facility as cost of sales, while the costs incurred in operating our Houston, Texas and Exton, Pennsylvania facilities (except for costs related to general corporate administration) are classified as research and development expenses.

Costs of sales includes salaries and benefits, costs paid to third-party contractors to develop and manufacture drug materials and delivery devices, inventory used in the manufacturing process, a portion of facilities cost and other indirect manufacturing costs. Those costs, except for the costs of raw materials that have not been used, are expensed as incurred.

As discussed under "Business—Our Solution," historically, autologous cell companies have been hampered by manufacturing technologies that use traditional methodology for culturing cells through the utilization of plastic flasks. This methodology is labor intensive, slow, involves many sterile interventions and is costly. The use of this process to produce Isolagen Process injections in commercial quantities would not, over time, be profitable. We have been using the commercialization of our process as a means of researching and developing manufacturing technologies that would be more automated and therefore could be used to produce commercial quantities of injections on a profitable basis. Through the end of 2005 our cost of sales has exceeded our revenue. This reflects the fact that the level of our sales from our commercialization efforts primarily in the United Kingdom, while increasing, have not yet reached the levels necessary for profitable operations, and the development and implementation of improved and/or automated processes has not yet achieved all of the cost efficiencies we hope to achieve in the future.

If, in the future, the purposes for which we operate our Exton, Pennsylvania, Houston, Texas, or London facilities, or any other facilities or new facilities we open, changes, the allocation of the costs incurred in operating that facility between cost of sales and research and development expenses could change to reflect such operational changes.

*Research and Development Expenses:* Research and development costs are expensed as incurred and include salaries and benefits, costs paid to third-party contractors to perform research, conduct clinical trials, develop and manufacture drug materials and delivery devices, and a portion of facilities cost. Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. Invoicing from third-party contractors for services performed can lag several months. We accrue the costs of services rendered in connection with third-party contractor activities based on our estimate of management fees, site management and monitoring costs and data management costs. Actual clinical trial costs may differ from estimated clinical trial costs and are adjusted for in the period in which they become known.

*Stock-Based Compensation—The Acceleration of Unvested Employee and Director Stock Options and Forthcoming Changes in Stock-based Compensation Accounting:* We account for our stock-based compensation under the provisions of SFAS No. 123 "Accounting for Stock Based Compensation." Under SFAS No. 123, we are permitted to either record expenses for stock options and other employee

compensation plans based on their fair value at the date of grant or to continue to apply the provisions of Accounting Principles Board Opinion No. 25 "Accounting for Stock Issued to Employees," ("APB No. 25"), and recognize compensation expense, if any, based on the intrinsic value of the equity instrument at the measurement date. Any such compensation cost is charged to expense on a straight-line basis over the periods the options vest. To the extent we previously had cashless exercise provisions, we utilized variable accounting. We have elected to continue following the provisions of APB No. 25 through December 31, 2005. Stock options issued to other than employees or directors are recorded on the basis of their fair value as required by SFAS No. 123.

During December 2005, the board of directors approved the full vesting of all unvested, outstanding stock options issued to current employees and directors. The board decided to take this action ("the acceleration event") in anticipation of the adoption of SFAS No. 123 (Revised 2004), "*Share Based Payments*" (discussed further below). As a result of this acceleration event, approximately 1.4 million stock options were vested that would have otherwise vested during 2006 and later periods. At the time of the acceleration event, the unamortized grant date fair value of the affected options was approximately \$3.6 million (for SFAS No. 123 and SFAS No. 148 pro forma disclosure purposes), which has been charged to pro forma expense in the fourth quarter of 2005 (see Note 2 of Notes to the Consolidated Financial Statements). Substantially all of the unvested employee stock options that were subject to the acceleration event had exercise prices above market price of our common stock at the time the board approved the acceleration event. However, because, as discussed below, we will have to adopt SFAS No. 123 (Revised 2004) effective January 1, 2006, if we had not completed this acceleration event in December 2005, the majority of the \$3.6 million amount discussed above would have been charged against the future results of operations, as reported in the statements of operations, beginning in the first quarter of fiscal 2006 and continuing through later periods as the options vested. As discussed above, substantially all of the unvested employee stock options which were accelerated had exercise prices above market price at the time of acceleration. For the purposes of applying APB No. 25 to such stock options in the statement of operations for the year ended December 31, 2005, the acceleration event was treated as the acceleration of the vesting of employee and director options that otherwise would have vested as originally scheduled, and accordingly was not a modification requiring the remeasurement of the intrinsic value of the options, or the application of variable option accounting, under APB No. 25. For stock options that had exercise prices below market price at the time of acceleration and that would not have vested originally, a charge of approximately \$15,000 was recorded in the statement of operations for the year ended December 31, 2005.

In December 2004, the FASB issued SFAS No. 123 (Revised 2004), "*Share Based Payment*," which eliminates the use of APB Opinion No. 25 and will require us to measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost will be recognized over the period during which an employee is required to provide service in exchange for the reward—the requisite service period. No compensation cost is recognized for equity instruments for which employees do not render the requisite service. The grant-date fair value of employee share options and similar instruments will be estimated using option-pricing models adjusted for the unique characteristics of those instruments. SFAS No. 123 (Revised 2004) is effective for the first interim or annual reporting period that begins after December 31, 2005 (the quarter beginning January 1, 2006 for the Company) and must be applied to all options granted or modified after its effective date and also to recognize the cost associated with the portion of any option awards made before its effective date for which the associated service has not been rendered as of its effective date. We will adopt SFAS No. 123 (Revised 2004) using a modified version of prospective application, *or* modified prospective application. Under modified prospective application, SFAS No. 123 (Revised 2004) applies to new awards and to awards modified, repurchased, or cancelled after the required effective date. Additionally, compensation cost for the portion of awards for which the requisite service has not been rendered that are outstanding as of the required effective date shall be recognized as the requisite service is rendered on or after the required effective date. The compensation cost for that portion of awards shall be based on the grant-date

fair value of those awards as calculated for either recognition or pro forma disclosures under Statement 123. However, as we accelerated the vesting of outstanding employee and director stock options during December 2005, there is no remaining expense related to such options to be expensed in future periods. As such, the impact of SFAS No. 123 (Revised 2004) on our future financial statements will be based upon the number of stock based payments awarded in the future, requisite service requirements and the value of such awards on the award dates; factors which are not currently estimable. We anticipate utilizing the Black-Scholes valuation model in order to value future stock option awards, and anticipate utilizing the binomial lattice model when considered by management to be more appropriate.

*Federal Securities and Derivative Actions:* As discussed in Note 8 of Notes to Consolidated Financial Statements and Part I, Item 3, Legal Proceedings, set forth elsewhere in this Report, we are currently defending ourselves against various class and derivative actions. We intend to defend ourselves vigorously against these actions. We cannot currently estimate the amount of loss, if any, that may result from the resolution of these actions, and no provision has been recorded in our consolidated financial statements. Generally, a loss must be both reasonably estimable and probable in order to record a provision for loss. We will expense our legal costs as they are incurred and will record any insurance recoveries on such legal costs in the period the recoveries are received. Although we have not recorded a provision for loss regarding these matters, a loss could occur in a future period.

We are involved in various other legal matters that are being defended and handled in the ordinary course of business. Although it is not possible to predict the outcome of these matters, management believes that the results will not have a material impact on our financial statements.

#### **Results of Operations—Comparison of Years Ending December 31, 2005 and 2004**

**REVENUE.** Revenue increased \$4.6 million, to \$8.8 million for the year ended December 31, 2005, as compared to \$4.2 million for the year ended December 31, 2004. The increase in revenue is primarily attributable to the continuation of the level of operations in the United Kingdom achieved in the second half of 2004, as approximately 80% of 2004 revenue was earned during the last six months of 2004. However, the increase in 2005 revenue was less than management anticipated. In terms of product volumes as measured by milliliter of product, volumes increased by approximately 180% during the year ended December 31, 2005, as compared to the year ended December 31, 2004. Average selling price per milliliter of treatment decreased approximately 22% during the year ended December 31, 2005, as compared to the year ended December 31, 2004. The average selling price has fluctuated as we continue to investigate various price points in the United Kingdom market. In addition, our average selling price per milliliter has declined due to the increase in four and six milliliter treatment programs sold during the year ended 2005 as compared to primarily three milliliter treatments sold during the year ended 2004. Generally, higher milliliter treatments have a higher selling price than lower milliliter treatments, however, the average price per milliliter decreases.

In addition, after the completion of a standard treatment, a patient may request and pay for an additional milliliter of treatment. Such additional treatment volumes increased by approximately 620% during the year ended December 31, 2005, as compared to the year ended December 31, 2004. This increase in volume was offset by a decrease in average selling price of approximately 22%.

The revenue which we recognized during the year ended December 31, 2005 and 2004 was in part reduced by the effects of promotional incentives provided to doctors utilizing the Isologen Process. From time to time, we provide promotional incentives, or no charge treatments, to doctors utilizing the Isologen Process. Such promotional incentives are not reflected as revenue, but rather, are reflected as marketing expense in selling, general and administrative expenses. We expect to continue, on a reduced basis in 2006, providing such promotional incentives to doctors during the introduction phase of the Isologen Process in the United Kingdom and elsewhere.



We also offer a service whereby we store a patient's cells for later use in the preparation of injections. The fees charged for this service are recognized as revenue ratably over the length of the storage agreement. Revenue from this service in the year ended December 31, 2005 and 2004 was less than \$0.3 million and less than \$0.1 million, respectively. Additionally, we offer a service whereby we process a patient's cells to expand the cells to the mass necessary to prepare an injection, but then store the expanded cells for later use in the preparation of injections. Revenue from this service, since our inception, is less than \$0.1 million.

Overall we believe our 2005 revenue, as compared to anticipated 2005 revenue, was adversely affected by the following factors:

- Our 2005 sales remained heavily concentrated in the United Kingdom. We envisioned a much greater geographical reach.
- Our marketing efforts in the United Kingdom were curtailed by marketing restrictions.
- We were unable to effectively and efficiently implement manufacturing process and technology improvements in the United Kingdom which led to a high variable cost base and negative margins during the period of implementation of these improvements. As a result, we dedicated less resources toward market development.
- At the time of our initial projections, we assumed a positive BLA submission during 2005. As a result of our trial results and our inability to file the BLA, we dedicated less resources than we previously anticipated towards market development.

**COST OF SALES.** Costs of sales increased to \$9.2 million for the year ended December 31, 2005, as compared to \$5.5 million for the year ended December 31, 2004. The increase of \$3.8 million in cost of sales is primarily related to the increase in sales. The increase in cost of sales resulted from increases in essentially all categories of costs as the United Kingdom operation increased its commercialization of our process. During the year ended December 31, 2005, we continued to increase manufacturing headcount and related overhead costs commensurate with demand. For the year ended December 31, 2005, our cost of sales exceeded revenue as the development and implementation of improved manufacturing processes has not yet achieved all of the cost efficiencies we anticipate.

As a percentage of revenue, cost of sales were approximately 106% for the year ended December 31, 2005 and approximately 131% for the year ended December 31, 2004. The change in this percentage is the result of the lower level of sales activity during 2004, our early stage of commercial development and the associated lower level of operational activity. As product volumes have increased, our fixed costs have been spread over a greater number of units, thereby lowering cost of sales as a percentage of revenue. In addition, as a result of certain manufacturing initiatives, we have experienced improvements regarding the quantity of certain materials utilized in our manufacturing process, thereby lowering our cost of sale as a percentage of revenue. As previously discussed, we have been using the commercialization of the Isologen Process in the UK market as a means aimed at improving and/or automating our manufacturing process, which would be used to produce commercial quantities of injections on a profitable basis in the future. As the London facility operations continue to develop and mature, resulting in significant changes to its stage of commercial development, large fluctuations in the percentage of cost of sales to revenue are anticipated.

**SELLING, GENERAL AND ADMINISTRATIVE EXPENSES.** Selling, general and administrative expenses increased approximately \$7.9 million, or 52%, to \$23.0 million for the year ended December 31, 2005, as compared to \$15.1 million for the year ended December 31, 2004. The increase in selling, general and administrative expense is primarily due to the following:

- a) Other general and administrative costs increased by approximately \$4.9 million to \$10.2 million for the year ended December 31, 2005, as compared to \$5.4 million for the year ended

December 31, 2004, due primarily to increased facility occupancy costs of \$1.6 million, increased accounting fees of \$0.6 million, increased insurance and office costs of \$0.8 million and increased general costs related to increasing headcount and higher overall business activity of \$0.5 million. Further, a \$1.4 million impairment charge related to certain third party developed software costs was recorded during the year ended December 31, 2005 as such software was taken out of service and not expected to provide future value.

b) Promotional expense increased by approximately \$1.8 million to \$3.2 million for the year ended December 31, 2005, as compared to \$1.3 million for year ended December 31, 2004 due to increased marketing and promotional efforts related to the efforts to expand our operations in the United Kingdom and increase our 2005 revenue.

c) Legal expenses increased approximately \$0.9 million to \$1.5 million for the year ended December 31, 2005, as compared to \$0.6 million for the year ended December 31, 2004, due primarily to costs related to the securities and derivative lawsuits, for which we are defendants, and employment termination matters.

d) Salaries and compensation increased by approximately \$1.0 million to \$5.0 million for the year ended December 31, 2005, as compared to \$4.0 million for year ended December 31, 2004, due to an increase in the number of our employees. This increase in the number of employees was offset by decrease in severance expenses during 2005 of \$0.5 million. We incurred \$1.1 million of severance expense in the year ended December 31, 2004, as compared to \$0.6 million in the year ended December 31, 2005.

e) Travel expense increased by approximately \$0.3 million to \$1.3 million for the year ended December 31, 2005, as compared to \$1.0 million for year ended December 31, 2004, due primarily to increased travel between our Houston, Texas and Exton, Pennsylvania locations as compared to the prior year.

f) Consulting expense decreased by approximately \$1.1 million to \$1.7 million for the year ended December 31, 2005, as compared to \$2.8 million for the year ended December 31, 2004. For the year ended December 31, 2004, the consulting costs included \$1.6 million of stock based expenses related to options and warrants issued under consulting and distribution agreements and \$0.3 million of stock compensation related to stock options issued to directors. During the year ended December 31, 2005, there was approximately (\$0.1) million of stock based expense. The level of the expense recorded for the warrants issued under consulting and distribution contracts varies from quarter to quarter based on changes in the market price of our common stock, and the negative expense in 2005 reflects the effects of the 2005 decline in the price of our common stock. The decrease in stock based expenses of \$1.9 million, discussed above, was offset by an increase of \$0.9 million related to increase recruiting costs, general consulting expenses and investor relations costs during 2005.

**RESEARCH AND DEVELOPMENT.** Research and development expenses increased by approximately \$6.4 million during the year ended December 31, 2005 to \$11.4 million, as compared to \$5.1 million in the year ended December 31, 2004. Research and development costs are composed primarily of costs related to our efforts to gain FDA approval for the Isolagen Process for specific dermal applications in the United States and also include costs to develop more automated manufacturing, cell collection and logistical process improvements. Our initial pivotal Phase III dermal studies and our Phase II dental studies concluded during the first half of 2005. We subsequently commenced preparations for a confirmatory Phase III dermal trial during the fourth quarter of 2005. Such costs include personnel and laboratory costs related to these FDA trials and certain consulting costs. The total inception to date cost of research and development as of December 31, 2005 was \$23.4 million. The FDA approval process is extremely complicated and is dependent upon our study protocols and the results of our studies. In the event

that the FDA requires additional studies for dermal applications or requires changes in our study protocols or in the event that the results of the studies are not consistent with our expectations, as occurred during 2005 with respect to our pivotal Phase III dermal trial (see the Recent Developments section), the process will be more expensive and time consuming. Due to the complexities of the FDA approval process, we are unable to predict what the cost of obtaining approval for the dermal applications will be at this time. Also, during the third quarter of 2005, we began an investigational study related to patients subjectively considered to be poor responders to the Isologen Process (or the "suboptimal program"). Approximately 105 patients are ultimately expected to be included in the suboptimal program and the program is expected to be completed during the first half of 2006 at an estimated total cost ranging from \$0.3 million to \$0.4 million. We have other research projects currently underway. However, research and development costs related to these projects were not material during 2005 and 2004.

The major changes in research and development expense are due primarily to the following: a) consulting expense increased by approximately \$4.4 million to \$7.2 million for the year ended December 31, 2005, as compared to \$2.8 million for the year ended December 31, 2004, as a result of increased expenditures related to our clinical trials and automated manufacturing research and development, b) salaries and payroll taxes increased by approximately \$1.6 million to \$3.3 million for the year ended December 31, 2005, as compared to \$1.8 million for the year ended December 31, 2004, as a result of increased employees engaged in research and development activities and c) facility costs, including rent, utilities and other related costs, increased approximately \$0.4 million, due primarily to the new Exton, Pennsylvania lease which commenced during 2005.

**INTEREST INCOME.** Interest income increased to \$2.8 million for the year ended December 31, 2005 compared to \$0.6 million for the year ended December 31, 2004. The increase in interest income of \$2.3 million resulted principally from an increase in the amount of cash held in interest bearing accounts, and our investment in marketable debt securities, due to the investment of the proceeds from the issuance of \$90.0 million of 3.5% convertible subordinated debt in the fourth quarter of 2004; as well as an increase in interest rates over the comparable period. We expect our interest income to decrease in 2006 as we continue to utilize our cash and available-for-sale investments to fund operations and capital expenditures.

**INTEREST EXPENSE.** Interest expense increased to \$3.9 million for the year ended December 31, 2005, as compared to \$0.6 million for the year ended December 31, 2004. The increase in interest expense of \$3.3 million is related to the interest expense associated with the issuance on November 1, 2004 of \$90 million in principal amount of 3.5% convertible subordinated notes, as well as the related amortization of deferred debt issuance costs of \$0.8 million for the year ended December 31, 2005. Our notes were outstanding for approximately two months in 2004, as compared to outstanding for the full year in 2005.

**NET LOSS.** Net loss for the year ended December 31, 2005 was \$35.8 million as compared to a net loss of \$21.5 million for the year ended December 31, 2004. This increase in net loss of \$14.3 million represents the effects of the increases in selling, general and administrative expenses, research and development expenses and interest expense, partially offset by the increase in our interest income and improvement in gross margin. As a result of declining foreign currency exchange rates since December 31, 2004, specifically the exchange rate between the US dollar and the British pound and the Swiss franc, our accumulated other comprehensive income of \$0.5 million at December 31, 2004 has decreased to an accumulated other comprehensive loss of \$0.8 million at December 31, 2005; or a change of \$1.3 million. However, this loss is considered unrealized and is reflected on the Consolidated Balance Sheet. Accordingly, this unrealized loss may increase or decrease in the future, based on the movement of foreign currency exchange rates, but will not have an impact on net income (loss) until the related foreign capital investments are sold or otherwise realized.

### Results of Operations—Comparison of Years Ending December 31, 2004 and 2003

**REVENUE.** Revenue increased 838% or \$3.7 million, to \$4.2 million for year ended December 31, 2004, from \$0.5 million in the prior year. The increase in revenue is primarily attributable to the continuation of operations in the United Kingdom. The revenue which we did recognize during the years ended December 31, 2004 and 2003 from our United Kingdom operations was in part reduced by the effects of promotional incentives provided to doctors utilizing the Isolgen Process.

We also offer a service whereby we store a patient's cells for later use in the preparation of injections. The fees charged for this service are recognized as revenue ratably over the length of the storage agreement. We also provide a service whereby we processes a patient's cells to expand the cells to the mass necessary to prepare an injection, but then store the expanded cells for later use in the preparation of injections. Revenue from these services was less than \$0.1 million in 2004 and zero in 2003.

**COST OF SALES.** Costs of sales increased 150%, or \$3.2 million, to \$5.5 million during the year ended December 31, 2004, from \$2.2 million in the prior year. The increase in cost of sales was primarily related to the increase in activities of our London and Australia facilities. The increase resulted from increases in essentially all categories of costs as these facilities increased their commercialization of our process. Cost of sales exceeded revenue as the development and implementation of automated processes had not yet achieved all of the cost efficiencies we hope to achieve in the future.

**SELLING, GENERAL AND ADMINISTRATIVE EXPENSES.** Selling, general and administrative expenses increased 140%, or \$8.8 million, to \$15.1 million for the year ended December 31, 2004, from \$6.3 million in the prior year. The major components of the approximate \$8.8 million increase in selling, general and administrative expense are as follows:

- a) Salaries increased by approximately \$2.9 million to \$4.0 million for the year ended December 31, 2004, as compared to \$1.1 million in the prior year, due to an increase in our number of employees. The expense for year ended December 31, 2004 included \$1.1 million related to employee severances. Of this \$1.1 million, \$0.9 million results from the severance of two employees who are entitled, under their contracts, to receive salary payments through July 2006 and \$0.2 million results from our decision to close our facility in Australia and serve the Australian market through our existing facility in Europe (see Note 2 of Notes to Consolidated Financial Statements). The year ended December 31, 2004 expense included an imputed expense of \$0.2 million for the fair market value of services provided by certain officers for which they will not be compensated.
- b) Office and other costs increased by approximately \$2.3 million to \$4.5 million for the year ended December 31, 2004, as compared to \$2.2 million in the prior year, which increase is primarily related to the commencement of our operations in the United Kingdom and the completion of our U.S. laboratory in Texas. There was a \$0.2 million loss on disposal of an asset, primarily consisting of assets in Australia, for the year ended December 31, 2004. There was a \$0.4 million loss on disposal of an asset, primarily consisting of the write-off of software in the prior year.
- c) Consulting expense increased by approximately \$2.1 million to \$2.8 million for the year ended December 31, 2004, as compared to \$0.7 million in the prior year. The increase included \$1.5 million of stock based expenses related to options and warrants issued under consulting and distribution agreements, and \$0.4 million of stock compensation related to stock options issued to directors and officers. There was a \$0.4 million stock based expense in the prior year. The level of the expense recorded for the warrants issued under consulting and distribution contracts can vary from quarter to quarter based on changes in the market price of our common stock.
- d) Promotional expense increased by approximately \$0.7 million to \$1.3 million for the year ended December 31, 2004 compared to \$0.6 million to the year ended December 2003 due to

increased marketing and promotional efforts related to the expansion of our operations in the United Kingdom.

e) Depreciation and amortization increased by approximately \$0.4 million to \$0.9 million for the year ended December 31, 2004, as compared to \$0.5 million in the prior year, which increase was based on assets placed into service during 2003 with the commencement of our operations in the United Kingdom and the completion of our U.S. laboratory.

f) Travel expense increased by approximately \$0.2 million to \$1.0 million for the year ended December 31, 2004, as compared to \$0.8 million in the prior year.

g) Legal expense increased by approximately \$0.1 million to \$0.6 million for the year ended December 31, 2004, as compared to \$0.5 million in the prior year.

**RESEARCH AND DEVELOPMENT.** Research and development expenses increased by approximately \$1.8 million during the year ended December 31, 2004, to \$5.1 million from \$3.3 million in the prior year. Research and development costs are composed primarily of costs related to our efforts to gain FDA approval for our products in the United States. These costs include those personnel and laboratory costs related to the current FDA trials and certain consulting costs. The total cumulative cost of research and development incurred through December 31, 2004 was \$11.9 million. The FDA approval process is extremely complicated and is dependent upon our study protocols and the results of our studies. In the event that the FDA requires additional studies for dermal applications or requires changes in our study protocols or in the event that the results of the studies are not consistent with our expectations the process will be more expensive and time consuming. Due to the complexities of the FDA approval process we are unable to predict what the cost of obtaining approval for the initial dermal applications will be. We have other research projects currently underway. However, research and development costs related to these projects were not material during the 2004 or 2003 periods. The major components of the approximately \$1.8 million increase in research and development expense were as follows: a) consulting expense increased by approximately \$1.2 million to \$2.8 million during the year ended December 31, 2004, as compared to \$1.6 million in the prior year; b) salaries and payroll taxes increased by approximately \$0.7 million to \$1.8 million during the year ended December 31, 2004, as compared to \$1.1 million in the prior year; and c) laboratory expense decreased by approximately \$0.1 million to \$0.5 million during the year ended December 31, 2004, as compared to \$0.6 million in the prior year.

**INTEREST INCOME.** Interest income increased 1,292%, or \$0.5 million, to \$0.6 million during the year ended December 31, 2004, from \$40,691 in the prior year. The increase in interest income resulted principally from an increase in the amount of cash held in interest bearing accounts, and our investment in marketable debt securities, as the result of our receipt of the proceeds of \$56.8 million from the issuance of common stock in the second quarter of 2004 and the issuance of \$90.0 million of 3.5% Convertible Subordinated Notes in the fourth quarter of 2004.

**INTEREST EXPENSE.** Interest expense increased \$0.6 million, to \$0.6 million during the year ended December 31, 2004, from \$0 in the prior year. The increase in interest expense resulted principally from the issuance of \$90.0 million in principal amount of 3.5% Convertible Subordinated Notes.

**NET LOSS.** Net loss for the year ended December 31, 2004 was \$21.5 million, as compared to a net loss of \$11.3 million in the prior year. This increase in net loss is attributed primarily to the increases in our selling, general and administrative expenses and research and development expenses discussed above. We compute our net loss per share on the basis of net loss attributable to common shareholders, which included the effects of certain items not included in the determination of net income. Net loss attributable to common shareholders for the year ended December 31, 2004 was \$21.5 million as compared to a net loss attributable to common shareholders of \$13.6 million in the prior year. These amounts include

\$1.2 million of deemed dividend associated with beneficial conversion of preferred stock in 2003 and include \$1.1 million of preferred stock dividends in 2003.

### Liquidity and Capital Resources

Net cash provided by (used in) operating, investing and financing activities for the three years ended December 31, 2005 were as follows:

	<u>Year Ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
	(in millions)		
Cash flows from operating activities	\$ (34.0)	\$ (14.8)	\$ (9.3)
Cash flows from investing activities	11.6	(54.6)	(1.2)
Cash flows from financing activities	\$ 0.1	\$ 117.4	\$ 21.9

**OPERATING ACTIVITIES.** Cash used in operating activities during the year ended December 31, 2005 amounted to \$34.0 million, an increase of \$19.1 million over the year ended December 31, 2004. The increase in our cash used in operating activities over the prior year is primarily due to an increase in net losses (adjusted for non-cash items) of \$14.7, with the balance of \$4.4 million attributable to our changes in operating assets and liabilities. Our negative operating cash flows in 2005 were funded from cash on hand at December 31, 2004 and the net proceeds from the liquidation of available-for-sale investments held at December 31, 2004, both of which we derived from the proceeds of our 2004 issuances of common stock and 3.5% convertible subordinated notes.

**INVESTING ACTIVITIES.** Cash provided by investing activities during the year ended December 31, 2005 amounted to \$11.6 million, an increase of \$66.2 million over the year ended December 31, 2004 outflow of \$54.6 million. This increase in cash provided is due primarily to the net \$81.1 million increase in the liquidation of our available-for-sale investments. The characterization of investments between available-for-sale investments and cash equivalents varies based upon the maturity date of the investment. Accordingly, if an available-for-sale investment matures or is sold and the proceeds are used to purchase a cash equivalent security, then this would represent a liquidation of available-for-sale investments. In 2005 we liquidated a net of \$29.3 million of short-term investments, which has been purchased with net proceeds of our 2004 issuances of common stock and 3.5% convertible subordinated notes. This net reduction of short-term investments was used to fund \$17.7 million of 2005 purchases of property and equipment and to partially fund our negative operating cash flows. The 2005 purchases of property and equipment primarily related to our acquisition of land and buildings in Switzerland, and related improvements, and the build-out of our Exton, Pennsylvania manufacturing facility.

**FINANCING ACTIVITIES.** Cash provided by financing activities was \$0.1 million during the year ended December 31, 2005, as compared to cash provided of \$117.4 million in the prior year. The current year amount consists of the funds received related to one stock option exercise. The prior year 2004 proceeds consisted substantially of a) the proceeds from the sale of 7,200,000 shares of common stock in a public offering in June 2004 for cash totaling \$56.8 million, after deducting the costs and expenses associated with the sale and b) the proceeds from the sale of \$90.0 million in principal amount of 3.5% Convertible Subordinated Notes due November 1, 2024, netting \$60.2 million, after deducting the costs and expenses associated with the sale and our 4,000,000 share purchase of treasury stock.

In November 2004, we issued \$90.0 million in principal amount of 3.5% Convertible Subordinated Notes due November 1, 2024. The 3.5% Convertible Subordinated Notes are convertible at the option of the holder into our common stock at an initial conversion rate (subject to adjustment) of 109.2001 shares of common stock per \$1,000 principal amount of 3.5% Convertible Subordinated Notes, which is equivalent to an initial conversion price of approximately \$9.16 per share, at any time prior to the stated maturity. In the event of certain fundamental changes that occur prior to November 1, 2009, we are

required to pay a make-whole premium to the holders of the 3.5% Convertible Subordinated Notes that convert their 3.5% Convertible Subordinated Notes into our common stock on or after the date on which notice of such fundamental change is given. The net proceeds from the 3.5% Convertible Subordinated Notes were approximately \$86.2 million. We used approximately \$26 million of the proceeds to repurchase 4,000,000 shares of common stock, and intend to use the remainder for general corporate purposes

**WORKING CAPITAL:** At December 31, 2005, we had cash, cash equivalents, restricted cash and available-for-sale investments of \$67.0 million and working capital of \$61.1 million (including our cash, cash equivalents, restricted cash and available-for-sale investments). The substantial majority of our working capital change relates to the use of our cash, cash equivalents, restricted cash and available-for-sale investments for the purpose of funding and operating our business, including capital expenditures. We believe our existing capital resources are adequate to finance our operations until June 30, 2007; however, our long-term viability is dependent upon successful operation of our business, our ability to improve and/or automate our manufacturing process, the approval of our products and the ability to raise additional debt and equity to meet our business objectives.

**FACTORS AFFECTING OUR CAPITAL RESOURCES:** In April 2005, we acquired a two-building, 100,000 square foot corporate campus in Bevaix, Canton of Neuchâtel, Switzerland for \$10 million. The \$10 million purchase price was paid using cash on hand from the proceeds of our 2004 issuances of common stock and 3.5% convertible subordinated notes. Our initial estimate of the total cost of acquisition and renovation of the facility, including the purchase of required equipment, was \$25 million. We have spent approximately \$1.8 million to date on the first phase of the renovation. At the present time, management is re-assessing the need for a second manufacturing facility in Europe. Until such an assessment is made, we do not expect to incur any material additional expenditures for renovation. We received a financing offer of approximately \$14 million for the purchase and renovation. In addition, we obtained a financial incentive package of government grants and a number of years of tax-free status. However, we do not intend to avail ourselves of the foregoing financial arrangements. If we determine to proceed with further renovations, it will require a significant cash expenditure.

The European Union has introduced new legislation, Directive 2004/23/EC relating to human tissue and cells for human application and the facilities in which they are manufactured, which was to be effective April 7, 2006. Our facility in the United Kingdom does not currently comply with the Directive. The European Commission has not yet developed or adopted required technical guidelines relating to this Directive. We believe that implementation of the Directive is unlikely until these guidelines are developed and adopted both by the European Commission and by the member states of the European Union. We currently estimate that if we are required to comply with the Directive, such compliance will require approximately \$3 million in renovations to our United Kingdom facility.

## Contractual Obligations

The following table summarizes the amounts of payments due under specified contractual obligations as of December 31, 2005:

Contractual Obligations	Payments Due by Period			
	Less than 1 Year	1 - 3 Years	4 - 5 Years	More than 5 Years
	(in millions)			
Long-Term Debt Obligations, excluding interest*	\$ —	\$ 90.0	\$ —	\$ —
Interest*	3.2	8.9	—	—
Lease Obligations	1.6	3.7	2.3	1.4
Purchase Obligations**	2.1	0.1	—	—
Other Long-Term Liabilities Reflected on the Registrant's Balance Sheet Under GAAP	—	—	0.1	—
Total	<u>\$ 6.9</u>	<u>\$ 102.7</u>	<u>\$ 2.4</u>	<u>\$ 1.4</u>

\* The table above assumes that our 3.5% convertible subordinated notes will be called due on November 1, 2009. Refer to the below for a description of our 3.5% convertible subordinated notes.

\*\* In addition to the above, we have, in the ordinary course of business, various contractual agreements with various consultants and service providers whereby a fee or rate per hour has been agreed to, but no guaranteed minimums have been established. Generally, such agreements are related to our research and development efforts or general operating matters. The above table should be read in conjunction with our consolidated financial statements, which illustrate a 2005 net loss of \$35.8 million, net cash used in operations of \$34.0 million during 2005 and cash paid for capital expenditures of \$17.7 million during 2005.

In November 2004, we issued \$90.0 million in principal amount of 3.5% convertible subordinated notes due November 1, 2024, although these notes may be due sooner as discussed below. The notes are our general, unsecured obligations. The notes are subordinated in right of payment, which means that they will rank in right of payment behind other indebtedness of ours. In addition, the notes are effectively subordinated to all existing and future liabilities of our subsidiaries. We will be required to repay the full principal amount of the notes on November 1, 2024 unless they are previously converted, redeemed or repurchased.

The notes bear interest at an annual rate of 3.5% from the date of issuance of the notes. We will pay interest twice a year, on each May 1 and November 1, until the principal is paid or made available for payment or the notes have been converted. Interest will be calculated on the basis of a 360-day year consisting of twelve 30-day months.

The note holders may convert the notes into shares of our common stock at any time before the close of business on November 1, 2024, unless the notes have been previously redeemed or repurchased. The initial conversion rate (which is subject to adjustment) for the notes is 109.2001 shares of common stock per \$1,000 principal amount of notes, which is equivalent to an initial conversion price of approximately \$9.16 per share. Holders of notes called for redemption or submitted for repurchase will be entitled to convert the notes up to and including the business day immediately preceding the date fixed for redemption or repurchase.

At any time on or after November 1, 2009, we may redeem some or all of the notes at a redemption price equal to 100% of the principal amount of such notes plus accrued and unpaid interest (including additional interest, if any) to, but excluding, the redemption date.



The note holders will have the right to require us to repurchase their notes on November 1 of 2009, 2014 and 2019. In addition, if we experience a fundamental change (which generally will be deemed to occur upon the occurrence of a change in control or a termination of trading of our common stock), note holders will have the right to require us to repurchase their notes. In the event of certain fundamental changes that occur on or prior to November 1, 2009, we will also pay a make-whole premium to holders that require us to purchase their notes in connection with such fundamental change.

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

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

#### **Other**

INFLATION. Inflation did not have a significant impact on our results for year ended December 31, 2005.

#### **Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

Market risk is the potential loss arising from adverse changes in market rates and prices, such as foreign currency exchange rates or interest rates. We are exposed to market risk in the form of foreign exchange rate risk and interest rate risk.

##### *Foreign Exchange Rate Risk*

Our revenue earned in the year ended December 31, 2005 was derived from operations in the United Kingdom. The results of operations and financial position of our foreign operations were principally measured in their respective functional currencies and translated into U.S. dollars. The effect of U.S. dollar currency fluctuations against the foreign currency in these countries is somewhat mitigated by the fact that expenses are generally incurred in the same currencies in which the revenue is generated. Our income will be higher or lower depending on the weakening or strengthening of the U.S. dollar against the respective foreign currency. Additionally, approximately 17% of our assets at December 31, 2005 were based in our foreign operations and translated into U.S. dollars at the foreign currency exchange rate in effect as of the end of each accounting period, with the effect of such translation reflected as a separate component of consolidated shareholders' equity (deficit). Accordingly, our consolidated shareholders' equity (deficit) will fluctuate depending on the weakening or strengthening of the U.S. dollar against the respective foreign currency.

During 2005, we purchased approximately \$10 million of land and buildings located in Switzerland, and expended approximately an additional \$1.8 million for related build-out costs. These assets are translated from Swiss francs into U.S. dollars each accounting period and the effect of such translation is reflected as a separate component of consolidated shareholders' equity (deficit). As discussed above, our consolidated shareholders' equity (deficit) fluctuates depending on the weakening or strengthening of the U.S. dollar against the foreign currency in which foreign assets and liabilities are denominated.

As a result of declining foreign currency exchange rates since December 31, 2004, specifically the exchange rate between the US dollar and the British pound and the Swiss franc, our accumulated other comprehensive income of \$0.5 million at December 31, 2004 has decreased to an accumulated other comprehensive loss of \$0.8 million at December 31, 2005; or a change of approximately \$1.3 million. However, this loss is considered unrealized and is reflected on the Consolidated Balance Sheet. Accordingly, this unrealized loss may increase or decrease in the future, based on the movement of foreign currency exchange rates, but will not have an impact on net income (loss) until the related foreign capital investments are sold or otherwise realized. Further, during December 2005 we completed the substantial liquidation of our Australian entity. As such, the accumulated translation adjustment component was

removed from equity by recording \$0.1 million as other income in the 2005 Consolidated Statement of Operations.

#### *Interest Rate Risk*

At December 31, 2005 we had \$23.0 million invested in available-for-sale investments, comprised of marketable debt securities (see Note 2 of Notes to Consolidated Financial Statements). Such investments would generally subject us to interest rate risk, in that increases in interest rates would cause the market value of the investments to decline and decreases in interest rates would cause the market value of the investments to increase. However, all \$23.0 million of our investments are in the form of Auction Rate Securities for which the interest rate is reset periodically through a Dutch auction process. As a result, the interest rate we earn on those investments in future periods could decline if market interest rates decline, and could increase if market interest rates increase, yet the value of the investments should remain relatively fixed as a result of the periodic resetting of interest rates. Our investments represent the temporary investment of the proceeds of our 2005 equity and debt placements until these funds are needed for operating purposes. Accordingly, the December 31, 2005 level of investments will not be held throughout 2006 and beyond, and as a result our exposure to interest rate risk must be judged accordingly.

Our 3.5%, \$90.0 million convertible subordinated notes, pay interest at a fixed rate and, accordingly, we are not exposed to interest rate risk as a result of this debt. However, the fair value of our \$90.0 million convertible subordinated notes does vary based upon, among other factors, the price of our common stock and current interest rates on similar instruments.

We do not enter into derivatives or other financial instruments for trading or speculative purposes.

#### **Item 8. Financial Statements and Supplementary Data**

The financial statements, including the notes thereto and report of the independent auditors thereon, are included in this report as set forth in the "Index to Financial Statements." See F-1 for Index to Consolidated Financial Statements.

#### **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

On April 22, 2004, we engaged BDO Seidman LLP ("BDO") as our independent accountants to audit our consolidated financial statements for the year ending December 31, 2004. Pannell Kerr Forster of Texas, P.C., who had been engaged as our principal independent accountants since 2001, was dismissed on such date. BDO also began performing a review of the unaudited condensed quarterly financial statements included in our quarterly reports on Form 10-Q beginning with the March 31, 2004 Form 10-Q.

#### **Item 9A. Controls and Procedures**

##### **Evaluation of Disclosure Controls and Procedures**

During the fourth quarter of 2005, management, including the principal executive officer and principal financial officer, evaluated the disclosure controls and procedures related to the recording, processing, summarization and reporting of information in the periodic reports that the Company files with the SEC. These disclosure controls and procedures have been designed to ensure that (a) material information relating to the Company, including its consolidated subsidiaries, is made known to management, including these officers, by other employees of the Company, and (b) this information is recorded, processed, summarized, evaluated and reported, as applicable, within the time periods specified in the SEC's rules and forms.

Accordingly, as of December 31, 2005, these officers (the principal executive officer and principal financial officer) concluded that the Company's disclosure controls and procedures were effective.

### Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America. Our internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

Based on our evaluation under the framework in *Internal Control—Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2005.

Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005 has been audited by BDO SEIDMAN, LLP, an independent registered public accounting firm, as stated in their report which appears below.

## Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Isolagen, Inc.  
Exton, Pennsylvania

We have audited management's assessment, included in the accompanying Management's Report on Internal Control over Financial Reporting, that Isolagen, Inc. (the "Company") maintained effective internal control over financial reporting as of December 31, 2005, based on the criteria established in Internal Control-Integrated Framework, issued by the Committee of Sponsoring Organizations, or COSO, of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. A company's internal control over financial reporting includes those policies and procedures that: (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

In our opinion, management's assessment that Isolagen, Inc. maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the criteria established in Internal Control-Integrated Framework issued by COSO. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on the criteria established in Internal Control-Integrated Framework issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Isolagen, Inc. as of December 31, 2005 and 2004, and the related consolidated statements of operations and comprehensive loss, shareholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2005, and our report dated March 10, 2006 expressed an unqualified opinion.

/s/ BDO Seidman, LLP  
Houston, Texas  
March 10, 2006

**Changes in Internal Controls**

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

**Item 9B. Other Information**

On March 13, 2006, we entered into an Amended and Restated Employment Agreement with Ms. Susan Ciallella (the "Amended Agreement") pursuant to which Ms. Ciallella agreed to serve as President and Chief Executive Officer of Isolagen for an initial term ending June 30, 2009, which may be renewed for an additional one-year term by mutual agreement. The Amended Agreement provides for an annual salary of \$480,000. Ms. Ciallella is entitled to receive an annual bonus each year, prorated for the period of employment in such year, payable subsequent to the issuance of our 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 mutually agreed upon criteria. The targeted amount of the annual bonus shall be 70% of Ms. Ciallella's base salary assuming that the criteria are satisfied, although the actual bonus may be higher or lower. Ms. Ciallella is entitled to a non-accountable expense allowance of \$1,800 per month for all expenses incurred in connection with her automobile and private club membership(s) and/or dues. The Amended Agreement provides that Ms. Ciallella receive a life insurance benefit in the amount of \$1 million and disability insurance benefits of at least 60% of her base salary. Upon termination of the Amended Agreement by Isolagen for a reason other than for "cause" (as defined in the Amended Agreement) or upon the death or disability of Ms. Ciallella or by Ms. Ciallella for "good reason" (as defined in the Amended Agreement), Ms. Ciallella is entitled to a severance payment equal to her base salary for the remaining term of the Amended Agreement, when, as and if such payments would have been made in the absence of the termination. The Amended Agreement allows the Company to hire a Chief Executive Officer without giving rise to "good reason" provided that Ms. Ciallella remains President. Upon termination of the Amended Agreement by Isolagen for "cause" or upon the death or disability of Ms. Ciallella, Ms. Ciallella is entitled to all amounts due to her for any portion of the payroll period worked but for which payment had not yet been made up to the date of termination. During any period in which severance payments are being made, Ms. Ciallella has agreed not to compete with Isolagen.

On March 13, 2006, we entered into an Employment Agreement with Mr. Todd Greenspan (the "Agreement") pursuant to which Mr. Greenspan agreed to serve as Vice President, Finance and Corporate Controller of Isolagen for an initial term ending December 31, 2008, which may be renewed for an additional one-year term by mutual agreement. The Agreement provides for an annual salary of \$180,000. Mr. Greenspan is entitled to receive an annual bonus each year, prorated for the period of employment in such year, payable subsequent to the issuance of our 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 established by our Chief Executive Officer and agreed to by the Compensation Committee. The targeted amount of the annual bonus shall be 35% of Mr. Greenspan's base salary, although the actual bonus may be higher or lower. Mr. Greenspan is entitled to a non-accountable automobile allowance of \$400 per month. Upon termination of the Agreement by Isolagen for a reason other than for "cause" (as defined in the Agreement) or upon the death or disability of Mr. Greenspan, Mr. Greenspan is entitled to a severance payment equal to his base salary for the lesser of twelve months from the date of termination or for the remaining term of the Agreement, when, as and if such payments would have been made in the absence of the termination; provided that if Mr. Greenspan becomes employed following termination, the severance payments will cease except that Mr. Greenspan shall receive at least six months of payments notwithstanding reemployment. Upon termination of the Agreement by Isolagen for "cause" or upon the death or disability of Mr. Greenspan, Mr. Greenspan is entitled to all amounts due to him for any portion of the payroll period worked but for which payment had not yet been made up to the date of termination. During any period in which severance payments are being made, Mr. Greenspan has agreed not to compete with Isolagen.

### Part III

#### Item 10. Directors and Executive Officers of the Registrant

The information required by this Item 10 will be included in the Company's Proxy Statement for the 2006 Annual Meeting of Stockholders which will be filed with the Securities and Exchange Commission no later than May 1, 2006 and is incorporated into this Item 10 by reference.

*Code of Ethics.* We have adopted a written code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller and any persons performing similar functions. The code of ethics is incorporated into this Item 10 by reference.

#### Item 11. Executive Compensation

The information required by this Item 11 will be included in the Company's Proxy Statement for the 2006 Annual Meeting of Stockholders which will be filed with the Securities and Exchange Commission no later than May 1, 2006 and is incorporated into this Item 11 by reference.

#### Item 12. Security Ownership of Certain Beneficial Owners and Management

Except as provided below, the information required by this Item 12 will be included in the Company's Proxy Statement for the 2006 Annual Meeting of Stockholders which will be filed with the Securities and Exchange Commission no later than May 1, 2006 and is incorporated into this Item 12 by reference.

#### Securities Authorized for Issuance Under Equity Compensation Plans

As of December 31, 2005, our equity compensation plan information was as follows:

	<u>Number of Securities to be issued upon exercise of outstanding options</u>	<u>Weighted-average exercise price of outstanding options</u>	<u>Number of securities remaining for future issuance</u>
Equity compensation plans approved by security holders	6,009,350	\$ 5.72	2,749,650
Equity compensation plans not approved by security holders(1)	903,333	5.24	—
<b>Total</b>	<u>6,912,683</u>	5.66	<u>2,749,650</u>

(1) Represents options issued to employees, in connection with initial employment, outside of our approved plans.

#### Item 13. Certain Relationships and Related Transactions

The information required by this Item 13 will be included in the Company's Proxy Statement for the 2006 Annual Meeting of Stockholders which will be filed with the Securities and Exchange Commission no later than May 1, 2006 and is incorporated into this Item 13 by reference.

#### Item 14. Principal Accounting Fees and Services

The information required by this Item 14 will be included in the Company's Proxy Statement for the 2006 Annual Meeting of Stockholders which will be filed with the Securities and Exchange Commission no later than May 1, 2006 and is incorporated into this Item 14 by reference.

**Part IV**

**Item 15. Exhibits and Financial Statement Schedules**

(a)(1) Financial Statements.

- Reports of Independent Registered Public Accounting Firms
- Consolidated Balance Sheets as of December 31, 2005 and 2004
- Consolidated Statements of Operations for the years ended December 31, 2005, 2004, and 2003 and inception to December 31, 2005
- Consolidated Statements of Shareholders' Equity and Comprehensive Loss from inception to December 31, 2005
- Consolidated Statements of Cash Flows for the years ended December 31, 2005, 2004 and 2003 and inception to December 31, 2005
- Notes to Consolidated Financial Statements

(a)(2) Financial Statement Schedule.

All schedules are omitted because of the absence of conditions under which they are required or because the required information is presented in the Financial Statements or Notes thereto.

(a)(3) The exhibits listed under Item 15(c) are filed or incorporated by reference herein

(b) Exhibits.

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

<u>EXHIBIT NO.</u>	<u>IDENTIFICATION OF EXHIBIT</u>
2	Agreement and Plan of Merger by and among American Financial Holding, Inc., ISO Acquisition Corp., Isolagen Technologies, Inc., Gemini IX, Inc., and William K. Boss, Jr., Olga Marko and Dennis McGill dated August 1, 2001(1)
3(i)	Amended Certificate of Incorporation(17)
3(ii)	Bylaws(10)
4.1	Specimen of Common Stock certificate(2)
4.2	Certificate of Designations of Series A Convertible Preferred Stock(7)
4.3	Certificate of Designations of Series B Convertible Preferred Stock(5)
4.4	Indenture, dated November 3, 2004, between the Company and The Bank of New York Trust Company, N.A., as trustee(11)
10.1	2003 Stock Option and Stock Appreciation Rights Plan(3)*
10.2	2001 Stock Option and Appreciation Rights Plan(4)*
10.3	Reserved
10.4	Reserved
10.5	Lease Agreement dated March 24, 2002 by and between the Registrant as Lessee and Claire O Aceti Gbmh as Lessor(7)
10.6	Intellectual Property Purchase Agreement between Isolagen Technologies, Inc., Gregory M. Keller, and PacGen Partners(8)
10.7	Purchase Agreement among CIBC World Market Corp., UBS Securities LLC, and Adams, Harkness & Hill, Inc. dated October 28, 2004(11)
10.8	Registration Rights Agreement among CIBC World Market Corp., UBS Securities LLC, and Adams, Harkness & Hill, Inc. dated November 3, 2004(11)



10.9	Lease Agreement between Isolagen Technologies, Inc. and Beltway 8 Service Center Investors Ltd. dated February 16, 2005(13)
10.10	Employment agreement dated March 25, 2005 between Isolagen, Inc. and Martin Schmieg(14)*
10.11	Lease Agreement between Isolagen, Inc and The Hankin Group dates April 7, 2005(15)
10.12	Purchase Option Agreement between Isolagen, Inc and 405 Eagleview Associates dated April 7, 2005(15)
10.13	Employment Agreement dated April 26, 2005 between Isolagen, Inc and Susan Stranahan Ciallella(16)*
10.14	Offer letter between Isolagen, Inc. and Todd Greenspan(16)*
10.15	Employment Agreement between Isolagen, Inc. and Marie Lindner, MD(17)*
10.16	2005 Equity Incentive Plan, as amended(18)
10.17	Separation and Release Agreement, dated October 27, 2005, among Isolagen, Inc., Isolagen Technologies, Inc. and Frank DeLape(19)
10.18	Amended Employment Agreement between Isolagen, Inc. and Susan Ciallella(20)*
10.19	Employment Agreement between Isolagen, Inc. and Todd Greenspan(20)*
14	Code of Ethics(9)
21	List of Subsidiaries(10)
23.1	Pannell Kerr Forster of Texas, P.C. Consent(20)
23.2	BDO Seidman, LLP Consent(20)
31.1	Certification pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002(20)
31.2	Certification pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002(20)
32.1	Certification pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002(20)
32.2	Certification pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002(20)

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\* Indicates a management contract or a compensatory plan or arrangement.

- (1) Previously filed as an exhibit to the company's Form 8-K, filed on August 22, 2001, and is incorporated by reference hereto.
- (2) Previously filed as an exhibit to the company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2001, and is incorporated by reference hereto.
- (3) Previously filed as an appendix to the company's Definitive Proxy Statement, as filed on May 6, 2003, in connection with the 2003 Annual Stockholder Meeting, and is incorporated by reference hereto.
- (4) Previously filed as an appendix to the company's Definitive Proxy Statement, as filed on October 23, 2001, in connection with the 2001 Annual Stockholder Meeting, and is incorporated by reference hereto.
- (5) Previously filed as an exhibit to the company's Form 10-Q for the fiscal quarter ended March 31, 2003, as filed on May 15, 2003, and is incorporated by reference hereto.
- (6) Previously filed as an exhibit to the company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2002, and is incorporated by reference hereto.
- (7) Previously filed as an exhibit to the company's Form S-1, as filed on September 12, 2003, and is incorporated by reference hereto.

- (8) Previously filed as an exhibit to the company's amended Form S-1, as filed on October 24, 2003, and is incorporated by reference hereto.
- (9) Previously filed as an exhibit to the company's Annual Report on Form 10-K for the fiscal year ended December 31, 2003, and is incorporated by reference hereto.
- (10) Previously filed as an exhibit to the company's Annual Report on Form 10-K/A for the fiscal year ended December 31, 2003, and is incorporated by reference hereto.
- (11) Previously filed as an exhibit to the company's Current Report on Form 8-K dated November 4, 2004, and is incorporated by reference hereto.
- (12) Reserved.
- (13) Previously filed as an exhibit to the company's Form 8-K, filed on February 16, 2005, and is incorporated by reference hereto.
- (14) Previously filed as an exhibit to the company's Form 8-K, filed on April 18, 2005, and is incorporated by reference hereto.
- (15) Previously filed as an exhibit to the company's Form 8-K, filed on April 7, 2005, and is incorporated by reference hereto.
- (16) Previously filed as an exhibit to the company's Form 10-Q for the fiscal quarter ended March 31, 2005, as filed on May 10, 2005, and is incorporated by reference hereto.
- (17) Previously filed as an exhibit to the company's Form 10-Q for the fiscal quarter ended June 30, 2005, as filed on August 9, 2005, and is incorporated by reference hereto.
- (18) Previously filed as an exhibit to the company's Form S-8, filed on February 13, 2006, and is incorporated by reference hereto.
- (19) Previously filed as an exhibit to the company's Form 8-K, filed on October 27, 2005, and is incorporated by reference hereto.
- (20) Filed Herewith

## SIGNATURES

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

ISOLAGEN, INC.

By: /s/ MARTIN E. SCHMIEG  
Martin E. Schmieg, Chief Financial Officer

Date: March 14, 2006

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the date indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ SUSAN STRANAHAN CIALLELLA</u> Susan Stranahan Ciallella	Chief Executive Officer and Director	March 14, 2006
<u>/s/ MARTIN E. SCHMIEG</u> Martin E. Schmieg	Chief Financial Officer	March 14, 2006
<u>/s/ TODD J. GREENSPAN</u> Todd J. Greenspan	Vice President of Finance and Corporate Controller	March 14, 2006
<u>/s/ STEVEN MORRELL</u> Steven Morrell	Director	March 14, 2006
<u>/s/ HENRY TOH</u> Henry Toh	Director	March 14, 2006
<u>/s/ RALPH DE MARTINO</u> Ralph De Martino	Director	March 14, 2006
<u>/s/ MARSHALL G. WEBB</u> Marshall G. Webb	Director	March 14, 2006

**Isolagen, Inc.**  
**(A Development Stage Company)**  
**Index to Consolidated Financial Statements**

	<u>PAGE</u>
<a href="#"><u>Reports of Independent Registered Public Accounting Firms</u></a>	F-2-3
<a href="#"><u>Consolidated Balance Sheets as of December 31, 2005 and 2004</u></a>	F-4
<a href="#"><u>Consolidated Statements of Operations for the years ended December 31, 2005, 2004 and 2003 and Inception to December 31, 2005</u></a>	F-5
<a href="#"><u>Consolidated Statements of Shareholders' Equity (Deficit) and Comprehensive Loss From Inception to December 31, 2005</u></a>	F-6-12
<a href="#"><u>Consolidated Statements of Cash Flows for the years ended December 31, 2005, 2004 and 2003 and Inception to December 31, 2005</u></a>	F-13
<a href="#"><u>Notes to Consolidated Financial Statements</u></a>	F-14-39

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Isolagen, Inc.  
Exton, Pennsylvania

We have audited the accompanying consolidated balance sheets of Isolagen, Inc. (in the development stage) as of December 31, 2005 and 2004, and the related consolidated statements of operations and comprehensive loss, shareholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2005 and the related statements of operations and cash flows for the period from inception (December 28, 1995) to December 31, 2005. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We did not audit the consolidated financial statements of Isolagen, Inc. for the period from inception (December 28, 1995) to December 31, 2003. Such statements are included in the cumulative inception to December 31, 2005 totals of the consolidated statements of operations and cash flows and reflect a net loss of 37.3% and total revenues of 14.2% of the related cumulative totals. Those consolidated statements were audited by other auditors whose report has been furnished to us and our opinion, insofar as it relates to amounts for the period from inception (December 28, 1995) to December 31, 2003 included in the cumulative totals, is based solely upon the report of the other auditors.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits and the report of other auditors provide a reasonable basis for our opinion.

In our opinion, based on our audits and the report of other auditors, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Isolagen, Inc. at December 31, 2005 and 2004 and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2005 and for the period from inception (December 28, 1995) to December 31, 2005 in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Isolagen, Inc.'s internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 10, 2006 expressed an unqualified opinion thereon.

/s/BDO Seidman, LLP  
Houston, Texas  
March 10, 2006

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Shareholders of Isolagen, Inc.

We have audited the accompanying consolidated statements of operations, shareholders' equity, and cash flows of Isolagen, Inc. for the year ended December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated results of Isolagen, Inc.'s operations and cash flows for the year ended December 31, 2003, in conformity with U.S. generally accepted accounting principles.

/s/ PANNELL KERR FORSTER OF TEXAS, P.C.

Houston, Texas  
February 17, 2004

**Isolagen, Inc.**  
**(A Development Stage Company)**  
**Consolidated Balance Sheets**

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 41,554,203	\$ 64,329,356
Restricted cash	2,459,456	—
Available-for-sale investments	23,000,000	51,809,660
Accounts receivable, net of allowance for doubtful accounts of \$100,639 and \$50,533, respectively	719,000	1,516,591
Inventory	394,693	1,010,768
Other receivables	234,006	350,861
Prepaid expenses	901,582	769,984
Total current assets	<u>69,262,940</u>	<u>119,787,220</u>
Property and equipment, net of accumulated depreciation and amortization of \$2,188,519 and \$2,421,822, respectively	17,277,172	3,634,992
Other assets, net of amortization of \$874,112 and \$124,873, respectively	3,639,810	4,698,926
Total assets	<u>\$ 90,179,922</u>	<u>\$128,121,138</u>
<b>Liabilities and Shareholders' Equity (Deficit)</b>		
Current liabilities:		
Accounts payable	\$ 2,011,712	\$ 2,360,363
Accrued expenses	3,884,594	3,441,805
Deferred revenue	2,235,764	2,923,328
Total current liabilities	<u>8,132,070</u>	<u>8,725,496</u>
Long term debt	90,000,000	90,000,000
Other long term liabilities	144,749	410,217
Total liabilities	<u>98,276,819</u>	<u>99,135,713</u>
Commitments and contingencies		
Shareholders' equity (deficit):		
Preferred stock, \$.001 par value; 5,000,000 shares authorized	—	—
Common stock, \$.001 par value; 100,000,000 shares authorized	34,260	34,195
Additional paid-in capital	109,879,125	109,935,174
Treasury stock, at cost, 4,000,000 shares	(25,974,000)	(25,974,000)
Accumulated other comprehensive income (loss)	(784,644)	464,110
Accumulated deficit during development stage	(91,251,638)	(55,474,054)
Total shareholders' equity (deficit)	<u>(8,096,897)</u>	<u>28,985,425</u>
Total liabilities and shareholder's equity (deficit)	<u>\$ 90,179,922</u>	<u>\$128,121,138</u>

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

**Isolagen, Inc.**  
**(A Development Stage Company)**  
**Consolidated Statements of Operations**

	<u>For the Year Ended December 31,</u>			<u>Cumulative Period from December 28, 1995 (date of inception) to December 31, 2005</u>
	<u>2005</u>	<u>2004</u>	<u>2003</u>	
Revenue				
Product sales	\$ 8,753,684	\$ 4,179,247	\$ 445,689	\$ 14,819,725
License fees	—	—	—	260,000
Total revenue	8,753,684	4,179,247	445,689	15,079,725
Cost of sales	9,249,615	5,491,008	2,197,222	17,821,457
Gross loss	(495,931)	(1,311,761)	(1,751,533)	(2,741,732)
Selling, general and administrative expenses	23,012,458	15,127,365	6,311,774	51,389,883
Research and development	11,440,322	5,057,149	3,301,341	23,353,507
Operating loss	(34,948,711)	(21,496,275)	(11,364,648)	(77,485,122)
Other income (expense)				
Interest income	2,820,388	566,526	40,691	3,664,694
Other income	285,451	91,956	55,663	465,491
Interest expense	(3,934,712)	(636,676)	—	(4,883,016)
Net loss	\$(35,777,584)	\$(21,474,469)	\$(11,268,294)	\$(78,237,953)
Deemed dividend associated with beneficial conversion of preferred stock	—	—	(1,244,880)	(11,423,824)
Preferred stock dividends	—	—	(1,087,200)	(1,589,861)
Net loss attributable to common shareholders	\$(35,777,584)	\$(21,474,469)	\$(13,600,374)	\$(91,251,638)
Per share information				
Net loss—basic and diluted	\$ (1.18)	\$ (0.71)	\$ (0.58)	\$ (6.80)
Deemed dividend associated with beneficial conversion of preferred stock	—	—	(0.06)	(0.99)
Preferred stock dividends	—	—	(0.06)	(0.14)
Net loss per common share—basic and diluted	\$ (1.18)	\$ (0.71)	\$ (0.70)	\$ (7.93)
Weighted average number of basic and diluted common shares outstanding	30,245,283	30,116,827	19,297,865	11,513,983

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



**Isolagen, Inc.**  
**(A Development Stage Company)**  
**Consolidated Statements of Shareholders' Equity (Deficit) and Comprehensive Loss**

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

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

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

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

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

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

	Series A Preferred Stock		Series B Preferred Stock		Common Stock		Additional Paid-In Capital	Treasury Stock		Accumulated Other Comprehensive Income	Accumulated Deficit During Development Stage	Total Shareholders' Equity (Deficit)
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount		Number of Shares	Amount			
Uncompensated contribution of services—3rd quarter	—	\$ —	—	\$ —	—	\$ —	\$ 55,556	—	\$ —	\$ —	\$ —	\$ 55,556
Issuance of common stock for services on 11/1/01	—	—	—	—	145,933	146	218,754	—	—	—	—	218,900
Uncompensated contribution of services—4th quarter	—	—	—	—	—	—	100,000	—	—	—	—	100,000
Net loss	—	—	—	—	—	—	—	—	—	—	(1,652,004)	(1,652,004)
Balance, 12/31/01	—	\$ —	—	\$ —	15,189,563	\$ 15,190	\$ 5,321,761	—	\$ —	\$ —	\$ (4,284,551)	\$ 1,052,400
Uncompensated contribution of services—1st quarter	—	—	—	—	—	—	100,000	—	—	—	—	100,000
Issuance of preferred stock for cash on 4/26/02	905,000	905	—	—	—	—	2,817,331	—	—	—	—	2,818,236
Issuance of preferred stock for cash on 5/16/02	890,250	890	—	—	—	—	2,772,239	—	—	—	—	2,773,129
Issuance of preferred stock for cash on 5/31/02	795,000	795	—	—	—	—	2,473,380	—	—	—	—	2,474,175
Issuance of preferred stock for cash on 6/28/02	229,642	230	—	—	—	—	712,991	—	—	—	—	713,221
Uncompensated contribution of services—2nd quarter	—	—	—	—	—	—	100,000	—	—	—	—	100,000
Issuance of preferred stock for cash on 7/15/02	75,108	75	—	—	—	—	233,886	—	—	—	—	233,961
Issuance of common stock for cash on 8/1/02	—	—	—	—	38,400	38	57,562	—	—	—	—	57,600
Issuance of warrants for services on 9/06/02	—	—	—	—	—	—	103,388	—	—	—	—	103,388
Uncompensated contribution of services—3rd quarter	—	—	—	—	—	—	100,000	—	—	—	—	100,000
Uncompensated contribution of services—4th quarter	—	—	—	—	—	—	100,000	—	—	—	—	100,000
Issuance of preferred stock for dividends	143,507	144	—	—	—	—	502,517	—	—	—	(502,661)	—
Deemed dividend associated with beneficial conversion of preferred stock	—	—	—	—	—	—	10,178,944	—	—	—	(10,178,944)	—
Comprehensive income:												
Net loss	—	—	—	—	—	—	—	—	—	—	(5,433,055)	(5,433,055)
Other comprehensive income, foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	13,875	—	13,875
Comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	(5,419,180)
Balance, 12/31/02	3,038,507	\$ 3,039	—	\$ —	15,227,963	\$ 15,228	\$ 25,573,999	—	\$ —	\$ 13,875	\$ (20,399,211)	\$ 5,206,930

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

	Series A		Series B		Common Stock		Additional Paid-In Capital	Treasury Stock		Accumulated Other Comprehensive Income	Accumulated Deficit During Development Stage	Total Shareholders' Equity (Deficit)
	Preferred Stock		Preferred Stock		Common Stock			Number of				
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount		Number of Shares	Amount			
Issuance of common stock for cash on 1/7/03	—	—	—	—	61,600	62	92,338	—	—	—	—	92,400
Issuance of common stock for patent pending acquisition on 3/31/03	—	—	—	—	100,000	100	539,900	—	—	—	—	540,000
Cancellation of common stock on 3/31/03	—	—	—	—	(79,382)	(79)	(119,380)	—	—	—	—	(119,459)
Uncompensated contribution of services—1st quarter	—	—	—	—	—	—	100,000	—	—	—	—	100,000
Issuance of preferred stock for cash on 5/9/03	—	—	110,250	110	—	—	2,773,218	—	—	—	—	2,773,328
Issuance of preferred stock for cash on 5/16/03	—	—	45,500	46	—	—	1,145,704	—	—	—	—	1,145,750
Conversion of preferred stock into common stock—2nd qtr	(70,954)	(72)	—	—	147,062	147	40,626	—	—	—	—	40,701
Conversion of warrants into common stock—2nd qtr	—	—	—	—	114,598	114	(114)	—	—	—	—	—
Uncompensated contribution of services—2nd quarter	—	—	—	—	—	—	100,000	—	—	—	—	100,000
Issuance of preferred stock dividends	—	—	—	—	—	—	—	—	—	—	(1,087,200)	(1,087,200)
Deemed dividend associated with beneficial conversion of preferred stock	—	—	—	—	—	—	1,244,880	—	—	—	(1,244,880)	—
Issuance of common stock for cash—3rd qtr	—	—	—	—	202,500	202	309,798	—	—	—	—	310,000
Issuance of common stock for cash on 8/27/03	—	—	—	—	3,359,331	3,359	18,452,202	—	—	—	—	18,455,561
Conversion of preferred stock into common stock—3rd qtr	(2,967,553)	(2,967)	(155,750)	(156)	7,188,793	7,189	(82,875)	—	—	—	—	(78,809)
Conversion of warrants into Common stock—3rd qtr	—	—	—	—	212,834	213	(213)	—	—	—	—	—
Compensation expense on warrants issued to non-employees	—	—	—	—	—	—	412,812	—	—	—	—	412,812
Issuance of common stock for cash—4th qtr	—	—	—	—	136,500	137	279,363	—	—	—	—	279,500
Conversion of warrants into Common stock—4th qtr	—	—	—	—	393	—	—	—	—	—	—	—
Comprehensive income:												
Net loss	—	—	—	—	—	—	—	—	—	—	(11,268,294)	(11,268,294)
Other comprehensive income, foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	360,505	—	360,505
Comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	(10,907,789)
Balance, 12/31/03	—	\$ —	—	\$ —	26,672,192	\$ 26,672	\$ 50,862,258	—	\$ —	\$ 374,380	\$ (33,999,585)	\$ 17,263,725

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

	Series A		Series B		Common Stock		Additional Paid-In Capital	Treasury Stock		Accumulated Other Comprehensive Income	Accumulated Deficit During Development Stage	Total Shareholders' Equity (Deficit)
	Preferred Stock		Preferred Stock		Common Stock			Number of Shares	Amount			
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount						
Conversion of warrants into common stock—1 <sup>st</sup> qtr	—	—	—	—	78,526	79	(79)	—	—	—	—	—
Issuance of common stock for cash in connection with exercise of stock options—1 <sup>st</sup> qtr	—	—	—	—	15,000	15	94,985	—	—	—	—	95,000
Issuance of common stock for cash in connection with exercise of warrants—1 <sup>st</sup> qtr	—	—	—	—	4,000	4	7,716	—	—	—	—	7,720
Compensation expense on options and warrants issued to non-employees and directors—1 <sup>st</sup> qtr	—	—	—	—	—	—	1,410,498	—	—	—	—	1,410,498
Issuance of common stock in connection with exercise of warrants—2 <sup>nd</sup> qtr	—	—	—	—	51,828	52	(52)	—	—	—	—	—
Issuance of common stock for cash—2 <sup>nd</sup> qtr	—	—	—	—	7,200,000	7,200	56,810,234	—	—	—	—	56,817,434
Compensation expense on options and warrants issued to non-employees and directors—2 <sup>nd</sup> qtr	—	—	—	—	—	—	143,462	—	—	—	—	143,462
Issuance of common stock in connection with exercise of warrants—3 <sup>rd</sup> qtr	—	—	—	—	7,431	7	(7)	—	—	—	—	—
Issuance of common stock for cash in connection with exercise of stock options—3 <sup>rd</sup> qtr	—	—	—	—	110,000	110	189,890	—	—	—	—	190,000
Issuance of common stock for cash in connection with exercise of warrants—3 <sup>rd</sup> qtr	—	—	—	—	28,270	28	59,667	—	—	—	—	59,695
Compensation expense on options and warrants issued to non-employees and directors—3 <sup>rd</sup> qtr	—	—	—	—	—	—	229,133	—	—	—	—	229,133
Issuance of common stock in connection with exercise of warrants—4 <sup>th</sup> qtr	—	—	—	—	27,652	28	(28)	—	—	—	—	—
Compensation expense on options and warrants issued to non-employees, employees, and directors—4 <sup>th</sup> qtr	—	—	—	—	—	—	127,497	—	—	—	—	127,497
Purchase of treasury stock—4 <sup>th</sup> qtr	—	—	—	—	—	—	—	4,000,000	(25,974,000)	—	—	(25,974,000)
Comprehensive income:	—	—	—	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—	(21,474,469)	(21,474,469)
Other comprehensive income, foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	79,725	—	79,725
Other comprehensive income, net unrealized gain on available-for-sale investments	—	—	—	—	—	—	—	—	—	10,005	—	10,005
Comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	(21,384,739)
Balance, 12/31/04	—	\$ —	—	\$ —	34,194,899	\$ 34,195	\$ 109,935,174	4,000,000	\$ (25,974,000)	\$ 464,110	\$ (55,474,054)	\$ 28,985,425

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

	Series A		Series B		Common Stock		Additional Paid-In Capital	Treasury Stock		Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit During Development Stage	Total Shareholders' Equity (Deficit)
	Preferred Stock		Preferred Stock		Number of			Number of				
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount		Number of Shares	Amount			
Issuance of common stock for cash in connection with exercise of stock options—1 <sup>st</sup> qtr	—	—	—	—	25,000	25	74,975	—	—	—	—	75,000
Compensation expense on options and warrants issued to non-employees—1 <sup>st</sup> qtr	—	—	—	—	—	—	33,565	—	—	—	—	33,565
Conversion of warrants into common stock—2 <sup>nd</sup> qtr	—	—	—	—	27,785	28	(28)	—	—	—	—	—
Compensation expense on options and warrants issued to non-employees—2 <sup>nd</sup> qtr	—	—	—	—	—	—	(61,762)	—	—	—	—	(61,762)
Compensation expense on options and warrants issued to non-employees—3 <sup>rd</sup> qtr	—	—	—	—	—	—	(137,187)	—	—	—	—	(137,187)
Conversion of warrants into common stock—3 <sup>rd</sup> qtr	—	—	—	—	12,605	12	(12)	—	—	—	—	—
Compensation expense on options and warrants issued to non-employees—4 <sup>th</sup> qtr	—	—	—	—	—	—	18,844	—	—	—	—	18,844
Compensation expense on acceleration of options—4 <sup>th</sup> qtr	—	—	—	—	—	—	14,950	—	—	—	—	14,950
Compensation expense on restricted stock award issued to employee—4 <sup>th</sup> qtr	—	—	—	—	—	—	606	—	—	—	—	606
Conversion of predecessor company shares	—	—	—	—	94	—	—	—	—	—	—	—
Comprehensive loss:												
Net loss	—	—	—	—	—	—	—	—	—	—	(35,777,584)	(35,777,584)
Other comprehensive loss, foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	(1,372,600)	—	(1,372,600)
Foreign exchange gain on substantial liquidation of foreign entity	—	—	—	—	—	—	—	—	—	133,851	—	133,851
Other comprehensive loss, net unrealized gain on available-for-sale investments	—	—	—	—	—	—	—	—	—	(10,005)	—	(10,005)
Comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	(37,026,338)
Balance, 12/31/05	—	—	—	—	34,260,383	34,260	109,879,125	4,000,000	(25,974,000)	(784,644)	(91,251,638)	(8,096,897)

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

**Isolagen, Inc.**  
**(A Development Stage Company)**  
**Consolidated Statements of Cash Flows**

	<u>For the Year Ended December 31,</u>			<u>Cumulative</u>
	<u>2005</u>	<u>2004</u>	<u>2003</u>	<u>Period from</u> <u>December 28,</u> <u>1995 (date of</u> <u>inception) to</u> <u>December 31,</u> <u>2005</u>
<b>Cash flows from operating activities:</b>				
Net loss	\$ (35,777,584)	\$ (21,474,469)	\$ (11,268,294)	\$ (78,237,953)
Adjustments to reconcile net loss to net cash used in operating activities:				
Equity awards issued for services	(130,984)	1,910,590	412,812	3,402,201
Uncompensated contribution of services	—	—	200,000	755,556
Depreciation and amortization	1,701,423	1,303,298	835,430	4,007,680
Provision for doubtful accounts	133,412	50,533	—	183,945
Amortization of debt issue costs	749,239	124,873	—	874,112
Amortization of debt discounts on investments	(508,983)	—	—	(508,983)
Loss on disposal or impairment of property and equipment	1,369,527	161,226	406,413	1,945,388
Foreign exchange gain on substantial liquidation of foreign entity	(133,851)	—	—	(133,851)
Change in operating assets and liabilities:				
Increase in restricted cash	(2,459,456)	—	—	(2,459,456)
Decrease (increase) in accounts receivable	489,961	(1,285,925)	(166,998)	(1,003,167)
Decrease (increase) in other receivables	252,854	(237,883)	62,038	(76,574)
Decrease (increase) in inventory	556,184	(727,411)	(120,785)	(430,922)
Decrease (increase) in prepaid expenses	(159,046)	(490,315)	30,049	(903,869)
Decrease (increase) in other assets	320,404	(155,573)	(17,721)	31,603
Increase (decrease) in accounts payable	(336,103)	840,432	(420,758)	1,964,807
Increase in accrued expenses and other liabilities	340,577	2,731,782	423,751	3,608,334
Increase (decrease) in deferred revenue	(398,008)	2,408,180	327,013	2,394,460
Net cash used in operating activities	<u>(33,990,434)</u>	<u>(14,840,662)</u>	<u>(9,297,050)</u>	<u>(64,586,689)</u>
<b>Cash flows from investing activities:</b>				
Purchase of property and equipment	(17,712,723)	(2,811,715)	(1,193,157)	(24,054,259)
Proceeds from the sale of property and equipment	—	—	33,300	34,300
Purchase of investments	(77,498,313)	(72,800,000)	—	(150,298,313)
Proceeds from sales and maturities of investments	106,807,000	21,000,000	—	127,807,000
Net cash provided by (used in) investing activities	<u>11,595,964</u>	<u>(54,611,715)</u>	<u>(1,159,857)</u>	<u>(46,511,272)</u>
<b>Cash flows from financing activities:</b>				
Proceeds from convertible debt	—	90,000,000	—	91,450,000
Offering costs associated with the issuance of convertible debt	—	(3,746,193)	—	(3,746,193)
Proceeds from notes payable to shareholders, net	—	—	—	135,667
Proceeds from the issuance of preferred stock, net	—	—	3,919,078	12,931,800
Proceeds from the issuance of common stock, net	75,000	57,169,849	19,137,461	78,907,720
Cash dividends paid on preferred stock	—	—	(1,087,200)	(1,087,200)
Cash paid for fractional shares of preferred stock	—	—	(38,108)	(38,108)
Merger and acquisition expenses	—	—	—	(48,547)
Repurchase of common stock	—	(25,974,000)	—	(26,024,280)
Net cash provided by financing activities	<u>75,000</u>	<u>117,449,656</u>	<u>21,931,231</u>	<u>152,480,859</u>
Effect of exchange rate changes on cash balances	(455,683)	396,519	216,594	171,305
Net increase (decrease) in cash and cash equivalents	(22,775,153)	48,393,798	11,690,918	41,554,203
Cash and cash equivalents, beginning of period	64,329,356	15,935,558	4,244,640	—
Cash and cash equivalents, end of period	<u>\$ 41,554,203</u>	<u>\$ 64,329,356</u>	<u>\$ 15,935,558</u>	<u>\$ 41,554,203</u>
<b>Supplemental disclosures of cash flow information:</b>				
Cash paid for interest	<u>\$ 3,115,000</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 3,265,283</u>
<b>Non-cash investing and financing activities:</b>				
Deemed dividend associated with beneficial conversion of preferred stock	—	—	1,244,880	11,423,824
Preferred stock dividend	—	—	1,087,200	1,589,861
Uncompensated contribution of services	—	—	200,000	755,556
Common stock issued for intangible assets	—	—	540,000	540,000
Equipment acquired through capital lease	<u>\$ —</u>	<u>\$ 167,154</u>	<u>\$ —</u>	<u>\$ 167,154</u>

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



**Isolgen, Inc.**  
**(A Development Stage Company)**  
**Notes to Consolidated Financial Statements**

**Note 1—Basis of Presentation, Business and Organization**

Isolgen, Inc. f/k/a American Financial Holding, Inc., a Delaware corporation (“Isolgen” or the “Company”) is the parent company of Isolgen Technologies, Inc., a Delaware corporation (“Isolgen Technologies”). Isolgen Technologies is the parent company of Isolgen Europe Limited, a company organized under the laws of the United Kingdom (“Isolgen Europe”), Isolgen Australia Pty Limited, a company organized under the laws of Australia (“Isolgen Australia”), and Isolgen International, S.A., a company organized under the laws of Switzerland (“Isolgen Switzerland”). The common stock of the Company, par value \$0.001 per share, (“Common Stock”) is traded on the American Stock Exchange (“AMEX”) under the symbol “ILE.”

Isolgen specializes in the development and commercialization of autologous cellular therapies for soft tissue regeneration. Autologous cellular therapy is the process whereby a patient’s own cells are extracted, allowed to multiply and then injected into the patient for applications such as correction and reduction of the normal effects of aging like wrinkles and nasolabial folds. The procedure is minimally invasive and non-surgical.

Commencing in 1995, a predecessor of our Isolgen Process was used to correct facial defects, such as wrinkles, depressions and scars. From 1995 to 1999, approximately 200 physicians utilized this process on approximately 1,000 patients, for a total of approximately 4,000 injections. The physicians who used this process during this period did not document any significant adverse reactions.

In May 1996, the Food and Drug Administration, or FDA, in response to the increasing use of cellular therapy to treat serious illness, released draft regulation for public comment to regulate cellular therapy. In May 1998, this regulation was passed, and in 1999, the FDA notified the Company that the Isolgen Process would require FDA approval as a regulated biologic product. In October 1999, the Company filed an investigational new drug application, or “IND”, which was accepted by the FDA. In November 1999, the Company’s IND was placed on clinical hold while it established a cGMP facility and standard operating procedures, including quality control release criteria. The clinical hold was released in May 2002. From June 2002, the Company assembled its management and scientific team and improved its Isolgen Process. These improvements included the introduction of an improved transport medium to extend cell viability, the standardization of the injection technique and the standardization of the Company’s manufacturing and laboratory techniques. The Company commenced clinical trials in January 2003 upon completion of its previous cGMP facility.

The Company is developing its lead product candidate for the correction and reduction of the normal effects of aging, such as wrinkles and creases. In March 2004, the Company announced positive results of its first Phase III exploratory clinical trial for its lead product candidate. In July 2004, the Company announced the commencement of a pivotal Phase III trial, which was being conducted in two different geographic and demographic populations in the United States as two identical studies for the treatment of facial wrinkles. These studies were concluded during the second half of 2005. During the fourth quarter of 2005, the Company commenced preparations for a 200 subject Phase III confirmatory study, the results of which the Company intends to submit together with its previous study to support a Biological License Approval (“BLA”) filing in 2007.

The Company's goal is to become a leading provider of solutions for soft tissue regeneration. The Company currently sells its dermal product primarily in the United Kingdom. The Company plans to further expand sales of its dermal product to other parts of Europe, Asia and the Americas.

Through December 31, 2005, the Company has been primarily engaged in developing its initial product technology, recruiting personnel, commencing its United Kingdom operations and raising capital. In the course of its development activities, the Company has sustained losses and expects such losses to continue through at least 2006. The Company expects to finance its operations primarily through its existing cash and future financing.

The Company's ability to operate profitably under its current business plan is largely contingent upon its success in obtaining regulatory approval to sell its products and upon its successful development of markets for its products and profitable manufacturing processes. The Company may be required to obtain additional capital in the future to expand its operations. No assurance can be given that the Company will be able to obtain such regulatory approvals, successfully develop the markets for its products or develop profitable manufacturing methods, or obtain any such additional capital as it might need, either through equity or debt financing, on satisfactory terms or at all. Additionally, no assurance can be given that any such financing, if obtained, will be adequate to meet the Company's ultimate capital needs and to support the Company's growth. If adequate capital cannot be obtained on satisfactory terms, the Company's operations could be negatively impacted.

If the Company achieves growth in its operations in the next few years, such growth could place a strain on its management, administrative, operational and financial infrastructure. The Company may find it necessary to hire additional management, financial and sales and marketing personnel to manage the Company's expanding operations. In addition, the Company's ability to manage its current operations and future growth requires the continued improvement of operational, financial and management controls, reporting systems and procedures. If the Company is unable to manage this growth effectively and successfully, the Company's business, operating results and financial condition may be materially adversely affected.

As of December 31, 2005, the Company had cash and cash equivalents, restricted cash and available-for-sale investments of \$67.0 million. The Company believes that its existing capital resources are adequate to finance its operations through June 30, 2007; however, its long-term viability is dependent upon successful operation of its business, its ability to improve and/or automate its manufacturing process, the approval of its products and the ability to raise additional debt and equity to meet its business objectives.

#### *Acquisition and merger and basis of presentation*

On August 10, 2001, Isologen Technologies consummated a merger with American Financial Holdings, Inc. ("AFH") and Gemini IX, Inc. ("Gemini"). Pursuant to an Agreement and Plan of Merger, dated August 1, 2001, by and among AFH, ISO Acquisition Corp, a Delaware corporation and wholly-owned subsidiary of AFH ("Merger Sub"), Isologen Technologies, Gemini, a Delaware corporation, and William J. Boss, Jr., Olga Marko and Dennis McGill, stockholders of Isologen Technologies (the "Merger Agreement"), AFH (i) issued 5,453,977 shares of its common stock, par value \$0.001 to acquire, in a privately negotiated transaction, 100% of the issued and outstanding common stock (195,707 shares, par value \$0.01, including the shares issued immediately prior to the Merger for the conversion of certain liabilities, as discussed below) of Isologen Technologies, and (ii) issued 3,942,400 shares of its common stock to acquire 100% of the issued and outstanding common stock of Gemini. Pursuant to the terms of the Merger Agreement, Merger Sub, together with Gemini, merged with and into Isologen Technologies (the "Merger"), and AFH was the surviving corporation. AFH subsequently changed its name to Isologen, Inc. on November 13, 2001.

Prior to the Merger, Isologen Technologies had no active business and was seeking funding to begin FDA trials of the Isologen Process. AFH was a non-operating, public shell company with limited assets. Gemini was a non-operating private company with limited assets and was unaffiliated with AFH.

Since AFH and Gemini had no operations and limited assets at the time of the Merger, the merger has been accounted for as a recapitalization of Isologen Technologies and an issuance of common stock by Isologen Technologies for the net assets of AFH and Gemini. In the recapitalization, Isologen Technologies is treated as having affected (i) a 27.8694 for 1 stock split, whereby the 195,707 shares of its common stock outstanding immediately prior to the merger are converted into the 5,453,977 shares of common stock received and held by the Isologen Technologies stockholders immediately after the merger, and (ii) a change in the par value of its common stock, from \$0.01 per share to \$0.001 per share. The stock split and change in par value have been reflected in the accompanying consolidated financial statements by retroactively restating all share and per share amounts. The stock issuances are accounted for as the issuance of (i) 3,942,400 shares for the net assets of Gemini, recorded at their book value, and (ii) the issuance of 3,899,547 shares (the number of shares AFH had outstanding immediately prior to the Merger) for the net assets of AFH, recorded at their book value.

Immediately prior to and as a condition of the Merger, Isologen Technologies issued an aggregate of 2,328,972 shares (post split) of its common stock to convert to equity an aggregate of \$2,075,246 of liabilities, comprised of (i) accrued salaries of \$328,125, (ii) convertible debt and related accrued interest of \$1,611,346, (iii) convertible shareholder notes and related accrued interest of \$135,667 and (iv) bridge financing costs of \$108. Simultaneous with the Merger, the Company sold 1,346,669 shares of restricted common stock to certain accredited investors in a private placement transaction. The consideration paid by such investors for the shares of common stock aggregated \$2,020,000 in transactions exempt from the registration requirements of the Securities Act. The net cash proceeds of this private placement were used to fund Isologen's research and development projects and the initial FDA trials of the Isologen Process, to explore the viability of entering foreign markets, to provide working capital and for general corporate purposes.

The financial statements presented include Isologen, Inc. and its wholly-owned subsidiaries. All significant intercompany transactions and balances have been eliminated. Isologen Technologies was, for accounting purposes, the surviving entity of the Merger, and accordingly for the periods prior to the Merger, the financial statements reflect the financial position, results of operations and cash flows of Isologen Technologies. The assets, liabilities, operations and cash flows of AFH and Gemini are included in the consolidated financial statements from August 10, 2001 onward.

## **Note 2—Summary of Significant Accounting Policies**

### *Use of Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Examples include provisions for bad debts and inventory obsolescence, useful lives of property and equipment and intangible assets, impairment of property and equipment and intangible assets, deferred taxes, and the provision for and disclosure of litigation and loss contingencies (see Note 8). Actual results may differ materially from those estimates.

### *Foreign Currency Translation*

The financial position and results of operations of the Company's foreign subsidiaries are determined using the local currency as the functional currency. Assets and liabilities of these subsidiaries are translated

at the exchange rate in effect at each period-end. Income statement accounts are translated at the average rate of exchange prevailing during the period. Adjustments arising from the use of differing exchange rates from period to period are included in accumulated other comprehensive income in shareholders' equity. Gains and losses resulting from foreign currency transactions are included in earnings and have not been material in any one period.

Balances of related after-tax components comprising accumulated other comprehensive income included in shareholders' equity, at December 31, 2005 and December 31, 2004 are as follows:

	<u>December 31</u>	
	<u>2005</u>	<u>2004</u>
Unrealized gains on available-for-sale securities	—	\$ 10,005
Foreign currency translation adjustment	(784,644)	454,105
Accumulated other comprehensive income	<u>\$(784,644)</u>	<u>\$464,110</u>

Upon sale or upon complete or substantially complete liquidation of an investment in a foreign entity, the amount attributable to that entity and accumulated in the translation adjustment component of equity is removed from the separate component of equity and is reported as gain or loss for the period during which the sale or liquidation occurs. During December 2005, the Company substantially completed the liquidation of the Company's Australian entity. As such, the accumulated translation adjustment component was removed from equity by recording \$0.1 million as other income in the 2005 consolidated statement of operations.

#### *Statement of cash flows*

For purposes of the statements of cash flows, the Company considers all highly liquid investments (i.e., investments which, when purchased, have original maturities of three months or less) to be cash equivalents. At December 31, 2005, the Company had \$2.5 million of cash restricted for the payment of the non-cancelable portion of the Exton, Pennsylvania facility lease, due monthly through March 2008.

#### *Concentration of credit risk*

The Company maintains its cash primarily with major U.S. domestic banks. The amounts held in these banks generally exceed the insured limit of \$100,000. The terms of these deposits are on demand to minimize risk. The Company has not incurred losses related to these deposits. Cash equivalents are maintained in two financial institutions. The Company invests these funds primarily in government securities and/or mortgage-backed securities.

The Company's available-for-sale investments, as set forth below, subject it to certain credit risk that is concentrated in securities issued by U.S. government sponsored mortgage entities, and various U.S. states. Due to the credit ratings of these issuers, the Company does not believe that the credit risk is significant.

#### *Available-for-Sale Investments*

At December 31, 2005, the Company held certain investments in marketable debt securities as a means of temporarily investing the proceeds from its issuance of shares of common stock and 3.5% Convertible Subordinated Notes until the funds are needed for operating purposes. These investments are being accounted for as "available-for-sale" investments under Statement of Financial Accounting Standards ("SFAS") No. 115, "Accounting for Certain Investments in Debt and Equity Securities." As a result, the investments are reflected at their fair value, based on quoted market prices, with unrealized gains and losses recorded in accumulated other comprehensive income until the investments are sold, at which time the realized gains and losses are included in the results of operations.

#### *Allowance for Doubtful Accounts*

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

The Company did not have an allowance for doubtful accounts for year ended December 31, 2003. The following is a rollforward of the allowance for doubtful accounts for the years ended December 31, 2005 and 2004:

Balance, as of January 1, 2004	\$ —
Provision during 2004	50,533
Balance, as of December 31, 2004	50,533
Provision during 2005	133,412
Charges to the allowance account	(83,306)
Balance, as of December 31, 2005	<u>\$100,639</u>

#### *Inventory*

Inventory consists of raw materials used in the Isolagen Process. Inventory is stated at the lower of cost or market and cost is determined by the weighted average method. Costs of sales include labor, material and overhead associated with the manufacturing process. Those costs, except for the costs of raw materials that have not been used, are expensed as incurred.

#### *Property and equipment*

Property and equipment, consisting primarily of one tract of land and two buildings (located in Switzerland), lab equipment, computer equipment, software, leasehold improvements, office furniture and fixtures, is carried at cost less accumulated depreciation and amortization. Depreciation and amortization for financial reporting purposes is provided by the straight-line method over the estimated useful life of three years, except for buildings, which have an estimated useful life of up to 25 years. Leasehold improvements are amortized using the straight-line method over the remaining lease term or the life of the asset, whichever is shorter. The cost of repairs and maintenance is charged as an expense as incurred.

#### *Debt Issue Costs*

The costs incurred in issuing the Company's 3.5% Convertible Subordinated Notes, including placement agent fees, legal and accounting costs and other direct costs are included in Other Assets and are being amortized to expense using the effective interest method over five years, through November 2009. Debt issuance costs, net of amortization, were approximately \$2.9 million at December 31, 2005 and approximately \$3.6 million at December 31, 2004.

#### *Treasury Stock*

The Company utilizes the cost method for accounting for its treasury stock acquisitions and dispositions.

### *Revenue recognition*

The Company recognizes revenue over the period the service is performed in accordance with SEC Staff Accounting Bulletin No. 104, "Revenue Recognition in Financial Statements" ("SAB 104"). In general, SAB 104 requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services rendered, (3) the fee is fixed and determinable and (4) collectibility is reasonably assured.

The Isologen Process is administered to each patient using a recommended regimen of up to six injections. Due to the short shelf life, each injection is cultured on an as needed basis and shipped prior to the individual injection being administered by the physician. The Company believes each injection has stand alone value to the patient. The Company invoices the attending physician upon that physician submitting his or her patient's tissue sample to the Company; as a result of which the contractual arrangement is between the Company and the medical professional. The amount invoiced varies directly with the number of injections requested. Generally, orders are paid in advance by the physician prior to the first injection. There is no performance provision under any arrangement with any physician, and there is no right to refund or returns for unused injections.

As a result, the Company believes that the requirements of SAB 104 are met as each injection is shipped, as the risk of loss transfers to the customer at that time, the fee is fixed and determinable and collection is reasonably assured. Advance payments are deferred until shipment. The amount of the revenue deferred represents the fair value of the remaining undelivered injections measured in accordance with Emerging Issues Task Force Issue ("EITF") 00-21, "Accounting for Revenue Arrangements with Multiple Deliverables," which addresses the issue of accounting for arrangements that involve the delivery of multiple products or services. Should the physician discontinue the regimen prematurely all remaining deferred revenue is recognized.

The Company also offers a service whereby it stores a patient's cells for later use in the preparation of injections. In accordance with EITF 00-21, the fees charged for both of these services are recognized as revenue ratably over the length of the storage agreement. Revenue related to this service was approximately \$0.3 million in 2005 and were less than \$0.1 million prior to 2005. The Company also offers a service whereby it processes a patient's cells to expand the cells to the mass necessary to prepare an injection, but then store the expanded cells for later use in the preparation of injections. Revenue related to this service has been less than \$0.1 million inception to date.

### *Promotional incentives*

The Company periodically offers promotional incentives to physicians on a case-by-case basis. Promotional incentives are provided to physicians in the form of "at no charge" Isologen treatments and Isologen treatments offered at a discount from the suggested price list. The Company does not receive any identifiable benefit from the physicians in exchange for any promotional incentives granted.

In accordance with EITF 01-09, "Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)," the Company does not record any revenue related to "at no charge" Isologen treatments and the estimated cost to provide such treatments is expensed as selling, general and administrative expense at the time the promotion is granted. The Company records discounts granted as a reduction in revenue (i.e., net revenue after discount) from that specific transaction.

### *Shipping and handling costs*

The Company typically does not charge customers for shipping and handling costs. Such costs are included in selling, general and administrative expenses and totaled \$0.3 million, \$0.4 million and \$0.1 million in the years ended December 31, 2005, 2004 and 2003, respectively.

#### Advertising cost

Advertising costs are expensed as incurred and include the costs of public relations activities. These costs are included in selling, general and administrative expenses and totaled \$1.2 million, \$0.3 million and \$0.4 million in the years ended December 31, 2005, 2004 and 2003, respectively.

#### Research and development expenses

Research and development costs are expensed as incurred and include salaries and benefits, costs paid to third-party contractors to perform research, conduct clinical trials, develop and manufacture drug materials and delivery devices, and a portion of facilities cost. Research and development costs also include costs to develop improved and/or automated manufacturing, cell collection and logistical process improvements. It is anticipated that such improvements would eliminate several of the steps and materials involved in the current system, which the Company expects would lead to significant cost reductions in both skilled labor and materials and will enable scalable mass production. However, the commercial viability of the improvements and/or automation under consideration is uncertain, and the Company does not know whether it will be successful in its implementation.

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

#### Costs of Exit Activities

In September 2004, the Company approved a plan for the closure of its Australian facilities and the servicing of Australia from the Company's London, England facility. The Company adopted this plan because it believed that anticipated processing enhancements and improved delivery logistics will eliminate the need for an Australian laboratory. During 2005, all Australian fixed assets were sold or disposed of and the lease related to the Australian facility was terminated.

The costs associated with the closure of the Australian facilities, which are comprised principally of statutory or contractual employee severance costs and the cost of terminating certain contracts, are being accounted for in accordance with SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." Under SFAS No. 146, employee severance costs are accrued over the period beginning with the date on which the Company communicated the exit plan and the severance benefits to the affected employees, and ending on the date through which the affected employees must continue working to be entitled to the severance benefit, and costs incurred to terminate other contracts are accrued when the Company terminates the contract in accordance with the contract terms or has otherwise negotiated a termination with the counterparty. The exit costs charged to expense are included in selling, general and administrative expenses in the Consolidated Statements of Operations.

The following sets forth information about the major components of the exit costs:

	<b>Costs Incurred for the Year Ended December 31, 2005</b>	<b>Costs Incurred for the Year Ended December 31, 2004</b>	<b>Cumulative Costs Incurred to Date</b>
Employee severance	\$ 3,695	\$ 204,894	\$ 208,589
Lease decommission costs	81,252	—	81,252
Contract termination	66,527	361,625	428,152
Total	<u>\$ 151,474</u>	<u>\$ 566,519</u>	<u>\$ 717,993</u>

The following sets forth information about the changes in the accrued exit costs for the years ended December 31, 2004 and 2005:

	<u>Accrued Liability at January 1, 2004</u>	<u>Costs Charged to Expense</u>	<u>Costs Paid or Settled</u>	<u>Accrued Liability December 31, 2004</u>
Employee severance	\$ —	\$ 204,894	\$204,894	\$ —
Lease decommission costs	—	—	—	—
Contract Termination	—	361,625	—	361,625
Total	<u>\$ —</u>	<u>\$ 566,519</u>	<u>\$204,894</u>	<u>\$ 361,625</u>

  

	<u>Accrued Liability at January 1, 2005</u>	<u>Costs Charged to Expense</u>	<u>Costs Paid or Settled</u>	<u>Accrued Liability December 31, 2005</u>
Employee severance	\$ —	\$ 3,695	\$ 3,695	\$ —
Lease decommission costs	—	81,252	81,252	—
Contract Termination	361,625	66,527	428,152	—
Total	<u>\$ 361,625</u>	<u>\$ 151,474</u>	<u>\$513,099</u>	<u>\$ —</u>

*Stock-based compensation and Accelerated Vesting of Stock Options*

The Company accounts for its stock-based compensation under the provisions of SFAS No. 123 *“Accounting for Stock Based Compensation.”* Under SFAS No. 123, the Company is permitted to either record expenses for stock options and other employee compensation plans based on their fair value at the date of grant or to continue to apply the provisions of Accounting Principles Board Opinion No. 25 *“Accounting for Stock Issued to Employees,”* (“APB No. 25”), and recognize compensation expense, if any, based on the intrinsic value of the equity instrument at the measurement date. Any such compensation cost is charged to expense on a straight-line basis over the periods the options vest. To the extent the options had cashless exercise provisions, the Company utilized variable accounting. The Company has elected to continue following the provisions of APB No. 25 through December 31, 2005. Stock options issued to other than employees or directors are recorded on the basis of their fair value as required by SFAS No. 123.

The Company from time to time issues common stock, stock options or common stock warrants to acquire services or goods from non-employees. Common stock, stock options and common stock warrants issued to other than employees or directors are recorded on the basis of their fair value, as required by SFAS No. 123, which is measured as of the date required by EITF Issue 96-18, *“Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services.”* In accordance with EITF 96-18, the stock options or common stock warrants are valued using the Black-Scholes model on the basis of the market price of the underlying common stock on the “valuation date,” which for options and warrants related to contracts that have substantial disincentives to non-performance is the date of the contract, and for all other contracts is the vesting date. Expense related to the options and warrants is recognized on a straight-line basis over the shorter of the period over which services are to be received or the vesting period. Where expense must be recognized prior to a valuation date, the expense is computed under the Black-Scholes model on the basis of the market price of the underlying common stock at the end of the period, and any subsequent changes in the market price of the underlying common stock up through the valuation date is reflected in the expense recorded in the subsequent period in which that change occurs (see Note 9).

In December 2002, the Financial Accounting Standards Board (“FASB”) issued SFAS No. 148, *“Accounting for Stock-Based Compensation-Transition and Disclosure”*. SFAS No. 148 also amends the disclosure requirements of SFAS No. 123, requiring prominent disclosure in annual and interim financial statements regarding a company’s method for accounting for stock-based employee compensation and the



effect of the method on reported results. While Isolagen continues to utilize the disclosure-only provisions of SFAS No. 123, the Company has modified its disclosures to comply with SFAS No. 148.

During December 2005, the board of directors approved the full vesting of all unvested, outstanding stock options issued to current employees and directors. The board decided to take this action ("the acceleration event") in anticipation of the adoption of SFAS No. 123 (Revised 2004), "*Share Based Payments*" (discussed further below under *Recently Issued Accounting Standards Not Yet Effective*). As a result of this acceleration event, approximately 1.4 million stock options were vested that would have otherwise vested during 2006 and later periods. At the time of the acceleration event, the unamortized grant date fair value of the affected options was approximately \$3.6 million (for SFAS No. 123 and SFAS No. 148 pro forma disclosure purposes), which in the pro forma disclosures below has been charged to pro forma expense in the fourth quarter of 2005.

Substantially all of the unvested employee stock options that were subject to the acceleration event had exercise prices above market price of the Company's common stock at the time the board approved the acceleration event. However, because, as discussed below, the Company will have to adopt SFAS No. 123 (Revised 2004) effective January 1, 2006, if the Company had not completed this acceleration event in December 2005, the majority of the \$3.6 million amount discussed above would have been charged against the Company's results of operations, as reported in its Statements of Operations, beginning in the first quarter of fiscal 2006 and continuing through later periods as the options vested.

As discussed above, substantially all of the unvested employee stock options which were accelerated had exercise prices above market price at the time of acceleration. For the purposes of applying APB No. 25 to such stock options in the Company's statement of operations for the year ended December 31, 2005, the acceleration event was treated as the acceleration of the vesting of employee and director options that otherwise would have vested as originally scheduled, and accordingly was not a modification requiring the remeasurement of the intrinsic value of the options, or the application of variable option accounting, under APB No. 25. For stock options that had exercise prices below market price at the time of acceleration and that would not have vested originally, a charge of approximately \$15,000 was recorded in the Company's statement of operations for the year ended December 31, 2005.

The following table illustrates the effect on net results and per share amounts as if the fair value based method had been applied to all outstanding and unvested awards in each period. As discussed above, the 2005 amounts in this table include a pro forma charge of approximately \$3.6 million for the year ended December 31, 2005 related to the December 2005 acceleration event. Had compensation costs for the Company's stock option plan been determined based on the fair value at the grant date in 2005, 2004 and 2003 consistent with the provisions of SFAS No. 123 and SFAS 148, the Company's net loss and net loss per share would have increased to the pro forma amounts indicated below:

	<u>Year ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Net loss—as reported	\$(35,777,584)	\$(21,474,469)	\$(11,268,294)
Plus: stock-based employee compensation expense included in reported net loss, net of related tax effects of \$0	44,329	373,147	—
Less: total stock based employee compensation determined under fair value based method for all awards granted to employees, net of related tax effect of \$0	(5,967,467)	(4,665,753)	(13,678,048)
Net loss—pro forma	<u>\$(41,700,722)</u>	<u>\$(25,767,075)</u>	<u>\$(24,946,342)</u>
Net loss per share—as reported			
Basic and diluted	<u>\$ (1.18)</u>	<u>\$ (0.71)</u>	<u>\$ (0.58)</u>
Net loss per share—pro forma			
Basic and diluted	<u>\$ (1.38)</u>	<u>\$ (0.86)</u>	<u>\$ (1.29)</u>

As required under SFAS 123 and SFAS 148, the pro forma effects of stock-based compensation on net loss per share have been estimated at the date of grant using the Black Scholes option-pricing model based on the following weighted average assumptions:

	<u>Year ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Expected life (years)	5 years	5 years	3 years
Interest rate	4%	4%	4%
Dividend yield	—	—	—
Volatility	78%	71%	71-80%

#### *Income taxes*

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

#### *Loss per share data*

Basic loss per share is calculated based on the weighted average common shares outstanding during the period, after giving effect to the manner in which the merger was accounted for as described in Note 1. Diluted earnings per share also gives effect to the dilutive effect of stock options, warrants (calculated based on the treasury stock method) and convertible notes and convertible preferred stock. The Company

does not present diluted earnings per share for years in which it incurred net losses as the effect is antidilutive.

At December 31, 2005, options and warrants to purchase 7,600,939 shares of common stock at exercise prices ranging from \$1.50 to \$11.38 per share were outstanding, but were not included in the computation of diluted earnings per share as their effect would be antidilutive. Also, 9,828,009 shares issuable upon the conversion of the Company's convertible notes, at a conversion price of approximately \$9.16, were not included as their effect would be antidilutive.

#### *Fair Value of Financial Instruments*

The Company's financial instruments consist of accounts receivable, marketable debt securities, accounts payable and convertible subordinated debentures. The fair values of the Company's accounts receivable and accounts payable approximate, in the Company's opinion, their respective carrying amounts. The Company's marketable debt security investments are carried at fair value. The Company's convertible subordinated debentures were quoted at approximately 50% of par value at December 31, 2005. Accordingly, the fair value of our convertible subordinated debentures is approximately \$45,000,000 at December 31, 2005.

#### *Recently Issued Accounting Standards Not Yet Effective*

In December 2004, the FASB issued SFAS No. 123 (Revised 2004), "*Share Based Payment*," which eliminates the use of APB Opinion No. 25 and will require the Company to measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost will be recognized over the period during which an employee is required to provide service in exchange for the reward—the requisite service period. No compensation cost is recognized for equity instruments for which employees do not render the requisite service. The grant-date fair value of employee share options and similar instruments will be estimated using option-pricing models adjusted for the unique characteristics of those instruments. SFAS No. 123 (Revised 2004) is effective for the first interim or annual reporting period that begins after December 31, 2005 (the quarter beginning January 1, 2006 for the Company) and must be applied to all options granted or modified after its effective date and also to recognize the cost associated with the portion of any option awards made before its effective date for which the associated service has not been rendered as of its effective date. The Company will adopt SFAS No. 123 (Revised 2004) using a modified version of prospective application, *or* modified prospective application. Under modified prospective application, SFAS No. 123 (Revised 2004) applies to new awards and to awards modified, repurchased, or cancelled after the required effective date. Additionally, compensation cost for the portion of awards for which the requisite service has not been rendered that are outstanding as of the required effective date shall be recognized as the requisite service is rendered on or after the required effective date. The compensation cost for that portion of awards shall be based on the grant-date fair value of those awards as calculated for either recognition or pro forma disclosures under Statement 123. However, as the Company accelerated the vesting of outstanding employee and director stock options during December 2005, there is no remaining expense related to such options to be expensed in future periods. As such, the impact of SFAS No. 123 (Revised 2004) on the Company's future financial statements will be based upon the number of stock based payments awarded in the future, requisite service requirements and the value of such awards on the award dates; factors which are not currently estimable. The Company anticipates utilizing the Black-Scholes valuation model in order to value future stock option awards, and anticipates utilizing the binomial lattice model when considered by management to be more appropriate.

In November 2004, the FASB issued SFAS No. 151, "*Inventory Costs*, an amendment of ARB No. 43, Chapter 4." This statement clarifies that abnormal inventory costs such as costs of idle facilities, excess freight and handling costs, and wasted material (spoilage) are required to be recognized as current period

charges. In addition, the statement requires that allocation of fixed production overhead to the costs of conversion be based on the normal capacity of the production facilities. The provisions of this statement became effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The Company believes that the adoption of this statement will not have an impact on the Company's consolidated results of operations or financial condition.

In December 2004, the FASB issued SFAS No. 153, "Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29." The amendments made by SFAS 153 are based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. Further, the amendments broaden the exception for exchanges of nonmonetary assets that do not have commercial substance. SFAS 153 is effective for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. The Company believes that the adoption of SFAS 153 will not have a material impact on the Company's consolidated results of operations or financial position.

In May, 2005 the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections—a replacement of APB Opinion No. 20 and FASB Statement No. 3." SFAS No. 154 replaces APB Opinion ("APB") No. 20, "Accounting Changes", and SFAS No. 3, "Reporting Accounting Changes in Interim Financial Statements," and changes the requirements for the accounting for and reporting of a change in accounting principle. SFAS No. 154 will apply to all voluntary changes in accounting principle as well as to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. APB No. 20 previously required that most voluntary changes in accounting principle be recognized by including in net income of the period of the change the cumulative effect of changing to the new accounting principle. SFAS No. 154 requires retrospective application to prior periods' financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. When it is impracticable to determine the period-specific effects of an accounting change on one or more individual prior periods presented, SFAS No. 154 requires that the new accounting principle be applied to the balances of assets and liabilities as of the beginning of the earliest period for which retrospective application is practicable and that a corresponding adjustment be made to the opening balance of retained earnings (or other appropriate components of equity or net assets in the statement of financial position) for that period rather than being reported in an income statement. When it is impracticable to determine the cumulative effect of applying a change in accounting principle to all prior periods, SFAS No. 154 requires that the new accounting principle be applied as if it were adopted prospectively from the earliest date practicable. SFAS No. 154 carries forward without change the guidance contained in APB No. 20 for reporting the correction of an error in previously issued financial statements and a change in accounting estimate, and also the guidance in APB No. 20 requiring justification of a change in accounting principle on the basis of preferability. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. Early adoption is permitted for accounting changes and corrections of errors made in fiscal years beginning after the date SFAS No. 154 was issued. The Company presently does not believe that the adoption of the provisions of SFAS No. 154 will have a material affect on its financial statements.

### Note 3—Available-for-Sale Investments

The following sets forth information concerning marketable debt securities as of December 31, 2005:

Type of issue	Maturity	Face amount	Cost	Gross unrealized gains	Gross unrealized losses	Fair value
State and local government	2012-2043	\$23,000,000	\$23,000,000	—	—	\$23,000,000
			<u>\$23,000,000</u>	<u>—</u>	<u>—</u>	<u>\$23,000,000</u>

The following sets forth information concerning marketable debt securities as of December 31, 2004:

Type of issue	Maturity	Face amount	Cost	Gross unrealized gains	Gross unrealized losses	Fair value
Freddie Mac and Fannie Mae	2005	\$ 9,075,000	\$ 8,999,655	\$10,005	\$—	\$ 9,009,660
State and local government	2012-2044	\$32,150,000	32,150,000	—	—	32,150,000
Corporate	2021-2043	\$10,650,000	10,650,000	—	—	10,650,000
			<u>\$51,799,655</u>	<u>\$10,005</u>	<u>\$—</u>	<u>\$51,809,660</u>

The Company's investments in state and local government and corporate issues are principally investments in Auction Rate Securities ("ARS"), for which the interest rates are reset periodically through a Dutch auction process. The following sets forth the aggregate maturities of the Company's investments in marketable debt securities at December 31, 2005, without regard to the dates at which the interest rates for ARS investments reset:

Maturity	Cost	Fair Value
2005	\$ —	\$ —
2006-2010	—	—
2011-2015	2,700,000	2,700,000
2016 and after	20,300,000	20,300,000
	<u>\$23,000,000</u>	<u>\$23,000,000</u>

Proceeds from the sale of available-for-sale marketable debt securities were \$106.8 million, \$21.0 million and \$0 for the years ended December 31, 2005, 2004 and 2003, respectively, and no realized gains and losses based on specific identification, were included in the results of operations upon those sales.

#### Note 4—Property and Equipment

Property and equipment is comprised of:

	December 31,	
	2005	2004
Land	\$ 2,613,102	\$ —
Building	1,187,774	—
Construction-in-process	7,091,261	—
Leasehold improvements	4,833,843	2,250,921
Lab equipment	2,335,656	1,788,159
Computer equipment and software	1,309,841	1,975,502
Office furniture and fixtures	94,214	42,232
	19,465,691	6,056,814
Less: Accumulated depreciation and amortization	(2,188,519)	(2,421,822)
Property and equipment, net	<u>\$17,277,172</u>	<u>\$ 3,634,992</u>

The amounts of depreciation and amortization expense for property and equipment included in the statement of operations are as follows:

	<u>Year ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Cost of sales	\$ 632,416	\$ 399,644	\$387,951
Selling, general, administrative, research and development expenses	1,069,007	903,654	447,479
<b>Total depreciation expense</b>	<b><u>\$1,701,423</u></b>	<b><u>\$1,303,298</u></b>	<b><u>\$835,430</u></b>

In April 2005, the Company acquired a 100,000 square foot, two-building corporate campus in Bevaix, Canton of Neuchâtel, Switzerland for \$10.0 million cash. Approximately \$2.7 million of the purchase price was allocated to the land and the remaining \$7.3 million was allocated to the buildings and construction-in-progress.

Included in property and equipment at December 31, 2005, as construction-in-progress, is \$7.1 million related to one of the Switzerland buildings that is currently under renovation.

During the third quarter of 2005, the Company determined that a certain third-party developed software system (the “MES” system) was impaired and, accordingly, recorded a charge of \$1.3 million to selling, general and administrative expense. Previous to the impairment charge, certain components of the MES system had been placed in use and certain components were still in development. The gross balance and accumulated depreciation related to the MES system components placed in use were \$0.6 million and \$0.1 million, respectively, at the time of the impairment charge and was being depreciated over five years. The balance related to the MES system components still in development, for which amortization had not commenced at the time of the impairment charge, was \$0.9 million.

In the first quarter of 2005, the Company terminated its related party lease (see Notes 8 and 10). The gross balance and accumulated depreciation of the leasehold improvements were \$0.7 million and \$0.7 million, respectively, at the time of exit. In addition, at December 31, 2004 the Company had \$1.1 million and \$0.7 million of gross property and equipment and accumulated depreciation related to its Australian facility. All Australian property and equipment had been disposed of by December 31, 2005, as discussed in Note 2.

#### **Note 5—Accrued Liabilities**

Accrued liabilities consist of the following at December 31, 2005 and 2004:

	<u>December 31,</u>	
	<u>2005</u>	<u>2004</u>
Accrued professional fees	\$1,722,794	\$ 757,119
Accrued compensation	680,139	580,321
Accrued severance	644,915	480,769
Accrued interest	525,000	507,500
Accrued contract termination costs	—	361,625
Accrued other	311,746	754,471
<b>Accrued liabilities</b>	<b><u>\$3,884,594</u></b>	<b><u>\$3,441,805</u></b>

## Note 6—Convertible Subordinated Notes

On November 3, 2004, the Company completed the private placement of \$75.0 million aggregate principal amount of 3.5% Convertible Subordinated Notes Due 2024 (the “3.5% Subordinated Notes”). The 3.5% Subordinated Notes could be due sooner than 2024, as discussed below. The Company received net proceeds of approximately \$71.7 million after the deduction of commissions and offering expenses. The Company also granted the purchasers of the 3.5% Subordinated Notes the option to purchase up to \$15.0 million of additional 3.5% Subordinated Notes through December 2, 2004. On November 5, 2004, the Company completed the private placement of the additional \$15.0 million aggregate principal amount of 3.5% Subordinated Notes. The Company received net proceeds of approximately \$14.5 million after the deduction of discounts, commissions and offering expenses. The total net proceeds to the Company were approximately \$86.2 million after the deduction of commissions and offering expenses.

The Company used approximately \$26 million of the net proceeds to repurchase 4,000,000 shares of its common stock, of which 2,000,000 shares were repurchased from Frank DeLape, who was then the Chairman of the Board of Directors, Michael Macaluso, a former director and the former President and Chief Executive Officer, Olga Marko, the former Senior Vice President and Director of Research, Michael Avignon, the former Manager of International Operations, and Timothy J. Till, a shareholder. The purchase price from the insiders, affiliates and founders of the Company listed above was \$6.33 per share which represented a 5% discount from the closing price of the Company’s common stock on the American Stock Exchange on October 28, 2004, the date the offering of the 3.5% Subordinated Notes was priced. The purchase of the shares from the insiders was approved by a special committee of independent directors in partial reliance on a fairness opinion issued by an investment bank. The remaining 2,000,000 shares were repurchased in private transactions at a price of \$6.66 per share. The remaining net proceeds of approximately \$60.2 million were added to the Company’s general working capital.

The 3.5% Subordinated Notes are unsecured obligations and are subordinated in right of payment to all of the Company’s existing and future senior indebtedness. The 3.5% Subordinated Notes are also effectively subordinated to all indebtedness and other liabilities of the Company’s subsidiaries.

The 3.5% Subordinated Notes require the semi-annual payment of interest, on May 1 and November 1 of each year beginning May 1, 2005, at 3.5% interest per annum on the principal amount outstanding. The 3.5% Subordinated Notes will mature on November 1, 2024. Prior to maturity the holders may convert their 3.5% Subordinated Notes into shares of the Company’s common stock. The initial conversion rate is 109.2001 shares per \$1,000 principal amount of 3.5% Subordinated Notes, which is equivalent to an initial conversion price of approximately \$9.16 per share.

On or after November 1, 2009, the Company may at its option redeem the 3.5% Subordinated Notes, in whole or in part, for cash, at a redemption price equal to 100% of the principal amount of the 3.5% Subordinated Notes to be redeemed plus accrued and unpaid interest.

On each of November 1, 2009, November 1, 2014 and November 1, 2019, the holders may require the Company to purchase all or a portion of their 3.5% Subordinated Notes at a purchase price in cash equal to 100% of the principal amount of 3.5% Subordinated Notes to be purchased plus accrued and unpaid interest. The holders of the 3.5% Subordinated Notes may also require the Company to repurchase their 3.5% Subordinated Notes in the event its common stock (or other common stock into which the 3.5% Convertible Subordinated Notes are then convertible) ceases to be listed for trading on a U.S. national securities exchange or approved for trading on an established automated over-the-counter market in the United States.

In the event a change in control occurs on or before November 9, 2009, the holders of the 3.5% Subordinated Notes may require the Company to purchase all or a portion of their notes at a purchase price equal to 100% of the principal amount of the 3.5% Subordinated Notes to be purchased plus accrued

and unpaid interest and the payment of a “make-whole” payment which is based on the date on which the change in control occurs and the price per share paid for the Company’s common stock in such change in control transaction. The Company will be allowed to pay for the repurchase of the 3.5% Subordinated Notes and accrued and unpaid interest in cash or, at its option, shares of its common stock, and the Company will be allowed to make the make-whole payment in cash or, at its option, such other form of consideration as is paid to its common stockholders in the change of control transaction. In addition, in the event a change in control occurs on or before November 9, 2009, the holders of the 3.5% Subordinated Notes that convert their 3.5% Subordinated Notes into shares of the Company’s common stock in connection with such change of control transaction will also be entitled to receive the make-whole payment.

The 3.5% Subordinated Notes were issued in an offering not registered under the Securities Act of 1933, as amended (“the Securities Act”). However, the Company was obligated to file with the SEC, on or prior to 90 days following the date the 3.5% Subordinated Notes were originally issued, a shelf registration statement covering resales of the 3.5% Subordinated Notes and the shares of the Company’s common stock issuable upon the conversion of the 3.5% Subordinated Notes, and to use its reasonable best efforts to cause the shelf registration statement to be declared effective under the Securities Act on or prior to 180 days following the date the 3.5% Subordinated Notes were originally issued. The shelf registration statement was subsequently declared effective on May 2, 2005.

#### Note 7—Income Taxes

The Company and its domestic subsidiary file a consolidated U.S. Federal income tax return. The Company’s foreign subsidiaries file income tax returns in their respective jurisdictions. The components of the net loss were:

	Year ended December 31.		
	2005	2004	2003
US	\$25,695,952	\$14,353,454	\$ 7,494,993
Non-US	10,081,632	7,121,015	3,773,301
	<u>\$35,777,584</u>	<u>\$21,474,469</u>	<u>\$11,268,294</u>

The components of the Company’s deferred tax assets (liabilities) at December 31, 2005 and 2004 are as follows:

	December 31.	
	2005	2004
Deferred tax assets and liabilities:		
Loss carryforwards	\$ 25,649,210	\$ 12,918,221
Accrued expenses and other	1,237,345	1,317,536
Property and equipment	51,920	(40,282)
	<u>26,938,475</u>	<u>14,195,475</u>
Less: Valuation allowance	(26,938,475)	(14,195,475)
	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2005, the Company had generated US net operating loss carryforwards of approximately \$52.1 million which expire from 2011 to 2025 and net loss carryforwards in certain non-US jurisdictions of approximately \$21.4 million. These net operating loss carryforwards are available to reduce future taxable income. However, a change in ownership, as defined by federal income tax regulations, could significantly limit the Company’s ability to utilize its U.S. net operating loss carryforwards. Additionally, because federal tax laws limit the time during which the net operating loss carryforwards may



be applied against future taxes, if the Company fails to generate taxable income prior to the expiration dates it may not be able to fully utilize the net operating loss carryforwards to reduce future income taxes. As the Company has had cumulative losses and there is no assurance of future taxable income, valuation allowances have been recorded to fully offset the deferred tax asset at December 31, 2005 and 2004. The valuation allowance increased \$12.7, \$9.0 million and \$0.8 million during 2005, 2004 and 2003, respectively, due to the Company's current period 2005, 2004 and 2003 net losses, respectively.

## **Note 8—Commitments and Contingencies**

### *Federal Securities Litigation*

The Company and certain of its current and former officers and directors are defendants in class action cases pending in the United States District Court for the Southern District of Texas and the United States District Court for the Eastern District of Pennsylvania.

On August 18, 2005, Elliot Liff brought an action styled, C.A. No. H-05-2887, *Elliot Liff v. Isolagen, Inc. et al.*, in the United States District Court for the Southern District of Texas. In this action, the Plaintiff purports to bring a federal securities fraud class action on behalf of purchasers of the publicly traded securities of Isolagen between March 3, 2004 and August 1, 2005, including purchasers of Isolagen stock issued in connection with and traceable to Isolagen's June 2004 common stock offering. The action asserts that the defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 by making certain false statements and omissions to the investing public regarding the Company's business operations, management, and intrinsic value of Isolagen's publicly traded securities. The Complaint also alleges liability against the individual defendants under Section 20(a) of the Exchange Act.

On September 6, 2005, Michael Cummiskey brought an action styled C.A. No. 05-cv-03105, *Michael Cummiskey v. Isolagen, Inc. et al.*, in the United States District Court for the Southern District of Texas. On September 16, 2005, Ronald Gargiulo brought an action styled, C.A. No. 05-cv-4983, *Ronald A. Gargiulo v. Isolagen, Inc. et al.*, in the United States District Court for the Eastern District of Pennsylvania. On September 23, 2005, Gregory J. Newman brought an action styled, C.A. No. 05-cv-5090, *Gregory J. Newman v. Frank M. DeLape, et al.*, in the United States District Court for the Eastern District of Pennsylvania. These actions make allegations against the defendants substantially similar to those made in the *Liff* action. Together, the *Liff*, *Cummiskey*, *Gargiulo* and *Newman* actions comprise the "Federal Securities Actions."

The *Liff* and *Cummiskey* actions were consolidated on October 7, 2005. The *Gargiulo* and *Newman* actions were consolidated on November 29, 2005. On November 18, 2005, the Company filed a motion with the Judicial Panel on Multidistrict Litigation (the "MDL Motion") to transfer the Federal Securities Actions and the *Keene* derivative case (described below) to the United States District Court for the Eastern District of Pennsylvania. The *Liff* and *Cummiskey* actions were stayed on November 23, 2005, pending resolution of the MDL Motion. The *Gargiulo* and *Newman* actions were stayed on December 7, 2005, pending resolution of the MDL Motion. The MDL Motion was heard on January 7, 2006 and a ruling was issued on February 23, 2006. The ruling transferred the actions pending in the Southern District of Texas to the Eastern District of Pennsylvania. The Company anticipates that a Lead Plaintiff and Lead Counsel will be selected and an amended complaint will be filed in the near future.

The Company anticipates that after Lead Plaintiff and Lead Counsel are selected, an amended consolidated complaint will be filed and that the Company and the individual defendants will move to dismiss that complaint. If the Company is unsuccessful in its motion to dismiss the complaint, it intends to defend these actions vigorously. However, the Company cannot currently estimate the amount of loss, if any, that may result from the resolution of these actions, and no provision has been recorded in the consolidated financial statements. The Company will expense its legal costs as they are incurred and will record any insurance recoveries on such legal costs in the period the recoveries are received.

### *Derivative Actions*

The Company is the nominal defendant in derivative actions (the "Derivative Actions") pending in State District Court in Harris County, Texas, the United States District Court for the Southern District of Texas, and the Court of Common Pleas of Chester County, Pennsylvania.

On September 28, 2005, Carmine Vitale filed an action styled Cause No. 2005-61840, *Carmine Vitale v. Frank DeLape, et al.* in the 55<sup>th</sup> Judicial District Court of Harris County, Texas and in February 2006 Mr. Vitale filed an amended complaint. In this action, the plaintiff purports to bring a shareholder derivative action on behalf of the Company against certain of the Company's current and former officers and directors. The Plaintiff alleges that the individual defendants breached their fiduciary duties to the Company and engaged in other wrongful conduct. Certain individual defendants are accused of improper trading in Isolagen stock. The plaintiff did not make a demand on the Board of Isolagen prior to bringing the action and plaintiff alleges that a demand was excused under the law as futile.

On December 2, 2005, the Company filed its answer and special exceptions pursuant to Rule 91 of the Texas Rules of Civil Procedure based on pleading defects inherent in the *Vitale* complaint. The plaintiff filed an amended complaint on February 15, 2006.

On October 8, 2005, Richard Keene, filed an action styled, C.A. No. H-05-3441, *Richard Keene v. Frank M. DeLape et al.*, in the United States District Court for the Southern District of Texas. This action makes substantially similar allegations as the original complaint in the *Vitale* action. The plaintiff also alleges that his failure to make a demand on the Board prior to filing the action is excused as futile.

The Company has sought to transfer the *Keene* action to the United States District Court for the Eastern District of Pennsylvania as part of the MDL Motion. On January 21, 2006, the court stayed the *Keene* action pending resolution of the MDL Motion.

On October 31, 2005, William Thomas Fordyce filed an action styled, C.A. No. GD-05-08432, *William Thomas Fordyce v. Frank M. DeLape, et al.*, in the Court of Common Pleas of Chester County, Pennsylvania. This action makes substantially similar allegations as the original complaint in the *Vitale* action. The plaintiff also alleges that his failure to make a demand on the Board prior to filing the action is excused as futile.

On January 20, 2006, the Company filed its preliminary objections to the complaint. The Company filed a memorandum of law in support of its objections on February 23, 2006. If the Company is unsuccessful in its motion to dismiss the complaint, it intends to defend these actions vigorously. However, the Company cannot currently estimate the amount of loss, if any, that may result from the resolution of these actions, and no provision has been recorded in the consolidated financial statements. Company will expense its legal costs as they are incurred and will record any insurance recoveries on such legal costs in the period the recoveries are received.

### *Other Litigation*

The Company is involved in various other legal matters that are being defended and handled in the ordinary course of business. Although it is not possible to predict the outcome of these matters, management believes that the results will not have a material impact on the Company's financial statements.

### Leases

The Company has entered into leases for office, warehouse and laboratory facilities in Exton, Pennsylvania, Houston, Texas and London, England under third party non-cancelable operating leases through 2010. Future minimum lease commitments at December 31, 2005 are as follows:

<u>Year Ending December 31,</u>	
2006	\$1,566,890
2007	1,231,351
2008	1,244,630
2009	1,279,346
2010	1,145,984
Thereafter	2,518,452
Total	<u>\$8,986,653</u>

For the years ended December 31, 2005, 2004 and 2003, rental expense totaled \$1.8 million, \$0.5 million and \$0.4 million, respectively.

In April 2005, the Company commenced a non-cancelable three year operating lease for approximately 86,500 square feet in Exton, Pennsylvania. This new Exton facility houses members of our senior management team, quality and manufacturing personnel, and the corporate finance department. The Company began constructing a production line in a portion of this facility in anticipation of eventual FDA approval. The facility was completed during September 2005. This production line is expected to be utilized for the production of clinical supplies. If the lease is not cancelled by the Company prior to March 31, 2007, at least one year prior to the end of the non-cancelable portion of the lease, then the lease shall end on March 31, 2013. The Company would then have the option to extend the term of the lease for five years, beginning on April 1, 2013. The Company believes that extending the lease through March 31, 2013 is probable, and accordingly, the Company amortizes its leasehold improvements related to this facility through March 31, 2013. Lease expense is recognized on a straight-line basis through March 31, 2013.

Certain former officers of the Company had previously provided office space and laboratory facilities in Houston, Texas at no charge until August 2003. Beginning September 2003, the lease rate was approximately \$1.80 per month per square foot. During the first quarter of 2005, this lease with certain former officers of the Company was terminated. Commencing March 2005, the Company entered into a new lease with a third-party for approximately 14,850 square feet lease of office and laboratory space in Houston, Texas. The lease term is through April 2008. The Company no longer leases or occupies office space or laboratory facilities from related parties.

As discussed in Note 2, in September 2004 the Company adopted a plan to close its Australia facility. The lease related to the Company's Australia facility was originally due to expire on December, 31, 2004. The Company terminated this lease in October 2005.

As discussed in Note 4, in April 2005 the Company acquired a two-building corporate campus in Bevaix, Canton of Neuchâtel, Switzerland. The Company leases one of these buildings to a third party for approximately \$0.3 million per year. This lease began April 15, 2005 and concludes on December 31, 2010.

### License agreement

In 2000, the Company granted exclusive rights to develop and market its technologies and products within Japan. Should the development efforts result in a marketable product, the Company will receive royalties based on product sales. Upon execution of the license agreement, the Company received an initial up-front fee of \$400,000 which was deferred and was being recognized on a ratable basis over the five year

term of the agreement in accordance with the terms of the agreement. For the year ended December 31, 2002, the Company recognized \$40,000 of contract revenue pursuant to this agreement. During 2002, the Company began negotiations to revoke the license agreement. As a result, the Company reclassified to a payable the remaining deferred revenue totaling \$0.2 million and accrued an additional \$0.2 million in anticipation of a settlement totaling approximately \$0.4 million. The \$0.4 million was settled and paid in the fourth quarter of 2004. No revenue was recognized in 2004 or 2003.

#### *Distribution agreement*

In April 2003, the Company entered into a distribution agreement with Equipmed Pty. Ltd (“Equipmed”). Equipmed had the exclusive right as the Company’s distributor in Australia and New Zealand of services utilizing the Company’s technology for its autologous cellular system for soft tissue regeneration and other therapies in the cosmetic dermatological surgery markets (i.e., exclusively for wrinkle and acne reduction) within Australia and New Zealand. The Company terminated this agreement in exchange for a payment to Equipmed of approximately \$0.4 million during 2005. Approximately \$0.3 million and \$0.1 million of this payment was charged to selling, general and administrative expense in the consolidated statement of operations during 2004 and 2005, respectively.

#### *Consulting agreement*

Effective August 20, 2001, the Company entered into an agreement with Cato Research Ltd. to provide drug development, regulatory advisory and other services. Pursuant to the terms of the agreement, the Company issued 133,333 shares of common stock with an assigned value of \$0.2 million as a retainer fee, which was capitalized as a prepaid expense. As services were rendered, 80% of the invoiced amount was payable in cash with the remaining 20% payable through a reduction in the retainer fee. At December 31, 2002, approximately \$0.1 million was capitalized as other assets related to this agreement. On March 31, 2003, the agreement with Cato Research Ltd. was terminated and 79,382 shares of common stock were cancelled.

#### *Departure of Former Chief Executive Officers*

On October 3, 2005, we announced that the Board of Directors had appointed Susan Ciallella to the position of Interim Chief Executive Officer. Ms. Ciallella’s appointment followed the resignation of Frank DeLape from the post of interim CEO.

Effective October 27, 2005 Mr. DeLape also resigned as Chairman of the Board and member of the Board of Directors. In connection with Mr. DeLape’s resignation Mr. DeLape and the Company entered into a Separation and Release Agreement (the “Agreement”). Pursuant to the Agreement, Mr. DeLape agreed, among other things, to (a) resign all positions with the Company and all of its subsidiaries and to terminate his employment with the Company, (b) certain lock-up and standstill restrictions in respect of shares of the Company’s common stock he and his affiliates own through July 2006, and (c) execute a release for the benefit of the Company and its subsidiaries. The Company agreed, among other things, to pay a separation payment in the amount of \$210,000, beginning on Mr. DeLape’s resignation date through March 15, 2006. Mr. DeLape also will retain options to purchase (a) 650,000 shares of the Company’s common stock granted on September 1, 2001 at an exercise price of \$6.00, which were fully vested as of his resignation date and will be exercisable for a period of two years following his resignation date, (b) 400,000 shares of the Company’s common stock granted on February 25, 2003 at an exercise price of \$4.50, which were fully vested as of his resignation date and will be exercisable for a period of five years following his resignation date and (c) 150,000 shares of the Company’s common stock granted on September 5, 2003 at an exercise price of \$9.81, which were fully vested as of his resignation date and will be exercisable for a period of three years following his resignation date. All other unexercised options granted to Mr. DeLape to purchase shares of the Company’s common stock were cancelled as of Mr. DeLape’s resignation date.

The Amended and Restated Employment Agreement of June 2005 between Mr. DeLape and the Company was terminated. Any options to purchase stock under the 2005 Agreement were cancelled. The separation payment pursuant to the Separation and Release Agreement reflects the amount that would otherwise be owed under Mr. DeLape's 2003 Employment Agreement reduced by the amount of certain office expense reimbursements paid to him pursuant to the 2005 Agreement.

Mr. Michael Macaluso, former Chief Executive Officer and former Director, entered into an employment agreement dated September 5, 2003, with an initial term ending July 31, 2006 and providing for a base salary of \$300,000, subject to the right of the Board of Directors to increase his salary from time to time. Mr. Macaluso resigned from Chief Executive Officer and President effective September 1, 2004. Mr. Macaluso will continue to be paid his base salary until July 2006, which was fully accrued at the time of his resignation.

#### **Note 9—Equity, Stock Plan and Warrants**

##### *Uncompensated contributed services*

From the date of the Merger through July 15, 2003, the Company did not pay compensation to certain officers and directors. Accordingly, the Company recorded imputed compensation expense for the estimated fair value of these services. The uncompensated contributed services recorded totaled \$0.2 million in 2003. The value of the contributed services was based upon the Company's estimate of their fair market value. This contribution of services was recorded as an increase to compensation expense and increase in additional paid in capital.

##### *Equity instruments issued to non-employees*

From time to time, in order to preserve cash and to fund operating activities of the Company, common stock or other equity instruments may be issued for cash or in exchange for goods or services. Equity instruments issued for goods or services are recorded at the fair value of the goods or services received or the fair value of the equity instruments issued, whichever is more reliably measurable.

##### *Significant Common Stock Transactions*

In August 2003, the Company sold in a private offering 3,359,331 shares of Common Stock, par value \$0.001 per share, at an offering price of \$6 per share. After deducting the costs and expenses associated with the sale, the Company received net cash totaling \$18.5 million.

During the three months ended June 30, 2004, the Company issued a) 7,200,000 shares of common stock, at \$8.50 per share, for cash totaling net \$56.8 million in connection with the secondary offering completed in June 2004; and b) 51,828 shares of common stock in exchange for cashless exercise of warrants.

Refer to the consolidated statement of shareholders' equity (deficit) and comprehensive loss for common stock transactions from the period December 28, 1995 through December 31, 2005.

##### *Treasury Stock*

As discussed in Note 6, in November 2004 the Company repurchased 4,000,000 shares of its common stock for an aggregate of approximately \$26.0 million, of which 2,000,000 shares were repurchased from Frank DeLape, who was then the Chairman of the Board of Directors, Michael Macaluso, a former director and the former President and Chief Executive Officer, Olga Marko, the former Senior Vice President and Director of Research, Michael Avignon, the former Manager of International Operations, and Timothy J. Till, a shareholder. The purchase price from the insiders, affiliates and founders of the Company listed above was \$6.33 per share which represented a 5% discount from the closing price of the

Company's common stock on the American Stock Exchange on October 28, 2004, the date the offering of the 3.5% Subordinated Notes was priced. The purchase of the shares from the insiders was approved by a special committee of independent directors in partial reliance on a fairness opinion issued by an investment bank.

#### *2003 Conversion of Series A Convertible Preferred Stock and Series B Convertible Preferred Stock*

In July 2002, the Company completed a private offering of 2,895,000 shares of Series A Convertible Preferred Stock, par value \$0.001 per share, at an offering price of \$3.50 per share. Each share of Series A Preferred Stock was convertible into two shares of common stock at any time after issuance and accrued dividends at 8% per annum payable in cash or additional shares of Series A Preferred Stock. In conjunction with this private offering, the Company issued to the placement agent warrants to purchase 1,158,000 shares of common stock with an exercise price of \$1.93 per share. The warrants were exercisable immediately after grant and expire five years thereafter. The fair market of the warrants granted to the placement agent, based on the Black-Scholes valuation model, is estimated to be \$1.57 per warrant. The value of the warrants granted were offset against the proceeds received from the sale of the Series A Preferred Stock. During the year ended December 31, 2002, the Company issued an additional 143,507 shares of Series A Preferred Stock in lieu of cash for payment of dividends on the Series A Preferred Stock totaling approximately \$0.5 million.

The price of the preferred stock sold was \$3.50 per share. The market value of the Company's common stock sold on the dates that the preferred stock sold or was issued as a dividend had a range of \$2.30 - \$5.40 per common share. In accordance with EITF 00-27 this created a beneficial conversion to the holders of the preferred stock and a deemed dividend to the preferred stockholders totaling \$10.2 million was recorded by the Company with a corresponding amount recorded as additional paid-in capital. The deemed dividend associated with the beneficial conversion is calculated as the difference between the fair value of the underlying common stock less the proceeds that have been received for the Series A Preferred Stock limited to the value of the proceeds received.

In May 2003, the Company sold in a private offering 155,750 shares of Series B Convertible Preferred Stock, par value \$0.001 per share, at an offering price of \$28 per share. Each share of Series B preferred stock is convertible into 8 shares of common stock at any time after issuance and accrues dividends at 6% per annum payable in cash or additional shares of Series B Preferred Stock. After deducting the costs and expenses associated with the sale, the Company received cash totaling \$3.9 million. In conjunction with the private offering, the Company issued to the placement agent warrants to purchase 124,600 shares of common stock with an exercise price of \$3.50 per share. The warrants are exercisable immediately after grant and expire five years thereafter. The fair value of the warrants granted to the placement agent, based on the Black-Scholes valuation model is estimated to be \$2.77 per warrant. The value of the warrants granted has been offset from the proceeds received from the sale of the Series B Preferred Stock and recorded as additional paid in capital.

The price of the preferred stock sold was \$28 per share. The market value of the Company's common stock sold on the dates that the preferred stock was sold had a range of \$4.40 - \$4.54 per common share. In accordance with EITF 00-27 this created a beneficial conversion to the holders of the preferred stock and a deemed dividend to the preferred stockholders totaling approximately \$1.2 million was recorded by the Company with a corresponding amount recorded as additional paid-in capital. The deemed dividend associated with the beneficial conversion is calculated as the difference between the fair value of the underlying common stock less the proceeds that have been received for the Series B Preferred Stock limited to the value of the proceeds received.

In 2003, all outstanding shares of Series A and Series B Convertible Preferred Stock were converted into 7.3 million shares of common stock.

#### *2001 Stock Option and Stock Appreciation Rights Plan*

Effective August 10, 2001, the Company adopted the Isolagen, Inc. 2001 Stock Option and Stock Appreciation Rights Plan (the "Stock Plan"). The Stock Plan is discretionary and allows for an aggregate of up to 5,000,000 shares of the Company's common stock to be awarded through incentive and non-qualified stock options and stock appreciation rights. The Stock Plan is administered by the Company's Board of Directors, who has exclusive discretion to select participants who will receive the awards and to determine the type, size and terms of each award granted. As of December 31, 2005, there were 3,826,850 options outstanding under the Stock Plan.

#### *2003 Stock Option and Stock Appreciation Rights Plan*

On January 29, 2003, the Company's Board of Directors approved the 2003 Stock Option and Appreciation Rights Plan (the "2003 Stock Plan"). The 2003 Stock Plan is discretionary and allows for an aggregate of up to 2,250,000 shares of the Company's common stock to be awarded through incentive and non-qualified stock options and stock appreciation rights. The 2003 Stock Plan is administered by the Company's Board of Directors, who has exclusive discretion to select participants who will receive the awards and to determine the type, size and terms of each award granted. As of December 31, 2005, there were 1,987,500 options outstanding under the 2003 Stock Plan.

#### *2005 Equity Incentive Plan*

On April 26, 2005, the Company's Board of Directors approved the 2005 Equity Incentive Plan (the "2005 Stock Plan"). The 2005 Stock Plan is discretionary and allows for an aggregate of up to 2,100,000 shares of the Company's common stock to be awarded through incentive and non-qualified stock options, stock units, stock awards, stock appreciation rights and other stock-based awards. The 2005 Stock Plan is administered by the Compensation Committee of the Company's Board of Directors, who has exclusive discretion to select participants who will receive the awards and to determine the type, size and terms of each award granted. As of December 31, 2005, there were 195,000 options outstanding and 2,000 outstanding restricted stock awards under the 2005 Stock Plan.

#### *Other Stock Options*

The Company may also issue stock options outside of the aforementioned stock plans. As of December 31, 2005, there were 903,333 such options outstanding.

#### *Stock options Issued for Non-employee Services*

As of December 31, 2005, the Company has outstanding 641,100 stock options issued to non-employees under consulting and distribution agreements. The following sets forth certain information concerning these stock options:

	<u>Vested</u>	<u>Unvested</u>
Stock options outstanding	524,433	116,667
Remaining vesting period	n/a	5 to 12 months
Range of exercise prices	\$1.50 to \$10.49	\$3.50 to \$6.00
Weighted average exercise price	\$5.27	\$4.93
Expiration dates	2006 to 2013	2009 to 2013

Expense (income) related to these contracts was (\$0.2) million, \$1.5 million and \$0.4 million for the years ended December 31, 2005, 2004, 2003, respectively.

The expense was calculated using the Black Scholes option-pricing model based on the following weighted average assumptions for the years ended December 31, 2005, 2004 and 2003:

Expected life (years)	5-10 years
Interest rate	4%
Dividend yield	—
Volatility	83%

*Summary Stock Option and Warrant Information*

Information regarding the options and warrants granted in 2005, 2004 and 2003 is as follows:

	Options			Warrants		
	Year Ended December 31,			Year Ended December 31,		
	2005	2004	2003	2005	2004	2003
Outstanding, beginning of year	7,554,100	5,849,100	4,252,100	748,256	1,445,169	1,533,000
Granted	1,837,100	2,190,000	2,315,000	—	—	349,600
Exercised	(25,000)	(125,000)	(400,600)	(60,000)	(246,913)	(422,431)
Expired or cancelled	(2,453,517)	(360,000)	(317,400)	—	(450,000)	(15,000)
Outstanding, end of year	6,912,683	7,554,100	5,849,100	688,256	748,256	1,445,169
Exercisable, end of year	6,746,016	4,097,156	2,999,100	688,256	748,256	985,794
Available for grant, end of year	2,749,650	431,900	961,900	n/a	n/a	n/a

The weighted average fair value of options granted for the years ended December 31, 2005, 2004 and 2003 was \$2.90, \$5.08 and \$4.21, respectively.

The weighted average option and warrant exercise price information for 2005, 2004 and 2003 is as follows:

	Options			Warrants		
	Year Ended December 31,			Year Ended December 31,		
	2005	2004	2003	2005	2004	2003
Outstanding, beginning of year	\$6.45	\$5.81	\$5.08	\$2.48	\$2.53	\$2.05
Granted during the year	\$4.54	\$8.36	\$5.97	\$ —	\$ —	\$4.02
Exercised during the year	\$6.00	\$2.28	\$1.70	\$1.93	\$2.11	\$1.93
Expired or cancelled during the year	\$7.28	\$9.18	\$2.50	\$ —	\$2.83	\$5.94
Outstanding at end of year	\$5.66	\$6.45	\$5.81	\$2.53	\$2.48	\$2.53
Exercisable at end of year	\$5.67	\$5.65	\$5.81	\$2.53	\$2.48	\$2.35



Significant option groups outstanding and related weighted average exercise price and life information as of December 31, 2005 is as follows:

Range of Exercise Prices	Shares Outstanding as of December 31, 2005				Shares Exercisable as of December 31, 2005	
	Vested Shares	Unvested Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Life (in Years)	Exercisable Shares	Weighted-Average Exercise Price
\$1.22 - \$1.83	123,600	—	\$ 1.51	2.3	123,600	\$ 1.51
\$1.84 - \$2.75	105,000	—	\$ 2.41	4.0	105,000	\$ 2.41
\$2.76 - \$4.12	168,500	50,000	\$ 3.61	2.0	168,500	\$ 3.64
\$4.13 - \$6.20	5,571,433	116,667	\$ 5.47	3.3	5,571,433	\$ 5.46
\$6.21 - \$9.30	484,983	—	\$ 7.80	4.8	484,983	\$ 7.80
\$9.31 - \$11.38	292,500	—	\$10.16	2.3	292,500	\$10.16
	<u>6,746,016</u>	<u>166,667</u>			<u>6,746,016</u>	

Significant warrant groups outstanding and related weighted average exercise price and life information as of December 31, 2005 is as follows:

Grant date	Warrants Outstanding and Exercisable	Weighted-Average Exercise Price	Remaining Life (in Years)
July 2002.	151,015	\$ 1.93	1.5
August 2002	11,580	\$ 1.93	1.58
February 2003.	60,000	\$ 5.94	2.08
April 2003.	357,415	\$ 1.93	1.75
May 2003.	108,246	\$ 3.50	2.33
Total	<u>688,256</u>		

#### Note 10—Certain Relationships and Related Transactions

Certain former officers of the Company, through affiliated companies, previously provided services to the Company. During 2003, these services consisted primarily of the following: (i) office space and laboratory facilities in Houston, Texas, a portion of which was provided at no charge to the Company through August 2003 (beginning in September 2003, the Company began paying a lease rate of approximately \$1.80 per month per square foot), (ii) printing services, and (iii) computer and information technology systems support. As discussed in Note 8, the related party lease was terminated during the first quarter of 2005. Printing services and computer and information technology systems support services are no longer provided by related parties.

At December 31, 2005 and 2004, the Company had accrued in accounts payable \$0 and \$14,833, respectively, for services provided by these related parties. During 2005, 2004 and 2003, the Company incurred total expenses for services provided by these related parties of \$0.1 million, \$0.1 million and \$0.3 million, respectively.

As discussed in Notes 6 and 9, in November 2004 the Company repurchased 2,000,000 shares of its common stock from Frank DeLape, who was then the Chairman of the Board of Directors, Michael Macaluso, a former director and the former President and Chief Executive Officer, Olga Marko, the former Senior Vice President and Director of Research, Michael Avignon, the former Manager of International Operations, and Timothy J. Till, a shareholder. The purchase price from the insiders, affiliates and founders of the Company listed above was \$6.33 per share which represented a 5% discount

from the closing price of the Company's common stock on the American Stock Exchange on October 28, 2004, the date the offering of the 3.5% Subordinated Notes was priced. The purchase of the shares from the insiders was approved by a special committee of independent directors in partial reliance on a fairness opinion issued by an investment bank.

During 2005, the Company incurred research and development consulting costs of less than \$0.1 million payable to Olga Marko, the former Senior Vice President and Director of Research.

#### Note 11—Segment Information

The Company operates its business on the basis of a single reportable segment. The Company markets its products on a global basis. The Company's principal markets are the United States and the United Kingdom. While no commercial operations have commenced in the United States, the United States is presented separately as it is the Company's headquarters.

Geographical information concerning the Company's operations and assets is as follows:

	Revenue		
	Year ended December 31,		
	2005	2004	2003
United States	\$ —	\$ —	\$ —
United Kingdom	7,828,038	3,565,816	399,147
Australia	—	432,441	46,542
Other	925,646	180,990	—
	<u>\$8,753,684</u>	<u>\$4,179,247</u>	<u>\$445,689</u>

  

	Property and Equipment, net	
	As of December 31,	
	2005	2004
United States	\$ 4,602,417	1,824,296
United Kingdom	1,868,592	1,574,077
Switzerland	10,806,163	—
Australia	—	236,619
	<u>\$17,277,172</u>	<u>\$3,634,992</u>

#### Note 12—Summarized Quarterly Financial Data (unaudited)

For the following three-month periods ended	March 31	June 30	September 30	December 31
	<b>2005</b>			
Revenue	\$ 2,666,534	\$ 2,346,513	\$ 1,819,975	\$ 1,920,662
Cost of sales	2,419,672	2,764,931	2,025,006	2,040,006
Operating loss	(6,167,086)	(9,720,209)	(9,095,690)	(9,965,726)
Net loss	(6,431,206)	(9,989,213)	(9,267,067)	(10,090,098)
Net loss per share	\$ (0.21)	\$ (0.33)	\$ (0.31)	\$ (0.33)
<b>2004</b>				
Revenue	\$ 289,357	\$ 544,246	\$ 1,342,804	\$ 2,002,840
Cost of sales	742,440	1,013,991	1,753,172	1,981,405
Operating loss	(4,884,849)	(3,880,835)	(6,637,202)	(6,093,389)
Net loss	(4,866,744)	(3,859,319)	(6,435,414)	(6,312,992)
Net loss per share	\$ (0.18)	\$ (0.14)	\$ (0.19)	\$ (0.20)

AMENDED AND RESTATED EMPLOYMENT AGREEMENT

THIS AMENDED AND RESTATED EMPLOYMENT AGREEMENT (this "Agreement") dated as of March 13, 2006 (the "Effective Date"), is by and between Isolagen, Inc., a Delaware corporation (together with its subsidiaries, the "Company" or "Isolagen"), and Susan Stranahan Ciallella, an individual residing in Kennett Square, Pennsylvania (the "Executive").

WITNESSETH:

WHEREAS, the Executive and the Company are parties to an agreement dated April 26, 2005 providing for Executive to serve as the Company's General Counsel, Executive Vice President and Secretary (the "Original Employment Agreement"); and

WHEREAS, the Company effective October 3, 2005 appointed Executive to serve as its Interim Chief Executive Officer; and

WHEREAS, the Parties desire to conform the desires to amend the Original Employment Agreement to reflect Executive's current responsibilities and to extend the term through June 30, 2009;

NOW THEREFORE in consideration of the mutual benefits to be derived from this Agreement, the Company and the Executive hereby agree as follows:

1. Term of Employment; Office and Duties.

(a) Commencing on the date hereof (the "Employment Date"), and for an initial term ending June 30, 2009, the Company shall employ the Executive as a senior executive of the Company with the title of President and Chief Executive Officer. As President and Chief Executive Officer, Executive shall perform all duties and responsibilities which are consistent with the positions and such additional duties and responsibilities consistent with such positions as may from time to time be assigned to the Executive by the Board of Directors. Executive agrees to perform such duties and discharge such responsibilities in accordance with the terms of this Agreement. This Agreement shall be automatically renewed for an additional one (1) year term unless the Company notifies the Executive one year prior to the expiration of the Agreement of the Company's intention not to renew the Agreement.

(b) The Executive shall devote substantially all of her working time to the business and affairs of the Company other than during vacations of four weeks per year and periods of illness or incapacity; provided, however, that nothing in this Agreement shall preclude the Executive from devoting time required: (i) for serving as a director or officer of any organization or entity not in a competing business with the Company, and any other businesses

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in which the Company becomes involved; (ii) delivering lectures, writing articles or books, or fulfilling speaking engagements; or (iii) engaging in charitable and community activities provided that such activities do not interfere with the performance of her duties hereunder.

(c) The Board of Directors shall nominate Executive for re-election to the Board of Directors as her Board term matures during the Term of this Agreement.

2. Compensation and Benefits.

For all services rendered by the Executive in any capacity during the period of Executive's employment by the Company, including without limitation, services as an executive officer or member of any committee of the Board of Directors or any subsidiary, affiliate or division thereof, from and after the Effective Date, the Executive shall be compensated as follows:

(a) Base Salary. The Company shall pay the Executive a fixed salary ("Base Salary") at a rate of Four Hundred Eighty Thousand Dollars (\$480,000) per year. The Board of Directors may periodically review the Executive's Base Salary and may determine to increase (but not decrease) the Executive's salary, in accordance with such policies as the Company may hereafter adopt from time to time, if it deems appropriate. Base Salary will be payable in accordance with the customary payroll practices of the Company.

(b) Bonus. Executive is entitled to receive an annual bonus (the "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 the Company's 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 mutually agreed upon criteria, established with respect to the ensuing fiscal year, within thirty (30) days of the end of each fiscal year. Criteria for the Annual Bonus for 2005 (prorated) and 2006 (full year) shall be agreed upon prior to or within thirty (30) days after the execution of this Agreement. The Compensation Committee may also consider other more subjective factors in making its determination. The targeted amount of the Annual Bonus shall be 70% of the Executive's base salary. The actual Annual Bonus for any given period may be higher or lower than 70%. For any fiscal year in which Executive is employed for less than the full year, Executive shall receive a bonus which is prorated based on the number of full months in the year which are worked.

(c) Fringe Benefits, Option Grants and Miscellaneous Employment Matters.

(i) The Executive shall be entitled to participate in such disability, health and life insurance and other fringe benefit plans or programs offered to all employees of the Company, as well as to the key executive employees of Company, including a Section 401(k) and retirement plan of the Company as may be established from time to time by the Board of Directors, subject to the rules and regulations applicable thereto. At the Executive's option, in lieu of providing group medical benefits, the Company will reimburse the Executive for health insurance premium payments made pursuant to COBRA by the Executive under her existing group medical coverage (currently \$970 per month). Upon termination of Executive's group coverage under COBRA, she shall have the option of enrolling in the Company's group plan or

converting her prior coverage to an individual policy, at which time the Company would reimburse her for an amount equal to its monthly cost of covering Executive under its plan, and Executive would pay any additional amounts necessary to provide individual coverage. In addition, the Executive shall be entitled to the following benefits:

(ii) Contemporaneous with the execution of the Original Employment Agreement, the Executive was granted a non-qualified stock option (the "Employment Option") to purchase 300,000 shares of the Company's Common Stock, par value \$.001 per share (the "Common Stock") with an exercise price per share equal to the average closing transaction price on the Effective Date of that Agreement, which is the date of the grant. Those options have vested in full. The Company has also granted to Executive 80,000 restricted shares of Common Stock under the 2005 Equity Incentive Plan ("Restricted Stock Grant").

(iii) The vesting of the Restricted Stock Grant shall accelerate and vest immediately upon a change in control of the Company as defined in Rule 405 of the Securities Act of 1933 or upon sale of substantially all of the assets of the Company or the merger, consolidation or reorganization of the Company.

(d) Withholding and Employment Tax. Payment of all compensation hereunder shall be subject to customary withholding tax and other employment taxes as may be required with respect to compensation paid by an employer/corporation to an employee.

(e) Disability. The Company shall provide the Executive with a policy of disability insurance benefits of at least sixty percent (60%) of her gross Base Salary per month. To the extent permitted by the Company's existing disability policy, the Executive's disability policy will be a portable policy. The Executive agrees to pay for any additional premium payments resulting from providing a portable policy (in comparison to a group policy) and further agrees to have the additional premium payments deducted from her pay. In the event of the Executive's Disability (as hereinafter defined), the Executive and her family shall continue to be covered by all of the Company's life, medical, health and dental plans, at the Company's expense, to the extent such benefits can be obtained at a reasonable cost, for the lesser of the term of such Disability (as hereinafter defined) or eighteen (18) months, in accordance with the terms of such plans.

(f) Death. The Company shall provide the Executive with a policy of term life insurance benefits in the amount of at least One Million Dollars (\$1,000,000). To the extent permitted by the Company's existing life insurance policy, the Executive's life insurance policy will be a portable policy. The Executive agrees to pay for any additional premium payments resulting from providing a portable policy (in comparison to a group policy) and further agrees to have the additional premium payments deducted from her pay. In the event of the Executive's death, the Executive's family shall continue to be covered by all of the Company's medical, health and dental plans, at the Company's expense, to the extent such benefits can be obtained at a reasonable cost, for eighteen (18) months following the Executive's death in accordance with the terms of such plans.

(g) Vacation. Executive shall receive four (4) weeks of vacation annually, administered in accordance with the Company's existing vacation policy.

(h) Malpractice Insurance. The Company shall provide malpractice insurance in an amount to be agreed upon by the parties, but in any event a commercially reasonable amount consistent with the Company's insurance practices generally.

3. Business Expenses.

The Company shall pay or reimburse all reasonable travel and entertainment expenses incurred by the Executive in connection with the performance of her duties under this Agreement travel to the Company's various offices and facilities in the United States and abroad, reimbursement for attending out-of-town meetings of the Board of Directors, and such other travel as may be required or appropriate in Executive's discretion, consistent with duly approved Company budgets, to fulfill the responsibilities of her office, all in accordance with such policies and procedures as the Company may from time to time establish for senior officers and as required to preserve any deductions for federal income taxation purposes to which the Company may be entitled and subject to the Company's normal requirements with respect to reporting and documentation of such expenses. The Company shall pay to Executive a non-accountable allowance of one thousand eight hundred dollars (\$1,800) per month for all expenses incurred by the Executive for Executive's automobile (including lease payments, insurance, maintenance, and gasoline) and private club membership(s) and/or dues. The Company shall also pay or reimburse Executive for all membership fees and dues in appropriate professional associations and organizations utilized by Executive in the course of her service for the Company including expenses of bar membership and Continuing Legal Education, all costs of NACD membership and director certification, as well as all expenses incurred by the Executive for Executive's cellular telephone and portable text messaging including monthly service charges, equipment maintenance and all other ancillary charges including, but not limited to, text messaging, paging, and wireless communications.

4. Termination of Employment.

Notwithstanding any other provision of this Agreement, Executive's employment with the Company may be terminated upon written notice to the other party as follows:

(a) By the Company, in the event of the Executive's death or Disability (as hereinafter defined) or for Cause (as hereinafter defined). For purposes of this Agreement, "Cause" shall mean either: (i) the indictment of, or the bringing of formal charges against Executive on charges involving criminal fraud or embezzlement; (ii) the conviction of Executive of a crime involving an act or acts of dishonesty, fraud or moral turpitude by the Executive, which act or acts constitute a felony; (iii) Executive knowingly having caused the Company to violate the Company's Bylaws which results in material adverse consequences to the Company which is not cured or substantially cured to the satisfaction of the Board of Directors of the Company in a reasonable time, which time shall be at least 30 days from receipt of written notice from the Company of such material violation; (iv) Executive having committed acts or omissions constituting gross negligence or willful misconduct with respect to the Company including with respect to any valid contract to which the Company is a party; (v) Executive having committed acts or omissions constituting a breach of Executive's duty of loyalty or fiduciary duty to the Company or any material act of dishonesty or fraud with respect to the Company which are not cured or substantially cured to the satisfaction of the Board of Directors of the Company in a

reasonable time, which time shall be at least 30 days from receipt of written notice from the Company of such material breach; or (vi) Executive having committed acts or omissions constituting a material breach of this Agreement which are not cured or substantially cured to the satisfaction of the Board of Directors of the Company in a reasonable time, which time shall be at least 30 days from receipt of written notice from the Company setting forth with specificity the particulars of any such material breach as well as the corrective actions required. A determination that Cause exists as defined in clauses (iv), (v), or (vi) (as to this Agreement) of the preceding sentence shall be made by at least a majority of the members of the Board of Directors. For purposes of this Agreement, "Disability" shall mean the inability of Executive, in the reasonable judgment of a physician jointly appointed by the Executive and Board of Directors, to perform, even with reasonable accommodation, her duties of employment for the Company or any of its subsidiaries because of any physical or mental disability or incapacity, where such disability shall exist for an aggregate period of more than 120 days in any 365-day period or for any period of 90 consecutive days. The Company shall by written notice to the Executive specify the event relied upon for termination pursuant to this Section 4(a), and Executive's employment hereunder shall be deemed terminated as of the date of such notice. In the event of any termination under this Subsection 4(a), the Company shall pay all amounts then due to the Executive under Section 2(a) of this Agreement for any portion of the payroll period worked but for which payment had not yet been made up to the date of termination, and, if such termination was for Cause, the Company shall have no further obligations to Executive under this Agreement, and any and all options granted hereunder shall terminate according to their terms. In the event of a termination due to Executive's Disability or death, the Company shall comply with its obligations under Sections 2(e) and 2(f).

(b) By the Company, in the absence of Cause, for any reason and in its sole and absolute discretion, provided that in such event the Company shall, as liquidated damages or severance pay, or both, continue to pay to Executive the Base Salary (at a monthly rate equal to the rate in effect immediately prior to such termination) for the remaining term (the "Termination Payments"), when, as and if such payments would have been made in the absence of Executive's termination. The Termination Payments shall be made regardless of Executive's subsequent re-employment as long as any new employment is not in violation of Sections 5 or 6 of this Agreement.

(c) By the Executive for "Good Reason," (as the Executive shall reasonably determine in good faith) which shall be deemed to exist: (i) if the Company's Board of Directors or that of any successor entity of the Company fails to appoint or reappoint the Executive or removes the Executive from the title and/or office of President of the Company or from any successor entity operating the Company without her consent; (ii) if the Company's Board of Directors or that of any successor entity of the Company fails to renominate the Executive to serve on the Board of Directors; (iii) if Executive is assigned any duties materially inconsistent with the duties or responsibilities of the President of the Company as contemplated by this Agreement or any other action by the Company that results in a material diminution in such position, authority, duties, or responsibilities, excluding an isolated, insubstantial, and inadvertent action not taken in bad faith and which is remedied by the Company promptly after receipt of notice thereof given by Executive (but not excluding changes resulting from a sale of the Company, whether by merger, tender offer or otherwise) provided that Executive shall act within 30 days of becoming aware of any such diminution in the scope of her duties,

responsibilities, authority or position; provided that the appointment of a new Chief Executive Officer shall not constitute "Good Reason" under this Agreement; (iv) if the Company shall breach or shall have continued to fail to comply with any material provision of this Agreement after a 30-day period to cure (if such failure is curable) following written notice to the Company of such non-compliance; (v) if the Board of Directors requires Executive without her express written consent to relocate to any area outside a thirty-five (35) mile radius of Kennett Square, Pennsylvania, (vi) upon a change in control of the Company or within twelve (12) months of any such change in control (for these purposes the term "change in control" shall have the meaning set forth in Rule 405 of the Securities Act of 1933), or within twelve (12) months of a sale of substantially all of the assets of the Company or the merger, consolidation or reorganization of the Company. In the event of any termination for "Good Reason" under this Section 4(c), the Company shall, as liquidated damages or severance pay, or both, pay the Termination Payments, as defined in (b) of this Section 4, to Executive, when, as and if such payments would have been made in the absence of Executive's termination.

(d) During any period in which Executive is obligated not to compete with the Company pursuant to Section 5 hereof (unless Executive was terminated for Cause as defined herein), Executive and her family shall continue to be covered by the Company's life, medical, health and death plans. Such coverage shall be at the Company's expense to the same extent as if Executive were still employed by the Company. In the event of a termination pursuant to Sections 4(b) or 4(c), the Company shall provide to Executive the pro-rata share of her annual bonus, to the extent one is awarded by the Compensation Committee the consideration of which shall be taken in good faith, giving a full month's credit for any partial month worked in that bonus year. Additionally, in the event of a termination pursuant to Sections 4(b) or 4(c), the Company shall provide to Executive, at the Company's expense, outplacement services of a nature customarily provided to a senior executive. Notwithstanding the foregoing, the obligations of the Company pursuant to this Section 4(d) shall remain in effect no longer than the term of the Termination Payments.

(e) In the event that any amounts payable and/or any benefits provided to the Executive under the terms of this Agreement and/or under any other plan, agreement or arrangement by which she is to receive payments or benefits in the nature of compensation would constitute "excess parachute payments" as that term is defined for purposes of Section 280G of the Internal Revenue Code of 1986, as amended ("Code") and Treasury Regulations promulgated pursuant thereto, then the amounts payable under the terms of this Agreement and/or under any other plan, agreement or arrangement shall be reduced so that no payments are deemed "excess parachute payments." Any decisions regarding this requirement or implementation of reductions shall be made by tax counsel selected by the Company.

(f) If any payment to Executive under the terms of this Agreement is determined to constitute a payment of nonqualified deferred compensation for purposes of Section 409A of the Code, such payment shall be delayed until the date that is six months after the date of Executive's separation from service with the Company, so as to comply with the special rule for certain "specified employees" set forth in Code Section 409A(a)(2)(B)(i) unless it is determined that immediate distribution is permissible (and does not trigger any additional tax liability pursuant to Code Section 409A(a)(1)) pursuant to Code Section 409A(a)(2)(A)(v) by



reason of being payable in connection with a change in the ownership or effective control of the Company or in the ownership of a substantial position of the assets of the Company.

5. Non-Competition.

During the period of Executive's employment hereunder and during the period, if any, during which payments are required to be made to the Executive by the Company pursuant to Sections 4(b) or 4(c), the Executive shall not, within any state or foreign jurisdiction in which the Company or any subsidiary of the Company is then providing services or products or marketing its services or products (or engaged in active discussions to provide such services), or within a fifty (50) mile radius of any such state, directly or indirectly own any interest in, manage, control, participate in, consult with, render services for, or in any manner engage in any business engaged in by the Company (unless the Board of Directors shall have authorized such activity and the Company shall have consented thereto in writing). The foregoing sentence shall not prevent Executive from practicing in a law firm which represents a client which performs business engaged in by the Company as long as Executive herself provides no legal services, directly or indirectly to the client which performs business engaged in by the Company. The term "business engaged in by the Company" shall mean the development and commercialization of autologous fibroblast system technology for application in, among other therapies, dermatology, surgical and post-traumatic scarring, skin ulcers, cosmetic surgery, periodontal disease, reconstructive dentistry, vocal chord injuries, urinary incontinence, and digestive and gastroenterological disorders and other applications relating to the market for autologous fibroblast or UMC cells and the five derivative cell lines: osteoblast, chondroblast, fibroblast, adipocyte, and neuroectoderm. Investments in less than five percent of the outstanding securities of any class of a corporation subject to the reporting requirements of Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended, shall not be prohibited by this Section 5. At the option of Executive, Executive's obligations under this Section 5 arising after the termination of Executive shall be suspended during any period in which the Company fails to pay to her Termination Payments required to be paid to her pursuant to this Agreement. The provisions of this Section 5 are subject to the provisions of Section 14 of this Agreement.

6. Inventions and Confidential Information.

The parties hereto recognize that a major need of the Company is to preserve its specialized knowledge, trade secrets, and confidential information. The strength and good will of the Company is derived from the specialized knowledge, trade secrets, and confidential information generated from experience with the activities undertaken by the Company and its subsidiaries. The disclosure of this information and knowledge to competitors would be beneficial to them and detrimental to the Company, as would the disclosure of information about the marketing practices, pricing practices, costs, profit margins, design specifications, analytical techniques, and similar items of the Company and its subsidiaries. The Executive acknowledges that the proprietary information, observations and data obtained by her while employed by the Company concerning the business or affairs of the Company are the property of the Company. By reason of her being a senior executive of the Company, the Executive has or will have access to, and has obtained or will obtain, specialized knowledge, trade secrets and confidential information about the Company's operations and the operations of its subsidiaries, which operations extend throughout the United States. For purposes of this Section 6, "Company" shall

mean the Company and each of its controlled subsidiaries. Therefore, subject to the provisions of Section 14 hereof, the Executive hereby agrees as follows, recognizing that the Company is relying on these agreements in entering into this Agreement:

(i) The Executive will not use, disclose to others, or publish or otherwise make available to any other party any inventions or any confidential business information about the affairs of the Company, including but not limited to confidential information concerning the Company's products. "Confidential Information" shall include commercial or trade secrets about Company's products, methods, engineering designs and standards, analytical techniques, technical information, customer information, employee information, or financial and business records, any of which contains proprietary information created or acquired by the Company and which information is held in confidence by Company. Confidential Information does not include information which: (i) becomes generally available to the public, unless said Confidential Information was disclosed in violation of a confidentiality agreement; or (ii) becomes available to Executive on a non-confidential basis from a source other than the Company or its agents, provided that such source is not bound by a confidentiality agreement with the Company.

(ii) During the period of Executive's employment with the Company and for twelve (12) months thereafter, (a) the Executive will not directly or indirectly through another entity induce any employee of the Company to leave the Company's employ (unless the Board of Directors shall have authorized such employment and the Company shall have consented thereto in writing) or in any way interfere with the relationship between the Company and any employee thereof or (b) tortiously interfere with the Company's business relationship with any customer, supplier, licensee, licensor or other business relation of the Company.

7. Indemnification.

The Company will indemnify (and advance the costs of defense of) and hold harmless the Executive (and her legal representatives) to the fullest extent permitted by the laws of the state in which the Company is incorporated, as in effect at the time of the subject act or omission, or by the Certificate of Incorporation and Bylaws of the Company, as in effect at such time or on the date of this Agreement, whichever affords greater protection to the Executive, and the Executive shall be entitled to the protection of any insurance policies the Company may elect to maintain generally for the benefit of its executive officers, against all judgments, damages, liabilities, costs, charges and expenses whatsoever incurred or sustained by her or her legal representative in connection with any action, suit or proceeding to which she (or her legal representatives or other successors) may be made a party by reason of her being or having been an officer of the Company or any of its subsidiaries except that the Company shall have no obligation to indemnify Executive for liabilities resulting from conduct of the Executive with respect to which a court of competent jurisdiction has made a final determination that Executive committed gross negligence or willful misconduct.

8. Litigation Expenses.

In the event of any litigation or other proceeding between the Company and the Executive with respect to the subject matter of this Agreement and the enforcement of the rights

hereunder, the losing party shall reimburse the prevailing party for all of her/its reasonable costs and expenses relating to such litigation or other proceeding, including, without limitation, her/its reasonable attorneys' fees and expenses.

9. Consolidation; Merger; Sale of Assets; Change of Control.

Nothing in this Agreement shall preclude the Company from combining, consolidating or merging with or into, transferring all or substantially all of its assets to, or entering into a partnership or joint venture with, another corporation or other entity, or effecting any other kind of corporate combination provided that the corporation resulting from or surviving such combination, consolidation or merger, or to which such assets are transferred, or such partnership or joint venture assumes this Agreement and all obligations and undertakings of the Company hereunder. Upon such a consolidation, merger, transfer of assets or formation of such partnership or joint venture, this Agreement shall inure to the benefit of, be assumed by, and be binding upon such resulting or surviving transferee corporation or such partnership or joint venture, and the term "Company," as used in this Agreement, shall mean such corporation, partnership or joint venture or other entity, and this Agreement shall continue in full force and effect and shall entitle the Executive and her heirs, beneficiaries and representatives to exactly the same compensation, benefits, perquisites, payments and other rights as would have been their entitlement had such combination, consolidation, merger, transfer of assets or formation of such partnership or joint venture not occurred.

10. Survival of Obligations.

Sections 4, 5, 6, 7, 8, 9, 10, 11, 12 and 14 shall survive the termination for any reason of this Agreement (whether such termination is by the Company, by the Executive, upon the expiration of this Agreement or otherwise).

11. Executive's Representations.

The Executive hereby represents and warrants to the Company that to the best of her knowledge: (i) the execution, delivery and performance of this Agreement by the Executive do not and shall not conflict with, breach, violate or cause a default under any contract, agreement, instrument, order, judgment or decree to which the Executive is a party or by which she is bound, (ii) the Executive is not a party to or bound by any employment agreement, non-compete agreement or confidentiality agreement with any other person or entity and (iii) upon the execution and delivery of this Agreement by the Company, this Agreement shall be the valid and binding obligation of the Executive, enforceable in accordance with its terms. The Executive hereby acknowledges and represents that she has consulted with legal counsel regarding her rights and obligations under this Agreement and that she fully understands the terms and conditions contained herein.

12. Company's Representations.

The Company hereby represents and warrants to the Executive that (i) the execution, delivery and performance of this Agreement by the Company do not and shall not conflict with,

breach, violate or cause a default under any contract, agreement, instrument, order, judgment or decree to which the Company is a party or by which it is bound; (ii) upon the execution and delivery of this Agreement by the Executive, this Agreement shall be the valid and binding obligation of the Company, enforceable in accordance with its terms; and (iii) the Company's representations made by the Board of Directors and members of senior management prior to the execution of this Agreement regarding the science, business or fiscal propriety of the Company are accurate in all material respects

13. Enforcement.

Because the Executive's services are unique and because the Executive has access to confidential information concerning the Company, the parties hereto agree that money damages would not be an adequate remedy for any breach of this Agreement. Therefore, in the event of a material breach of this Agreement, the Company may, in addition to other rights and remedies existing in its favor, apply to any court of competent jurisdiction for specific performance and/or injunctive or other relief in order to enforce, or prevent any violations of, the provisions hereof (without posting a bond or other security).

14. Severability.

In case any one or more of the provisions or part of a provision contained in this Agreement shall for any reason be held to be invalid, illegal or unenforceable in any respect in any jurisdiction, such invalidity, illegality or unenforceability shall be deemed not to affect any other jurisdiction or any other provision or part of a provision of this Agreement, nor shall such invalidity, illegality or unenforceability affect the validity, legality or enforceability of this Agreement or any provision or provisions hereof in any other jurisdiction; and this Agreement shall be reformed and construed in such jurisdiction as if such provision or part of a provision held to be invalid or illegal or unenforceable had never been contained herein and such provision or part reformed so that it would be valid, legal and enforceable in such jurisdiction to the maximum extent possible. In furtherance and not in limitation of the foregoing, the Company and the Executive each intend that the covenants contained in Sections 5 and 6 shall be deemed to be a series of separate covenants, one for each and every state of the United States and any foreign country set forth therein. If, in any judicial proceeding, a court shall refuse to enforce any of such separate covenants, then such unenforceable covenants shall be deemed eliminated from the provisions hereof for the purpose of such proceedings to the extent necessary to permit the remaining separate covenants to be enforced in such proceedings. If, in any judicial proceeding, a court shall refuse to enforce any one or more of such separate covenants because the total time, scope or area thereof is deemed to be excessive or unreasonable, then it is the intent of the parties hereto that such covenants, which would otherwise be unenforceable due to such excessive or unreasonable period of time, scope or area, be enforced for such lesser period of time, scope or area as shall be deemed reasonable and not excessive by such court.

15. Entire Agreement: Amendment.

Except as otherwise set forth in this Agreement, this Agreement contains the entire agreement between the Company and the Executive with respect to the subject matter hereof and thereof. This Agreement may not be amended, waived, changed, modified or discharged except

by an instrument in writing executed by or on behalf of the party against whom enforcement of any amendment, waiver, change, modification or discharge is sought. No course of conduct or dealing shall be construed to modify, amend or otherwise affect any of the provisions hereof.

16. Notices.

All notices, requests, demands and other communications hereunder shall be in writing and shall be deemed to have been duly given if physically delivered, delivered by express mail or other expedited service or upon receipt if mailed, postage prepaid, via registered mail, return receipt requested, addressed as follows:

(a) To the Company:

Isolagen  
405 Eagleview Blvd.  
Exton, PA 19341

(b) To the Executive:

Susan Stranahan Ciallella  
107 Stonepine Drive  
Kennett Square, PA 19348

and/or to such other persons and addresses as any party shall have specified in writing to the other.

17. Assignability.

This Agreement shall not be assignable by either party and shall be binding upon, and shall inure to the benefit of, the heirs, executors, administrators, legal representatives, successors and assigns of the parties. In the event that all or substantially all of the business of the Company is sold or transferred, then this Agreement shall be binding on the transferee of the business of the Company whether or not this Agreement is expressly assigned to the transferee.

18. Governing Law.

This Agreement shall be governed by and construed under the laws of the Commonwealth of Pennsylvania.

19. Waiver and Further Agreement.

Any waiver of any breach of any terms or conditions of this Agreement shall not operate as a waiver of any other breach of such terms or conditions or any other term or condition, nor shall any failure to enforce any provision hereof operate as a waiver of such provision or of any other provision hereof. Each of the parties hereto agrees to execute all such further instruments and documents and to take all such further action as the other party may reasonably require in order to effectuate the terms and purposes of this Agreement.

20. Headings of No Effect.

The paragraph headings contained in this Agreement are for reference purposes only and shall not in any way affect the meaning or interpretation of this Agreement.

IN WITNESS WHEREOF, the parties hereto have executed this Employment Agreement as of the date first above written.

COMPANY:

ISOLAGEN, INC.

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By Ralph V. De Martino,  
Chairman of the Compensation Committee

EXECUTIVE:

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Susan Stranahan Ciallella

EMPLOYMENT AGREEMENT

THIS EXECUTIVE EMPLOYMENT AGREEMENT (this "Agreement") dated as of March 13, 2006, is by and between Isolagen, Inc., a Delaware corporation (together with its subsidiaries, the "Company" or "Isolagen"), and Todd J. Greenspan, an individual residing in Hockessin, Delaware (the "Executive").

WITNESSETH:

WHEREAS, the Executive desires to serve the Company as its Vice President, Finance and Corporate Controller; and

WHEREAS, the Company desires to employ Executive as its Vice President, Finance and Corporate Controller;

NOW THEREFORE in consideration of the mutual benefits to be derived from this Agreement, the Company and the Executive hereby agree as follows:

1. Term of Employment; Office and Duties.

(a) Commencing on the date hereof (the "Employment Date"), and for an initial term ending December 31, 2008 the Company shall employ the Executive as an executive of the Company with the title of Vice President, Finance and Corporate Controller, with the duties and responsibilities prescribed for such offices in the Bylaws of the Company and such additional duties and responsibilities consistent with such positions as may from time to time be assigned to the Executive by the Board of Directors. Specifically included in the Executive's responsibilities shall be the identification, recruitment and retention of the members of the finance and accounting team of the Company, with the advice and consent of the Board of Directors. Executive agrees to perform such duties and discharge such responsibilities in accordance with the terms of this Agreement. This Agreement shall be renewed for an additional one (1) year term, by the mutual written agreement of the Executive and the Company at least thirty (30) days prior to its expiration.

(b) The Executive shall devote substantially all of his working time to the business and affairs of the Company other than during vacations of four weeks per year and periods of illness or incapacity; provided, however, that nothing in this Agreement shall preclude the Executive from devoting time required: (i) delivering lectures or fulfilling speaking engagements; or (ii) engaging in charitable and community activities provided that such activities do not interfere with the performance of his duties hereunder.

2. Compensation and Benefits.

For all services rendered by the Executive in any capacity during the period of Executive's employment by the Company, including without limitation, services as an

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executive officer or member of any committee of the Board of Directors or any subsidiary, affiliate or division thereof, from and after the Effective Date, the Executive shall be compensated as follows:

(a) Base Salary. The Company shall pay the Executive a fixed salary ("Base Salary") at a rate of One Hundred Eighty Thousand Dollars (\$180,000) per year. The Board of Directors may periodically review the Executive's Base Salary and may determine to increase (but not decrease) the Executive's salary, in accordance with such policies as the Company may hereafter adopt from time to time, if it deems appropriate. Base Salary will be payable in accordance with the customary payroll practices of the Company.

(b) Executive will also be entitled to receive an annual bonus ("the "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 the Company's most recently completed fiscal year based upon a 35% target bonus, with the targets for any given fiscal year being established by the chief executive officer and agreed to by the Compensation Committee. The final determination on the amount of the Annual Bonus will be made by the Compensation Committee of the Board of Directors, within ninety (90) days of the end of each fiscal year. The Compensation Committee may also consider other more subjective factors in making its determination.

(c) Fringe Benefits, Option Grants and Miscellaneous Employment Matters.

(i) The Executive shall be entitled to participate in such disability, health and life insurance and other fringe benefit plans or programs, including a Section 401(k) retirement plan, of the Company established from time to time by the Board of Directors, if any, to the extent that his position, tenure, salary, age, health and other qualifications make him eligible to participate, subject to the rules and regulations applicable thereto. In addition, the Executive shall be entitled to the following benefits:

(ii) The Executive shall be eligible for grants of restricted stock and stock options in the discretion of the Compensation Committee or the Board as appropriate. The Executive previously has received stock options and restricted stock grants, including a recent grant of 15,000 shares of restricted stock subject to the vesting provisions set forth in the grant.

(d) Withholding and Employment Tax. Payment of all compensation hereunder shall be subject to customary withholding tax and other employment taxes as may be required with respect to compensation paid by an employer/corporation to an employee.

(e) Disability. The Company shall, to the extent such benefits can be obtained at a reasonable cost, provide the Executive with disability insurance benefits.

(f) Death. The Company shall, to the extent such benefits can be obtained at a reasonable cost, provide the Executive with life insurance benefits.



(g) Vacation. Executive shall receive four (4) weeks of vacation annually, administered in accordance with the Company's existing vacation policy.

3. Business Expenses.

The Company shall pay or reimburse all reasonable travel and entertainment expenses incurred by the Executive in connection with the performance of his duties under this Agreement, including travel between Executive's current domicile in the Hockessin, Delaware metropolitan area, travel to the Company's various offices (other than his primary assigned office in Exton, PA) and facilities in the United States and abroad, reimbursement for attending out-of-town meetings of the Board of Directors, and such other travel as may be required or appropriate to fulfill the responsibilities of his office, all in accordance with such policies and procedures as the Company may from time to time establish for senior officers and as required to preserve any deductions for federal income taxation purposes to which the Company may be entitled and subject to the Company's normal requirements with respect to reporting and documentation of such expenses. The Company shall pay to Executive a non-accountable automobile allowance of four hundred (\$400) dollars per month for all expenses incurred by the Executive for Executive's automobile (including lease payments, insurance, maintenance, and gasoline). The Company shall also pay or reimburse Executive for reasonable membership fees and dues in appropriate professional associations and organizations utilized by Executive in the course of his service for the Company including reasonable expenses of Continuing Education Courses to satisfy requirement of his State Society CPE requirements..

4. Termination of Employment.

Notwithstanding any other provision of this Agreement, Executive's employment with the Company may be terminated upon written notice to the other party as follows:

(a) By the Company, in the event of the Executive's death or Disability (as hereinafter defined) or for Cause (as hereinafter defined). For purposes of this Agreement, "Cause" shall mean either: (i) the indictment of, or the bringing of formal charges against, Executive by a governmental authority of competent jurisdiction for charges involving criminal fraud or embezzlement; (ii) the conviction of Executive of a crime involving an act or acts of dishonesty, fraud or moral turpitude by the Executive, which act or acts constitute a felony; (iii) Executive having willfully caused the Company, without the approval of the Board of Directors, to fail to abide by either a valid contract to which the Company is a party or the Company's Bylaws or; (iv) Executive having committed acts or omissions constituting gross negligence or willful misconduct with respect to the Company; (v) Executive having committed acts or omissions constituting a material breach of Executive's duty of loyalty or fiduciary duty to the Company or any material act of dishonesty or fraud with respect to the Company which are not cured in a reasonable time, which time shall be 30 days from receipt of written notice from the Company of such material breach; or (vi) Executive having committed acts or omissions constituting a material breach of this Agreement, including any failure of the Executive to follow a directive from the Board of Directors and/or its Audit

Committee, which are not cured in a reasonable time, which time shall be 30 days from receipt of written notice from the Company of such material breach (vii) Executive having failed to meet agreed upon minimum performance criteria. A determination that Cause exists as defined in clauses (iv), (v), (vi) or (vii) (as to this Agreement) of the preceding sentence shall be made in good faith and by at least a majority of the members of the Board of Directors. For purposes of this Agreement, "Disability" shall mean the inability of Executive, in the reasonable judgment of a physician appointed by the Board of Directors, to perform his duties of employment for the Company or any of its subsidiaries because of any physical or mental disability or incapacity, where such disability shall exist for an aggregate period of more than 120 days in any 365-day period or for any period of 90 consecutive days. The Company shall by written notice to the Executive specify the event relied upon for termination pursuant to this Section 4(a), and Executive's employment hereunder shall be deemed terminated as of the date of such notice. In the event of any termination under this Subsection 4(a), the Company shall pay all amounts then due to the Executive under Section 2(a) of this Agreement for any portion of the payroll period worked but for which payment had not yet been made up to the date of termination, and, if such termination was for Cause, the Company shall have no further obligations to Executive under this Agreement, and any and all options granted hereunder shall terminate according to their terms. In the event of a termination due to Executive's Disability or death, the Company shall comply with its obligations under Sections 2(e) and 2(f).

(b) By the Company, in the absence of Cause, for any reason and in its sole and absolute discretion, provided that in such event the Company shall, as liquidated damages or severance pay, or both, continue to pay to Executive the Base Salary (at a monthly rate equal to the rate in effect immediately prior to such termination) for the lesser of the remaining term as defined above or twelve months from the date of termination (the "Termination Payments"), when, as and if such payments would have been made in the absence of Executive's termination subject to the following limitation: if the Executive becomes employed following termination, all Termination Payments shall cease except that Executive shall receive at least six months of Termination Payments notwithstanding reemployment. Executive shall be obliged to make best efforts to attempt to mitigate the amount of Termination Payments due hereunder.

5. Non-Competition.

During the period of Executive's employment hereunder and during the period, if any, during which payments are required to be made to the Executive by the Company pursuant to Sections 4(b) or 4(c), the Executive shall not, within any state or foreign jurisdiction in which the Company or any subsidiary of the Company is then providing services or products or marketing its services or products (or engaged in active discussions to provide such services), or within a one hundred (100) mile radius of any such state, directly or indirectly own any interest in, manage, control, participate in, consult with, render services for, or in any manner engage in any business engaged in by the Company (unless the Board of Directors shall have authorized such activity and the Company shall have consented thereto in writing). The term "business engaged in by the Company" shall mean the development and

commercialization of autologous fibroblast system technology for application in, among other therapies, dermatology, surgical and post-traumatic scarring, skin ulcers, cosmetic surgery, periodontal disease, reconstructive dentistry, vocal chord injuries, urinary incontinence, and digestive and gastroenterological disorders and other applications relating to the market for autologous fibroblast or UMC cells and the five derivative cell lines: osteoblast, chondroblast, fibroblast, adipocyte, and neuroectoderm. Investments of less than five percent of the outstanding securities of any class of a corporation subject to the reporting requirements of Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended, shall not be prohibited by this Section 5. At the option of Executive and so long as Executive shall have executed the mutual release required under Section 4(d), Executive's obligations under this Section 5 arising after the termination of Executive shall be suspended during any period in which the Company fails to pay to him Termination Payments required to be paid to him pursuant to this Agreement. The provisions of this Section 5 are subject to the provisions of Section 14 of this Agreement.

6. Inventions and Confidential Information.

The parties hereto recognize that a major need of the Company is to preserve its specialized knowledge, trade secrets, and confidential information. The strength and good will of the Company is derived from the specialized knowledge, trade secrets, and confidential information generated from experience with the activities undertaken by the Company and its subsidiaries. The disclosure of this information and knowledge to competitors would be beneficial to them and detrimental to the Company, as would the disclosure of information about the marketing practices, pricing practices, costs, profit margins, design specifications, analytical techniques, and similar items of the Company and its subsidiaries. The Executive acknowledges that the proprietary information, observations and data obtained by him while employed by the Company concerning the business or affairs of the Company are the property of the Company. By reason of his being a senior executive of the Company, the Executive has or will have access to, and has obtained or will obtain, specialized knowledge, trade secrets and confidential information about the Company's operations and the operations of its subsidiaries, which operations extend throughout the United States. [For purposes of this Section 6, "Company" shall mean to Company and each of its controlled subsidiaries.] Therefore, subject to the provisions of Section 14 hereof, the Executive hereby agrees as follows, recognizing that the Company is relying on these agreements in entering into this Agreement:

(i) The Executive will not use, disclose to others, or publish or otherwise make available to any other party any inventions or any confidential business information about the affairs of the Company, including but not limited to confidential information concerning the Company's products, methods, engineering designs and standards, analytical techniques, technical information, customer information, employee information, and other confidential information acquired by him in the course of his past or future services for the Company. Executive agrees to hold as the Company's property all books, papers, letters, formulas, memoranda, notes, plans, records, reports, computer tapes, printouts, software and other documents, and all copies thereof and therefrom, in any way relating to the Company's

business and affairs, whether made by him or otherwise coming into his possession, and on termination of his employment, or on demand of the Company, at any time, to deliver the same to the Company within twenty four (24) hours of such termination or demand.

(ii) During the period of Executive's employment with the Company and for twenty-four (24) months thereafter, (a) the Executive will not directly or indirectly through another entity induce or otherwise attempt to influence any employee of the Company to leave the Company's employ and (b) the Executive will not directly or indirectly hire or cause to be hired or induce a third party to hire, any such employee (unless the Board of Directors shall have authorized such employment and the Company shall have consented thereto in writing) or in any way interfere with the relationship between the Company and any employee thereof and (c) induce or attempt to induce any customer, supplier, licensee, licensor or other business relation of the Company to cease doing business with the Company or in any way interfere with the relationship between any such customer, supplier, licensee or business relation of the Company.

7. Indemnification.

The Company will indemnify (and advance the costs of defense of) the Executive (and his legal representatives) to the extent required by the laws of the state in which the Company is incorporated, as in effect at the time of the subject act or omission, or by the Certificate of Incorporation and Bylaws of the Company, as in effect at such time or on the date of this Agreement, whichever affords greater protection to the Executive, and the Executive shall be entitled to the protection of any insurance policies the Company may elect to maintain generally for the benefit of its executive officers, against all judgments, damages, liabilities, costs, charges and expenses whatsoever incurred or sustained by him or his legal representative in connection with any action, suit or proceeding to which he (or his legal representatives or other successors) may be made a party by reason of his being or having been an officer of the Company or any of its subsidiaries except that the Company shall have no obligation to indemnify Executive for liabilities resulting from conduct of the Executive with respect to which a court of competent jurisdiction has made a final determination that Executive committed gross negligence or willful misconduct.

8. Litigation Expenses.

In the event of any litigation or other proceeding between the Company and the Executive with respect to the subject matter of this Agreement and the enforcement of the rights hereunder and such litigation or proceeding results in final judgment or order in favor of the Executive, which judgment or order is substantially inconsistent with the positions asserted by the Company in such litigation or proceeding, the Company shall reimburse the prevailing party for all of his/its reasonable costs and expenses relating to such litigation or other proceeding, including, without limitation, his/its reasonable attorneys' fees and expenses.

9. Consolidation; Merger; Sale of Assets; Change of Control.

Nothing in this Agreement shall preclude the Company from combining, consolidating or merging with or into, transferring all or substantially all of its assets to, or entering into a partnership or joint venture with, another corporation or other entity, or effecting any other kind of corporate combination provided that the corporation resulting from or surviving such combination, consolidation or merger, or to which such assets are transferred, or such partnership or joint venture assumes this Agreement and all obligations and undertakings of the Company hereunder. Upon such a consolidation, merger, transfer of assets or formation of such partnership or joint venture, this Agreement shall inure to the benefit of, be assumed by, and be binding upon such resulting or surviving transferee corporation or such partnership or joint venture, and the term "Company," as used in this Agreement, shall mean such corporation, partnership or joint venture or other entity, and this Agreement shall continue in full force and effect and shall entitle the Executive and his heirs, beneficiaries and representatives to exactly the same compensation, benefits, perquisites, payments and other rights as would have been their entitlement had such combination, consolidation, merger, transfer of assets or formation of such partnership or joint venture not occurred.

10. Survival of Obligations.

Sections 4, 5, 6, 7, 8, 9, 10, 11, 12 and 14 shall survive the termination for any reason of this Agreement (whether such termination is by the Company, by the Executive, upon the expiration of this Agreement or otherwise).

11. Executive's Representations.

The Executive hereby represents and warrants to the Company that (i) the execution, delivery and performance of this Agreement by the Executive do not and shall not conflict with, breach, violate or cause a default under any contract, agreement, instrument, order, judgment or decree to which the Executive is a party or by which he is bound, (ii) the Executive is not a party to or bound by any employment agreement, non-compete agreement or confidentiality agreement with any other person or entity and (iii) upon the execution and delivery of this Agreement by the Company, this Agreement shall be the valid and binding obligation of the Executive, enforceable in accordance with its terms. The Executive hereby acknowledges and represents that he has consulted with legal counsel regarding his rights and obligations under this Agreement and that he fully understands the terms and conditions contained herein.

12. Company's Representations.

The Company hereby represents and warrants to the Executive that (i) the execution, delivery and performance of this Agreement by the Company do not and shall not conflict with, breach, violate or cause a default under any contract, agreement, instrument, order, judgment or decree to which the Company is a party or by which it is bound and (ii) upon the

execution and delivery of this Agreement by the Executive, this Agreement shall be the valid and binding obligation of the Company, enforceable in accordance with its terms.

13. Enforcement.

Because the Executive's services are unique and because the Executive has access to confidential information concerning the Company, the parties hereto agree that money damages would not be an adequate remedy for any breach of this Agreement. Therefore, in the event of a breach or threatened breach of this Agreement, the Company may, in addition to other rights and remedies existing in its favor, apply to any court of competent jurisdiction for specific performance and/or injunctive or other relief in order to enforce, or prevent any violations of, the provisions hereof (without posting a bond or other security).

14. Severability.

In case any one or more of the provisions or part of a provision contained in this Agreement shall for any reason be held to be invalid, illegal or unenforceable in any respect in any jurisdiction, such invalidity, illegality or unenforceability shall be deemed not to affect any other jurisdiction or any other provision or part of a provision of this Agreement, nor shall such invalidity, illegality or unenforceability affect the validity, legality or enforceability of this Agreement or any provision or provisions hereof in any other jurisdiction; and this Agreement shall be reformed and construed in such jurisdiction as if such provision or part of a provision held to be invalid or illegal or unenforceable had never been contained herein and such provision or part reformed so that it would be valid, legal and enforceable in such jurisdiction to the maximum extent possible. In furtherance and not in limitation of the foregoing, the Company and the Executive each intend that the covenants contained in Sections 5 and 6 shall be deemed to be a series of separate covenants, one for each county of the State of Texas and one for each and every other state, territory or jurisdiction of the United States and any foreign country set forth therein. If, in any judicial proceeding, a court shall refuse to enforce any of such separate covenants, then such unenforceable covenants shall be deemed eliminated from the provisions hereof for the purpose of such proceedings to the extent necessary to permit the remaining separate covenants to be enforced in such proceedings. If, in any judicial proceeding, a court shall refuse to enforce any one or more of such separate covenants because the total time, scope or area thereof is deemed to be excessive or unreasonable, then it is the intent of the parties hereto that such covenants, which would otherwise be unenforceable due to such excessive or unreasonable period of time, scope or area, be enforced for such lesser period of time, scope or area as shall be deemed reasonable and not excessive by such court.

15. Entire Agreement; Amendment.

Except as otherwise set forth in this Agreement, this Agreement contains the entire agreement between the Company and the Executive with respect to the subject matter hereof and thereof. This Agreement may not be amended, waived, changed, modified or discharged except by an instrument in writing executed by or on behalf of the party against whom enforcement of any amendment, waiver, change, modification or discharge is sought. No course of conduct or dealing shall be construed to modify, amend or otherwise affect any of the provisions hereof.

16. Notices.

All notices, requests, demands and other communications hereunder shall be in writing and shall be deemed to have been duly given if physically delivered, delivered by express mail or other expedited service or upon receipt if mailed, postage prepaid, via registered mail, return receipt requested, addressed as follows:

(a) To the Company:

Isolagen, Inc.  
405 Eagleview Blvd.  
Exton, PA 19341  
Attention: Susan S. Ciallella

(b) To the Executive:

Todd J. Greenspan  
405 Willowbend Court  
Hockessin, DE 19707

with copy by like means to :

Cozen O'Connor  
1900 Market Street  
Philadelphia, PA 19103  
Attn: Cavas Pavri, Esq.

and/or to such other persons and addresses as any party shall have specified in writing to the other.

17. Assignability.

This Agreement shall not be assignable by either party and shall be binding upon, and shall inure to the benefit of, the heirs, executors, administrators, legal representatives, successors and assigns of the parties. In the event that all or substantially all of the business of the Company is sold or transferred, then this Agreement shall be binding on the transferee of the business of the Company whether or not this Agreement is expressly assigned to the transferee.

18. Governing Law.

This Agreement shall be governed by and construed under the laws of the Commonwealth of Pennsylvania.

19. Waiver and Further Agreement.

Any waiver of any breach of any terms or conditions of this Agreement shall not operate as a waiver of any other breach of such terms or conditions or any other term or condition, nor shall any failure to enforce any provision hereof operate as a waiver of such provision or of any other provision hereof. Each of the parties hereto agrees to execute all such further instruments and documents and to take all such further action as the other party may reasonably require in order to effectuate the terms and purposes of this Agreement.

20. Headings of No Effect.

The paragraph headings contained in this Agreement are for reference purposes only and shall not in any way affect the meaning or interpretation of this Agreement.

IN WITNESS WHEREOF, the parties hereto have executed this Employment Agreement as of the date first above written.

**COMPANY:**

ISOLAGEN, INC.

By: \_\_\_\_\_  
Susan S. Ciallella, President

**EXECUTIVE :**

\_\_\_\_\_  
Todd J. Greenspan



**Consent of Independent Registered Public Accounting Firm**

Isolagen, Inc.  
Exton, Pennsylvania

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-108769 and No. 333-122440), Form S-3/A (No. 333-122440) and Form S-8 (No. 333-108219 and No. 333-131803) of Isolagen, Inc. of our report dated February 17, 2004 relating to the consolidated financial statements which appears in this Form 10-K.

/s/ Pannell Kerr Forster of Texas, P.C.

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Pannell Kerr Forster of Texas, P.C.  
Houston, Texas

March 10, 2006

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**Consent of Independent Registered Public Accounting Firm**

Isolagen, Inc.  
Exton, Pennsylvania

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-108769 and No. 333-122440) and Form S-8 (No. 333-108219 and No. 333-131803) of Isolagen, Inc. of our reports dated March 10, 2006, relating to the consolidated financial statements and the effectiveness of Isolagen, Inc.'s internal control over financial reporting, which appears in this Annual Report on Form 10-K.

/s/BDO Seidman, LLP  
BDO Seidman, LLP  
Houston, Texas

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March 10, 2006

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## CERTIFICATION

I, Susan Stranahan Ciallella, Interim Chief Executive Officer of Isolagen, Inc., certify that:

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

Dated: March 14, 2006

By: /s/ Susan Stranahan Ciallella  
Susan Stranahan Ciallella  
Chief Executive Officer  
Isolagen, Inc.

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## CERTIFICATION

I, Martin E. Schmiege, Chief Financial Officer of Isolagen, Inc., certify that:

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

Dated: March 14, 2006

By: /s/ Martin E. Schmiege  
Martin E. Schmiege  
Chief Financial Officer  
Isolagen, Inc.

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

For purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned, Susan Stranahan Ciallella, the President and Chief Executive Officer of Isolagen, Inc. (the "Company"), hereby certifies that:

- i. the Annual Report on Form 10-K of the Company for the year ended December 31, 2005, as filed with the Securities and Exchange Commission on the date hereof (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Commission Act of 1934; and
- ii. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 14, 2006

By:           /s/ Susan Stranahan Ciallella            
Susan Stranahan Ciallella  
Chief Executive Officer  
Isolagen, Inc.

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