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

FORM 10-K

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

For the fiscal year ended December 31, 2008

OR

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

Isolagen, Inc.

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

Delaware
(State or other jurisdiction
of incorporation)

001-31564
(Commission File Number)

87-0458888
(I.R.S. Employer
Identification No.)

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

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

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

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

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 or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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, 2008, 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 \$12,392,273.

As of April 9, 2009, issuer had 41,887,266 shares issued and 37,887,266 shares outstanding of common stock, par value \$0.001.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the 2008 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed within 120 days of the end of the fiscal year ended December 31, 2008, are incorporated by reference in Part III hereof. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part hereof.

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Part I

This Annual Report on Form 10-K (including the section regarding Management's Discussion and Analysis of Financial Condition and Results of Operations) contains certain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, as well as information relating to Isolagen, Inc. and its subsidiaries (referred to as "Isolagen," "Company," "we," or "our") that is based on management's exercise of business judgment and assumptions made by and information currently available to management. Although forward-looking statements in this Annual Report on Form 10-K reflect the good faith judgment of our management, such statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in or anticipated by the forward-looking statements. When used in this document and other documents, releases and reports released by us, the words "anticipate," "believe," "estimate," "expect," "intend," "the facts suggest" and words of similar import, are intended to identify any forward-looking statements. You should not place undue reliance on these forward-looking statements. These statements reflect our current view of future events and are subject to certain risks and uncertainties as noted below. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, our actual results could differ materially from those anticipated in these forward-looking statements. Actual events, transactions and results may materially differ from the anticipated events, transactions or results described in such statements. Although we believe that our expectations are based on reasonable assumptions, we can give no assurance that our expectations will materialize. Many factors could cause actual results to differ materially from our forward looking statements including those set forth in Item 1A of this report. Other unknown, unidentified or unpredictable factors could materially and adversely impact our future results. We undertake no obligation and do not intend to update, revise or otherwise publicly release any revisions to our forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of any unanticipated events.

We file reports with the Securities and Exchange Commission ("SEC" or "Commission"). We make available on our website (www.Isolagen.com) free of charge our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports as soon as reasonably practicable after we electronically file such materials with or furnish them to the SEC. Information appearing at our website is not a part of this Annual Report on Form 10-K. You can also read and copy any materials we file with the Commission at its Public Reference Room at 100 F Street, NE, Washington, DC 20549. You can obtain additional information about the operation of the Public Reference Room by calling the Commission at 1-800-SEC-0330. In addition, the Commission maintains an Internet site (www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the Commission, including Isolagen.

Our corporate headquarters is located at 405 Eagleview Boulevard, Exton, Pennsylvania 19341. Our phone number is (484) 713-6000. Our fiscal year begins on January 1, and ends on December 31, and any references herein to "Fiscal 2008" mean the year ended December 31, 2008, and references to other "Fiscal" years mean the year ending December 31, of the year indicated.

We own or have rights to various copyrights, trademarks and trade names used in our business including but not limited to the following: Isolagen, Isolagen Therapy, Isolagen Process, Agera and Agera Rx. This report also includes other trademarks, service marks and trade names of other companies. Other trademarks and trade names appearing in this report are the property of the holder of such trademarks and trade names.

We obtained statistical data, market data and other industry data and forecasts used in this Form 10-K from publicly available information. While we believe that the statistical data, industry data, forecasts and market research are reliable, we have not independently verified the data, and we do not make any representation as to the accuracy of that information.

Item 1. Business

Overview

We are an aesthetic and therapeutic development stage company focused on developing novel skin and tissue rejuvenation products. Our clinical development product candidates are designed to improve the appearance of skin injured by the effects of aging, sun exposure, acne and burn scars with a patient's own, or autologous, fibroblast cells produced by our proprietary Isolagen Process. Our clinical development programs encompass both aesthetic and therapeutic indications. Our most advanced indication utilizing the Isolagen Therapy is for the treatment of nasolabial folds/wrinkles and has recently completed Phase III clinical studies, and the related Biologics License Application ("BLA") has been submitted to the Food and Drug Administration ("FDA"). During 2009 we completed one of two Phase II/III studies for the treatment of acne scars. During 2008 we completed our open-label Phase II study related to full face rejuvenation.

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

Going Concern and Risk of Bankruptcy

At December 31, 2008, we had cash and cash equivalents of \$2.9 million and negative working capital of \$(87.3) million. We believe that our existing capital resources are adequate to sustain our operation through approximately the end of April 2009, under our current, reduced operating plan. As such, we require additional cash resources prior to or during approximately the end of April 2009, or we will likely enter into bankruptcy and/or cease operations. Further, if we do raise additional cash resources prior to the end of April 2009, it may be raised in contemplation of or in connection with bankruptcy. In the event of a bankruptcy, it is likely that our common stock and common stock equivalents will become worthless and our creditors will receive significantly less than what is owed to them. As of the date of the filing of this annual report, we have no commitments for any such additional funding and there is no assurance that we will receive any such additional funding.

As of December 31, 2008, we had \$90 million of debt which could be called due as early as November 2009, at the option of the bond holders. Further, approximately \$1.6 million of interest related to this debt is due on May 1, 2009. We currently do not have the cash or available funding to pay the interest of \$1.6 million due May 1, 2009.

Through December 31, 2008, we have been primarily engaged in developing our initial product technology. In the course of our development activities, we have sustained losses and expect such losses to continue through at least 2009. In fiscal 2008 we financed our operations primarily through our existing cash, but as discussed above we now require additional financing. There is substantial doubt about our ability to continue as a going concern.

We will require additional capital to continue our operations past approximately the end of April 2009. There is no assurance that we will be able to obtain any such additional capital as we need to finance these efforts, through asset sales, equity or debt financing, or any combination thereof, on satisfactory terms or at all. Additionally, no assurance can be given that any such financing, if obtained, will be adequate to meet our ultimate capital needs and to support our growth. If adequate capital cannot be obtained on a timely basis and on satisfactory terms, our operations would be materially negatively impacted. If we do not obtain additional funding, or do not anticipate additional funding, prior to or during approximately the end of April 2009, we will likely enter into bankruptcy and/or cease operations. Further, if we do raise additional cash resources prior to the end of April 2009, it may be raised in contemplation of or in connection with bankruptcy.

We filed a shelf registration statement on Form S-3 during June 2007, which was subsequently declared effective by the SEC. The shelf registration allows us the flexibility to offer and sell, from time to time, up to an original amount of \$50 million of common stock, preferred stock, debt securities, warrants or any combination of the foregoing in one or more future public offerings. In August 2007, we sold under this shelf registration statement 6,746,647 shares of common stock to institutional investors, raising proceeds of \$13.8 million, net of offering costs. We may offer and sell up to an additional \$36.2 million of securities pursuant to this shelf registration. However, in general, companies that are under \$75 million in market capitalization, such as Isolagen, are limited to selling up to one-third of the value of such company's common stock held by non-affiliates in any twelve month period.

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Our ability to complete additional offerings, including any additional offerings under our shelf registration statement, is dependent on the state of the debt and/or equity markets at the time of any proposed offering, and such market's reception of the Company and the offering terms. Currently the credit and equity markets both in the United States and internationally are severely contracted, which will make our task of raising additional debt or equity capital even more difficult. In addition, our ability to raise additional financing through the issuance of common stock or convertible securities may be adversely affected by uncertainties regarding the continued listing of our common stock on the NYSE Amex (see Item 5). Finally, our ability to complete an offering may be dependent on the status of our FDA regulatory milestones and our clinical trials, and in particular, the status of our indication for the treatment of nasolabial folds, the status of the related Biologics License Application, and the status of our Phase II/III acne scar trial, which cannot be predicted. There is no assurance that capital in any form would be available to us, and if available, on terms and conditions that are acceptable.

As a result of the conditions discussed above, and in accordance with generally accepted accounting principles in the United States, there exists substantial doubt about our ability to continue as a going concern, and our ability to continue as a going concern is contingent, among other things, upon our ability to secure additional adequate financing or capital prior to or during approximately the end of April 2009. If we do not obtain additional funding, or do not anticipate additional funding, prior to or during approximately the end of April 2009, we will likely enter into bankruptcy and/or cease operations. Further, if we do raise additional cash resources prior to the end of April 2009, it may be raised in contemplation of or in connection with bankruptcy. If we enter into bankruptcy, it is likely that our common stock and common stock equivalents will become worthless and our creditors will receive significantly less than what is owed to them.

Due to the likelihood of bankruptcy and in connection with the Company's review for impairment of long-lived assets in accordance with SFAS 144, "Accounting for the Impairment or Disposal of Long-lived Assets," we have recorded a full impairment on all of our long-lived assets as of December 31, 2008, and as such, we have recorded an impairment charge of \$6.7 million during the year ended December 31, 2008.

Isolagen's Technology Platform

We use our proprietary Isolagen Process to produce an autologous living cell therapy. We refer to this autologous living cell therapy as the Isolagen Therapy. We believe this therapy addresses the normal effects of aging or injury to the skin. Each of our product candidates is designed to use Isolagen Therapy to treat an indicated condition. We use our Isolagen Process to harvest autologous fibroblasts from a small skin punch biopsy from behind the ear with the use of a local anesthetic. We chose this location both because of limited exposure to the sun and to avoid creating a visible scar. In the case of our dental product candidate, the biopsy is taken from the patient's palette. The biopsy is then packed in a vial in a special shipping container and shipped to our laboratory where the fibroblast cells are released from the biopsy and initiated into our cell culture process where the cells proliferate until they reach the required cell count. The fibroblasts are then harvested, tested by quality control and released by quality assurance prior to shipment. The number of cells and the frequency of injections may vary and will depend on the indication or application being studied.

If and when approved, we expect our product candidates will offer patients their own living fibroblast cells in a personalized therapy designed to improve the appearance of damaged skin and wrinkles; or in the case of restrictive burn scars, improve range of motion. Our product candidates are intended to be a minimally invasive alternative to surgical intervention and a viable natural alternative to other chemical, synthetic or toxic treatments. We also believe that because our product candidates are autologous, the risk of an immunological or allergic response is low. With regard to the therapeutic markets, we believe that our product candidates may address an insufficiently met medical need for the treatment of each of restrictive burn scars, acne scars and dental papillary insufficiency, or gum recession, and potentially help patients avoid surgical intervention. Certain of our product candidates are still in clinical development and, as such, benefits we expect to see associated with our product candidates may not be validated in our clinical trials. In addition, disadvantages of our product candidates may become known in the future.

Our Strategy

Our business strategy is primarily focused on our approval efforts related to our nasolabial fold/wrinkle indication, for which we have submitted a BLA in March 2009. Our additional objectives include achieving regulatory milestones related to our other Phase II/III Acne Scar program, as funding permits in the future (refer to Clinical Development Programs below).

Clinical Development Programs

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

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

Aesthetic Development Programs

Wrinkles/Nasolabial Folds — Phase III Trials: In October 2006, we reached an agreement with the U.S. Food and Drug Administration, or FDA, on the design of a Phase III pivotal study protocol for the treatment of nasolabial folds (lines which run from the sides of the nose to the corners of the mouth). The randomized, double-blind protocol was submitted to the FDA under the agency's Special Protocol Assessment, or SPA. Pursuant to this assessment process, the FDA has agreed that our study design for two identical trials, including subject numbers, clinical endpoints, and statistical analyses, is adequate to provide the necessary data that, depending on the outcome, could form the basis of an efficacy claim for a marketing application. The pivotal Phase III trials evaluated the efficacy and safety of Isolagen Therapy against placebo in approximately 400 subjects total with approximately 200 subjects enrolled in each trial. The injections were completed in January 2008 and the trial data results were disclosed in October 2008. The Phase III trial data results indicated statistically significant efficacy results for the treatment of nasolabial folds. The Phase III data analysis, including safety results, was disclosed in October 2008. We submitted the related Biologics License Application (BLA) to the FDA in March 2009.

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

Therapeutic Development Programs

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

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

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

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

In 2006, we commenced a Phase II open-label dental trial for the treatment of Interdental Papillary Insufficiency. This single site study included 11 subjects. The study was previously placed on internal hold due to our financial resource constraints. We currently do not expect to fund additional trial efforts related to this application

Agera Skincare Systems

We market and sell a skin care product line through our majority-owned subsidiary, Agera Laboratories, Inc., which we acquired in August 2006. Agera offers a complete line of skincare systems based on a wide array of proprietary formulations, trademarks and nano-peptide technology. These skincare products can be packaged to offer anti-aging, anti-pigmentary and acne treatment systems. Agera markets its products in both the United States and Europe (primarily the United Kingdom). In March, we announced that we were pursuing the potential sale of our 57% ownership interest in Agera. We did not receive an offer for the sale of this ownership interest that we deemed acceptable. We are no longer actively pursuing the potential sale of our 57% ownership interest in Agera.

Our Target Market Opportunities

Aesthetic Market Opportunity

Our Isolagen product candidate for wrinkles/nasolabial folds and full face rejuvenation are directed primarily at the aesthetic market. Aesthetic procedures have traditionally been performed by dermatologists, plastic surgeons and other cosmetic surgeons. According to the American Society for Aesthetic Plastic Surgery, or ASAPS, the total market for non-surgical cosmetic procedures was approximately \$4.6 billion in 2008. We believe the aesthetic procedure market is driven by:

- aging of the “baby boomer” population, which currently includes ages approximately 45 to 63;
- the desire of many individuals to improve their appearance;
- impact of managed care and reimbursement policies on physician economics, which has motivated physicians to establish or expand the menu of elective, private-pay aesthetic procedures that they offer; and
- broadening base of the practitioners performing cosmetic procedures beyond dermatologists and plastic surgeons to non-traditional providers.

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According to the ASAPS, 10.3 million surgical and non-surgical cosmetic procedures were performed in 2008, as compared to 11.7 million in 2007. Also according to the ASAPS, approximately 8.5 million non-surgical procedures were performed in 2008 and approximately 9.6 million non-surgical procedures were performed in 2007. We believe that the concept of non-surgical cosmetic procedures involving injectable materials has become more mainstream and accepted. According to the ASAPS, the following table shows the top five non-surgical cosmetic procedures performed in 2008:

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

Procedures among the 35 to 50 year old age group made up approximately 45% of all non-surgical cosmetic procedures in 2008. The 51 to 64 year old age group made up 27% of all non-surgical cosmetic procedures in 2008, while the 19 to 34 year old age group made up 20% of all non-surgical cosmetic procedures in 2008. Botox injection was the most popular treatment among the 35 to 50 year old age group.

Therapeutic Market Opportunities

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

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

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

Agera Skincare Market Opportunities

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

Sales and Marketing

While our Isolagen Therapy product candidates are still in the pre-approval phase in the United States, no marketing or sales can occur within the United States. Our Agera skincare products are primarily sold directly to our established distributors and salons, with historically and recently very little focus on marketing efforts. We continue to attempt to identify additional third party distributors for our Agera product line. We believe that our Agera products have the potential to complement our Isolagen Therapy product candidates in the future.

Intellectual Property

We believe that patents, trademarks, copyrights, proprietary formulations (related to our Agera skincare products) and other proprietary rights are important to our business. We also rely on trade secrets, know-how and continuing technological innovations to develop and maintain our competitive position. We seek to protect our intellectual property rights by a variety of means, including obtaining patents, maintaining trade secrets and proprietary know-how, and technological innovation to operate without infringing on the proprietary rights of others and to prevent others from infringing on our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, actively seeking patent protection in the United States and certain foreign countries.

As of December 31, 2008, we had 9 issued U.S. patents, 2 pending U.S. patent applications, 31 granted foreign patents and 1 pending international patent application. 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.

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

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

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

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

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

Competition

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

If certain of our product candidates are approved, we will compete with a variety of companies in the dermatology and plastic surgery markets, many of which offer substantially different treatments for similar problems. These include silicone injections, laser procedures, facial surgical procedures, such as facelifts and eyelid surgeries, fat injections, dermabrasion, collagen, allogenic cell therapies, hyaluronic acid injections and Botulinum toxin injections, and other dermal fillers. Indirect competition comes from facial care treatment products. Items catering to the growing demand for therapeutic skin care products include facial scrubs, anti-aging treatments, tonics, astringents and skin-restoration formulas.

Many of our competitors are large, well-established pharmaceutical, chemical, cosmetic or health care companies with considerably greater financial, marketing, sales and technical resources than those available to us. Additionally, many of our present and potential competitors have research and development capabilities that may allow them to develop new or improved products that may compete with our product lines. Our products could be rendered obsolete or made uneconomical by the development of new products to treat the conditions addressed by our products, technological advances affecting the cost of production, or marketing or pricing actions by one or more of our competitors. Our facial aesthetics product may compete for a share of the existing market with numerous products and/or technologies that have become relatively accepted treatments recommended or prescribed by dermatologists and administered by plastic surgeons and aesthetic dermatologists.

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

The field for therapeutic treatments or tissue regeneration for use in wound healing is rapidly evolving. A number of companies are either developing or selling therapies involving stem cells, human-based, animal-based or synthetic tissue products. If approved as a therapy for acne scars, restrictive burn scars or periodontal disease, our product candidates would or may compete with synthetic, human or animal derived cell or tissue products marketed by companies like Genzyme, Integra Life Sciences, Johnson & Johnson, C.R. Bard, LifeCell, Organogenesis, Intercytex, and others.

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

Government Regulation

Our Isolagen Therapy technologies are subject to extensive government regulation, principally by the FDA and state and local authorities in the United States and by comparable agencies in foreign countries. Governmental authorities in the United States extensively regulate the pre-clinical and clinical testing, safety, efficacy, research, development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution, among other things, of pharmaceutical products under various federal laws including the Federal Food, Drug and Cosmetic Act, or FFCA, the Public Health Service Act, or PHSA, and under comparable laws by the states and in most foreign countries.

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Domestic Regulation

In the United States, the FDA, under the FDCA, the PHSA, and other federal statutes and regulations, subjects pharmaceutical and biologic products to rigorous review. If we do not comply with applicable requirements, we may be subjected to administrative or judicial enforcement action, the government may refuse to approve our marketing applications or to allow us to manufacture or market our products or product candidates, and we may be criminally prosecuted. The FDA also has the authority to suspend or revoke previously granted marketing authorizations, or seek a product withdrawal or recall (or order a recall of a biologic or a human cellular or tissue-based product under certain circumstances) if we fail to comply with regulatory standards or if we encounter problems following initial marketing.

FDA Approval Process

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

The FDA does not apply a single regulatory scheme to human tissues and the products derived from human tissue. On a product-by-product basis, the FDA may regulate such products as drugs, biologics, or medical devices, in addition to regulating them as human cells, tissues, or cellular or tissue-based products ("HCT/Ps"), depending on whether or not the particular product triggers any of an enumerated list of regulatory factors. A fundamental difference in the treatment of products under these classifications is that the FDA generally permits HCT/Ps that do not trigger any of those regulatory factors to be commercially distributed without marketing approval. In contrast, products that trigger those factors, such as if they are more than minimally manipulated when processed or manufactured, are regulated as drugs, biologics, or medical devices and require FDA approval. We have determined that our Isologen Therapy (TM) triggers regulatory factors that make it a biologic, in addition to an HCT/P, and consequently, we must obtain approval from FDA before marketing Isologen Therapy (TM) and must also satisfy all regulatory requirements for HCT/Ps.

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

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

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

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

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

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

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

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The sponsor must submit to the FDA the results of the pre-clinical and clinical trials, together with, among other things, detailed information on the manufacturing and composition of the product, and proposed labeling, in the form of an NDA, or, in the case of a biologic, a BLA. The applicant must also submit with the NDA or BLA a substantial user fee payment, unless a waiver or reduction applies. We believe that a waiver reduction applies to Isolgen related to our BLA submission for the nasolabial folds/wrinkles indication. For fiscal year 2009 this fee is \$1,247,200. The FDA has advised us it is regulating our Isolgen Therapy as a biologic. Therefore, we expect to submit BLAs to obtain approval of our product candidates. Each NDA or BLA submitted for FDA approval is usually reviewed for administrative completeness and reviewability within 45 to 60 days following submission of the application. If deemed complete, the FDA will “file” the NDA or BLA, thereby triggering substantive review of the application. The FDA can refuse to file any NDA or BLA that it deems incomplete or not properly reviewable. Once the submission has been accepted for filing, the FDA will review the application and will usually respond to the applicant in accordance with performance goals the FDA has established for the review of NDAs and BLAs — six months for priority applications and 10 months for regular applications. The review process is often significantly extended by FDA requests for additional information, preclinical or clinical studies, clarification, or a risk evaluation and mitigation strategy, or REMS, or by changes to the application submitted by the applicant in the form of amendments. The FDA may refer the BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved, but the FDA is not bound by the recommendation of an advisory committee.

It is possible that our product candidates will not successfully proceed through this approval process or that the FDA will not approve them in any specific period of time, or at all. The FDA may deny or delay approval of applications that do not meet applicable regulatory criteria, or if the FDA determines that the clinical data do not adequately establish the safety and efficacy of the product. Satisfaction of FDA pre-market approval requirements for a new biologic is a process that may take a number of years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. The FDA reviews these applications and, when and if it decides that adequate data are available to show that the product is both safe and effective and that other applicable requirements have been met, approves the drug or biologic for marketing. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon our activities. Success in early stage clinical trials does not assure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Upon approval, a product candidate may be marketed only for those indications approved in the BLA or NDA and may be subject to labeling and promotional requirements or limitations, including warnings, precautions, contraindications and use limitations, which could materially impact profitability. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-market regulatory standards is not maintained or if safety, efficacy or other problems occur after the product reaches the marketplace.

The FDA may, during its review of an NDA or BLA, ask for additional test data. If the FDA does ultimately approve the product, it may require post-marketing testing, including potentially expensive Phase IV studies, to confirm or otherwise further evaluate the safety and effectiveness of the product. The FDA also may require, as a condition to approval or continued marketing of a drug, a risk evaluation and mitigation strategy, or REMS, if deemed necessary to manage a known or potential serious risk associated with the product. An REMS can include additional educational materials for healthcare professionals and patients such as Medication Guides and Patient Package Inserts, a plan for communicating information to healthcare professionals, and restricted distribution of the product. In addition, the FDA may, in some circumstances, impose restrictions on the use of the product, which may be difficult and expensive to administer and may require prior approval of promotional materials. Following approval, FDA may require labeling changes or impose new post-approval study, risk management, or distribution restriction requirements.

Ongoing FDA Requirements

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

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The labeling, advertising, promotion, marketing and distribution of a drug or biologic product also must be in compliance with FDA and FTC requirements which include, among others, standards and regulations for direct-to-consumer advertising, industry-sponsored scientific and educational activities, and promotional activities involving the internet. In general, all product promotion must be consistent with the FDA approval for such product, contain a balanced presentation of information on the product's uses and benefits and important safety information and limitations on use, and otherwise not be false or misleading. The FDA and FTC have very broad enforcement authority, and failure to abide by these regulations can result in penalties, including the issuance of a Warning Letter directing a company to correct deviations from regulatory standards and enforcement actions that can include seizures, injunctions and criminal prosecution.

Manufacturers are also subject to various laws and regulations governing laboratory practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances in connection with their research. In each of the above areas, the FDA has broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products and deny or withdraw approvals.

HIPAA Requirements

Other federal legislation may affect our ability to obtain certain health information in conjunction with our research activities. The Health Insurance Portability and Accountability Act of 1996, or HIPAA, mandates, among other things, the adoption of standards designed to safeguard the privacy and security of individually identifiable health information. In relevant part, the U.S. Department of Health and Human Services, or HHS, has released two rules to date mandating the use of new standards with respect to such health information. The first rule imposes new standards relating to the privacy of individually identifiable health information. These standards restrict the manner and circumstances under which covered entities may use and disclose protected health information so as to protect the privacy of that information. The second rule released by HHS establishes minimum standards for the security of electronic health information. While we do not believe we are directly regulated as a covered entity under HIPAA, the HIPAA standards impose requirements on covered entities conducting research activities regarding the use and disclosure of individually identifiable health information collected in the course of conducting the research. As a result, unless they meet these HIPAA requirements, covered entities conducting clinical trials for us may not be able to share with us any results from clinical trials that include such health information.

Other U.S. Regulatory Requirements

In the United States, the research, manufacturing, distribution, sale, and promotion of drug and biological products are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection, unfair competition, and other laws.

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International Regulation

The regulation of our product candidates outside of the United States varies by country. Certain countries regulate human tissue products as a pharmaceutical product, which would require us to make extensive filings and obtain regulatory approvals before selling our product candidates. Certain other countries classify our product candidates as human tissue for transplantation but may restrict its import or sale. Other countries have no application regulations regarding the import or sale of products similar to our product candidates, creating uncertainty as to what standards we may be required to meet.

Manufacturing

We currently have one operational manufacturing facility located in Exton, Pennsylvania. As part of our continuing efforts to evaluate the best uses of our resources, in the fourth quarter of 2006, the Board of Directors approved the proposed closing of our UK operation. We completed the closure of our London manufacturing facility on March 31, 2007. We previously used our London facility for the commercialization of our process (for which we earned revenue from the sale of Isolagen Therapy in the United Kingdom and other non-US markets) and as a means to improve our manufacturing process.

The costs incurred in operating our Exton facility (except for costs related to general corporate administration) are currently classified as research and development expenses as the activities there have been devoted to the research and development of our clinical applications and the development of a commercial scale and in a cost-effective production method. All component parts used in our Exton, Pennsylvania manufacturing process are readily available with short lead times, and all machinery is maintained and calibrated. We believe we have made improvements in our manufacturing processes, and we expect to continue such efforts in the future.

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

Research and Development

In addition to our clinical development activities, our research and development activities include improving our manufacturing processes and reducing manufacturing costs. We expense research and development costs as they are incurred. For the years ended December 31, 2008 and 2007, we incurred research and development expenses of \$10.2 million and \$13.3 million, respectively.

Employees

As of April 13, 2009, we employed 9 people on a full-time basis, all located in the United States, and one employee, our Chief Executive Officer, who is based in Ireland and works in both Ireland and the United States. We also employ two full-time and one part-time Agera employees. None of our employees are covered by a collective bargaining agreement, and we consider our relationship with our employees to be good. We also employ consultants and temporary labor on an as needed basis to supplement existing staff.

Segment Information

Financial information concerning the Company's business segments and geographic areas of operation is included in Note 15 in the Notes to Consolidated Financial Statements contained in Item 8 of this Form 10-K.

Discontinued Operations

As part of our continuing efforts to evaluate the best uses of our resources, in the fourth quarter of 2006 our Board of Directors approved the closing of our United Kingdom operation. On March 31, 2007, we completed the closure of the United Kingdom manufacturing facility. As a result of the completion of the closure of the United Kingdom manufacturing facility, as of March 31, 2007 our United Kingdom operation was classified as a discontinued operation. In addition, as a result of the closure of our United Kingdom operation, the operations that we previously conducted in Switzerland and Australia, which had been absorbed into the United Kingdom operation, were also classified as discontinued operations as of March 31, 2007. Accordingly, the historical results of the United Kingdom, Switzerland and Australia have been retrospectively adjusted herein, for all periods presented, to reflect the treatment of these operations as discontinued operations.

Corporate History

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

Item 1A. Risk Factors

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

We could fail to remain a going concern. We may likely file for bankruptcy in the very near term. We will need to raise substantial additional capital to fund our operations through the very near term and through commercialization of our product candidates, and we do not have any commitments for that capital.

There exists substantial doubt regarding our ability to continue as a going concern. As discussed in Note 2 to the Consolidated Financial Statements—*Going Concern*, as of December 31, 2008 we had cash and cash equivalents of \$2.9 million and negative working capital of \$(87.3) million (including our cash and cash equivalents). We believe our existing capital resources are inadequate to finance our operations past the end of April 2009. Beyond our efforts to obtain immediate financing, which may not occur, we are incurring losses from operations, have limited capital resources, and do not have access to a line of credit or other debt facility.

We will need additional capital to achieve commercialization of our product candidates and to execute our business strategy, and if we are unsuccessful in raising additional capital we will be unable to achieve commercialization of our product candidates or unable to fully execute our business strategy on a timely basis, if at all. If we raise additional capital through the issuance of debt securities, the debt securities may be secured and any interest payments would reduce the amount of cash available to operate and grow our business. If we raise additional capital through the issuance of equity securities, such issuances will likely cause dilution to our stockholders, particularly if we are required to do so during periods when our common stock is trading at historically low price levels. If we file for bankruptcy, it is likely that our common stock will become worthless, given that there currently exists approximately \$90 million of debt, which has a priority over common shareholders.

Additionally, we do not know whether any financing, if obtained, will be adequate to meet our capital needs and to support our growth. Currently the credit and equity markets both in the United States and internationally are severely contracted, which will make our task of raising additional debt or equity capital even more difficult. If adequate capital cannot be obtained on satisfactory terms, we may terminate or delay our efforts related to regulatory approval of one or more of our product candidates, curtail or delay the implementation of manufacturing process improvements or delay the expansion of our sales and marketing capabilities, any of which could cause our business to fail.

If we do not obtain additional funding, we will likely enter into bankruptcy and/or cease operations. Further, if we do raise additional cash resources prior to the end of April 2009, it may be raised in contemplation of or in connection with bankruptcy. If we enter into bankruptcy, it is likely that our common stock and common stock equivalents will become worthless and our creditors will receive significantly less than what is owed to them.

Our independent registered public accounting firm has modified their report for our fiscal year ended December 31, 2008 with respect to our ability to continue as a going concern. Due to the likelihood of bankruptcy and in connection with the Company's review for impairment of long-lived assets in accordance with SFAS 144, "Accounting for the Impairment or Disposal of Long-lived Assets," we have recorded a full impairment on all of our long-lived assets as of December 31, 2008, and as such, we have recorded an impairment charge of \$6.7 million during the year ended December 31, 2008 in the consolidated statement of operations. If we became unable to continue as a going concern, we would have to liquidate our assets and we may likely receive significantly less than the values at which they are carried on our consolidated financial statements. The inclusion of a going concern modification in our independent registered public accounting firm's audit opinion for the year ended December 31, 2008 may materially and adversely affect our stock price and our ability to raise new capital.

We submitted our Biologics License Application for the treatment of wrinkles/nasolabial folds to the FDA in March 2009, and the FDA may deem this Biologics License Application to be unacceptable.

We submitted a Biologics License Application (“BLA”) for our Isolagen Therapy (TM) for the treatment of wrinkles/nasolabial folds, to the FDA in March 2009. The FDA has 60 days to deem the application to be filed or to refuse to file it on incompleteness grounds. Even if the FDA files the BLA, the FDA may ultimately not approve our application.

Any failure or delay in receiving regulatory approval for the sale of any product candidate, has the potential to materially harm our business, and may prevent us from raising necessary, additional financing.

Obtaining FDA and other regulatory approvals is complex, time consuming and expensive, and the outcomes are uncertain.

The process of obtaining FDA and other regulatory approvals is time consuming, expensive and difficult. Clinical trials are required and the marketing and manufacturing of our product candidates are subject to rigorous testing procedures. We have finished injections related to our pivotal Phase III clinical trial for our lead facial product candidate and have submitted the related BLA to the FDA. Our other product candidates will require additional clinical trials. The commencement and completion of clinical trials for any of our product candidates could be delayed or prevented by a variety of factors, including:

- delays in obtaining regulatory approvals to commence a study;
- delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;
- delays or failures in obtaining approval of our clinical trial protocol from an institutional review board, or IRB, to conduct a clinical trial at a prospective study site;
- delays in the enrollment of subjects;
- manufacturing difficulties;
- failure of our clinical trials and clinical investigators to be in compliance with the FDA’s Good Clinical Practices, or GCP;
- failure of our third-party contract research organizations, clinical site organizations and other clinical trial managers, to satisfy their contractual duties, comply with regulations or meet expected deadlines;
- lack of efficacy during clinical trials; or
- unforeseen safety issues.

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

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

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

- labeling and advertising requirements, restrictions or limitations, including the inclusion of warnings, precautions, contra-indications or use limitations that could have a material impact on the future profitability of our product candidates;
- testing and surveillance to further evaluate or monitor our future products and their continued compliance with regulatory standards and requirements;
- submitting products for inspection; or
- imposing a risk evaluation and mitigation strategy (“REMS”) to ensure that the benefits of the drug outweigh the risks.

Protocol deviations may release the FDA from its binding acceptance of our Special Protocol Assessment (“SPA”) study design, which may result in the delay, or non-approval, by the FDA of the Isolagen Therapy.

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

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

Prior to receiving approval to commercialize any of our product candidates, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA and other regulatory authorities in the United States and abroad, that our product candidates are both safe and effective. We will need to demonstrate our product candidates’ efficacy and monitor their safety throughout the process. We have recently completed a pivotal Phase III clinical trial related to our lead facial aesthetic product candidate. The success of prior pre-clinical or clinical trials does not ensure the success of these trials, which are being conducted in populations with different racial and ethnic demographics than our previous trials. If our current trials or any future clinical trials are unsuccessful, our business and reputation would be harmed and the price at which our stock trades could be adversely affected. In addition, if our Phase III clinical trials related to our lead facial aesthetic product candidate is deemed to be unacceptable or deficient in anyway by the FDA, we may be unable to raise additional equity or debt financing that we may require to continue our operations.

All of our product candidates are subject to the risks of failure inherent in the development of biotherapeutic products. The results of early-stage clinical trials of our product candidates do not necessarily predict the results of later-stage clinical trials. Product candidates in later-stage clinical trials may fail to demonstrate desired safety and efficacy traits despite having successfully progressed through initial clinical testing. Even if we believe the data collected from clinical trials of our product candidates is promising, this data may not be sufficient to support approval by the FDA or any other U.S. or foreign regulatory approval. Pre-clinical and clinical data can be interpreted in different ways. Accordingly, FDA officials could reach different conclusions in assessing such data than we do, which could delay, limit or prevent regulatory approval. In addition, the FDA, other regulatory authorities, our Institutional Review Boards or we, may suspend or terminate clinical trials at any time.

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Unlike our Phase III Nasolabial/Wrinkle trial, our Phase II/III Acne Scar trial is not subject to a Special Protocol Assessment (“SPA”) with the FDA. In addition, we have developed a photo guide for use in the evaluators’ assessment of acne study subjects. Our evaluator assessment scale and photo guide have not been previously used in a clinical trial. To obtain FDA approval with respect to the acne scar indication, we will require FDA concurrence with the use of our evaluator assessment scale and photo guide.

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

We are not in compliance with the American Stock Exchange’s continued listing standards and, as a result, our common stock may be delisted from the American Stock Exchange.

On March 17, 2009, we received notice from the NYSE Amex (the “Exchange”) notifying us that we are not in compliance with Section 1003(a)(iv) of the Exchange’s Company Guide (the “Company Guide”). Specifically, the Exchange staff noted that we sustained losses which are so substantial in relation to our overall operations or our existing financial sources that it appears questionable, in the opinion of the Exchange, as to whether we will be able to continue operations and/or meet our obligations as they mature. As previously disclosed, we received a notice from the Exchange on March 12, 2008, advising us that we were not in compliance with Sections 1003 (a)(i)-(iii) of the Company Guide.

We currently intend to submit a plan in response to the most recent notice by April 17, 2009 outlining our compliance strategy with the current continued listing deficiency by September 14, 2009, subject to our successfully completing a sufficient financing transaction or strategic partnership prior to April 17, 2009. As of the date of the filing of this annual report, we have no commitments for any such additional funding and there is no assurance that we will receive any such additional funding. If we submit a plan and our plan to regain compliance is accepted by the Exchange, we may be able to continue our listing during this period, during which time we will be subject to periodic review to determine progress consistent with the plan. If we do not submit a plan or if the plan is not accepted by the Exchange, we will be subject to delisting procedures as set forth in the Company Guide. Under Company Guide rules, we have the right to appeal the determination by the Exchange staff to initiate delisting proceedings and to seek a hearing before an Exchange Panel. The time and place of such a hearing will be determined by the Panel. If the Panel does not grant the relief sought by us, our common stock could be delisted from the Exchange. There is no assurance that the Exchange staff will accept our plan of compliance or that, even if such plan is accepted, we will be able to implement the plan within the prescribed timeframe.

In addition, the Exchange’s notice states that our common stock has closed at between \$0.15 and \$0.87 per share over the last six months, and that the Staff is concerned that, as a result of the low selling price, our common stock may not be suitable for auction market trading. Pursuant to Section 1003(f)(v) of the Company Guide, the Exchange has notified us that it deems it appropriate that we effect a reverse stock split within a reasonable amount of time in view of the fact that our common stock has been selling for a substantial period of time at a low price per share.

These uncertainties regarding the continued listing of our common stock on the Exchange will add to the difficulty of raising additional financing through the issuance of common stock or convertible securities.

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

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

We have yet to be profitable, losses may continue to increase from current levels and we will continue to experience significant negative cash flow as we expand our operations, which may limit or delay our ability to become profitable.

We have incurred losses since our inception, have never generated significant revenue from commercial sales of our products, and have never been profitable. We are focused on product development, and we have expended significant resources on our clinical trials, personnel and research and development. We expect these costs to continue to rise in the future. Our consolidated net losses for the years ended 2008 and 2007 were \$31.4 million and \$35.6 million, respectively. As of December 31, 2008, we had an accumulated development stage net loss attributable to common shareholders of \$194.1 million. We expect to continue to experience increasing operating losses and negative cash flow as we expand our operations.

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

- FDA clinical trials and regulatory approvals;
- expansion of laboratory and manufacturing operations;
- research and development;
- brand development;
- personnel costs;
- development of relationships with strategic business partners, including physicians who might use our future products; and
- interest expense and amortization of issuance costs related to our outstanding note payables.

If our product candidates fail in clinical trials or do not gain regulatory approval, if our product candidates do not achieve market acceptance, or if we do not succeed in effectively and efficiently implementing manufacturing process and technology improvements to make our product commercially viable, we will not be profitable. If we fail to become and remain profitable, or if we are unable to fund our continuing losses, our business may fail.

We will continue to experience operating losses and significant negative cash flow until we begin to generate significant revenue from (a) the sale of our product candidates, which is dependent on the receipt of FDA approval for our product candidates and is dependent on our ability to successfully market and sell such product candidates, and (b) our Agera product line, which is dependent on achieving significant market penetration in its markets.

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

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

- conduct substantial additional research and development;
- successfully complete lengthy and expensive pre-clinical and clinical testing, including the Phase II/III clinical trial for our acne scar product candidate;
- successfully improve our manufacturing process; and
- obtain FDA approvals.

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

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

We are focused on product development and have not generated significant revenue from commercial sales of our products to date. Prior to the fourth quarter of 2006 we offered the Isolgen Therapy for sale in the United Kingdom. Our United Kingdom operation had been operating on a negative gross margin as we investigated means to improve manufacturing technologies for the Isolgen Process. During the fourth quarter of 2006 we determined to cease offering our Isolgen Therapy in the United Kingdom, as part of our continuing efforts to evaluate the best uses of our resources. Our revenue for the years ended December 31, 2008 and 2007, which excludes historical revenue from discontinued operations, was \$1.1 million and \$1.4 million, respectively.

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

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

As part of the approval process, we must pass a pre-approval inspection of our manufacturing facility before we can obtain marketing approval for our product candidates. We have never gone through a FDA pre-approval regulatory inspection of our manufacturing facility, and we cannot guarantee that we will satisfy the requirements for approval. All of our manufacturing methods, equipment and processes for the active pharmaceutical ingredient and finished product must comply with the FDA's current Good Manufacturing Practices, or cGMP, requirements. We will also need to perform extensive audits of our suppliers, vendors and contract laboratories. The cGMP requirements govern all areas of recordkeeping, production processes and controls, personnel and quality control. To ensure that we meet these requirements, we will expend significant time, money and effort. Due to the unique nature of our Isolgen Therapy, we cannot predict the likelihood that the FDA will approve our facility as compliant with cGMP requirements even if we believe that we have taken the steps necessary to achieve compliance.

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

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

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

In order to successfully commercialize any approved product candidates, we will be required to produce such products on a commercial scale and in a cost-effective manner. As stated in the preceding risk factor, we intend to seek FDA approval of our manufacturing process as a component of the BLA application and approval process. However, we can provide no assurance that we will be able to cost-effectively and commercially scale our operations using our current manufacturing process. If we are unable to develop suitable techniques to produce and manufacture our product candidates, our business prospects will suffer.

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

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

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

Our revenues, which relate solely to the Agera business segment, are highly concentrated in one large, international customer. This large customer represented 64% and 69% of 2008 and 2007 consolidated revenues, respectively. Further, this large customer represented 94% of consolidated accounts receivable, net, at December 31, 2008 and 2007. A reduction of revenue related to this large customer, due to competitor product alternatives, pricing pressures, the financial health of the large customer, or otherwise, would have a significant, negative impact on the business of Agera, and the related value thereof.

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

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

If physicians do not follow our established protocols, the efficacy and safety of our product candidates may be adversely affected.

We are dependent on physicians to follow our established protocols both as to the administration and the handling of our product candidates in connection with our clinical trials, and we will continue to be dependent on physicians to follow such protocols if our product candidates are commercialized. The treatment protocol requires each physician to verify the patient's name and date of birth with the patient and the patient records immediately prior to injection. In the event more than one patient's cells are delivered to a physician or we deliver the wrong patient's cells to the physician, which has occurred in the past, it is the physician's obligation to follow the treatment protocol and assure that the patient is treated with the correct cells. If the physicians do not follow our protocol, the efficacy and safety of our product candidates may be adversely affected.

Our business, which depends on one facility, is vulnerable to natural disasters, telecommunication and information systems failures, terrorism and similar problems, and we are not fully insured for losses caused by all of these incidents.

We currently conduct all our research, development and manufacturing operations in one facility located in Exton, Pennsylvania. As a result, if we obtain FDA approval of any of our product candidates, all of the commercial manufacturing for the U.S. market are currently expected take place at a single U.S. facility. If regulatory, manufacturing or other problems require us to discontinue production at that facility, we will not be able to supply product, which would adversely impact our business.

Our Exton facility could be damaged by fire, floods, power loss, telecommunication and information systems failures or similar events. Our insurance policies have limited coverage levels for loss or damages in these events and may not adequately compensate us for any losses that may occur. In addition, terrorist acts or acts of war may cause harm to our employees or damage our Exton facility. The potential for future terrorist attacks, the national and international responses to terrorist attacks or perceived threats to national security, and other acts of war or hostility have created many economic and political uncertainties that could adversely affect our business and results of operations in ways that we cannot predict, and could cause our stock price to fluctuate or decline. We are uninsured for these types of losses.

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

We have a limited operating history and our primary business activities consist of conducting clinical trials. As such, our historical financial data is of limited value in estimating future operating expenses. Our budgeted expense levels are based in part on our expectations concerning the costs of our clinical trials, which depend on the success of such trials and our ability to effectively and efficiently conduct such trials, and expectations related to our efforts to achieve FDA approval with respect to our product candidates. In addition, our budgeted expense levels are based in part on our expectations of future revenue that we may receive from our Agera product line, and the size of future revenue depends on the choices and demand of individuals. Our limited operating history and clinical trial experience make these costs and revenues difficult to forecast accurately. We may be unable to adjust our operations in a timely manner to compensate for any unexpected increase in costs or shortfall in revenue. Further, our fixed manufacturing costs and business development and marketing expenses will increase significantly as we expand our operations. Accordingly, a significant increase in costs or shortfall in revenue could have an immediate and material adverse effect on our business, results of operations and financial condition.

Our operating results may fluctuate significantly in the future, which may cause our results to fall below the expectations of securities analysts, stockholders and investors.

Our operating results may fluctuate significantly in the future as a result of a variety of factors, many of which are outside of our control. These factors include, but are not limited to:

- the level of demand for the products that we may develop;
- the timely and successful implementation of improved manufacturing processes;
- our ability to attract and retain personnel with the necessary strategic, technical and creative skills required for effective operations;
- the amount and timing of expenditures by practitioners and their patients;
- introduction of new technologies;
- product liability litigation, class action and derivative action litigation, or other litigation;

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- the amount and timing of capital expenditures and other costs relating to the expansion of our operations;
- the state of the debt and/or equity markets at the time of any proposed offering we choose to initiate;
- our ability to successfully integrate new acquisitions into our operations;
- government regulation and legal developments regarding our Isolagen Therapy in the United States and in the foreign countries in which we may operate in the future; and
- general economic conditions.

As a strategic response to changes in the competitive environment, we may from time to time make pricing, service, technology or marketing decisions or business or technology acquisitions that could have a material adverse effect on our operating results. Due to any of these factors, our operating results may fall below the expectations of securities analysts, stockholders and investors in any future period, which may cause our stock price to decline.

We may be liable for product liability claims not covered by insurance, and we have been publicly threatened with claims related to our product in the United Kingdom.

Physicians who used our facial aesthetic product in the past, or who may use any of our future products, and patients who have been treated by our facial aesthetic product in the past, or who may use any of our future products, may bring product liability claims against us. In particular, we have received negative publicity and negative correspondence from patients in the United Kingdom that had previously received our treatment. To date, we have received written demands by an attorney representing approximately 132 former patients each claiming, on average, £3,500 (or approximately \$5,250), plus unquantified interest and incidental expenses. To date, no formal legal action has been brought by the attorney against us. Further, one former United Kingdom patient has claimed personal injury as a result of the use of the Isolagen Therapy; although no formal legal action has been brought against us to date with respect to this matter. While we have taken, and continue to take, what we believe are appropriate precautions, we may be unable to avoid significant liability exposure. We currently keep in force product liability insurance, although such insurance may not be adequate to fully cover any potential claims or may lapse in accordance with its terms prior to the assertion of claims. We may be unable to obtain product liability insurance in the future, or we may be unable to do so on acceptable terms. Any insurance we obtain or have obtained in the past may not provide adequate coverage against any asserted claims. In addition, regardless of merit or eventual outcome, product liability claims may result in:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The human healthcare products and services industry is extremely competitive. Our competitors include major pharmaceutical, medical device and biotechnology companies. Most of these competitors have more extensive research and development, marketing and production capabilities and greater financial resources than we do. Our future success will depend on our ability to develop and market effectively our future products against those of our competitors. If our future products receive marketing approval but cannot compete effectively in the marketplace, our results of operations and financial position will suffer.

We are dependent on our key scientific and other management personnel, and the loss of any of these individuals could harm our business.

We are dependent on the efforts of our key management and scientific staff. The loss of any of these individuals, or our inability to recruit and train additional key personnel in a timely manner, could materially and adversely affect our business and our future prospects. A loss of one or more of our current officers or key personnel could severely and negatively impact our operations. We have employment agreements with most of our key management personnel, but some of these people are employed “at-will,” and any of them may elect to pursue other opportunities at any time. We have no present intention of obtaining key man life insurance on any of our executive officers or key management personnel.

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

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

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

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

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

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

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

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As of December 31, 2008, we had 9 issued U.S. patents, 2 pending U.S. patent applications, 31 granted foreign patents, and 1 pending international application. However, we may not be able to obtain additional patents relating to our technology or otherwise protect our proprietary rights. If we fail to obtain or maintain patents from our pending and future applications, we may not be able to prevent third parties from using our proprietary technology. We will be able to protect our proprietary rights from unauthorized use only to the extent that these rights are covered by valid and enforceable patents that we control or are effectively maintained by us as trade secrets. Furthermore, the degree of future protection of our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep a competitive advantage.

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

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

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

- other individual companies, universities or research institutions may independently develop or have developed similar or alternative technologies or duplicate our technologies and commercialize discoveries that we attempt to patent;
- other companies, universities or research institutions may design around technologies we have licensed, patented or developed; and
- many of our patent claims are method, rather than composition of matter, claims; generally composition of matter claims are easier to enforce and are more difficult to circumvent.

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

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

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

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

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

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

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

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

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

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

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

We have not declared any dividends on our common stock to date, and we have no intention of declaring dividends in the foreseeable future.

The decision to pay cash dividends on our common stock rests with our Board of Directors and will depend on our earnings, unencumbered cash, capital requirements and financial condition. We do not anticipate declaring any dividends in the foreseeable future, as we intend to use any excess cash to fund our operations. Investors in our common stock should not expect to receive dividend income on their investment, and investors will be dependent on the appreciation of our common stock to earn a return on their investment.

Provisions in our charter documents could prevent or delay stockholders' attempts to replace or remove current management.

Our charter documents provide for staggered terms for the members of our Board of Directors. Our Board of Directors is divided into three staggered classes, and each director serves a term of three years. At stockholders' meetings, only those directors comprising one of the three classes will have completed their term and be subject to re-election or replacement.

In addition, our Board of Directors is authorized to issue "blank check" preferred stock, with designations, rights and preferences as they may determine. Accordingly, our Board of Directors may, without stockholder approval, issue shares of preferred stock with dividend, liquidation, conversion, voting or other rights that could adversely affect the voting power or other rights of the holders of our common stock. This type of preferred stock could also be issued to discourage, delay or prevent a change in our control.

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

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

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

Our bylaws provide for the indemnification of our officers and directors. We have in the past and may in the future be required to advance costs incurred by an officer or director and to pay judgments, fines and expenses incurred by an officer or director, including reasonable attorneys’ fees, as a result of actions or proceedings in which our officers and directors are involved by reason of being or having been an officer or director of our company. Funds paid in satisfaction of judgments, fines and expenses may be funds we need for the operation of our business and the development of our product candidates, thereby affecting our ability to attain profitability.

Future sales of our common stock may depress our stock price.

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market, or as a result of the perception that these sales could occur, which could occur if we issue a large number of shares of common stock (or securities convertible into our common stock) in connection with a future financing, as our common stock is trading at historically low levels. These factors could make it more difficult for us to raise funds through future offerings of common stock. As of April 9, 2009, there were 41,887,266 shares of common stock issued and 37,887,266 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.

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

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

Our debt obligations expose us to risks that could adversely affect our business, operating results and financial condition, and prevent us from fulfilling our obligations under the notes.

We have a substantial level of debt. As of December 31, 2008, we had approximately \$90.5 million of indebtedness outstanding (including related accrued interest of \$0.5 million). As of the date of this report, approximately \$89.7 million of this indebtedness could be called due as early as November 2009 at the option of the bond holders. Further, the \$89.7 million of indebtedness would become due immediately upon a change in control of the Company. We also have approximately \$1.6 million of interest due on May 1, 2009, for which we currently do not have the available capital to pay when due. The level and nature of our indebtedness, among other things, could:

- make it difficult for us to make payments on our debt outstanding from time to time or to refinance it;
- make it difficult for us to obtain any necessary financing in the future for working capital, capital expenditures, debt service, acquisitions or general corporate purposes;
- limit our flexibility in planning for or reacting to changes in our business;
- reduce funds available for use in our operations, as we will be required to use a portion of our cash for the payment of any principal or interest due on our outstanding indebtedness;
- make us more vulnerable in the event of a downturn in our business;
- place us at a possible competitive disadvantage relative to less leveraged competitors and competitors that have better access to capital resources;
- increase the impact to us of negative changes in general economic and industry conditions, as compared to less leveraged competitors; or
- impair our ability to merge or otherwise affect the sale of the company due to the right of the holders of certain of our indebtedness to accelerate the maturity date of the indebtedness in the event of a change of control of the company.

If we do not grow our revenues, we could have difficulty making required payments on our indebtedness in the future. If we are unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments, or if we fail to comply with the various requirements of our indebtedness, we would be in default, which would permit the holders of our indebtedness to accelerate the maturity of the indebtedness and could cause defaults under any indebtedness we may incur in the future. Any default under our indebtedness would have a material adverse effect on our business, operating results and financial condition.

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, which 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, and the documentation governing any future financing may contain covenants that limit or restrict our strategic, operating or financing activities;
- refinance or restructure all or a portion of our indebtedness;
- sell selected assets;
- reduce or delay planned capital expenditures;

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- reduce or delay planned research and development expenditures; and/or
- enter into bankruptcy protection.

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.

The price of our common stock has in the past and may in the future fluctuate significantly, which may make it difficult for holders of our common stock to sell our common stock when desired or at attractive prices.

On April 1, 2009, the per share closing price of our common stock was \$0.16. From January 1, 2007 through April 1, 2009, the per share closing price of our common stock ranged from \$0.15 to \$5.00 per share. The value of our common stock may decline regardless of our operating performance or prospects. The market price of our common stock is subject to significant fluctuations in response to the factors in this section and other factors, including:

- market reaction to our capitalization, cash reserves and utilization of cash;
- market reaction to announcements regarding our management;
- the success or failure of our product development efforts, especially those related to obtaining regulatory approvals domestically and internationally;
- the implementation of improved 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, or development with respect to threatened litigation.

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. These broad market fluctuations may adversely affect the price of our securities, regardless of our operating performance.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our corporate headquarters and manufacturing operations are located in one location, Exton, Pennsylvania. The Exton, Pennsylvania location is leased and consists of approximately 86,500 square feet. The lease is noncancelable through March 31, 2013.

Item 3. Legal Proceedings

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 Eastern District of Pennsylvania.

In August 2005 and September 2005, various lawsuits were filed alleging securities fraud and asserting claims on behalf of a putative class of purchasers of publicly traded Isolagen securities between March 3, 2004 and August 1, 2005. These lawsuits were *Elliot Liff v. Isolagen, Inc. et al.*, C.A. No. H-05-2887, filed in the United States District Court for the Southern District of Texas; *Michael Cumiskey v. Isolagen, Inc. et al.*, C.A. No. 05-cv-03105, filed in the United States District Court for the Southern District of Texas; *Ronald A. Gargiulo v. Isolagen, Inc. et al.*, C.A. No. 05-cv-4983, filed in the United States District Court for the Eastern District of Pennsylvania, and *Gregory J. Newman v. Frank M. DeLape, et al.*, C.A. No. 05-cv-5090, filed in the United States District Court for the Eastern District of Pennsylvania.

The *Liff* and *Cumiskey* 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 *Cumiskey* 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. On February 23, 2006, the MDL Motion was granted and the actions pending in the Southern District of Texas were transferred to the Eastern District of Pennsylvania, where they have been captioned *In re Isolagen, Inc. Securities & Derivative Litigation*, MDL No. 1741 (the “Federal Securities Litigation”).

On April 4, 2006, the United States District Court for the Eastern District of Pennsylvania appointed Silverback Asset Management, LLC, Silverback Master, Ltd., Silverback Life Sciences Master Fund, Ltd., Context Capital Management, LLC and Michael F. McNulty as Lead Plaintiffs, and the law firms of Bernstein Litowitz Berger & Grossman LLP and Kirby McInerney & Squire LLP as Lead Counsel in the Federal Securities Litigation.

On July 14, 2006, Lead Plaintiffs filed a Consolidated Class Action Complaint in the Federal Securities Litigation on behalf of a putative class of persons or entities who purchased or otherwise acquired Isolagen common stock or convertible debt securities between March 3, 2004 and August 9, 2005. The complaint purports to assert claims for securities fraud in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 against Isolagen and certain of its former officers and directors. The complaint also purports to assert claims for violations of Section 11 and 12 of the Securities Act of 1933 against the Company and certain of its current and former directors and officers in connection with the registration and sale of certain shares of Isolagen common stock and certain convertible debt securities. The complaint also purports to assert claims against the underwriters of an April 2004 public offering of Isolagen common stock and a 2005 sale of convertible notes. On November 1, 2006, the defendants moved to dismiss the complaint. On September 26, 2007, the court denied the Company’s motions to dismiss the complaint. On November 6, 2007, the court entered a scheduling order that provides for discovery to be complete by June 8, 2009. On February 4, 2008, Lead Plaintiffs moved for class certification. On February 15, 2008, Lead Plaintiffs dismissed without prejudice their claims against certain of the underwriters named as defendants in the Federal Securities Class Action, but maintained claims against CIBC World Markets Corp. and UBS Securities LLC (the “Underwriters”).

On April 1, 2008, the court entered an order staying the schedule set forth in its November 6, 2007 order for a period of 90 days and directing the parties (together with the parties in the Beattie action, described under “Derivative Actions,” below) to participate in mediation before a private mediator. The mediation occurred on June 2, 2008 and June 5, 2008, at which the parties reached an agreement in principle to settle the Federal Securities Litigation. On October 23, 2008, the parties executed a definitive settlement agreement. In November 2008, the Company received settlement proceeds from its directors and officers liability insurance carrier, of which \$4.4 million was paid to the class action plaintiffs in December 2008 in accordance with the definitive settlement agreement. On March 25, 2009, the court entered an order and final judgment approving the settlement and dismissing the Federal Securities Litigation with prejudice. There is no accrual in the accompanying consolidated balance sheet at December 31, 2008 and 2007 with respect to the Federal Securities Litigation.

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 Eastern District of Pennsylvania, and the Court of Common Pleas of Chester County, Pennsylvania.

On September 28, 2005, Carmine Vitale filed an action styled, Case No. 2005-61840, *Carmine Vitale v. Frank DeLape, et al.* in the 55th Judicial District Court of Harris County, Texas, and in February 2006, Mr. Vitale filed an amended petition. 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. Jeffrey Tomz, who formerly served as Isolagen’s Chief Financial Officer, was accused of engaging in insider trading of Isolagen stock through a proxy. 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 petition. The plaintiff filed an amended petition on February 15, 2006, to which the defendants renewed their special exceptions. On September 6, 2006, the Court granted the special exceptions and permitted the plaintiff thirty days to attempt to replead. Thereafter, the plaintiff moved the Court for an order compelling discovery, which the Court denied on October 2, 2006. On October 18, 2006, the Court entered an order explaining its grounds for granting the special exceptions. On November 3, 2006, the plaintiff filed a second amended petition. On February 8, 2007, the Company filed its answer and special exceptions to the second amended petition. On August 9, 2007, the Court granted the special exceptions and dismissed the second amended petition with prejudice. On September 4, 2007, the plaintiff moved for reconsideration of the dismissal with prejudice of the second amended petition, for a new trial, and for leave to further amend the petition, and the defendants opposed that motion on September 20, 2007. On October 23, 2007, that motion was deemed denied by operation of law because the court had not acted on it by that date.

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 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 February 23, 2006, the Keene action was transferred with the Federal Securities Actions from the Southern District of Texas to the Eastern District of Pennsylvania. Thereafter, on May 15, 2006, the plaintiff filed an amended complaint, and on June 5, 2006, the defendants moved to dismiss the amended complaint. On August 21, 2006, the plaintiff moved for leave to file a second amended complaint, and on September 15, 2006, defendants filed an opposition to that motion. On January 24, 2007, the court denied the plaintiff’s motion to file a second amended complaint, and on April 10, 2007 the court granted the defendants’ motion to dismiss and dismissed the amended complaint without prejudice. On May 9, 2007, plaintiff filed a notice of appeal from the January 24, 2007 order denying plaintiff’s motion to file a second amended complaint, and from the April 10, 2007 order dismissing plaintiff’s amended complaint without prejudice. The appeal is fully briefed. On or about April 5, 2008, Keene moved the appeals court to stay the appeal for a period of 90 days to permit Keene to participate in the mediation of the federal securities litigation (described above) and the Beattie derivative litigation (described below). The mediation is described under “Federal Securities Litigation” above.

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.

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On January 20, 2006, the Company filed its preliminary objections to the complaint. On August 31, 2006, the Court of Common Pleas entered an opinion and order sustaining the preliminary objections and dismissing the complaint with prejudice. On September 19, 2006, Fordyce filed a motion for reconsideration, which the Court of Common Pleas denied. On September 28, 2006, Fordyce filed a notice of appeal to the Superior Court of Pennsylvania. On July 27, 2007, the Superior Court affirmed the decision of the Court of Common Pleas.

On February 14, 2008, Ronald Beattie filed an action styled C.A. No. 08-724, Ronald Beattie v. Michael Macaluso, et al., in the United States District Court for the Eastern District of Pennsylvania. This action makes substantially similar allegations as the original complaint in the Vitale action.

On April 1, 2008, the court entered an order extending the defendants' time to respond to the complaint for a period ending 150 days from April 1, 2008 and directing the parties, together with the parties to the federal securities litigation described above, to mediation before a private mediator. The mediation is described under "Federal Securities Litigation" above.

The mediation occurred on June 2, 2008 and June 5, 2008, at which the parties reached an agreement in principle to settle the Keene and Beattie Derivative Actions, and on January 27, 2009, the parties executed a definitive settlement agreement. The settlement is subject to court approval. The court has scheduled a hearing to consider whether to approve the settlement for May 12, 2009. The proposed settlement of the Keene and Beattie Derivative Actions provides for the Company to make certain payments of attorneys' fees and expenses to counsel for Keene and Beattie. Those payments are to be made by the Company from proceeds previously received by the Company from its directors and officers liability insurance. An accrual of \$0.3 million and \$0.0 million has been recorded in the accompanying consolidated balance sheets at December 31, 2008 and 2007, respectively, in connection with the proposed settlement.

Indemnity Demands

Mr. Jeffrey Tomz

After the above referenced litigations were commenced, Mr. Jeffrey Tomz, who formerly served as Isolagen's Chief Financial Officer, demanded reimbursement of his costs of defense, and reimbursement for the costs of responding to a Securities and Exchange Commission investigation of his alleged insider trading in Isolagen stock. It is understood that Mr. Tomz's defense costs to date amount to in excess of approximately \$0.3 million.

As the Vitale matter has now been resolved in favor of all defendants, including Mr. Tomz, the Company is presently obligated to reimburse him for the reasonable and necessary costs of defending all claims asserted therein other than the insider trading allegations. Although decided on jurisdictional grounds, it is likely the Company is also obligated to reimburse Mr. Tomz for the reasonable and necessary costs incurred in defending the Fordyce matter given that it has also been resolved in favor of all defendants. The Company could potentially be liable to reimburse Mr. Tomz for the reasonable and necessary costs of defense in the Keene case and in the putative securities cases, both of which have been resolved by settlement, as described above. The Company has refused to pay the amount of fees and expenses for which Mr. Tomz has sought reimbursement because it believes they are excessive, duplicative and have not been properly segregated between reimbursable and non-reimbursable claims. The Company has negotiated an acceptable compromise for the amounts billed by Mr. Tomz's local Pennsylvania counsel for an amount less than \$0.1 million.

Prior to the resolution of the various derivative actions, Mr. Tomz filed a demand for arbitration seeking advancement of his defense costs. He subsequently agreed to stay those proceedings. At present, Mr. Tomz has not sought to lift this stay and it is uncertain whether he will attempt to do so in the future.

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The Company has accrued less than \$0.1 million in the accompanying consolidated financial statements as of December 31, 2008 with respect to Mr. Tomz's existing defense costs in dispute.

Underwriters

The Underwriters have each demanded that the Company indemnify, hold harmless and defend them with respect to the claims asserted in the putative securities actions. The total amount demanded to date is approximately \$0.8 million. The Underwriters demands for indemnification were a subject of the ongoing mediation efforts described under "Federal Securities Litigation" above, and as part of the proposed settlement of the Federal Securities Litigation the Underwriters agreed to release their claims for indemnification. Accordingly, no accrual has been recorded in the accompanying consolidated balance sheets at December 31, 2008 and December 31, 2007 in connection with the Underwriters original demand of approximately \$0.8 million.

United Kingdom

Subsequent to the Company's public announcement regarding the closure of the United Kingdom operation, the Company received negative publicity and negative correspondence from former patients in the United Kingdom that previously received the Company's treatment. To date, the Company has received written demands by an attorney representing approximately 132 former patients, as of December 31, 2008, each claiming negligent misstatements were made and each claiming, on average, £3,500 (or approximately \$5,250), plus unquantified interest and incidental expenses. The Company has responded to the written demand and is in the process of evaluating the merits of the claims. To date, no formal legal action has been brought by the attorney against the Company, and no provision has been recorded in the consolidated financial statements related to this matter.

During 2008, the Company received written correspondence from one former patient claiming physical injury allegedly from the use of Isologen Therapy. The Company believes this claim is without merit. To date, no formal legal action has been brought by the former patient against the Company, and no provision has been recorded in the consolidated financial statements related to this matter.

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 2008.

Part II**Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities****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 NYSE Amex.

	December 31, 2008		December 31, 2007	
	High	Low	High	Low
First Quarter	\$ 2.45	\$ 0.28	\$ 3.93	\$ 1.98
Second Quarter	0.86	0.31	5.00	3.54
Third Quarter	1.66	0.37	4.19	2.04
Fourth Quarter	0.84	0.17	3.40	2.24

The closing price of our common stock on March 31, 2009 was \$0.17.

On March 17, 2009, we received notice from the NYSE Amex (the "Exchange") notifying us that we are not in compliance with Section 1003(a)(iv) of the Exchange's Company Guide (the "Company Guide"). Specifically, the Exchange staff noted that we sustained losses which are so substantial in relation to our overall operations or our existing financial sources that it appears questionable, in the opinion of the Exchange, as to whether we will be able to continue operations and/or meet our obligations as they mature. As previously disclosed, we received a notice from the Exchange on March 12, 2008, advising us that we were not in compliance with Sections 1003 (a)(i)-(iii) of the Company Guide.

We currently intend to submit a plan in response to the most recent notice by April 17, 2009 outlining our compliance strategy with the current continued listing deficiency by September 14, 2009, subject to our successfully completing a sufficient financing transaction or strategic partnership prior to April 17, 2009. As of the date of the filing of this annual report, we have no commitments for any such additional funding and there is no assurance that we will receive any such additional funding. If we submit a plan and if our plan to regain compliance is accepted by the Exchange, we may be able to continue our listing during this period, during which time we will be subject to periodic review to determine progress consistent with the plan. If we do not submit a plan or if the plan is not accepted by the Exchange, we will be subject to delisting procedures as set forth in the Company Guide. Under Company Guide rules, we have the right to appeal the determination by the Exchange staff to initiate delisting proceedings and to seek a hearing before an Exchange Panel. The time and place of such a hearing will be determined by the Panel. If the Panel does not grant the relief sought by us, our common stock could be delisted from the Exchange. There is no assurance that the Exchange staff will accept our plan of compliance or that, even if such plan is accepted, we will be able to implement the plan within the prescribed timeframe.

In addition, the Exchange's notice states that our common stock has closed at between \$0.15 and \$0.87 per share over the last six months, and that the Staff is concerned that, as a result of the low selling price, our common stock may not be suitable for auction market trading. Pursuant to Section 1003(f)(v) of the Company Guide, the Exchange has notified us that it deems it appropriate that we effect a reverse stock split within a reasonable amount of time in view of the fact that our common stock has been selling for a substantial period of time at a low price per share.

These uncertainties regarding the continued listing of our common stock on the Exchange will add to the difficulty of raising additional financing through the issuance of common stock or convertible securities.

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Holders

As of March 31, 2009, we had 367 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

We did not sell unregistered securities during the fourth quarter of 2008.

Purchases of Equity Securities.

We did not repurchase any of our equity securities during the fourth quarter of 2008.

Item 6. Selected Financial Data

We are a smaller reporting company, and are not required to report this information.

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

General

We are an aesthetic and therapeutic company focused on developing novel skin and tissue rejuvenation products. Our clinical development product candidates are designed to improve the appearance of skin injured by the effects of aging, sun exposure, acne and burns with a patient's own, or autologous, fibroblast cells produced in our proprietary Isolagen Process. Our clinical development programs encompass both aesthetic and therapeutic indications. Our most advanced indication utilizing the Isolagen Process is for the treatment of nasolabial folds, or wrinkles. We completed Phase III clinical trials with respect to this indication during 2008 and submitted the related Biologics License Application to the FDA in March 2009.

We completed a Phase II/III study in acne scars in March 2009, which yielded statistically significant efficacy results, and an open-label Phase II trial with respect to full face rejuvenation during 2008, which yielded positive top line efficacy results. During 2008, we began preparations for a Phase II burn scar study, however, due to funding limitations, this study was suspended in order to preserve cash resources. Our efforts and resources are now primarily focused on obtaining FDA approval for the Isolagen Therapy nasolabial folds/wrinkle indication.

We sometimes refer to our product candidates in the aggregate as Isolagen Therapy. From 2002 through 2006, we made Isolagen Therapy available to physicians primarily in the United Kingdom. In the fourth quarter of 2006, our Board of Directors approved closing our United Kingdom operation. Our United Kingdom operation was shutdown on March 31, 2007 (as more fully discussed in Note 5 in Notes to the Consolidated Financial Statements and below).

We also develop and market an advanced skin care product line through our Agera Laboratories, Inc. subsidiary, in which we acquired a 57% interest in August 2006. Agera offers a complete line of skincare systems based on a wide array of proprietary formulations, trademarks and nano-peptide technology. Agera markets its product in both the United States and Europe (primarily the United Kingdom).

We are considered to be a "development stage" enterprise.

Going Concern and Risk of Bankruptcy

At December 31, 2008, we had cash and cash equivalents of \$2.9 million and negative working capital of \$(87.3) million. We believe that our existing capital resources are adequate to sustain our operation through approximately the end of April 2009, under our current, reduced operating plan. As such, we require additional cash resources prior to or during approximately the end of April 2009, or we will likely enter into bankruptcy and/or cease operations. Further, if we do raise additional cash resources prior to the end of April 2009, it may be raised in contemplation of or in connection with bankruptcy. In the event of a bankruptcy, it is likely that our common stock and common stock equivalents will become worthless and our creditors will receive significantly less than what is owed to them. As of the date of the filing of this annual report, we have no commitments for any such additional funding and there is no assurance that we will receive any such additional funding.

As of December 31, 2008, we had \$90 million of debt which could be called due as early as November 2009, at the option of the bond holders. Further, approximately \$1.6 million of interest related to this debt is due on May 1, 2009. We currently do not have the cash or available funding to pay the interest of \$1.6 million due May 1, 2009.

Through December 31, 2008, we have been primarily engaged in developing our initial product technology. In the course of our development activities, we have sustained losses and expect such losses to continue through at least 2009. In fiscal 2008 we financed our operations primarily through our existing cash, but as discussed above we now require additional financing. There is substantial doubt about our ability to continue as a going concern.

We will require additional capital to continue our operations past approximately the end of April 2009. There is no assurance that we will be able to obtain any such additional capital as we need to finance these efforts, through asset sales, equity or debt financing, or any combination thereof, on satisfactory terms or at all. Additionally, no assurance can be given that any such financing, if obtained, will be adequate to meet our ultimate capital needs and to support our growth. If adequate capital cannot be obtained on a timely basis and on satisfactory terms, our operations would be materially negatively impacted. If we do not obtain additional funding, or do not anticipate additional funding, prior to approximately the end of April 2009, we will likely enter into bankruptcy and/or cease operations. Further, if we do raise additional cash resources prior to the end of April 2009, it may be raised in contemplation of or in connection with bankruptcy.

We filed a shelf registration statement on Form S-3 during June 2007, which was subsequently declared effective by the SEC. The shelf registration allows us the flexibility to offer and sell, from time to time, up to an original amount of \$50 million of common stock, preferred stock, debt securities, warrants or any combination of the foregoing in one or more future public offerings. In August 2007, we sold under this shelf registration statement 6,746,647 shares of common stock to institutional investors, raising proceeds of \$13.8 million, net of offering costs. We may offer and sell up to an additional \$36.2 million of securities pursuant to this shelf registration. However, in general, companies that are under \$75 million in market capitalization, such as Isolagen, are limited to selling up to one-third of the value of such company's common stock held by non-affiliates in any twelve month period.

Our ability to complete additional offerings, including any additional offerings under our shelf registration statement, is dependent on the state of the debt and/or equity markets at the time of any proposed offering, and such market's reception of the Company and the offering terms. Currently the credit and equity markets both in the United States and internationally are severely contracted, which will make our task of raising additional debt or equity capital even more difficult. In addition, our ability to raise additional financing through the issuance of common stock or convertible securities may be adversely affected by uncertainties regarding the continued listing of our common stock on the NYSE Amex (see Part II, Item 5). Finally, our ability to complete an offering may be dependent on the status of our FDA regulatory milestones and our clinical trials, and in particular, the status of our indication for the treatment of nasolabial folds, the status of the related Biologics License Application, and the status of our Phase II/III acne scar trial, which cannot be predicted. There is no assurance that capital in any form would be available to us, and if available, on terms and conditions that are acceptable.

As a result of the conditions discussed above, and in accordance with generally accepted accounting principles in the United States, there exists substantial doubt about our ability to continue as a going concern, and our ability to continue as a going concern is contingent, among other things, upon our ability to secure additional adequate financing or capital prior to or during approximately the end of April 2009. If we do not obtain additional funding, or do not anticipate additional funding, prior to or during approximately the end of April 2009, we will likely enter into bankruptcy and/or cease operations. Further, if we do raise additional cash resources prior to the end of April 2009, it may be raised in contemplation of or in connection with bankruptcy. If we enter into bankruptcy, it is likely that our common stock and common stock equivalents will become worthless and our creditors will receive significantly less than what is owed to them.

Due to the likelihood of bankruptcy and in connection with the Company's review for impairment of long-lived assets in accordance with SFAS 144, "Accounting for the Impairment or Disposal of Long-lived Assets," we have recorded a full impairment on all of our long-lived assets as of December 31, 2008, and as such, we have recorded an impairment charge of \$6.7 million during the year ended December 31, 2008.

Closure of the United Kingdom Operation

As part of our continuing efforts to evaluate the best uses of our resources, in the fourth quarter of 2006 our Board of Directors approved the proposed closing of the United Kingdom operation. On March 31, 2007, we completed the closure of the United Kingdom manufacturing facility.

Since our public announcement regarding the closure of the United Kingdom operation, we have received negative publicity and negative correspondence from former patients in the United Kingdom that previously received our treatment. We received a written demand by an attorney representing approximately 132 former patients each claiming negligent misstatements were made and each claiming, on average, £3,500 (or approximately \$5,250), plus unquantified interest and incidental expenses. To date, no formal legal action has been brought by the attorney against the Company, and no provision has been recorded in the consolidated financial statements related to this matter. Further, during 2008 we received written correspondence from one former patient claiming physical injury allegedly from the use of Isolagen Therapy. To date, no formal legal action has been brought by the former patient against the Company, and no provision has been recorded in the consolidated financial statements related to this matter.

With the closure of the United Kingdom operation on March 31, 2007, our European operations (both the United Kingdom and Switzerland) and Australian operations have been presented in the financial statements as discontinued operations for all periods presented. See Note 5 of Notes to Consolidated Financial Statements.

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 3 of the 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 of the control of management. As a result they are subject to an inherent degree of uncertainty. In applying these policies, our management uses their judgment to determine the appropriate assumptions to be used in the determination of certain estimates. Those estimates are based on our historical operations, our future business plans and projected financial results, the terms of existing contracts, our observance of trends in the industry, information provided by our customers and information available from other outside sources, as appropriate. The following discusses our critical accounting policies and estimates.

Going Concern: As disclosed in Note 2 to the Consolidated Financial Statements, management has concluded that substantial doubt exists about the Company's ability to continue as a going concern. This conclusion is based on estimates of our future spending and future funding required during 2009. We will be required to obtain additional capital in April 2009 to continue and expand our operations. There is no assurance that we will be able to obtain any such additional capital as we need to finance these efforts, through asset sales, equity or debt financing, or any combination thereof, or on satisfactory terms or at all.

At December 31, 2008, our cash and cash equivalents was \$2.9 million. For the year ended December 31, 2008, our cash used for operations was \$20.0 million. These factors, as well as our future spending estimates, were important factors in concluding that substantial doubt exists about our ability to continue as a going concern. We believe these estimates are particularly important to the understanding of our financial position.

Due to the likelihood of bankruptcy and in connection with the Company's review for impairment of long-lived assets in accordance with SFAS 144, "Accounting for the Impairment or Disposal of Long-lived Assets," we have recorded a full impairment on all of our long-lived assets as of December 31, 2008, and as such, we have recorded an impairment charge of \$6.7 million during the year ended December 31, 2008.

Stock-Based Compensation: In December 2004, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 123 (revised 2004), "Share-Based Payment" ("SFAS No. 123 (R)"). SFAS No. 123 (R) replaces SFAS No. 123, "Accounting for Stock-Based Compensation," supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB No. 25"), and amends SFAS No. 95, "Statement of Cash Flows." SFAS No. 123 (R) requires entities to recognize compensation expense for all share-based payments to employees and directors, including grants of employee stock options, based on the grant-date fair value of those share-based payments, adjusted for expected forfeitures.

We adopted SFAS No. 123(R) as of January 1, 2006 using the modified prospective application method. Under the modified prospective application method, the fair value measurement requirements of SFAS No. 123(R) is applied to new awards and to awards modified, repurchased, or cancelled after January 1, 2006. Additionally, compensation cost for the portion of awards for which the requisite service has not been rendered that were outstanding as of January 1, 2006 is recognized as the requisite service is rendered on or after January 1, 2006. The compensation cost for that portion of awards is based on the grant-date fair value of those awards as calculated for pro forma disclosures under SFAS No. 123. Changes to the grant-date fair value of equity awards granted before January 1, 2006 are precluded.

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The fair value of stock options is determined using the Black-Scholes valuation model, which is consistent with our valuation techniques previously utilized for awards in footnote disclosures required under SFAS No. 123. Prior to the adoption of SFAS No. 123(R), we followed the intrinsic value method in accordance with APB No. 25 to account for our employee and director stock options. Historically, substantially all stock options have been granted with an exercise price equal to the fair market value of the common stock on the date of grant. Accordingly, no compensation expense was recognized from substantially all option grants to employees and directors prior to the adoption of SFAS No. 123(R). However, compensation expense was recognized in connection with the issuance of stock options to non-employee consultants in accordance with EITF 96-18, "Accounting for Equity Instruments That are Issued to Other than Employees for Acquiring, or in Conjunction with Selling Goods and Services." SFAS No. 123(R) did not change the accounting for stock-based compensation related to non-employees in connection with equity based incentive arrangements.

The adoption of SFAS No. 123(R) requires additional accounting related to the income tax effects and additional disclosure regarding the cash flow effects resulting from share-based payment arrangement. This change in accounting resulted in the recognition of compensation expense of \$0.7 million and \$1.8 million related to our employee and director stock options for the years ended December 31, 2008 and 2007, respectively. During the year ended December 31, 2008, we granted stock options to purchase 1.1 million shares of our common stock. As of December 31, 2008, there was \$0.7 million of total unrecognized compensation cost related to non-vested director and employee stock options which vest over time. That cost is expected to be recognized over a weighted-average period of 1.7 years. As of December 31, 2008, there was \$0.3 million of total unrecognized compensation cost related to performance-based, non-vested employee stock options. That cost will begin to be recognized when the performance criteria within the respective performance-base option grants become probable of achievement.

In March 2007, and in connection with the separation of the Company's President, the Company agreed to modify certain of the President's stock options such that (1) 120,000 unvested, time-based stock options would vest immediately and (2) of 400,000 performance based stock options, 100,000 would be cancelled and the remaining 300,000 would be extended such that the 300,000 options would expire 10 years from the original grant date, as opposed to expiring upon termination of employment. The 300,000 performance based stock options will continue to be subject to the same performance based vesting requirements. The 120,000 modified stock options were valued using the Black-Scholes valuation model, and resulted in \$0.3 million charge to selling, general and administrative expense during the year ended December 31, 2007. The 300,000 modified performance stock options were valued using the Black-Scholes valuation model, and resulted in \$0.8 million charge to selling, general and administrative expense during the year ended December 31, 2007. Two other employee stock option modifications resulted in less than \$0.1 million charge to selling, general and administrative expense during the year ended December 31, 2007.

On January 7, 2008, we and Mr. Nicholas L. Teti, Jr. entered into a consulting and non-competition agreement (the "Consulting Agreement"), pursuant to which Mr. Teti agreed to continue as our non-executive Chairman of the Board and to become a consultant to the company, and Mr. Teti resigned his position as Chief Executive Officer and President. Mr. Teti retained his previously issued stock options which were modified such that Mr. Teti will continue to vest in accordance with the original terms, except as a non-employee. As a result of the modifications to Mr. Teti's stock options set forth in the Consulting Agreement, we recorded a non-cash compensation charge during the three months ended March 31, 2008 of approximately \$1.3 million related to Mr. Teti's 1,166,665 vested stock options. Further, related to Mr. Teti's 833,335 unvested stock options at the date of modification, we record stock option expense over the remaining periods those stock options are earned in accordance with EITF 96-18, "Accounting for Equity Instruments That are Issued to Other than Employees for Acquiring, or in Conjunction with Selling Goods and Services."

Accounting for Legal Matters: As discussed in Note 11 of Notes to Consolidated Financial Statements, set forth elsewhere in this Report, we have settled in principle our class and derivative actions. We have also received threats of litigation and demands from former patients associated with our United Kingdom operation. 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 is not recorded until it is probable that a liability has been incurred and the amount of the liability can be reasonably estimated. We expense our legal costs as they are incurred and 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.

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.

Impairment of Long-lived Assets: SFAS No.144 (“SFAS 144”), “Accounting for the Impairment of Long-lived Assets and for Long-lived Assets to be Disposed Of” addresses financial accounting and reporting for the impairment or disposal of long-lived assets. SFAS 144 requires that long-lived assets be reviewed for impairment whenever events or changes in circumstances indicate that their carrying amounts may not be recoverable. If the cost basis of a long-lived asset is greater than the projected future undiscounted net cash flows from such asset (excluding interest), an impairment loss is recognized. Impairment losses are calculated as the difference between the cost basis of an asset and its estimated fair value.

Due to the likelihood of bankruptcy and in connection with the Company’s review for impairment of long-lived assets in accordance with SFAS 144, “Accounting for the Impairment or Disposal of Long-lived Assets,” we have recorded a full impairment on all of our long-lived assets as of December 31, 2008, and as such, we have recorded an impairment charge of \$6.7 million during the year ended December 31, 2008 in the consolidated statement of operations.

-Results of Operations—Comparison of Years Ending December 31, 2008 and 2007

REVENUES. Revenue decreased \$0.3 million to \$1.1 million for the year ended December 31, 2008, as compared to \$1.4 million for the year ended December 31, 2007. Our revenue from continuing operations is from the operations of Agera which we acquired on August 10, 2006. Agera markets and sells a complete line of advanced skin care systems based on a wide array of proprietary formulations, trademarks and non-peptide technology. Due to our financial statement presentation of our United Kingdom operation as a discontinued operation, our revenue for all periods presented is representative of only Agera, as all historical United Kingdom revenue is reflected in loss from discontinued operations. We believe that the decline in Agera’s sales in fiscal 2008 was due to the general economic conditions during 2008. In addition, for cash conservation purposes, we have reduced marketing expenses from the prior year. Agera management is undergoing efforts to increase and diversify its customer base. We currently expect first quarter 2009 revenue to be approximately \$0.2 million.

COST OF SALES. Costs of sales decreased \$0.1 million to \$0.6 million for the year ended December 31, 2008, as compared to \$0.7 million for the year ended December 31, 2007. Our cost of sales relates to the operation of Agera.

As a percentage of revenue, Agera cost of sales were approximately 55% for the year ended December 31, 2008 and approximately 47% for the year ended December 31, 2007. The increase in 2008 cost of sales as a percentage of revenue, as compared to 2007, is primarily due to inventory reserves recorded during 2008 of less than \$0.1 million. Excluding the increase in inventory reserve, Agera cost of sales as a percentage of revenue would have been approximately 46% for the year ended December 31, 2008.

IMPAIRMENT OF LONG-LIVED ASSETS. Due to the likelihood of bankruptcy and in connection with the Company’s review for impairment of long-lived assets in accordance with SFAS 144, “Accounting for the Impairment or Disposal of Long-lived Assets,” we have recorded a full impairment on all of our long-lived assets as of December 31, 2008, and as such, we have recorded an impairment charge of \$6.7 million during the year ended December 31, 2008 in the consolidated statement of operations.

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SELLING, GENERAL AND ADMINISTRATIVE EXPENSES. Selling, general and administrative expenses decreased approximately \$10.3 million, or 55%, to \$8.5 million for the year ended December 31, 2008, as compared to \$18.7 million for the year ended December 31, 2007. The decrease in selling, general and administrative expense is primarily due to the following:

a) For the year ended December 31, 2008, there was no severance expense as compared to the year ended December 31, 2007. Severance expense and related costs associated with the termination of our former president, pursuant to a settlement agreement executed in June 2007, resulted in an additional \$4.6 million of selling, general and administrative expense for the year ended December 31, 2007 (see Notes 11 and 13 of Notes to Consolidated Financial Statements).

b) Salaries, bonuses and payroll taxes decreased by approximately \$1.5 million to \$3.8 million for the year ended December 31, 2008, as compared to \$5.3 million for the year ended December 31, 2007, due to a decrease in the number of our employees, primarily at the executive management level, which resulted in lower salary expense. In addition to the lower salary expense, there was no bonus expense for the year ended December 31, 2008 as compared to December 31, 2007, due to our financial position at December 31, 2008.

c) Marketing expense decreased by approximately \$0.7 million to \$0.1 million for the year ended December 31, 2008, as compared to \$0.8 million during the year ended December 31, 2007 due primarily to decreased marketing and promotional efforts related to marketing and selling our Agera line of advanced skin care systems.

d) Travel expense decreased by approximately \$0.5 million to \$0.2 million for the year ended December 31, 2008, as compared to \$0.7 million for the year ended December 31, 2007 due to the decrease in the number of our employees, primarily at the executive management level, decrease in business development activities during 2008, and focused efforts to conserve cash resources during 2008.

e) Other general and administrative expenses decreased by approximately \$2.7 million to \$4.1 million for the year ended December 31, 2008, as compared to \$6.8 million for the year ended December 31, 2007. The majority of this decrease, or \$1.5 million, was due to 2007 activities which did not occur during 2008, such as costs related to debt restructuring and business development activities. The remaining decrease of \$1.2 million in other general and administrative expenses are due to cost-saving measures implemented during 2008, including savings related to accounting and audit expenses, insurance premiums, consultants and other general costs.

f) Legal expenses decreased by approximately \$0.3 million to \$0.3 million for the year ended December 31, 2008, as compared to \$0.6 million for the year ended December 31, 2007. For the years ended December 31, 2008 and December 30, 2007, we received \$1.3 million and \$1.7 million, respectively, of reimbursements from our insurance carrier as reimbursement for defense costs related to our class action and derivative matters. If we had not received these reimbursements, our legal expenses would have been \$1.6 million for the year ended December 31, 2008 and \$2.3 million for the year ended December 31, 2007. As such, excluding reimbursements of legal defense costs, our legal expenses have decreased \$0.7 million in 2008 from the prior year as a result of the June 2008 mediation efforts which resulted in a settlement in principle related to our class action and derivative action matters. Our legal expenses fluctuate primarily as a result of the amount and timing of defense costs related to our class action and derivative action matters, as well as a result of the amount and timing of defense cost reimbursements from our insurance carrier. Such reimbursements are recorded when received. We also incurred \$0.2 million in legal costs, during the year ended December 31, 2008, related to investigating and responding to claims related to our previous United Kingdom operation (see Note 11 — Commitments and Contingencies for a discussion of our various legal matters).

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RESEARCH AND DEVELOPMENT. Research and development expenses decreased by approximately \$3.1 million for the year ended December 31, 2008 to \$10.2 million, as compared to \$13.3 million for the year ended December 31, 2007. Research and development costs are composed primarily of costs related to our efforts to gain FDA approval for our Isolagen Therapy for specific dermal applications in the United States, as well as costs related to other potential indications for our Isolagen Therapy, such as acne scars and burn scars. Also, research and development expense includes costs to develop manufacturing, cell collection and logistical process improvements. Research and development costs primarily include personnel and laboratory costs related to these FDA trials and certain consulting costs. The total inception to date cost of research and development as of December 31, 2008 was \$54.2 million.

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

The major changes in research and development expenses are due primarily to the following:

- a) Consulting expense decreased by approximately \$1.7 million to \$4.9 million for the year ended December 31, 2008, as compared to \$6.6 million for the year ended December 31, 2007, primarily as a result of decreased expenditures related to our Phase III wrinkle/nasolabial fold study, which concluded during 2008.
- b) Salaries, bonuses and payroll taxes decreased by approximately \$0.6 million to \$2.4 million for the year ended December 31, 2008, as compared to \$3.0 million for the year ended December 31, 2007, as a result of decreased employees engaged in research and development activities. In addition to lower salary expense, there was no bonus expense for the year ended December 31, 2008 as compared to December 31, 2007, due to our financial position at December 31, 2008.
- c) Laboratory costs decreased by approximately \$0.5 million to \$1.0 million for the year ended December 31, 2008, as compared to \$1.5 million for the year ended December 31, 2007, as a result of decreased clinical and manufacturing activities in our Exton, Pennsylvania location, primarily due to the completion of the Phase III nasolabial folds trials during 2008.
- d) Contract labor support related to our clinical manufacturing operation decreased \$0.3 million to \$0.2 million for the year ended December 31, 2008, as compared to \$0.5 million for the year ended December 31, 2007, as a result of decreased clinical activities in our Exton, Pennsylvania location.
- e) Facilities, depreciation and travel costs remained constant at \$1.7 million for the year ended December 31, 2008 and December 31, 2007.

LOSS FROM DISCONTINUED OPERATIONS. As discussed above under “—Closure of the United Kingdom Operation,” during the three months ended December 31, 2006, the Board of Directors approved the closure of our United Kingdom operation. The United Kingdom operation was closed in March 2007.

The loss from discontinued operations increased by approximately \$2.8 million for the year ended December 31, 2008 to \$4.5 million, as compared to \$1.7 million for the year ended December 31, 2007. The \$4.5 million loss from discontinued operations for the year ended December 31, 2008, primarily related to the sale of our Swiss campus in March 2008. In connection with this sale, we recorded a loss on sale of \$6.3 million, offset by a foreign currency exchange gain of \$2.1 million upon the substantial liquidation of the Swiss subsidiary. The foreign exchange gain recorded during the three months ended March 31, 2008 results from removing from the accumulated foreign currency translation adjustment account in stockholders' equity, a credit balance which related to the translation into U.S. dollars of our Swiss franc assets and liabilities. The credit balance which had accumulated, and the resulting gain recorded upon the substantial liquidation of our Swiss franc assets, reflected the increase in the value of the Swiss franc relative to the U.S. dollar over the period that we had operated in Switzerland. Refer to Notes 3 and 5 of Notes to the Consolidated Financial Statements for further discussion regarding the sale of the Swiss campus and results from discontinued operations. Administrative costs and facility costs related to the United Kingdom and Swiss operations comprised approximately \$0.3 million, net, during the year ended December 31, 2008.

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The \$1.7 million loss from discontinued operations during the year ended December 31, 2007 consisted of \$1.1 million of losses incurred during the first quarter 2007, which was the United Kingdom's last quarter of full operations, and \$0.6 million of second, third and fourth quarter 2007 losses. The \$1.1 million loss from discontinued operations during the three months ended March 31, 2007 primarily consisted of the following:

- a) Salaries, severance expense and payroll taxes were approximately \$0.3 million for the three months ended March 31, 2007.
- b) Other general and administrative operating costs were approximately \$0.5 million primarily related to lease expense and operating costs incurred during the three months ended March 31, 2007.
- c) Gross loss was \$0.3 million during the three months ended March 31, 2007, primarily due to low production volumes during the shutdown period and due to the write-off of unrealizable inventory used in the manufacturing process.

As of December 31, 2008, all previously leased facilities related to discontinued operations have been exited, and all buildings, property and equipment related to discontinued operations have been sold or otherwise disposed of.

INTEREST INCOME. Interest income decreased approximately \$0.7 million to \$0.2 million for the year ended December 31, 2008, as compared to \$0.9 million for the year ended December 31, 2007. The decrease in interest income of \$0.7 million resulted from a decrease in the amount of cash, cash equivalents and restricted cash balances, as a result of our use of these balances primarily to fund our operating activities related to our efforts to gain FDA approval for our Isolgen Therapy.

INTEREST EXPENSE. Interest expense remained constant at \$3.9 million for the year ended December 31, 2008, as compared to the year ended December 31, 2007. Our interest expense is related to our \$90.0 million, 3.5% convertible subordinated notes, as well as the related amortization of deferred debt issuance costs of \$0.8 million for each of the years ended December 31, 2008 and 2007, respectively.

MINORITY INTEREST. Minority interest income increased to \$1.7 million for the year ended December 31, 2008, as compared to \$0.2 million for the year ended December 31, 2007. The increase in minority interest income of \$1.5 million is primarily due to an impairment charge recorded during the year ended December 31, 2008 of \$3.7 million, which related to the full impairment of the Agera segment intangible assets, and the associated 43% minority interest ownership of Agera.

NET LOSS. Net loss decreased \$4.2 million to \$31.4 million for the year ended December 31, 2008, as compared to a net loss of \$35.6 million for the year ended December 31, 2007. This decrease in our net loss primarily represents the effects of decreased research and development expenses and general and administrative expenses as a result of decreased spending for clinical trials, the reduction in employees and compensation expense and cost saving measures implemented during 2008, and increased minority interest income, offset by the impairment charge of \$6.7 million related to long-lived assets for the year ended December 31, 2008, the increase in loss from discontinued operations and reductions in interest income, as discussed above.

Liquidity and Capital Resources

Cash Flows

Net cash provided by (used in) operating, investing and financing activities for the two years ended December 31, 2008 and 2007 were as follows:

	Year Ended December 31,	
	2008	2007
	(in millions)	
Cash flows from operating activities	\$ (20.0)	\$ (29.7)
Cash flows from investing activities	6.4	(0.1)
Cash flows from financing activities	—	14.7

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OPERATING ACTIVITIES. Cash used in operating activities during the year ended December 31, 2008 amounted to \$20.0 million, a decrease of \$9.7 million over the year ended December 31, 2007. The decrease in our cash used in operating activities over the prior year is primarily due to a decrease in net losses (adjusted for non-cash items) of \$12.6 million, offset by operating cash outflows from changes in operating assets and liabilities. The change in operating assets and liabilities is primarily due to a large decrease in accrued liabilities (see Note 8 of Notes to the Consolidated Financial Statements) at December 31, 2008 as compared to December 31, 2007.

Our negative operating cash flows in 2008 were funded from cash on hand at December 31, 2007, which were primarily the result of previously completed debt and equity offerings, as well as from the proceeds of the sale of our Swiss campus in March 2008, discussed further below.

INVESTING ACTIVITIES. Cash provided by investing activities during the year ended December 31, 2008 amounted to approximately \$6.4 million as compared to cash used in investing activities of \$0.1 million during the year ended December 31, 2007. Investing activities during the year ended December 31, 2008 related primarily to the sale of our Swiss campus in March 2008 for approximately \$6.4 million, net of selling costs.

FINANCING ACTIVITIES. There were no financing activities during the year ended December 31, 2008, as compared to \$14.7 million cash proceeds from financing activities during the year ended December 31, 2007. In August 2007, we raised \$13.8 million, net of offering costs, via the sale of 6.8 million shares of our common stock to institutional investors. In addition, during the year ended December 31, 2007, we received cash proceeds of approximately \$0.9 million as a result of stock option and warrant exercises.

Cash Flows Related to Discontinued Operations

Cash flows related to discontinued operations, which are included in the table of cash flows above, were as follows:

	<u>Years Ended December 31,</u>	
	<u>2008</u>	<u>2007</u>
	<u>(in millions)</u>	
Cash flows used in operating activities	\$ (0.3)	\$ (2.6)
Cash flows provided by investing activities	6.4	0.1

The cash provided by investing activities during the year ended December 31, 2008 of \$6.4 million, related to the sale of our Swiss campus, during 2008 is discussed above under "Investing Activities."

Cash flows used in discontinued operations during the year ended December 31, 2007 was \$2.6 million. Our United Kingdom operation was active during the three months ended March 31, 2007, and was shutdown on March 31, 2007. The net loss from our United Kingdom operation during the three months ended March 31, 2007 was \$1.1 million. In addition, accrued expenses and deferred revenue decreased by \$1.2 million during this shutdown period (cash outflows), primarily related to the payment of severance and refunds to customers.

Working Capital

GENERAL: As of December 31, 2008, we had cash and cash equivalents of \$2.9 million and negative working capital of \$(87.3) million (including our cash and cash equivalents). We believe our existing capital resources are adequate to finance our operation through approximately the second half of April 2009, under our current reduced operating plan; however, our long-term viability is dependent upon our ability to raise additional debt and/or equity to meet our business objectives, the approval of our products, the successful operation of our business, and our ability to improve our manufacturing process. We estimate that we will require additional cash resources by the end of the second half of April 2009. As of the date of the filing of this annual report, we have no commitments for any such additional funding and there is no assurance that we will receive any such additional funding. See "— Going Concern and Risk of Bankruptcy" above.

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DEBT: 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 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 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 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. As the holders have the right to require us to repurchase their notes on November 1, 2009, the notes are recorded as a current liability on our consolidated balance sheet as of December 31, 2008, resulting in negative working capital of \$(87.3) as of December 31, 2008. Further, approximately \$1.6 million of interest is due on May 1, 2009, and we currently do not have the available capital resources to pay this interest when due.

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, 2008.

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.

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

During the fourth quarter of 2008, management, including our principal executive officer and principal financial officer, evaluated the disclosure controls and procedures related to the recording, processing, summarization and reporting of information in the periodic reports that the Company files with the SEC. These disclosure controls and procedures have been designed to ensure that (a) material information relating to the Company, including its consolidated subsidiaries, is made known to management, including these officers, by other employees of the Company, and (b) this information is recorded, processed, summarized, evaluated and reported, as applicable, within the time periods specified in the SEC's rules and forms.

Accordingly, as of December 31, 2008, 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, 2008. This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report.

Changes in Internal Controls

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

Item 9B. Other Information

Since December 31, 2008, two note holders have converted \$2.3 million of the 3.5% Subordinated Notes into 247,774 common shares of the Company.

Part III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item 10 will be included in the Company's Proxy Statement for the 2009 Annual Meeting of Stockholders which will be filed with the Securities and Exchange Commission no later than April 30, 2009 and is incorporated into this Item 10 by reference.

Code of Ethics. We have adopted a written code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller and any persons performing similar functions. The code of ethics is on our website at www.isolagen.com. We intend to disclose any future amendments to, or waivers from, the code of ethics within four business days of the waiver or amendment through a website posting or by filing a Current Report on Form 8-K with the SEC.

Item 11. Executive Compensation

The information required by this Item 11 will be included in the Company's Proxy Statement for the 2009 Annual Meeting of Stockholders which will be filed with the Securities and Exchange Commission no later than April 30, 2009 and is incorporated into this Item 11 by reference.

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

Except as provided below, the information required by this Item 12 will be included in the Company's Proxy Statement for the 2009 Annual Meeting of Stockholders which will be filed with the Securities and Exchange Commission no later than April 30, 2009 and is incorporated into this Item 12 by reference.

Securities Authorized for Issuance Under Equity Compensation Plans

As of December 31, 2008, our equity compensation plan information was as follows:

	<i>Number of Securities to be issued upon exercise of outstanding options</i>	<i>Weighted-average exercise price of outstanding options</i>	<i>Number of securities remaining for future issuance</i>
Equity compensation plans approved by security holders	4,868,500	\$ 3.49	3,773,652
Equity compensation plans not approved by security holders (1)	<u>3,568,333</u>	\$ 2.42	—
Total	<u>8,436,833</u>	\$ 3.04	<u>3,773,652</u>

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

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

The information required by this Item 13 will be included in the Company's Proxy Statement for the 2009 Annual Meeting of Stockholders which will be filed with the Securities and Exchange Commission no later than April 30, 2009 and is incorporated into this Item 13 by reference.

Item 14. Principal Accountant Fees and Services

The information required by this Item 14 will be included in the Company's Proxy Statement for the 2009 Annual Meeting of Stockholders which will be filed with the Securities and Exchange Commission no later than April 30, 2009 and is incorporated into this Item 14 by reference.

Part IV

Item 15. Exhibits and Financial Statement Schedule

(a)(1) Financial Statements.

- Report of Independent Registered Public Accounting Firm
- Consolidated Balance Sheets as of December 31, 2008 and 2007
- Consolidated Statements of Operations for the years ended December 31, 2008 and 2007 and inception to December 31, 2008
- Consolidated Statements of Shareholders' Equity and Comprehensive Loss from inception to December 31, 2008
- Consolidated Statements of Cash Flows for the years ended December 31, 2008 and 2007 and inception to December 31, 2008
- Notes to Consolidated Financial Statements

(a)(2) Financial Statement Schedule.

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

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

(b) Exhibits.

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

EXHIBIT NO. IDENTIFICATION OF EXHIBIT

EXHIBIT NO.	IDENTIFICATION OF EXHIBIT
2	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)	Third Amended and Restated Bylaws(25)
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)
4.5	Rights Agreement, dated as of May 12, 2006, by and between the registrant and American Stock Transfer & Trust Company, including the Form of Certificate of Designation, Preferences and Rights of Series C Junior Participating Preferred Stock attached as Exhibit A thereto, the Form of Rights Certificate attached as Exhibit B thereto and the Summary of Rights to Purchase Preferred Stock attached as Exhibit C thereto. (21)
10.1	2003 Stock Option and Stock Appreciation Rights Plan(3)*
10.2	2001 Stock Option and Appreciation Rights Plan(4)*
10.3	Lease Agreement dated March 24, 2002 by and between the Registrant as Lessee and Claire O Aceti Gbmh as Lessor(7)

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EXHIBIT NO.	IDENTIFICATION OF EXHIBIT
10.4	Intellectual Property Purchase Agreement between Isolagen Technologies, Inc., Gregory M. Keller, and PacGen Partners(8)
10.5	Purchase Agreement among CIBC World Market Corp., UBS Securities LLC, and Adams, Harkness & Hill, Inc. dated October 28, 2004(11)
10.6	Registration Rights Agreement among CIBC World Market Corp., UBS Securities LLC, and Adams, Harkness & Hill, Inc. dated November 3, 2004(11)
10.7	Lease Agreement between Isolagen Technologies, Inc. and Beltway 8 Service Center Investors Ltd. dated February 16, 2005(13)
10.8	Lease Agreement between Isolagen, Inc and The Hankin Group dates April 7, 2005(15)
10.9	Purchase Option Agreement between Isolagen, Inc and 405 Eagleview Associates dated April 7, 2005(15)
10.10	2005 Equity Incentive Plan, as amended(18)
10.11	Separation and Release Agreement, dated October 27, 2005, among Isolagen, Inc., Isolagen Technologies, Inc. and Frank DeLape(19)
10.12	Employment Agreement dated March 12, 2007 between Isolagen, Inc. and Steven Trider(23)*
10.13	Settlement Agreement and Release between Susan Stranahan Ciallella and Isolagen, Inc. dated June 8, 2007 (24)
10.14	Consulting and Non-Competition Agreement dated January 7, 2008 between Isolagen, Inc. and Nicholas L. Teti * (26)
10.15	Employment Agreement dated January 7, 2008 between Isolagen, Inc. and Declan Daly(26)*
10.16	Employment Agreement between Isolagen, Inc. and Todd J. Greenspan, dated March 11, 2008.(27)*
10.17	Agreement related to the Sale of Swiss Real Estate, dated March 19, 2008, between Isolagen International, SA and Dernier Batz SA.(27)
10.18	Settlement, Mutual Release and Lease Termination Agreement, dated August 2008, among Isolagen, Inc., Isolagen Technologies, Inc. and Claire O Aceti GmbH.(28)
14	Code of Ethics(9)
21	List of Subsidiaries(23)
23	BDO Seidman, LLP Consent(29)
31.1	Certification pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002(29)
31.2	Certification pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002(29)
32.1	Certification pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002(29)
32.2	Certification pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002(29)

* 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.

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- (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 23, 2005, and is incorporated by reference hereto.
- (14) Reserved.
- (15) Previously filed as an exhibit to the company's Form 8-K, filed on April 12, 2005, and is incorporated by reference hereto.
- (16) Reserved.
- (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 November 2, 2005, and is incorporated by reference hereto.
- (20) Reserved.
- (21) Previously filed as an exhibit to the company's Form 8-K, filed on May 15, 2006, and is incorporated by reference hereto.
- (22) Reserved.
- (23) Previously filed as an exhibit to the company's Annual Report on Form 10-K for the fiscal year ended December 31, 2006, and is incorporated by reference hereto.
- (24) Previously filed as an exhibit to the company's Form 8-K, filed on June 13, 2007, and is incorporated by reference hereto.
- (25) Previously filed as an exhibit to the company's Form 8-K, filed on January 8, 2008, and is incorporated by reference hereto.
- (26) Previously filed as an exhibit to the company's Annual Report on Form 10-K for the fiscal year ended December 31, 2007, and is incorporated by reference hereto.
- (27) Previously filed as an exhibit to the company's Form 10-Q for the fiscal quarter ended March 31, 2008, as filed on May 9, 2008, and is incorporated by reference hereto.
- (28) Previously filed as an exhibit to the company's Form 10-Q for the fiscal quarter ended September 30, 2008, as filed on November 6, 2008, and is incorporated by reference hereto.
- (29) 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/ Declan Daly
Declan Daly, Chief Executive Officer

Date: April 14, 2009

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/ Nicholas L. Teti</u> Nicholas L. Teti	Chairman of the Board of Directors	April 14, 2009
<u>/s/ Declan Daly</u> Declan Daly	Chief Executive Officer and Director	April 14, 2009
<u>/s/ Todd J. Greenspan</u> Todd J. Greenspan	Chief Financial Officer	April 14, 2009
<u>/s/ Steven Morrell</u> Steven Morrell	Director	April 14, 2009
<u>/s/ Henry Toh</u> Henry Toh	Director	April 14, 2009
<u>/s/ Marshall G. Webb</u> Marshall G. Webb	Director	April 14, 2009
<u>/s/ Terry E. Vandewarker</u> Terry E. Vandewarker	Director	April 14, 2009
<u>/s/ Kenneth A. Selzer</u> Kenneth A. Selzer	Director	April 14, 2009

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Isolagen, Inc.
(A Development Stage Company)

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Isolagen, Inc. (a development stage company)
Exton, Pennsylvania

We have audited the accompanying consolidated balance sheets of Isolagen, Inc. (in the development stage) as of December 31, 2008 and 2007 and the related consolidated statements of operations, shareholders' equity (deficit) and comprehensive loss, and cash flows for each of the years then ended. We have also audited the statements of shareholders' equity (deficit) for the period from December 28, 1995 (inception) to December 31, 2006. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of internal control over financial reporting as of December 31, 2008. Our audit for the year ended December 31, 2008 included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Isolagen, Inc. at December 31, 2008 and 2007, and the results of its operations and its cash flows for each of the years then ended and the statements of shareholders' equity (deficit) for the period from December 28, 1995 (inception) to December 31, 2008 in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations, has a net capital deficit, and the remaining outstanding obligations of the debt balance of \$90 million at December 31, 2008 may be put to the Company in November 2009 that raise substantial doubt about its ability to continue as a going concern. Management's plan in regard to these matters is also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ BDO Seidman, LLP
Houston, Texas
April 14, 2009

Isolagen, Inc.
(A Development Stage Company)

Consolidated Balance Sheets

	December 31,	
	2008	2007
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,854,300	\$ 16,590,720
Restricted cash	—	451,382
Accounts receivable, net	338,850	319,674
Inventory, net	467,246	669,119
Other receivables	—	29,250
Prepaid expenses	738,652	701,214
Other current assets, net of amortization of \$3,121,828 and \$0, respectively	624,365	—
Current assets of discontinued operations, net	29,992	14,515
Total current assets	<u>5,053,405</u>	<u>18,775,874</u>
Property and equipment, net of accumulated depreciation, impairment and amortization of \$6,320,549 and \$2,921,651, respectively	—	3,395,723
Intangibles, net of amortization and impairment of \$5,318,300 and \$718,762, respectively	—	4,599,538
Other assets, net of amortization of \$0 and \$2,372,589, respectively	—	1,424,456
Assets of discontinued operations held for sale	—	11,202,725
Other long-term assets of discontinued operations	—	92,874
Total assets	<u>\$ 5,053,405</u>	<u>\$ 39,491,190</u>
Liabilities, Minority Interests and Shareholders' Deficit		
Current liabilities:		
Current debt	\$ 90,072,286	\$ —
Accounts payable	415,909	403,815
Accrued expenses	1,647,713	4,348,256
Deferred revenue	7,522	—
Current liabilities of discontinued operations	209,458	217,822
Total current liabilities	92,352,888	4,969,893
Long term debt	—	90,000,000
Other long term liabilities of continuing operations	1,171,638	1,206,721
Long term liabilities of discontinued operations	—	107,511
Total liabilities	<u>93,524,526</u>	<u>96,284,125</u>
Commitments and contingencies (see Note 11)	—	—
Minority interests	<u>177,350</u>	<u>1,858,026</u>
Shareholders' deficit:		
Preferred stock, \$.001 par value; 5,000,000 shares authorized	—	—
Series C junior participating preferred stock, \$.001 par value; 10,000 shares authorized	—	—
Common stock, \$.001 par value; 100,000,000 shares authorized	41,639	41,640
Additional paid-in capital	131,341,227	129,208,631
Treasury stock, at cost, 4,000,000 shares	(25,974,000)	(25,974,000)
Accumulated other comprehensive income	—	718,926
Accumulated deficit during development stage	(194,057,337)	(162,646,158)
Total shareholders' deficit	<u>(88,648,471)</u>	<u>(58,650,961)</u>
Total liabilities, minority interests and shareholders' deficit	<u>\$ 5,053,405</u>	<u>\$ 39,491,190</u>

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

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

	For the Year Ended December 31,		Cumulative Period from
	2008	2007	December 28, 1995 (date of inception) to December 31, 2008 (Unaudited)
Revenue			
Product sales	\$ 1,104,885	\$ 1,400,986	\$ 4,280,374
License fees	—	—	260,000
Total revenue	1,104,885	1,400,986	4,540,374
Cost of sales	602,511	656,029	1,855,196
Gross profit	502,374	744,957	2,685,178
2008 Impairment of long-lived assets	6,732,754	—	6,732,754
Selling, general and administrative expenses	8,499,307	18,730,863	74,645,392
Research and development	10,173,117	13,298,338	54,162,151
Operating loss	(24,902,804)	(31,284,244)	(132,855,119)
Other income (expense)			
Interest income	181,514	901,262	6,989,291
Other income	—	150,138	322,581
Interest expense	(3,899,239)	(3,899,239)	(16,558,080)
Minority interest	1,680,676	246,347	2,005,155
Loss before income taxes from continuing operations	(26,939,853)	(33,885,736)	(140,096,172)
Income tax benefit	—	—	190,754
Loss from continuing operations	(26,939,853)	(33,885,736)	(139,905,418)
Loss from discontinued operations, net of tax	(4,471,326)	(1,687,378)	(41,138,234)
Net loss	(31,411,179)	(35,573,114)	(181,043,652)
Deemed dividend associated with beneficial conversion of preferred stock	—	—	(11,423,824)
Preferred stock dividends	—	—	(1,589,861)
Net loss attributable to common shareholders	<u>\$ (31,411,179)</u>	<u>\$ (35,573,114)</u>	<u>\$ (194,057,337)</u>
Per share information:			
Loss from continuing operations — basic and diluted	\$ (0.72)	\$ (1.02)	\$ (8.41)
Loss from discontinued operations — basic and diluted	(0.12)	(0.05)	(2.47)
Deemed dividend associated with beneficial conversion of preferred stock	—	—	(0.69)
Preferred stock dividends	—	—	(0.10)
Net loss per common share — basic and diluted	<u>\$ (0.84)</u>	<u>\$ (1.07)</u>	<u>\$ (11.67)</u>
Weighted average number of basic and diluted common shares outstanding	<u>37,639,492</u>	<u>33,093,370</u>	<u>16,627,354</u>

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.

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	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 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.

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	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 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

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	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
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	<u>3,038,507</u>	<u>\$ 3,039</u>	<u>—</u>	<u>\$ —</u>	<u>15,227,963</u>	<u>\$ 15,228</u>	<u>\$25,573,999</u>	<u>—</u>	<u>\$ —</u>	<u>\$ 13,875</u>	<u>\$ (20,399,211)</u>	<u>\$ 5,206,930</u>	

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	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 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.

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	Series A Preferred Stock		Series B Preferred Stock		Common Stock		Additional Paid-In Capital	Treasury Stock		Accumulated Other Comprehensive Income	Accumulated Deficit During Development Stage	Total Shareholders' Equity (Deficit)
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount		Number of Shares	Amount			
Conversion of warrants into common stock—1st qtr	—	\$ —	—	\$ —	78,526	\$ 79	(79)	—	\$ —	—	\$ —	—
Issuance of common stock for cash in connection with exercise of stock options—1st qtr	—	—	—	—	15,000	15	94,985	—	—	—	—	95,000
Issuance of common stock for cash in connection with exercise of warrants—1st qtr	—	—	—	—	4,000	4	7,716	—	—	—	—	7,720
Compensation expense on options and warrants issued to non-employees and directors—1st qtr	—	—	—	—	—	—	1,410,498	—	—	—	—	1,410,498
Issuance of common stock in connection with exercise of warrants—2nd qtr	—	—	—	—	51,828	52	(52)	—	—	—	—	—
Issuance of common stock for cash—2nd qtr	—	—	—	—	7,200,000	7,200	56,810,234	—	—	—	—	56,817,434
Compensation expense on options and warrants issued to non-employees and directors—2nd qtr	—	—	—	—	—	—	143,462	—	—	—	—	143,462
Issuance of common stock in connection with exercise of warrants—3rd qtr	—	—	—	—	7,431	7	(7)	—	—	—	—	—
Issuance of common stock for cash in connection with exercise of stock options—3rd qtr	—	—	—	—	110,000	110	189,890	—	—	—	—	190,000
Issuance of common stock for cash in connection with exercise of warrants—3rd qtr	—	—	—	—	28,270	28	59,667	—	—	—	—	59,695
Compensation expense on options and warrants issued to non-employees and directors—3rd qtr	—	—	—	—	—	—	229,133	—	—	—	—	229,133

Issuance of common stock in connection with exercise of warrants—4th qtr	—	—	—	—	27,652	28	(28)	—	—	—	—	—	—
Compensation expense on options and warrants issued to non-employees, employees, and directors—4th qtr	—	—	—	—	—	—	127,497	—	—	—	—	—	127,497
Purchase of treasury stock—4th 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.

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

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	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					
Compensation expense on options and warrants issued to non-employees—1st qtr	—	\$ —	—	\$ —	—	\$ —	—	\$ —	42,810	—	\$ —	—	\$ —	42,810
Compensation expense on option awards issued to employee and directors—1st qtr	—	—	—	—	—	—	—	—	46,336	—	—	—	—	46,336
Compensation expense on restricted stock issued to employees—1st qtr	—	—	—	—	128,750	129	23,368	—	—	—	—	—	—	23,497
Compensation expense on options and warrants issued to non-employees—2nd qtr	—	—	—	—	—	—	—	—	96,177	—	—	—	—	96,177
Compensation expense on option awards issued to employee and directors—2nd qtr	—	—	—	—	—	—	—	—	407,012	—	—	—	—	407,012
Compensation expense on restricted stock to employees—2nd qtr	—	—	—	—	—	—	—	—	4,210	—	—	—	—	4,210
Cancellation of unvested restricted stock—2nd qtr	—	—	—	—	(97,400)	(97)	97	—	—	—	—	—	—	—
Issuance of common stock for cash in connection with exercise of stock options—2nd qtr	—	—	—	—	10,000	10	16,490	—	—	—	—	—	—	16,500
Compensation expense on options and warrants issued to non-employees—3rd qtr	—	—	—	—	—	—	—	—	25,627	—	—	—	—	25,627
Compensation expense on option awards issued to employee and directors—3rd qtr	—	—	—	—	—	—	—	—	389,458	—	—	—	—	389,458
Compensation expense on restricted stock to employees—3rd qtr	—	—	—	—	—	—	—	—	3,605	—	—	—	—	3,605

Issuance of common stock for cash in connection with exercise of stock options—3rd qtr	—	—	—	—	76,000	76	156,824	—	—	—	—	156,900
Compensation expense on options and warrants issued to non-employees—4th qtr	—	—	—	—	—	—	34,772	—	—	—	—	34,772
Compensation expense on option awards issued to employee and directors—4th qtr	—	—	—	—	—	—	390,547	—	—	—	—	390,547
Compensation expense on restricted stock to employees—4th qtr	—	—	—	—	—	—	88	—	—	—	—	88
Cancellation of unvested restricted stock award—4th qtr	—	—	—	—	(15,002)	(15)	15	—	—	—	—	—
Comprehensive loss:												
Net loss	—	—	—	—	—	—	—	—	—	—	(35,821,406)	(35,821,406)
Other comprehensive gain, foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	657,182	—	657,182
Comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	(35,164,224)
Balance 12/31/06	—	\$ —	—	\$ —	34,362,731	\$ 34,363	\$111,516,561	4,000,000	\$ (25,974,000)	\$ (127,462)	\$ (127,073,044)	\$ (41,623,582)

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

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	Series A Preferred Stock		Series B Preferred Stock		Common Stock		Additional Paid-In Capital	Treasury Stock		Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit During Development Stage	Total Shareholders' Equity (Deficit)
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount		Number of Shares	Amount			
Compensation expense on options and warrants issued to non-employees—1st qtr	—	\$ —	—	\$ —	—	\$ —	\$ 39,742	—	\$ —	\$ —	\$ —	\$ 39,742
Compensation expense on option awards issued to employee and directors—1st qtr	—	—	—	—	—	—	448,067	—	—	—	—	448,067
Compensation expense on restricted stock issued to employees—1st qtr	—	—	—	—	—	—	88	—	—	—	—	88
Issuance of common stock for cash in connection with exercise of stock options—1st qtr	—	—	—	—	15,000	15	23,085	—	—	—	—	23,100
Expense in connection with modification of employee stock options —1st qtr	—	—	—	—	—	—	1,178,483	—	—	—	—	1,178,483
Compensation expense on options and warrants issued to non-employees—2nd qtr	—	—	—	—	—	—	39,981	—	—	—	—	39,981
Compensation expense on option awards issued to employee and directors—2nd qtr	—	—	—	—	—	—	462,363	—	—	—	—	462,363
Compensation expense on restricted stock issued to employees—2nd qtr	—	—	—	—	—	—	88	—	—	—	—	88
Compensation expense on option awards issued to employee and directors—3rd qtr	—	—	—	—	—	—	478,795	—	—	—	—	478,795
Compensation expense on restricted stock issued to employees—3rd qtr	—	—	—	—	—	—	88	—	—	—	—	88
Issuance of common stock upon exercise of warrants —3rd qtr	—	—	—	—	492,613	493	893,811	—	—	—	—	894,304

Issuance of common stock for cash, net of offering costs—3rd qtr	—	—	—	—	6,767,647	6,767	13,745,400	—	—	—	—	13,752,167
Issuance of common stock for cash in connection with exercise of stock options—3rd qtr	—	—	—	—	1,666	2	3,164	—	—	—	—	3,166
Compensation expense on option awards issued to employee and directors—4thqtr	—	—	—	—	—	—	378,827	—	—	—	—	378,827
Compensation expense on restricted stock issued to employees—4thqtr	—	—	—	—	—	—	88	—	—	—	—	88
Comprehensive loss:												
Net loss	—	—	—	—	—	—	—	—	—	—	(35,573,114)	(35,573,114)
Other comprehensive gain, foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	846,388	—	846,388
Comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	(34,726,726)
Balance 12/31/07	—	\$ —	—	\$ —	41,639,657	\$ 41,640	\$129,208,631	4,000,000	\$(25,974,000)	\$ 718,926	\$(162,646,158)	\$(58,650,961)

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

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	Series A Preferred Stock		Series B Preferred Stock		Common Stock		Additional Paid-In Capital	Treasury Stock		Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit During Development Stage	Total Shareholders' Equity (Deficit)
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount		Number of Shares	Amount			
Compensation expense on vested options related to non-employees—1st qtr	—	\$ —	—	\$ —	—	\$ —	\$ 44,849	—	\$ —	\$ —	\$ —	\$ 44,849
Compensation expense on option awards issued to employee and directors—1st qtr	—	—	—	—	—	—	151,305	—	—	—	—	151,305
Expense in connection with modification of employee stock options —1st qtr	—	—	—	—	—	—	1,262,815	—	—	—	—	1,262,815
Retirement of restricted stock	—	—	—	—	(165)	(1)	—	—	—	—	—	(1)
Compensation expense on vested options related to non-employees—2nd qtr	—	—	—	—	—	—	62,697	—	—	—	—	62,697
Compensation expense on option awards issued to employee and directors—2nd qtr	—	—	—	—	—	—	193,754	—	—	—	—	193,754
Compensation expense on vested options related to non-employees—3rd qtr	—	—	—	—	—	—	166,687	—	—	—	—	166,687
Compensation expense on option awards issued to employee and directors—3rd qtr	—	—	—	—	—	—	171,012	—	—	—	—	171,012
Compensation expense on vested options related to non-employees—4th qtr	—	—	—	—	—	—	(86,719)	—	—	—	—	(86,719)
Compensation expense on option awards issued to employee and directors—4th qtr	—	—	—	—	—	—	166,196	—	—	—	—	166,196
Comprehensive loss:												
Net loss	—	—	—	—	—	—	—	—	—	—	(31,411,179)	(31,411,179)
Reclassification of foreign exchange gain on substantial liquidation of foreign entities	—	—	—	—	—	—	—	—	—	(2,152,569)	—	(2,152,569)

Other comprehensive gain, foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	—	1,433,643	—	1,433,643
Comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	—	(32,130,105)
Balance 12/31/08	—	\$ —	—	\$ —	41,639,492	\$ 41,639	\$131,341,227	4,000,000	\$ (25,974,000)	\$ —	\$ (194,057,337)	\$ —	\$ (88,648,471)

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

Isolagen, Inc.
(A Development Stage Company)

Consolidated Statements of Cash Flows

	For the Year Ended December 31,		Cumulative Period from
	2008	2007	December 28, 1995
			(date of inception) to
			December 31, 2008
			(Unaudited)
Cash flows from operating activities:			
Net loss	\$ (31,411,179)	\$ (35,573,114)	\$ (181,043,652)
Adjustments to reconcile net loss to net cash used in operating activities:			
Equity awards issued for services	2,132,597	3,026,610	10,025,546
Uncompensated contribution of services	—	—	755,556
Depreciation and amortization	1,376,863	1,505,218	9,091,990
Provision for doubtful accounts	7,191	11,803	337,309
Provision for inventory reserve	90,342	—	90,342
Amortization of debt issue costs	749,239	749,239	3,121,830
Amortization of debt discounts on investments	—	—	(508,983)
Loss on disposal or impairment of long-lived assets	13,059,375	59,871	17,668,477
Foreign exchange gain on substantial liquidation of foreign entity	(2,152,569)	—	(2,286,420)
Minority interest	(1,680,676)	(246,347)	(2,005,155)
Change in operating assets and liabilities, excluding effects of acquisition:			
Decrease (increase) in restricted cash	451,383	1,031,815	—
Decrease (increase) in accounts receivable	(26,367)	(187,603)	(183,162)
Decrease (increase) in other receivables	46,870	268,912	195,346
Decrease (increase) in inventory	111,530	(393,778)	(484,825)
Decrease (increase) in prepaid expenses	64,362	431,390	(593,856)
Decrease (increase) in other assets	42,937	122,149	183,441
Increase (decrease) in accounts payable	(6,021)	(898,831)	288,240
Increase (decrease) in accrued expenses and other liabilities	(2,874,518)	704,436	1,443,390
Increase (decrease) in deferred revenue	7,522	(348,642)	(42,574)
Net cash used in operating activities	<u>(20,011,119)</u>	<u>(29,736,872)</u>	<u>(143,947,160)</u>
Cash flows from investing activities:			
Acquisition of Agera, net of cash acquired	(6,679)	—	(2,016,520)
Purchase of property and equipment	(33,337)	(184,538)	(25,515,170)
Proceeds from the sale of property and equipment	6,444,386	57,153	6,542,434
Purchase of investments	—	—	(152,998,313)
Proceeds from sales and maturities of investments	—	—	153,507,000
Net cash provided by (used in) investing activities	<u>6,404,370</u>	<u>(127,385)</u>	<u>(20,480,569)</u>
Cash flows from financing activities:			
Proceeds from convertible debt	—	—	91,450,000
Offering costs associated with the issuance of convertible debt	—	—	(3,746,193)
Proceeds from notes payable to shareholders, net	—	—	135,667
Proceeds from the issuance of preferred stock, net	—	—	12,931,800
Proceeds from the issuance of common stock, net	—	14,672,737	93,753,857
Principle payments on insurance loan	(15,336)	—	(15,336)
Cash dividends paid on preferred stock	—	—	(1,087,200)
Cash paid for fractional shares of preferred stock	—	—	(38,108)
Merger and acquisition expenses	—	—	(48,547)
Repurchase of common stock	—	—	(26,024,280)
Net cash provided by (used in) financing activities	<u>(15,336)</u>	<u>14,672,737</u>	<u>167,311,660</u>
Effect of exchange rate changes on cash balances	(114,335)	(1,305)	(29,631)
Net increase (decrease) in cash and cash equivalents	(13,736,420)	(15,192,825)	2,854,300
Cash and cash equivalents, beginning of period	16,590,720	31,783,545	—
Cash and cash equivalents, end of period	<u>\$ 2,854,300</u>	<u>\$ 16,590,720</u>	<u>\$ 2,854,300</u>
Supplemental disclosures of cash flow information:			
Cash paid for interest	\$ 3,150,000	\$ 3,150,000	\$ 12,715,283
Non-cash investing and financing activities:			
Deemed dividend associated with beneficial conversion of preferred stock	—	—	\$ 11,423,824
Preferred stock dividend	—	—	1,589,861
Uncompensated contribution of services	—	—	755,556

Common stock issued for intangible assets	—	—	540,000
Equipment acquired through capital lease	—	—	167,154
Financing of insurance premiums	87,623	—	87,623
Increase in receivable in connection with sale of Swiss property	27,125	—	27,125

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

Isolagen, Inc.
(A Development Stage Company)

Notes to Consolidated Financial Statements

Note 1—Basis of Presentation, Business and Organization

Isolagen, Inc. (“Isolagen”), a Delaware corporation, is the parent company of Isolagen Technologies, Inc., a Delaware corporation (“Isolagen Technologies”) and Agera Laboratories, Inc., a Delaware corporation (“Agera”). Isolagen Technologies is the parent company of Isolagen Europe Limited, a company organized under the laws of the United Kingdom (“Isolagen Europe”), Isolagen Australia Pty Limited, a company organized under the laws of Australia (“Isolagen Australia”), and Isolagen International, S.A., a company organized under the laws of Switzerland (“Isolagen Switzerland”). The common stock of the Company, par value \$0.001 per share, (“Common Stock”) is traded on the NYSE Amex exchange (formerly known as the American Stock Exchange or “AMEX”) under the symbol “ILE.”

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

The Company acquired 57% of the outstanding common shares of Agera on August 10, 2006. Agera offers a complete line of skincare systems based on a wide array of proprietary formulations, trademarks and nano-peptide technology. These technologically advanced skincare products can be packaged to offer anti-aging, anti-pigmentary and acne treatment systems. Agera markets its product in both the United States and Europe (primarily the United Kingdom). The results of Agera’s operations and cash flows have been included in the consolidated financial statements from the date of the acquisition. The assets and liabilities of Agera have been included in the consolidated balance sheet since the date of the acquisition.

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

During 2006 and prior, the Company sold its aesthetic product primarily in the United Kingdom. However, during the fourth quarter of fiscal 2006, the Company decided to close the United Kingdom operation. The Company completed the closure of the United Kingdom operation on March 31, 2007, and as of March 31, 2007, the United Kingdom, Swiss and Australian operations were presented as discontinued operations for all periods presented, as more fully discussed in Note 5.

Through December 31, 2008, the Company has been primarily engaged in developing its initial product technology. In the course of its development activities, the Company has sustained losses and expects such losses to continue through at least 2009. In fiscal 2008 the Company financed its operations primarily through its existing cash. However, the Company now requires additional financing. As a result, as described in Note 2, there exists substantial doubt about the Company’s ability to continue as a going concern. The Company’s ability to operate profitably is largely contingent upon its success in obtaining financing, obtaining regulatory approval to sell one or a variety of applications of the Isolagen Therapy, upon its successful development of markets for its products and upon the development of profitable scaleable manufacturing processes. There is no assurance that the Company will be able to obtain any such additional capital as it needs to finance these efforts, through asset sales, equity or debt financing, or any combination thereof, on satisfactory terms or at all. Additionally, no assurance can be given that any such financing, if obtained, will be adequate to meet the Company’s ultimate capital needs and to support the Company’s growth. If adequate capital cannot be obtained on a timely basis and on satisfactory terms, the Company’s operations would be materially negatively impacted. In addition, even if the Company were to obtain the capital it requires, no assurance can be given that the Company will be able to obtain necessary regulatory approvals, successfully develop the markets for its products or develop profitable manufacturing methods in the future.

Acquisition and merger and basis of presentation

On August 10, 2001, Isolagen 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”), Isolagen Technologies, Gemini, a Delaware corporation, and William J. Boss, Jr., Olga Marko and Dennis McGill, stockholders of Isolagen 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 Isolagen 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 Isolagen Technologies (the “Merger”), and AFH was the surviving corporation. AFH subsequently changed its name to Isolagen, Inc. on November 13, 2001. Prior to the Merger, Isolagen Technologies had no active business and was seeking funding to begin FDA trials of the Isolagen Therapy. 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.

The consolidated financial statements presented include Isolagen, Inc., its wholly-owned subsidiaries and its majority-owned subsidiary. All significant intercompany transactions and balances have been eliminated. Isolagen 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 Isolagen Technologies. The assets, liabilities, operations and cash flows of AFH and Gemini are included in the consolidated financial statements from August 10, 2001 onward.

Unless the context requires otherwise, the “Company” refers to Isolagen, Inc. and all of its consolidated subsidiaries, “Isolagen” refers to Isolagen, Isolagen Technologies, Isolagen Europe, Isolagen Australia and Isolagen Switzerland, and “Agera” refers to Agera Laboratories, Inc.

Note 2—Going Concern

At December 31, 2008, the Company had cash and cash equivalents of \$2.9 million and negative working capital of \$(87.3) million. The Company believes that its existing capital resources are adequate to finance its operation through approximately the second half of April 2009, under the Company’s current reduced operating conditions. As such, the Company estimates that it will require additional cash resources prior to or during the second half of April 2009. The Company has no commitments for any such additional funding and there is no assurance that the Company will receive any such additional funding.

Through December 31, 2008, the Company has been primarily engaged in developing its initial product technology. In the course of its development activities, the Company has sustained losses and expects such losses to continue through at least 2009. In fiscal 2008 the Company financed its operations primarily through its existing cash. However, as discussed above, the Company now requires additional financing. There exists substantial doubt about the Company’s ability to continue as a going concern.

The Company will require additional capital to continue its operations past approximately the second half of April 2009. There is no assurance that the Company will be able to obtain any such additional capital as it needs to finance these efforts, through asset sales, equity or debt financing, or any combination thereof, on satisfactory terms or at all. Additionally, no assurance can be given that any such financing, if obtained, will be adequate to meet the Company’s ultimate capital needs and to support the Company’s growth. If adequate capital cannot be obtained on a timely basis and on satisfactory terms, the Company’s operations would be materially negatively impacted. If the Company does not obtain additional funding, or does not anticipate additional funding, prior to or during approximately the second half of April 2009, it will likely enter into bankruptcy and possibly cease operations. Further, if the Company does raise additional cash resources prior to the end of April 2009, it may be raised in contemplation of or in connection with bankruptcy.

The Company filed a shelf registration statement on Form S-3 during June 2007, which was subsequently declared effective by the SEC. The shelf registration allows the Company the flexibility to offer and sell, from time to time, up to an original amount of \$50 million of common stock, preferred stock, debt securities, warrants or any combination of the foregoing in one or more future public offerings. In August 2007, the Company sold under this shelf registration statement 6,746,647 shares of common stock to institutional investors, raising proceeds of \$13.8 million, net of offering costs. The Company may offer and sell up to an additional \$36.2 million of securities pursuant to this shelf registration. However, in general, companies that are under \$75 million in market capitalization are limited to selling up to one-third of the value of such company’s common stock held by non-affiliates in any twelve month period.

The Company's ability to complete additional offerings, including any additional offerings under its shelf registration statement, is dependent on the state of the debt and/or equity markets at the time of any proposed offering, and such market's reception of the Company and the offering terms. Currently the credit and equity markets both in the United States and internationally are severely contracted, which will make the Company's task of raising additional debt or equity capital even more difficult. In addition, the Company's ability to raise additional financing through the issuance of common stock or convertible securities may be adversely affected by uncertainties regarding the continued listing of the Company's common stock on the NYSE Amex (see Note 11). Finally, the Company's ability to complete an offering may be dependent on the status of its clinical trials, and in particular, the status of the Biologics License Application related to its indication for nasolabial folds/wrinkles, which cannot be predicted. There is no assurance that capital in any form would be available to the Company, and if available, on terms and conditions that are acceptable.

As a result of the conditions discussed above, and in accordance with generally accepted accounting principles in the United States, there exists substantial doubt about the Company's ability to continue as a going concern, and the Company's ability to continue as a going concern is contingent, among other things, upon its ability to secure additional adequate financing or capital prior to or during approximately the second half of April 2009. If the Company is unable to obtain additional sufficient funds, the Company will be required to terminate or delay its efforts to obtain regulatory approval of one, more than one, or all of its product candidates, curtail or delay the implementation of manufacturing process improvements and/or delay the expansion of its sales and marketing capabilities. Any of these actions would have an adverse effect on the Company's operations, the realization of its assets and the timely satisfaction of its liabilities. If the Company does not obtain additional funding, or does not anticipate additional funding, prior to or during approximately the second half of April 2009, it will likely enter into bankruptcy and possibly cease operations. Further, if the Company does raise additional cash resources prior to the end of April 2009, it may be raised in contemplation of or in connection with bankruptcy.

Due to the likelihood of bankruptcy and in connection with the Company's review for impairment of long-lived assets in accordance with SFAS 144, "Accounting for the Impairment or Disposal of Long-lived Assets," the Company has recorded a full impairment on all of its long-lived assets as of December 31, 2008, and as such, has recorded an impairment charge of \$6.7 million during the year ended December 31, 2008.

Note 3—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, the provision for and disclosure of litigation and loss contingencies (see Note 11) and estimates and assumptions related to equity-based compensation expense (see Note 13). In addition, management's assessment of the Company's ability to continue as a going concern involves the estimation of the amount and timing of future cash inflows and outflows. Actual results may differ materially from those estimates.

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' deficit. Gains and losses resulting from foreign currency transactions are included in earnings and, other than discussed below, have not been material in any one period. Balances of related after-tax components comprising accumulated other comprehensive income included in shareholders' deficit at December 31, 2007 related solely to foreign currency translation adjustments.

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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 March 2008, the Company substantially liquidated the assets of the Company's Swiss entity (in connection with the sale of the Company's Swiss campus; see *Assets of Discontinued Operations Held for Sale* below). As such, the amount of the accumulated foreign currency translation adjustment account in stockholders' deficit which related to the Company's Swiss franc assets and liabilities was removed from equity by recording income of \$2.1 million, which is included in loss from discontinued operations in the accompanying consolidated statement of operations for the year ended December 31, 2008.

Balances of related after-tax components comprising accumulated other comprehensive income included in shareholders' deficit at December 31, 2008 and December 31, 2007 are as follows:

	December 31,	
	2008	2007
Foreign currency translation adjustment	\$ —	\$ 718,926
Accumulated other comprehensive income	\$ —	\$ 718,926

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, 2008 and December 31, 2007, the Company had \$0.0 million and \$0.5 million of cash restricted related to the payment of the non-cancelable portion of the Exton, Pennsylvania facility lease, due monthly through March 2008, respectively.

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 \$250,000. 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, money market accounts and demand deposit accounts.

Allowance for Doubtful Accounts

The Company maintains an allowance for doubtful accounts related to its accounts receivable that have been deemed to have a high risk of collectability. Management reviews its accounts receivable on a monthly basis to determine if any receivables will potentially be uncollectible. One foreign customer represents 94% and 94% of accounts receivable, net, at December 31, 2008 and 2007, respectively. Management analyzes historical collection trends and changes in its customer payment patterns, customer concentration, and creditworthiness when evaluating the adequacy of its allowance for doubtful accounts. In its overall allowance for doubtful accounts, the Company includes any receivable balances that are determined to be uncollectible. Based on the information available, management believes the allowance for doubtful accounts is adequate; however, actual write-offs might exceed the recorded allowance.

The allowance for doubtful accounts related to continuing operations was \$25,303 and \$18,112 at December 31, 2008 and 2007, respectively. The allowance for doubtful accounts related to discontinued operations was \$51,354 and \$70,840 at December 31, 2008 and 2007, respectively.

Inventory

Agera purchases the large majority of its inventory from one contract manufacturer. Agera accounts for its inventory on the first-in-first-out method. At December 31, 2008, Agera's inventory of \$0.5 million consisted of \$0.2 million of raw materials and \$0.3 million of finished goods. At December 31, 2007, Agera's inventory of \$0.7 million consisted of \$0.1 million of raw materials and \$0.6 million of finished goods.

Assets of discontinued operations held for sale

In April 2005, the Company acquired land and a two-building, 100,000 square foot campus (the "Swiss campus") in Bevaix, Canton of Neuchâtel, Switzerland. In March 2008, the Company sold its Swiss campus to a third party for approximately \$6.4 million, net of transaction costs. The net book value of the Swiss campus on the date of sale was approximately \$12.7 million (or \$10.6 million, net of the related cumulative foreign currency translation gain of approximately \$2.1 million, as discussed in *Foreign Currency Translation* above). In connection with this sale of the Swiss campus, the Company recorded a net loss of \$4.2 million which is reflected in loss from discontinued operations in the accompanying consolidated statement of operations for the year ended December 31, 2008 (refer to Note 5 for further detail related to the net loss on the sale of the Swiss campus). As of December 31, 2008, \$6.4 million of the net sale proceeds had been paid to the Company, and less than \$0.1 million was recorded as a receivable within current assets of discontinued operations in the accompanying consolidated balance sheet.

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Property and equipment

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

Due to the likelihood of bankruptcy and in connection with the Company's review for impairment of long-lived assets in accordance with SFAS 144, "Accounting for the Impairment or Disposal of Long-lived Assets," the Company has recorded a full impairment on all of its long-lived assets as of December 31, 2008, and as such, has recorded an impairment charge of \$6.7 million during the year ended December 31, 2008 in the accompanying consolidated statement of operations. \$2.4 million of this \$6.7 million impairment charge recorded during the year ended December 31, 2008 related to property and equipment, as discussed in Note 7.

Intangible assets

Intangible assets primarily include proprietary formulations and trademarks, which were acquired in connection with the acquisition of Agera (see Note 4), as well as certain in-process patents. Intangibles are tested for recoverability whenever events or changes in circumstances indicate the carrying amount may not be recoverable. An impairment loss, if any, would be measured as the excess of the carrying value over the fair value determined by discounted cash flows. Due to the likelihood of bankruptcy and in connection with the Company's review for impairment of long-lived assets in accordance with SFAS 144, "Accounting for the Impairment or Disposal of Long-lived Assets," the Company has recorded a full impairment on all of its long-lived assets as of December 31, 2008, and as such, has recorded an impairment charge of \$6.7 million during the year ended December 31, 2008. \$4.3 million of this \$6.7 million impairment charge recorded during the year ended December 31, 2008 in the accompanying consolidated statement of operations related to intangible assets, as shown in the table below.

Intangible assets are comprised as follows:

	December 31,	
	2008	2007
Proprietary formulations	\$ 3,101,100	\$ 3,101,100
Trademarks	1,511,400	1,511,400
Other intangibles	<u>705,800</u>	<u>705,800</u>
	5,318,300	5,318,300
Less: Accumulated amortization	(1,063,593)	(718,762)
Less: Impairment valuation	<u>(4,254,707)</u>	<u>—</u>
Intangible assets, net	<u>\$ —</u>	<u>\$ 4,599,538</u>

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 \$0.6 million at December 31, 2008 and approximately \$1.4 million at December 31, 2007 and were included in other current assets, net, at December 31, 2008 and other assets, net, at December 31, 2007 in the accompanying consolidated balance sheets. The unamortized debt issue costs are classified as a current asset at December 31, 2008 because the related debt is classified as a current liability at that date (see Note 9).

The Company filed registration statements on Form S-3 and Form S-4 (the "Combined Registration Statements") during July 2007. The Combined Registration Statements related to (1) a proposed exchange offer of new 3.5% convertible senior notes due 2024 to the holders of the currently outstanding \$90 million, in principal amount, 3.5% convertible subordinated notes due 2024 and (2) a proposed offer to the public of an additional \$30 million, in principal amount, of new 3.5% convertible senior notes due 2024. In August, 2007 the Company decided not to proceed with the offerings covered by the Combined Registration Statements, and the Combined Registration Statements were subsequently withdrawn by the Company in August 2007 prior to being declared effective by the SEC. During the year ended December 31, 2007, the Company incurred \$0.8 million of costs related to the Combined Registration Statements. As a result of the Company's withdrawal of the Combined Registration Statements in August 2007, such \$0.8 million of costs were expensed and are included in selling, general and administrative expenses in the consolidated statement of operations for the year ended December 31, 2007.

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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.

Continuing operations: Revenue from the sale of Agera's products is recognized upon transfer of title, which is upon shipment of the product to the customer. The Company believes that the requirements of SAB 104 are met when the ordered product is shipped, as the risk of loss transfers to our customer at that time, the fee is fixed and determinable and collection is reasonably assured. Any advanced payments are deferred until shipment.

Discontinued operations: The Isolagen Therapy was administered, in the United Kingdom, to each patient using a recommended regimen of 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 had stand alone value to the patient. The Company invoiced the attending physician when the physician sent his or her patient's tissue sample to the Company which created a contractual arrangement between the Company and the medical professional. The amount invoiced varied directly with the dose and number of injections requested. Generally, orders were paid in advance by the physician prior to the first injection. There was 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 were met as each injection was shipped, as the risk of loss transferred to our physician customer at that time, the fee was fixed and determinable and collection was reasonably assured. Advance payments were deferred until shipment of the injection(s). The amount of the revenue deferred represented 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 was recognized.

Shipping and handling costs

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

Advertising cost

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

Research and development expenses

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

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. Invoicing from third-party contractors for services performed can lag several months. The 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.

Stock-based compensation

Effective January 1, 2006, the Company adopted the provisions of Statement of Financial Accounting Standards (“SFAS”) No. 123 (revised 2004), “Share-Based Payment” (“SFAS No. 123(R)”). SFAS No. 123(R) replaces SFAS No. 123, “Accounting for Stock-Based Compensation”, supersedes APB Opinion No. 25, “Accounting for Stock Issued to Employees” (“APB No. 25”), and amends SFAS No. 95, “Statement of Cash Flows.” SFAS No. 123(R) requires entities to recognize compensation expense for all share-based payments to employees and directors, including grants of employee stock options, based on the grant-date fair value of those share-based payments, adjusted for expected forfeitures. The Company adopted SFAS No. 123(R) using the modified prospective application method. Under the modified prospective application method, the fair value measurement requirements of SFAS No. 123(R) is applied to new awards and to awards modified, repurchased, or cancelled after January 1, 2006. Additionally, compensation cost for the portion of awards for which the requisite service has not been rendered that were outstanding as of January 1, 2006 is recognized as the requisite service is rendered on or after January 1, 2006. The compensation cost for that portion of awards is based on the grant-date fair value of those awards as calculated for pro forma disclosures under SFAS No. 123. Changes to the grant-date fair value of equity awards granted before January 1, 2006 are precluded.

Prior to the adoption of SFAS No. 123(R), the Company followed the intrinsic value method in accordance with APB No. 25 to account for its employee stock options. Historically, substantially all stock options have been granted with an exercise price equal to the fair market value of the common stock on the date of grant. Accordingly, no compensation expense was recognized from substantially all option grants to employees and directors. Compensation expense was recognized in connection with the issuance of stock options to non-employee consultants in accordance with EITF 96-18, “Accounting for Equity Instruments That are Issued to Other than Employees for Acquiring, or in Conjunction with Selling Goods and Services.” SFAS No. 123(R) did not change the accounting for stock-based compensation related to non-employees in connection with equity based incentive arrangements.

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.

In the event the Company is charged interest or penalties related to income tax matters, the Company would record such interest as interest expense and would record such penalties as other expense in the consolidated statement of operations. No such charges have been incurred by the Company. As of December 31, 2008 and 2007, the Company had no accrued interest related to uncertain tax positions.

The Company adopted the provisions of Financial Standards Accounting Board Interpretation No. 48 Accounting for Uncertainty in Income Taxes (“FIN 48”) an interpretation of FASB Statement No. 109 (“SFAS 109”) on January 1, 2007. No material adjustment in the liability for unrecognized income tax benefits was recognized as a result of the adoption of FIN 48. At the adoption date of January 1, 2007, we had \$40.4 million of unrecognized tax benefits, all of which would affect the Company’s effective tax rate if recognized. At December 31, 2008, the Company has \$63.9 million of unrecognized net deferred tax assets, the large majority of which relates to the future benefit of loss carryforwards. The Company has provided a full valuation allowance for the net deferred tax assets. The tax years 2005 through 2008 remain open to examination by the major taxing jurisdictions to which we are subject. Refer to Note 10 for further discussion of income tax related matters.

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.

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At December 31, 2008, options and warrants to purchase 8,496,833 million shares of common stock at exercise prices ranging from \$0.41 to \$9.00 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 million 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.

At December 31, 2007, options and warrants to purchase 7,892,245 shares of common stock at exercise prices ranging from \$1.50 to \$9.81 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 million 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, 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 15% and 74% of par value at December 31, 2008 and 2007, respectively. Accordingly, the fair value of our convertible subordinated debentures was approximately \$13.5 million and \$66.6 million at December 31, 2008 and 2007, respectively. The Company's convertible subordinated debentures are publicly traded, although not actively traded. The fair value of the convertible subordinated debentures are estimated based on primary factors such as (1) the most recent trade prices of the convertible subordinated debentures on or near the respective reporting period end and/or (2) the bid and ask prices of the convertible subordinated debentures at the end of the reporting period. Historically, these factors have fluctuated significantly, and these factors are expected to fluctuate in future periods. Accordingly, the fair value of the convertible subordinated debentures has historically fluctuated significantly and is expected to fluctuate in future periods.

Recently Issued Accounting Standards Not Yet Effective

In December 2007, the Financial Accounting Standards Board released SFAS No. 141-R, "Business Combinations." This Statement applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008, which is any business combination in the year ending December 31, 2009 for the Company. SFAS No. 141-R makes changes to the manner in which purchase business combinations, and in particular partial and step acquisitions, and minority interests, are measured and recorded. The objective of this Statement is to improve the relevance, representational faithfulness, and comparability of the information that a reporting entity provides in its financial reports about a business combination and its effects. The Company is currently assessing the impact the adoption of this pronouncement will have on the financial statements.

In December 2007, the Financial Accounting Standards Board released SFAS No. 160, "Noncontrolling Interests in Consolidated Financial Statements — an amendment of ARB No. 51." This Statement is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008, which for the Company is the year ending December 31, 2009 and the interim periods within that fiscal year. SFAS No. 160 changes the manner in which minority interests are classified in consolidated financial statements, and the accounting for changes in minority interests. The objective of this pronouncement is to improve the relevance, comparability and transparency of the financial information that a reporting entity provides in its consolidated financial statements. The Company is currently assessing the impact the adoption of this pronouncement will have on the financial statements.

Note 4—Acquisition of Agera Laboratories, Inc.

On August 10, 2006, the Company acquired 57% of the outstanding common shares of Agera Laboratories, Inc. ("Agera"). Agera is a skincare company that has proprietary rights to a scientifically-based advanced line of skincare products. Agera markets its product in both the United States and Europe. The Company believes that the acquisition of Agera will complement the Company's Isolagen Therapy and will broaden the Company's position in the skincare market as Agera has a comprehensive range of technologically advanced skincare products that can be packaged to offer anti-aging, anti-pigmentary and acne treatment systems.

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The acquisition has been accounted for as a purchase. Accordingly, the bases in Agera's assets and liabilities have been adjusted to reflect the allocation of the purchase price to the 57% interest the Company acquired (with the remaining 43% interest, and the minority interest in Agera's net assets, recorded at Agera's historical book values), and the results of Agera's operations and cash flows have been included in the consolidated financial statements from the date of the acquisition.

The Company paid \$2.7 million in cash to acquire the 57% interest in Agera and in connection with the acquisition contributed \$0.3 million to the working capital of Agera. Included in the purchase price was an option to acquire an additional 8% of Agera's outstanding common shares for an exercise price of \$0.5 million in cash. This option expired unexercised in February 2007. In addition, the acquisition agreement includes future contingent payments up to a maximum of \$8.0 million. Such additional purchase price is based upon certain percentages of Agera's cost of sales incurred after June 30, 2007. Accordingly, based upon the financial performance of Agera, up to an additional \$8.0 million of purchase price may be due the selling shareholder in future periods. Less than \$0.1 million is due to the selling shareholder as of December 31, 2008.

Due to the likelihood of bankruptcy and in connection with the Company's review for impairment of long-lived assets in accordance with SFAS 144, "Accounting for the Impairment or Disposal of Long-lived Assets," the Company has recorded a full impairment on all of its long-lived assets as of December 31, 2008, and as such, has recorded an impairment charge of \$6.7 million during the year ended December 31, 2008. \$3.7 million of this \$6.7 million impairment charge recorded during the year ended December 31, 2008 in the accompanying consolidated statement of operations related to intangible assets of the Agera segment (refer to Note 15 for additional segment information).

Note 5—Discontinued Operations and Exit Costs

As part of the Company's continuing efforts to evaluate the best uses of its resources, in the fourth quarter of 2006 the Company's Board of Directors approved the closing of the Company's United Kingdom operation. On March 31, 2007, the Company completed the closure of its United Kingdom manufacturing facility. The United Kingdom operation was located in London, England with two locations; a manufacturing site and an administrative site. Both sites were under operating leases. The manufacturing site lease originally expired during February 2010, and during the three months ended September 30, 2008, the Company entered into a settlement and release agreement with the landlord. The settlement and release agreement released the Company from any and all obligations under the lease contract in exchange for a payment of less than \$0.1 million, which was paid during the three months ended September 30, 2008. In addition, the Company agreed to release its claim on the related lease deposit, which was less than \$0.1 million. The administrative site lease expired in April 2007. The Company believes that substantially all costs related to the closure of the United Kingdom operation have been incurred by December 31, 2008, excluding any potential claims or contingencies unknown or which cannot be estimated at this time (see Note 11).

As a result of the closure of the Company's United Kingdom operation, the operations that the Company previously conducted in Switzerland and Australia, which when closed had been absorbed into the United Kingdom operation, were also classified as discontinued operations as of March 31, 2007. The Company recorded a fixed asset impairment charge related to its United Kingdom operation of \$1.4 million during 2006, which is included in loss from discontinued operations in the consolidated statement of operations for the year ended December 31, 2006. During March 2008, the Company sold its buildings located in Switzerland (see Note 3). All assets, liabilities and results of operations of the United Kingdom, Switzerland and Australian operations are reflected as discontinued operations in the accompanying consolidated financial statements. All prior period information has been restated to reflect the presentation of discontinued operations.

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The following sets forth the components of assets and liabilities of discontinued operations as of December 31, 2008 and December 31, 2007:

(in millions)	December 31, 2008	December 31, 2007
Accounts receivable, net	\$ —	\$ —
Inventory	—	—
Value-added tax refund due	—	—
Other current assets	—	—
Total current assets	—	—
Assets held for sale	—	11.2
Long term assets	—	0.1
Total assets	<u>\$ —</u>	<u>\$ 11.3</u>
Accounts payable	\$ —	\$ —
Accrued expenses and other current liabilities	0.2	0.2
Total current liabilities	0.2	0.2
Long term liabilities	0.0	0.1
Total liabilities	<u>\$ 0.2</u>	<u>\$ 0.3</u>

The following sets forth the results of operations of discontinued operations for the years ended December 31, 2008 and December 31, 2007:

(in millions)	December 31, 2008	December 31, 2007
Net revenue	\$ —	\$ 0.2
Gross loss	—	(0.3)
Loss on sale of Swiss campus, before foreign currency gain	(6.3)	—
Operating loss	(6.7)	(2.0)
Foreign exchange gain on substantial liquidation of foreign entity	2.1	—
Other income	0.1	0.3
Loss from discontinued operations	<u>\$ (4.5)</u>	<u>\$ (1.7)</u>

The following sets forth information about the major components of the United Kingdom operation exit costs incurred during 2007. No such costs were incurred during 2008:

	Costs Incurred for the Year Ended December 31, 2007	Cumulative Costs Incurred to Date
Employee severance	\$ 183,222	\$ 467,318
Fixed asset impairment	—	1,445,647
Total	<u>\$ 183,222</u>	<u>\$ 1,912,965</u>

The following sets forth information about the changes in the United Kingdom accrued exit costs for the year ended December 31, 2007:

	Accrued Liability at January 1, 2007	Costs Charged to Expense	Costs Paid or Settled	Accrued Liability December 31, 2007
Employee severance	\$ 284,096	\$ 183,222	\$ 467,318	\$ —
Total	<u>\$ 284,096</u>	<u>\$ 183,222</u>	<u>\$ 467,318</u>	<u>\$ —</u>

Note 6—Available-for-Sale Investments

The Company had no available-for-sale investments at December 31, 2008 or 2007. Proceeds from the sale of available-for-sale marketable debt securities were \$0.0 million for the years ended December 31, 2008 and 2007, respectively, and no realized gains and losses based on specific identification, were included in the results of operations upon those sales.

Note 7—Property and Equipment

Property and equipment is comprised of:

	December 31,	
	2008	2007
Leasehold improvements	\$ 3,753,998	\$ 3,751,030
Lab equipment	1,447,218	1,423,840
Computer equipment and software	1,101,097	1,101,097
Office furniture and fixtures	18,236	41,407
	<u>6,320,549</u>	<u>6,317,374</u>
Less: Accumulated depreciation and amortization	<u>(3,938,622)</u>	<u>(2,921,651)</u>
Less: Impairment valuation	<u>(2,381,927)</u>	<u>—</u>
Property and equipment, net	<u>\$ —</u>	<u>\$ 3,395,723</u>

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

	Year ended December 31,	
	2008	2007
Depreciation expense related to continuing operations: Selling, general, administrative, research and development expenses	\$ 1,032,032	\$ 1,168,251

Due to the likelihood of bankruptcy and in connection with the Company’s review for impairment of long-lived assets in accordance with SFAS 144, “Accounting for the Impairment or Disposal of Long-lived Assets,” the Company has recorded a full impairment on all of its long-lived assets as of December 31, 2008, and as such, has recorded an impairment charge of \$6.7 million during the year ended December 31, 2008. \$2.4 million of this \$6.7 million impairment charge recorded during the year ended December 31, 2008 related to property and equipment, as shown in the table above.

Note 8—Accrued Expenses

Accrued expenses are comprised of the following:

	December 31,	
	2008	2007
Accrued professional fees	\$ 479,943	\$ 2,243,319
Accrued settlement fees	325,000	—
Accrued compensation	17,570	840,641
Accrued severance	—	379,402
Accrued interest	525,000	525,000
Accrued other	300,200	359,894
Accrued expenses	<u>\$ 1,647,713</u>	<u>\$ 4,348,256</u>

Note 9—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.

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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 in 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 in 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 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. The shelf registration statement was subsequently declared effective on May 2, 2005. At December 31, 2008, the Company has recorded the 3.5% Subordinated Notes as a current liability on the accompanying consolidated balance sheet as the holders may require the Company to purchase all of the 3.5% Subordinated Notes as early as November 2009.

Note 10—Income Taxes

Isolagen, Inc. and Isolagen Technologies, Inc. file a consolidated U.S. Federal income tax return. During the third quarter of 2006, the Company acquired a 57% interest in Agera (see Note 4). Agera files a separate U.S. Federal income tax return. The Company's foreign subsidiaries, which comprise loss from discontinued operations, file income tax returns in their respective jurisdictions. The geographic source of loss from continuing operations is the United States.

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The components of the income tax benefit below, which relate solely to continuing operations, are as follows for the years ended December 31:

	2008	2007
United States		
Current	\$ —	\$ —
Deferred	—	—
Foreign		
Current	—	—
Deferred	—	—
Total income tax benefit	<u>\$ —</u>	<u>\$ —</u>

The reconciliation between income tax expense (benefit) at the U.S. federal statutory rate and the amount recorded in the accompanying consolidated financial statements is as follows for the years ended December 31:

	2008	2007
Tax at U.S. federal statutory rate	\$ (9,428,949)	\$ (11,860,007)
Increase in domestic valuation allowance	11,238,433	13,833,925
State income taxes before valuation allowance, net of federal benefit	(1,790,419)	(1,694,287)
Other	(19,065)	(279,631)
	<u>\$ —</u>	<u>\$ —</u>

The components of the Company's deferred tax assets (liabilities) at December 31, 2008 and 2007 are as follows:

	December 31,	
	2008	2007
Deferred tax assets and liabilities:		
Loss carryforwards	\$ 57,112,820	\$ 50,360,697
Accrued expenses and other	2,625,285	1,568,776
Stock option compensation	2,476,915	2,039,475
Property and equipment	1,708,838	814,503
	63,923,858	54,783,451
Less: Valuation allowance	(63,923,858)	(54,783,451)
	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2008, the Company had generated U.S. net operating loss carryforwards of approximately \$128.6 million which expire from 2011 to 2027 and net loss carryforwards in certain non-US jurisdictions of approximately \$22.9 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, 2008 and 2007. The valuation allowance increased \$9.1 million and \$14.4 million during 2008 and 2007, respectively, due primarily to the Company's 2008 and 2007 net losses.

Note 11—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 Eastern District of Pennsylvania.

In August 2005 and September 2005, various lawsuits were filed alleging securities fraud and asserting claims on behalf of a putative class of purchasers of publicly traded Isolagen securities between March 3, 2004 and August 1, 2005. These lawsuits were *Elliot Liff v. Isolagen, Inc. et al.*, C.A. No. H-05-2887, filed in the United States District Court for the Southern District of Texas; *Michael Cumiskey v. Isolagen, Inc. et al.*, C.A. No. 05-cv-03105, filed in the United States District Court for the Southern District of Texas; *Ronald A. Gargiulo v. Isolagen, Inc. et al.*, C.A. No. 05-cv-4983, filed in the United States District Court for the Eastern District of Pennsylvania, and *Gregory J. Newman v. Frank M. DeLape, et al.*, C.A. No. 05-cv-5090, filed in the United States District Court for the Eastern District of Pennsylvania.

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The *Liff* and *Cummiskey* actions were consolidated on October 7, 2005. The *Gargiolo* 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 *Gargiolo* and *Newman* actions were stayed on December 7, 2005 pending resolution of the MDL Motion. On February 23, 2006, the MDL Motion was granted and the actions pending in the Southern District of Texas were transferred to the Eastern District of Pennsylvania, where they have been captioned *In re Isolagen, Inc. Securities & Derivative Litigation*, MDL No. 1741 (the “Federal Securities Litigation”).

On April 4, 2006, the United States District Court for the Eastern District of Pennsylvania appointed Silverback Asset Management, LLC, Silverback Master, Ltd., Silverback Life Sciences Master Fund, Ltd., Context Capital Management, LLC and Michael F. McNulty as Lead Plaintiffs, and the law firms of Bernstein Litowitz Berger & Grossman LLP and Kirby McInerney & Squire LLP as Lead Counsel in the Federal Securities Litigation.

On July 14, 2006, Lead Plaintiffs filed a Consolidated Class Action Complaint in the Federal Securities Litigation on behalf of a putative class of persons or entities who purchased or otherwise acquired Isolagen common stock or convertible debt securities between March 3, 2004 and August 9, 2005. The complaint purports to assert claims for securities fraud in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 against Isolagen and certain of its former officers and directors. The complaint also purports to assert claims for violations of Section 11 and 12 of the Securities Act of 1933 against the Company and certain of its current and former directors and officers in connection with the registration and sale of certain shares of Isolagen common stock and certain convertible debt securities. The complaint also purports to assert claims against the underwriters of an April 2004 public offering of Isolagen common stock and a 2005 sale of convertible notes. On November 1, 2006, the defendants moved to dismiss the complaint. On September 26, 2007, the court denied the Company’s motions to dismiss the complaint. On November 6, 2007, the court entered a scheduling order that provides for discovery to be complete by June 8, 2009. On February 4, 2008, Lead Plaintiffs moved for class certification. On February 15, 2008, Lead Plaintiffs dismissed without prejudice their claims against certain of the underwriters named as defendants in the Federal Securities Class Action, but maintained claims against CIBC World Markets Corp. and UBS Securities LLC (the “Underwriters”).

On April 1, 2008, the court entered an order staying the schedule set forth in its November 6, 2007 order for a period of 90 days and directing the parties (together with the parties in the Beattie action, described under “Derivative Actions,” below) to participate in mediation before a private mediator. The mediation occurred on June 2, 2008 and June 5, 2008, at which the parties reached an agreement in principle to settle the Federal Securities Litigation. On October 23, 2008, the parties executed a definitive settlement agreement. In November 2008, the Company received settlement proceeds of \$5.25 million from its directors and officers liability insurance carrier, of which \$4.4 million was paid to the class action plaintiffs in December 2008 in accordance with the definitive settlement agreement. The \$5.25 million cash received by the Company from the directors and officers liability insurance carrier, the \$4.4 million that the Company paid to the class action plaintiffs, and the \$0.3 million which remains due to be paid by the Company to the derivative action plaintiffs (discussed further below) were each recorded as selling, general and administrative expense, net, for the year ended December 31, 2008 in the accompanying statement of operations. On March 25, 2009, the court entered an order and final judgment approving the settlement and dismissing the Federal Securities Litigation with prejudice. There is no accrual in the accompanying consolidated balance sheet at December 31, 2008 and 2007 with respect to the Federal Securities Litigation.

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 Eastern District of Pennsylvania, and the Court of Common Pleas of Chester County, Pennsylvania.

On September 28, 2005, Carmine Vitale filed an action styled, Case No. 2005-61840, *Carmine Vitale v. Frank DeLape, et al.* in the 55th Judicial District Court of Harris County, Texas, and in February 2006, Mr. Vitale filed an amended petition. 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. Jeffrey Tomz, who formerly served as Isolagen’s Chief Financial Officer, was accused of engaging in insider trading of Isolagen stock through a proxy. 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.

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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 petition. The plaintiff filed an amended petition on February 15, 2006, to which the defendants renewed their special exceptions. On September 6, 2006, the Court granted the special exceptions and permitted the plaintiff thirty days to attempt to replead. Thereafter, the plaintiff moved the Court for an order compelling discovery, which the Court denied on October 2, 2006. On October 18, 2006, the Court entered an order explaining its grounds for granting the special exceptions. On November 3, 2006, the plaintiff filed a second amended petition. On February 8, 2007, the Company filed its answer and special exceptions to the second amended petition. On August 9, 2007, the Court granted the special exceptions and dismissed the second amended petition with prejudice. On September 4, 2007, the plaintiff moved for reconsideration of the dismissal with prejudice of the second amended petition, for a new trial, and for leave to further amend the petition, and the defendants opposed that motion on September 20, 2007. On October 23, 2007, that motion was deemed denied by operation of law because the court had not acted on it by that date.

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 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 February 23, 2006, the Keene action was transferred with the Federal Securities Actions from the Southern District of Texas to the Eastern District of Pennsylvania. Thereafter, on May 15, 2006, the plaintiff filed an amended complaint, and on June 5, 2006, the defendants moved to dismiss the amended complaint. On August 21, 2006, the plaintiff moved for leave to file a second amended complaint, and on September 15, 2006, defendants filed an opposition to that motion. On January 24, 2007, the court denied the plaintiff's motion to file a second amended complaint, and on April 10, 2007 the court granted the defendants' motion to dismiss and dismissed the amended complaint without prejudice. On May 9, 2007, plaintiff filed a notice of appeal from the January 24, 2007 order denying plaintiff's motion to file a second amended complaint, and from the April 10, 2007 order dismissing plaintiff's amended complaint without prejudice. The appeal is fully briefed. On or about April 5, 2008, Keene moved the appeals court to stay the appeal for a period of 90 days to permit Keene to participate in the mediation of the federal securities litigation (described above) and the Beattie derivative litigation (described below). The mediation is described under "Federal Securities Litigation" above.

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. On August 31, 2006, the Court of Common Pleas entered an opinion and order sustaining the preliminary objections and dismissing the complaint with prejudice. On September 19, 2006, Fordyce filed a motion for reconsideration, which the Court of Common Pleas denied. On September 28, 2006, Fordyce filed a notice of appeal to the Superior Court of Pennsylvania. On July 27, 2007, the Superior Court affirmed the decision of the Court of Common Pleas.

On February 14, 2008, Ronald Beattie filed an action styled C.A. No. 08-724, Ronald Beattie v. Michael Macaluso, et al., in the United States District Court for the Eastern District of Pennsylvania. This action makes substantially similar allegations as the original complaint in the Vitale action.

On April 1, 2008, the court entered an order extending the defendants' time to respond to the complaint for a period ending 150 days from April 1, 2008 and directing the parties, together with the parties to the federal securities litigation described above, to mediation before a private mediator. The mediation is described under "Federal Securities Litigation" above.

The mediation occurred on June 2, 2008 and June 5, 2008, at which the parties reached an agreement in principle to settle the Keene and Beattie Derivative Actions, and on January 27, 2009, the parties executed a definitive settlement agreement. The settlement is subject to court approval. The court has scheduled a hearing to consider whether to approve the settlement for May 12, 2009. The proposed settlement of the Keene and Beattie Derivative Actions provides for the Company to make certain payments of attorneys' fees and expenses to counsel for Keene and Beattie. Those payments are to be made by the Company from proceeds previously received by the Company from its directors and officers liability insurance. An accrual of \$0.3 million and \$0.0 million has been recorded in the accompanying consolidated balance sheets at December 31, 2008 and 2007, respectively, in connection with the proposed settlement.

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Indemnity Demands

Mr. Jeffrey Tomz

After the above referenced litigations were commenced, Mr. Jeffrey Tomz, who formerly served as Isolagen's Chief Financial Officer, demanded reimbursement of his costs of defense, and reimbursement for the costs of responding to a Securities and Exchange Commission investigation of his alleged insider trading in Isolagen stock. It is understood that Mr. Tomz's defense costs to date amount to in excess of approximately \$0.3 million.

As the Vitale matter has now been resolved in favor of all defendants, including Mr. Tomz, the Company is presently obligated to reimburse him for the reasonable and necessary costs of defending all claims asserted therein other than the insider trading allegations. Although decided on jurisdictional grounds, it is likely the Company is also obligated to reimburse Mr. Tomz for the reasonable and necessary costs incurred in defending the Fordyce matter given that it has also been resolved in favor of all defendants. The Company could potentially be liable to reimburse Mr. Tomz for the reasonable and necessary costs of defense in the Keene case and in the putative securities cases, both of which have been resolved by settlement, as described above. The Company has refused to pay the amount of fees and expenses for which Mr. Tomz has sought reimbursement because it believes they are excessive, duplicative and have not been properly segregated between reimbursable and non-reimbursable claims. The Company has negotiated an acceptable compromise for the amounts billed by Mr. Tomz's local Pennsylvania counsel for an amount less than \$0.1 million.

Prior to the resolution of the various derivative actions, Mr. Tomz filed a demand for arbitration seeking advancement of his defense costs. He subsequently agreed to stay those proceedings. At present, Mr. Tomz has not sought to lift this stay and it is uncertain whether he will attempt to do so in the future.

The Company has accrued less than \$0.1 million in the accompanying consolidated financial statements as of December 31, 2008 with respect to Mr. Tomz's existing defense costs in dispute.

Underwriters

The Underwriters have each demanded that the Company indemnify, hold harmless and defend them with respect to the claims asserted in the putative securities actions. The total amount demanded to date is approximately \$0.8 million. The Underwriters demands for indemnification were a subject of the ongoing mediation efforts described under "Federal Securities Litigation" above, and as part of the proposed settlement of the Federal Securities Litigation the Underwriters agreed to release their claims for indemnification. Accordingly, no accrual has been recorded in the accompanying consolidated balance sheets at December 31, 2008 and December 31, 2007 in connection with the Underwriters original demand of approximately \$0.8 million.

Dispute with Former President and Member of the Board of Directors

On March 16, 2007, the Company disclosed in its Form 10-K for the year ended December 31, 2006 (the "Form 10-K"), that the Company and Susan Ciallella had reached an understanding pursuant to which Ms. Ciallella would resign from the Company in all capacities. The understanding, which was described in the Form 10-K, was subject to the negotiation and execution of a definitive agreement. On May 10, 2007, the Company disclosed in its Form 10-Q for the quarter ended March 31, 2007, that no such definitive agreement had been concluded with Ms. Ciallella, and that Ms. Ciallella was asserting claims against the Company in connection with her separation from the Company. On June 8, 2007, the Company and Ms. Ciallella participated in a voluntary mediation before a former federal judge. Upon conclusion of the mediation, the Company and Ms. Ciallella entered into a Settlement Agreement and Release (the "Settlement Agreement") pursuant to which the parties agreed to settle and resolve all claims that Ms. Ciallella may have against the Company as well as all aspects of Ms. Ciallella's separation from the Company. The Settlement Agreement provided Ms. Ciallella the following:

(i) severance payments as follows: (a) \$450,000, which was paid by June 2007; (b) \$240,000 paid on September 17, 2007; and (c) \$40,000 per month to be paid each month beginning October 17, 2007 through July 15, 2008 with a \$20,000 payment to be made on July 30, 2008;

(ii) \$1,745,000, which was paid during June 2007 in satisfaction and settlement of Ms. Ciallella's legal claims relating to her termination;

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(iii) \$5,000 paid during June 2007 in connection with Ms. Ciallella's release of claims under the Age Discrimination in Employment Act;

(iv) \$159,245 paid during June 2007 for the reimbursement of Ms. Ciallella's legal fees in connection with the negotiation and execution of the Settlement Agreement;

(v) \$198,950 related to Ms. Ciallella's legal support services to be provided to the Company, of which approximately \$158,000 had been paid as of December 31, 2007;

(vi) Ms. Ciallella retained 300,000 of the 400,000 performance options issued to her in June 2006, which expire in June 2016; Ms. Ciallella retained 160,000 of the options issued to her in April 2006, which expire in April 2016 and which were fully vested; and Ms. Ciallella retained her vested 300,000 options, which were issued to her in April 2005 and expire in April 2015 (see Note 8).

Each of the Company and Ms. Ciallella released the other party from any and all claims that it/she may have; and Ms. Ciallella agreed to resign from all officer and director positions she held with the Company or any of its subsidiaries.

During the three months ended March 31, 2007, the Company recorded termination costs aggregating \$2.6 million to reflect the March 16, 2007 understanding between the parties, which were included in selling, general, and administrative expenses. As a result of the June 2007 Settlement Agreement, during the three months ended June 30, 2007 the Company recorded an additional \$2.0 million of termination costs, which are also included in selling, general, and administrative expenses. No such expenses were incurred subsequent to June 30, 2007. Accordingly, for the year ended December 31, 2007, the Company recorded total termination costs of approximately \$4.6 million, as follows:

(in millions)	Year ended December 31, 2007
Salary and severance	\$ 2.8
Consulting fee	0.2
Legal fee reimbursement to Ms. Ciallella	0.2
Company legal fees	0.3
Stock option modifications (see Note 13)	1.1
	<u>\$ 4.6</u>

Of the \$0.3 million of Company legal fees above, approximately \$133,000 related to the Board of Directors' Special Committee legal counsel retained in connection with the Ciallella matter and was paid directly by the Company. Less than \$10,000 related to the legal fees of one of the Company's Board members in connection with the Ciallella matter was paid directly by the Company. Also, less than \$10,000 related to the legal fees of the Company's Chief Executive Officer in connection with the Ciallella matter was paid directly by the Company. The Company pursued reimbursement of the amounts paid in excess of Ms. Ciallella's contractual severance, plus defense costs, from its insurance carriers and in November 2008, the Company received \$0.3 million of reimbursements. As of December 31, 2008, all amounts due to Ms. Ciallella had been paid.

United Kingdom Customer Settlement

During 2005, the Company began an informal study and surveyed a number of patients who had previously received the Isolagen treatment to assess patient satisfaction. Some patients surveyed reported sub-optimal results from treatment. One hundred forty-nine patients who claimed to have received sub-optimal results were retreated for the purpose of determining the reasons for sub-optimal results. Only those patients who completed the survey, provided adequate medical records including before and after photographs and who were deemed both to have received a sub-optimal result from a first treatment administered according to the Isolagen protocol and who were considered to be appropriate patients for treatment with the Isolagen Therapy received re-treatment. No one completing the survey was offered re-treatment unless they agreed to these conditions. Following re-treatment, a number of patients reported better results than first obtained through the initial treatment by their initial treating physician.

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During the first quarter of 2006, the Company received a number of complaints from certain patients who had learned of the limited re-treatment program and also learned that a number of physicians with dissatisfied patients were generating public ill-will as a result of the Company's decision to limit the number of patients offered re-treatment and were encouraging dissatisfied patients to seek recourse against the Company. In response, in March 2006 the Company decided that it was in its best interest to address these complaints to foster goodwill in the marketplace and avoid the cost of any potential patient claims. Accordingly, the Company agreed to resolve any properly documented and substantiated patient complaints by offering to retreat the patient pursuant to the same criteria stated above or pay £1,000 (approximately US\$1,750) to the patients identified to the Company as having received a sub-optimal result. In order to have qualified for re-treatment and in addition to the criteria set forth above, the patient would be treated by a physician identified by the Company who would treat these patients pursuant to a protocol. In addition, these patients must have agreed to follow-up visits and assessments of their response to treatment. No patient unlikely to benefit from Isologen Therapy has been or would be retreated.

The Company made this offer to approximately 290 patients during late March 2006. Accordingly, the Company believed its range of liability was between £290,000 (or approximately \$0.5 million), assuming all 290 patients were to choose the £1,000 payment, and approximately £580,000 (or approximately \$1.0 million), assuming all 290 patients elected to be retreated. The estimated costs for retreatment include the cost of treatment, physician fees and other ancillary costs. The Company estimated that 60% of the patients would elect the £1,000 offer and 40% would elect to be retreated. Accordingly, the Company recorded a charge reflected under loss from discontinued operations for the three months ended March 31, 2006 of \$0.7 million. During the three months ended June 30, 2006, an additional 31 patients were entered into the settlement program, resulting in an additional charge reflected under loss from discontinued operations of \$0.1 million.

During the year ended December 31, 2006, payments to patients and retreatments reduced the accrual by \$0.6 million. During the year ended December 31, 2007, payments and retreatments to patients reduced the accrual by approximately \$0.1 million. As of December 31, 2008, the accrual, which is included in current liabilities of discontinued operations in the consolidated balance sheet, was \$0.1 million. As discussed in Note 5, on March 31, 2007, the Company completed the closure of its United Kingdom manufacturing facility.

United Kingdom Claims

Subsequent to the Company's public announcement regarding the closure of the United Kingdom operation, the Company received negative publicity and negative correspondence from former patients in the United Kingdom that previously received the Company's treatment. To date, the Company received written demand by an attorney representing approximately 132 former patients, as of December 31, 2008, each claiming negligent misstatements were made and each claiming, on average, £3,500 (or approximately \$5,250), plus unquantified interest and incidental expenses. The Company has responded to the written demand and is in the process of evaluating the merits of the claims. To date, no formal legal action has been brought by the attorney against the Company, and no provision has been recorded in the consolidated financial statements related to this matter.

During 2008, the Company received written correspondence from one former patient claiming physical injury allegedly from the use of Isologen Therapy. The Company believes this claim is without merit. To date, no formal legal action has been brought by the former patient against the Company, and no provision has been recorded in the consolidated financial statements related to this matter.

NYSE Amex Noncompliance

On March 17, 2009, the Company received notice from the NYSE Amex (the "Exchange") notifying the Company it is not in compliance with Section 1003(a)(iv) of the Exchange's Company Guide (the "Company Guide"). Specifically, the Exchange staff noted that the Company sustained losses which are so substantial in relation to its overall operations or its existing financial sources that it appears questionable, in the opinion of the Exchange, as to whether the Company will be able to continue operations and/or meet its obligations as they mature. As previously disclosed, the Company received a notice from the Exchange on March 12, 2008, advising the Company that it was not in compliance with Sections 1003 (a)(i)-(iii) of the Company Guide.

The Company currently intends to submit a plan in response to the most recent notice by April 17, 2009 outlining its compliance strategy with the current continued listing deficiency by September 14, 2009, subject to the Company successfully completing a sufficient financing transaction or strategic partnership prior to April 17, 2009. As of the date of the filing of this annual report, the Company has no commitments for any such additional funding and there is no assurance that the Company will receive any such additional funding. If the Company submits a plan and if the plan to regain compliance is accepted by the Exchange, the Company may be able to continue its listing during this period, during which time it will be subject to periodic review to determine progress consistent with the plan. If the Company does not submit a plan or if the plan is not accepted by the Exchange, the Company will be subject to delisting procedures as set forth in the Company Guide. Under Company Guide rules, the Company has the right to appeal the determination by the Exchange staff to initiate delisting proceedings and to seek a hearing before an Exchange Panel. The time and place of such a hearing will be determined by the Panel. If the Panel does not grant the relief sought by the Company, its securities could be delisted from the Exchange. There is no assurance that the Exchange staff will accept the Company's plan of compliance or that, even if such plan is accepted, the Company will be able to implement the plan within the prescribed timeframe.

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In addition, the Exchange's notice states that the Company's common stock has closed at between \$0.15 and \$0.87 per share over the last six months, and that the Staff is concerned that, as a result of the low selling price, the Company's common stock may not be suitable for auction market trading. Pursuant to Section 1003(f)(v) of the Company Guide, the Exchange has notified the Company that it deems it appropriate that the Company effect a reverse stock split within a reasonable amount of time in view of the fact that the Company's common stock has been selling for a substantial period of time at a low price per share.

Leases

The Company has entered into a lease for office, warehouse and laboratory facilities in Exton, Pennsylvania under a third party non-cancelable operating lease through 2013. Future minimum lease commitments at December 31, 2008 are as follows:

Year Ending December 31,	
2009	\$ 1,177,570
2010	1,177,570
2011	1,177,570
2012	1,177,570
2013	294,393
Thereafter	—
Total	\$ 5,004,673

For the years ended December 31, 2008 and 2007, rental expense totaled \$1.5 million and \$1.7 million, respectively, (which includes rent expense related to discontinued operations of \$0.1 million and \$0.4 million for the years ended December 31, 2008 and 2007, respectively).

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

Note 12—Equity

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.

In June 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.

In June 2007, the Company filed a shelf registration statement on Form S-3, which was subsequently declared effective by the SEC. The shelf registration allowed the Company the flexibility to offer and sell, from time to time, up to an original amount of \$50 million of common stock, preferred stock, debt securities, warrants or any combination of the foregoing in one or more future public offerings. In August 2007, the Company sold under this shelf registration statement 6,767,647 shares of common stock to institutional investors, raising proceeds of \$13.8 million, net of offering costs. The Company may offer and sell up to an additional \$36.2 million of common stock pursuant to this shelf registration. However, in general, companies that are under \$75 million in market capitalization are limited to selling up to one-third of the value of such company's common stock held by non-affiliates in any twelve month period.

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, 2008.

Treasury Stock

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.

Stockholder Rights Plan

In May 2006, the Board of Directors of the Company adopted a Stockholder Rights Plan, as set forth in the Rights Agreement, dated as of May 12, 2006, by and between the Company and American Stock Transfer & Trust Company, a trust company organized under the laws of the State of New York (the "Rights Agent"). Pursuant to the Rights Agreement, stockholders of record at the close of business on May 22, 2006 received one right ("Right") for each share of Isolagen common stock held on that date. The Rights, which will initially trade with the common stock and represent the right to purchase one ten-thousandth of a share of the Company's newly created Series C Preferred Stock at \$35 per Right, become exercisable when a person or group acquires 15% or more of the Company's common stock (20% in the case of certain institutional stockholders) or announces a tender offer for 15% or more of the common stock. In that event, in lieu of purchasing the Series C Preferred Stock, the Rights permit the Company's stockholders, other than the acquiror, to purchase Isolagen common stock having a market value of twice the exercise price of the Rights. In addition, in the event of certain business combinations, the Rights permit holders to purchase the common stock of the acquiror at a 50% discount. Rights held by the acquiror will become null and void in each case.

The Rights have certain anti-takeover effects, in that they would cause substantial dilution to a person or group that attempts to acquire a significant interest in the Company on terms not approved by the Board of Directors. In the event that the Board of Directors determines a transaction to be in the best interests of the Company and its stockholders, the Board of Directors will be entitled to redeem the Rights for \$.001 per Right at any time before the tenth business day after the Company's announcement that a person or group has acquired ownership of 15% or the tenth business day after commencement of a tender or exchange offer for more than 15% of the outstanding common stock. The Rights expire on May 12, 2016.

Note 13—Equity-based Compensation

In December 2004, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 123 (revised 2004), "Share-Based Payment" ("SFAS No. 123(R)"). SFAS No. 123(R) replaces SFAS No. 123, "Accounting for Stock-Based Compensation", supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB No. 25"), and amends SFAS No. 95, "Statement of Cash Flows." SFAS No. 123(R) requires entities to recognize compensation expense for all share-based payments to employees and directors, including grants of employee stock options, based on the grant-date fair value of those share-based payments, adjusted for expected forfeitures. The Company adopted SFAS No. 123(R) as of January 1, 2006 using the modified prospective application method. Under the modified prospective application method, the fair value measurement requirements of SFAS No. 123(R) is applied to new awards and to awards modified, repurchased, or cancelled after January 1, 2006. Additionally, compensation cost for the portion of awards for which the requisite service has not been rendered that were outstanding as of January 1, 2006 is recognized as the requisite service is rendered on or after January 1, 2006. The compensation cost for that portion of awards is based on the grant-date fair value of those awards as calculated for pro forma disclosures under SFAS No. 123. Changes to the grant-date fair value of equity awards granted before January 1, 2006 are precluded.

Prior to the adoption of SFAS No. 123(R), the Company followed the intrinsic value method in accordance with APB No. 25 to account for its employee stock options. Historically, substantially all stock options have been granted with an exercise price equal to the fair market value of the common stock on the date of grant. Accordingly, no compensation expense was recognized from substantially all option grants to employees and directors. Compensation expense was recognized in connection with the issuance of stock options to non-employee consultants in accordance with EITF 96-18, "Accounting for Equity Instruments That are Issued to Other than Employees for Acquiring, or in Conjunction with Selling Goods and Services." SFAS No. 123(R) did not change the accounting for stock-based compensation related to non-employees in connection with equity based incentive arrangements.

The Company utilizes the straight-line attribution method for recognizing stock-based compensation expense under SFAS No. 123(R). The Company recorded \$0.7 million and \$1.8 million of compensation expense, net of tax, during the years ended December 31, 2008 and 2007, respectively, for stock option awards to employees and directors based on the estimated fair values, at the grant dates, of the awards. In addition, refer to *Equity Instruments Issued for Services* for discussion below of additional stock option expense incurred by the Company in accordance with EITF 96-18.

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The weighted average fair market value using the Black-Scholes option-pricing model of the options granted was \$0.92 and \$1.91 for the years ended December 31, 2008 and 2007, respectively. The fair market value of the stock options at the date of grant was estimated using the Black-Scholes option-pricing model with the following weighted average assumptions:

	Year Ended December 31,	
	2008	2007
Expected life (years)	5.8	4.1
Interest rate	2.9%	4.8%
Dividend yield	—	—
Volatility	92%	76%

The risk-free interest rate is based on U.S. Treasury interest rates at the time of the grant, which term is consistent with the expected life of the stock options. Expected volatility is based on the Company's historical experience. Expected life represents the period of time that options are expected to be outstanding and is based on the Company's historical experience or the simplified method, as permitted by SEC Staff Accounting Bulletin No. 107 where appropriate. Expected dividend yield was not considered in the option pricing formula since the Company does not pay dividends and has no current plans to do so in the future. The forfeiture rate used was based upon historical experience. As required by SFAS No. 123(R), the Company will adjust the estimated forfeiture rate based upon actual experience.

There were no stock options exercised during the year ended December 31, 2008, resulting in zero cash proceeds to the Company. There were 16,666 stock options exercised during the year ended December 31, 2007, resulting in cash proceeds to the Company of less than \$0.1 million. The exercised options in 2007 had an intrinsic value of less than \$0.1 million. A summary of option activity for the year ended December 31, 2008 is as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2008	7,723,999	\$ 3.45		
Granted	1,132,000	1.27		
Exercised	—	—		
Forfeited	(419,166)	5.89		
Outstanding at December 31, 2008	<u>8,436,833</u>	<u>3.04</u>	<u>5.30</u>	<u>\$ —</u>
Options exercisable at December 31, 2008	<u>6,207,662</u>	<u>\$ 3.49</u>	<u>4.89</u>	<u>\$ —</u>

The following table summarizes the status of the Company's non-vested stock options since January 1, 2008:

	Non-vested Options	
	Number of Shares	Weighted- Average Fair Value
Non-vested at January 1, 2008	2,546,838	\$ 1.43
Granted	1,132,000	0.92
Vested	(1,262,167)	1.27
Forfeited	(187,500)	2.03
Non-vested at December 31, 2008	<u>2,229,171</u>	<u>\$ 1.22</u>

The total fair value of shares vested during the years ended December 31, 2008 and 2007 was \$1.6 million and \$2.1 million, respectively. As of December 31, 2008, there was \$0.7 million of total unrecognized compensation cost related to non-vested director and employee stock options which vest over time. That cost is expected to be recognized over a weighted-average period of 1.7 years. As of December 31, 2008, there was \$0.3 million of total unrecognized compensation cost related to performance-based, non-vested employee stock options. That cost will begin to be recognized when the performance criteria within the respective performance-base option grants become probable of achievement.

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 "2001 Stock Plan"). The 2001 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 2001 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, 2008, there were 2,923,500 options outstanding under the Stock Plan and 1,450,834 options are available to be issued under the Stock Plan.

During the three months ended March 31, 2008, the Company issued under the 2001 Stock Plan the following ten-year life option grants to Mr. Declan Daly, Chief Executive Officer: (a) an option to purchase 350,000 shares of common stock at an exercise price of \$2.36, which vests in twelve equal quarterly installments commencing March 31, 2008; and (b) a performance stock option to purchase 100,000 shares of common stock at an exercise price of \$2.36 that shall vest as follows: (i) 50% of performance stock option shall vest upon the Company's accepted filing of a Biologics License Application by the FDA and (ii) the remaining 50% of the performance stock option shall vest upon the FDA's approval of the Company's Biologics License Application filing; provided in each case that Mr. Daly is the Company's Chief Executive Officer at the time of said event.

Further, during the three months ended March 31, 2008, the following options grants were issued: (1) options issued to nine employees to purchase a total of 102,000 shares of common stock at an exercise price of \$0.61, which vest in equal annual installments over three years and have a five year life, (2) an option issued to the Company's Chief Financial Officer to purchase 200,000 shares of common stock at an exercise price of \$0.48, which vests in equal annual installments over three years and have a ten year life and (3) performance options issued to two consultants to purchase 200,000 shares of common stock at an average exercise price of \$0.51 (or exercise price range of \$0.41 to \$0.61), which vest upon the attainment of certain performance criteria. No compensation cost has been recorded for the performance stock option grants as the Company does not currently believe that the vesting events are probable of occurrence. A total of 952,000 stock options were granted during the three months ended March 31, 2008 under the 2001 Stock Plan.

The grant date fair value of the employee performance option awards issued during the three months ended March 31, 2008 was approximately \$0.2 million. This fair value of \$0.2 million, or any portion thereof, will not be recognized as compensation expense until the vesting of the award becomes probable. The fair value of the total non-employee performance awards issued during the three months ended March 31, 2008 was less than \$0.1 million as of March 31, 2008. Compensation expense related to the non-employee performance option awards will not be recognized until vesting of the awards occur, and the actual amount of expense will be based upon the valuation factors in effect at that time.

During the three months ended June 30, 2008, the Company issued to its six independent Board of Director members, under the 2001 Stock Plan, a total of 180,000 options to purchase its common stock with an exercise price of \$0.62 per share and a ten year maximum contractual life. The options vested one-fourth upon grant and one-fourth over the three remaining fiscal quarters of 2008.

No stock options were issued during the six months ended December 31, 2008 under the 2001 Stock Plan.

During the three months ended March 31, 2007, the Company issued, under the 2001 Stock Plan, 395,000 options to employees and Board of Director members, with exercise prices ranging from \$2.37 to \$3.10 and with contractual lives of 5 years for employees and 10 years for Board members.

During the three months ended June 30, 2007, the Company issued, under the 2001 Stock Plan, 140,000 options to three employees, with exercise prices ranging from \$4.20 to \$4.55 and with contractual lives of 5 years.

During the three months ended September 30, 2007, the Company issued, under the 2001 Stock Plan, (1) a total of 102,500 options to four employees with an exercise price of \$3.38 per share, which have a five year maximum contractual life and which vest annually over a three year period from the date of grant and (2) a total of 50,000 performance-based options to one employee with an exercise price of \$3.38 per share and which have a maximum contractual life of five years. With respect to these 50,000 performance-based stock options, no compensation expense will be recorded until the performance-based vesting event is probable of occurrence. The grant date fair value of this award was less than \$0.1 million.

During the three months ended December 31, 2007, the Company issued, under the 2001 Stock Plan, 30,000 options to one newly appointed board member, with exercise price of \$3.14, with a contractual life of 10 years and a cliff-vesting period of one year.

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, 2008, there were 1,640,000 options outstanding under the 2003 Stock Plan and 610,000 shares were available for issuance under the 2003 Stock Plan. No options have been granted under the 2003 Stock Plan since November 2006.

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, 2008, there were 305,000 options outstanding and 1,712,818 shares were available for issuance under the 2005 Stock Plan. No options have been granted under the 2005 Stock Plan since June 2006.

During the three months ended March 31, 2007, the Company modified a 400,000 share performance option grant, as discussed below under *Modification of Stock Options*. This 400,000 share performance option grant was issued during the three months ended June 30, 2006 to purchase common stock with an exercise price of \$1.88 per share to the Company's President. These options had a ten year maximum contractual life and the options were to vest, and no longer be subject to forfeiture, upon the occurrence of any of the following events: (i) upon the closing of the sale of substantially all of the assets of the Company or the reorganization, consolidation or the merger of the Company; provided that the event results in the payment or distribution of consideration valued in good faith by the Board of Directors at \$25 per share or more; or (ii) upon the closing of a tender offer or exchange offer to purchase 50% or more of the issued and outstanding shares of common stock of the Company at a price per share valued in good faith by the Board of Directors at \$25 or more; or (iii) immediately following a "Stock Acquisition Date," as that term is defined in the Rights Plan adopted by the Company on May 12, 2006 (provided that said rights are not subsequently redeemed by the Company or that the Rights Plan is not subsequently amended to preclude exercise of the rights issued thereunder, prior to the Distribution Date, as that term is defined in the Rights Plan), or (iv) at such other time as the Board of Directors, in its sole discretion, deems appropriate; provided in each case that the President is employed by the Company at the time of said event. The 400,000 share option grant was considered a grant of a performance stock option.

Modification of Stock Options

On January 7, 2008, the Company and Mr. Nicholas L. Teti, Jr. entered into a consulting and non-competition agreement (the "Consulting Agreement"), pursuant to which Mr. Teti agreed to continue as the Company's non-executive Chairman of the Board and to become a consultant to the Company, and Mr. Teti resigned his position as Chief Executive Officer and President of the Company. Pursuant to the Consulting Agreement, Mr. Teti's original employment agreement, dated June 5, 2006, was terminated and the parties agreed that he was owed no severance payments under the original employment agreement. Mr. Teti retained his previously issued stock options which were modified such that Mr. Teti will continue to vest in accordance with the original terms, except as a non-employee. As a result of the modifications to Mr. Teti's stock options set forth in the Consulting Agreement, the Company recorded a non-cash compensation charge during the three months ended March 31, 2008 of approximately \$1.3 million related to Mr. Teti's 1,166,665 vested stock options on the date of modification.

Further, stock compensation expense relating to the 833,335 unvested stock options Mr. Teti held at the time of modification are being recorded as stock option expense over the remaining periods those stock options are earned in accordance with EITF 96-18, "Accounting for Equity Instruments That are Issued to Other than Employees for Acquiring, or in Conjunction with Selling Goods and Services." These stock options vest ratably through June 30, 2009.

In connection with the separation of the Company's former President (see Note 7), the Company agreed on March 16, 2007 to modify certain of her stock options such that (1) 120,000 unvested, time-based stock options would vest immediately and (2) of 400,000 performance based stock options, 100,000 would be cancelled and the remaining 300,000 would be extended such that the 300,000 options would expire 10 years from the original grant date, as opposed to expiring upon termination of employment. The 300,000 performance based stock options would continue to be subject to the same performance based vesting requirements. The 120,000 modified stock options were valued using the Black-Scholes valuation model, and resulted in \$0.3 million charge to selling, general and administrative expense during the months ended March 31, 2007. The 300,000 modified performance stock options were valued using the Black-Scholes valuation model, and resulted in \$0.8 million charge to selling, general and administrative expense in the year ended December 31, 2007.

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Restricted Stock

As of December 31, 2008 and December 31, 2007, 0 shares and 166 shares of unvested restricted stock were outstanding, respectively.

Other Stock Options

The Company has not issued any options outside the 2001 Stock Plan, the 2003 Stock Plan or the 2005 Stock Plan since June 2006. As of December 31, 2008 and 2007, there were 3,568,333 nonqualified stock options outstanding outside of the shareholder approved plans discussed above.

The Company's Chairman of the Board was issued 500,000 options to purchase the Company's common stock with an exercise price of \$1.88 per share issued in June 2006. These options have a ten year maximum contractual life and the options have identical vesting terms to the Performance Stock Option Grant issued to the Company's President under the 2005 Stock Plan as described above. No compensation cost has been recorded for this grant as the Company does not currently believe that the vesting events are probable of occurrence. The grant date fair value of the award was approximately \$0.7 million. The fair value of the award will not be recognized as compensation expense until the vesting of the award becomes probable.

Equity Instruments Issued for Services

As of December 31, 2008, the Company had outstanding 1,436,935 warrants and options issued to non-employees under consulting agreements. The following sets forth certain information concerning these warrants and options:

	Vested
Warrants and options outstanding	1,270,268
Range of exercise prices	\$1.50-6.00
Weighted average exercise price	\$2.97
Expiration dates	2009-2016
	Unvested
Warrants and options outstanding	166,667
Exercise price	\$ 1.88
Weighted average exercise price	\$ 1.88
Expiration date	2016

All of the above unvested equity instruments relate to the Company's former Chief Executive Officer and current Chairman, as of December 31, 2008. Expense related to these contracts was \$0.2 million and less than \$0.1 million for the years ended December 31, 2008 and 2007, respectively. This expense, which is in addition to the stock option expense related to employees and directors based on the grant date fair value discussed above, was calculated using the Black Scholes option-pricing model based on the following assumptions:

Expected life (years)	3.5-4.3 Years
Interest rate	1.0-3.13%
Dividend yield	—
Volatility	100-142%

Further, there were 60,000 and 168,246 warrants outstanding as of December 31, 2008 and as of December 31, 2007, which were primarily issued in connection with past equity offerings. During the year ended December 31, 2007, there were 520,010 warrants exercised. Of the warrants exercised during the year ended December 31, 2007, 463,370 were exercised via cash payment of the \$1.93 exercise price, and the remaining 56,640 warrants were exercised via net share exercise. In total, 492,613 shares of common stock were issued during 2007 as a result of these warrants exercised and \$0.9 million of cash proceeds were received by the Company in connection with the payment of the related warrant exercise price. The intrinsic value of the warrants exercised during the year ended December 31, 2007 was \$1.1 million. There were no warrants exercised during the year ended December 31, 2008.

Note 14—Certain Relationships and Related-Party Transactions

Five of the Company's current Board members and seven of the Company's former officers and directors are named defendants in certain pending class action and derivative legal proceedings discussed in Note 11 above. During 2008, the Company advanced an aggregate of \$0.5 million, or less than \$0.1 million per person, for legal expenses incurred on behalf of those five Board members and seven former officers and directors in connection with their defense in those proceedings. During 2007, the Company advanced an aggregate of \$0.8 million, or approximately \$0.1 million per person, for legal expenses incurred on behalf of those five Board members and seven former officers and directors in connection with their defense in those proceedings. Refer to Note 11 for a discussion of the related settlements in principle and reimbursements of associated legal expenses.

Since June 2005, Mr. Ralph De Martino, a member of the Company's Board of Directors until June 2008, has been a member of the law firm Cozen O'Connor in the firm's Washington, DC office. From January 2003 until June 2005, Mr. De Martino was the managing partner of the Washington, DC office of the law firm Dilworth Paxson LLP. Fees paid by the Company to Cozen O'Connor during 2008 and 2007 were \$0.3 million and \$0.7 million, respectively.

See Note 11, *Dispute with Former President and Member of the Board of Directors and Departure of Former Chief Executive Officers*, for discussion of severance arrangements with former senior employees. See Note 13, *Equity Based Compensation*, for discussion of the January 2008 departure of our former Chief Executive Officer.

Note 15—Segment Information and Geographical information

With the acquisition of Agera on August 10, 2006 (see Note 4), the Company now has two reportable segments: Isologen Therapy and Agera. Prior to the acquisition of Agera, the Company reported one reportable segment. The Isologen Therapy segment specializes in the development and commercialization of autologous cellular therapies for soft tissue regeneration. The Agera segment maintains proprietary rights to a scientifically-based advanced line of skincare products. The following table provides operating financial information for the continuing operations of the Company's two reportable segments:

Year Ended December 31, 2008	Segment		Consolidated
	Isologen Therapy	Agera	
External revenue	\$ —	\$ 1,104,885	\$ 1,104,885
Intersegment revenue	—	—	—
Total operating revenue	—	1,104,885	1,104,885
Cost of revenue	—	602,511	602,511
Impairment of long-lived assets during fiscal year 2008	2,989,930	3,742,824	6,732,754
Selling, general and administrative expense	7,811,172	688,135	8,499,307
Research and development expense	10,173,117	—	10,173,117
Management fee	(357,000)	357,000	—
Total operating expenses	20,617,219	4,787,959	25,405,178
Operating loss	(20,617,219)	(4,285,585)	(24,902,804)
Interest income	181,478	36	181,514
Interest expense	(3,899,239)	—	(3,899,239)
Minority interest	—	1,680,676	1,680,676
Segment loss	<u>\$(24,334,980)</u>	<u>\$(2,604,873)</u>	<u>\$(26,939,853)</u>

Supplemental information related to continuing operations

Depreciation and amortization expense	\$ 1,050,024	\$ 326,839	\$ 1,376,863
Capital expenditures	33,337	—	33,337
Equity awards issued for services	2,132,597	—	2,132,597
Amortization of debt issuance costs	749,239	—	749,239
Total assets, including assets from discontinued operations	4,019,714	1,033,691	5,053,405
Property and equipment, net	—	—	—
Intangible assets, net	—	—	—

An intercompany receivable of \$1.0 million, due from the Agera segment to the Isologen Therapy segment, is eliminated in consolidation. This intercompany receivable is primarily due to the intercompany management fee charge to Agera by Isologen, as well as Agera working capital needs provided by Isologen, and has been excluded from total assets of the Isologen Therapy segment in the above table.

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Year Ended December 31, 2007	Segment		Consolidated
	Isolagen Therapy	Agera	
External revenue	\$ —	\$ 1,400,986	\$ 1,400,986
Intersegment revenue	—	—	—
Total operating revenue	—	1,400,986	1,400,986
Cost of revenue	—	656,029	656,029
Selling, general and administrative expense	17,429,016	1,301,847	18,730,863
Research and development expense	13,278,796	19,542	13,298,338
Management fee	(600,000)	600,000	—
Total operating expenses	30,107,812	1,921,389	32,029,201
Operating loss	(30,107,812)	(1,176,432)	(31,284,244)
Interest income	897,731	3,531	901,262
Interest expense	150,138	—	150,138
Minority interest	(3,899,239)	—	(3,899,239)
Income tax benefit	—	246,347	246,347
Segment loss	<u>\$(32,959,182)</u>	<u>\$ (926,554)</u>	<u>\$(33,885,736)</u>

Supplemental information related to continuing operations

Depreciation and amortization expense	\$ 1,178,376	\$ 326,842	\$ 1,505,218
Capital expenditures	184,538	—	184,538
Equity awards issued for services	3,026,610	—	3,026,610
Amortization of debt issuance costs	749,239	—	749,239
Total assets, including assets from discontinued operations	34,162,693	5,328,497	39,491,190
Property and equipment, net	3,395,723	—	3,395,723
Intangible assets, net	529,875	4,069,663	4,599,538

An intercompany receivable of \$1.1 million, due from the Agera segment to the Isolagen Therapy segment, is eliminated in consolidation. This intercompany receivable is primarily due to the intercompany management fee charge to Agera by Isolagen, as well as Agera working capital needs provided by Isolagen, and has been excluded from total assets of the Isolagen Therapy segment in the above table. Total assets on the consolidated balance sheet at December 31, 2007 are approximately \$39.5 million, which includes assets of continuing operations of \$28.2 million and assets of discontinued operations of \$11.3 million.

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

	Revenue	
	Year ended December 31,	
	2008	2007
United States	\$ 312,139	\$ 368,784
United Kingdom	712,105	967,313
Other	80,641	64,889
	<u>\$ 1,104,885</u>	<u>\$ 1,400,986</u>

During 2008, revenue from one foreign customer and one domestic customer represented 64% and 20% of consolidated revenue, respectively. During 2007, revenue from one foreign customer and one domestic customer represented 69% and 16% of consolidated revenue, respectively.

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As of December 31, 2008 and December 31, 2007, one foreign customer represented 94% and 94%, respectively, of accounts receivable, net.

	Property and Equipment, net	
	As of December 31,	
	2008	2007
United States	\$ —	\$ 3,395,723

	Intangible Assets, net	
	As of December 31,	
	2008	2007
United States	\$ —	\$ 4,599,538

EXHIBIT INDEX

EXHIBIT NO.	IDENTIFICATION OF EXHIBIT
23	BDO Seidman, LLP Consent
31.1	Certification pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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, No. 333-122440 and No. 333-142959) and Form S-8 (No. 333-108219 and No. 333-131803) of Isolagen, Inc. of our report dated April 14, 2009 relating to the consolidated financial statements, which is incorporated by reference in this Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO Seidman, LLP
Houston, Texas

April 14, 2009

CERTIFICATION

I, Declan Daly, 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 officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a – 15(e) and 15d – 15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Dated: April 14, 2009

By: /s/ Declan Daly
Declan Daly
Chief Executive Officer
Isolagen, Inc.

CERTIFICATION

I, Todd J. Greenspan, 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 officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a – 15(e) and 15d – 15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Dated: April 14, 2009

By: /s/ Todd J. Greenspan
Todd J. Greenspan
Chief Financial Officer
Isolagen, Inc.

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

For purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned, Declan Daly, Chief 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, 2008, as filed with the Securities and Exchange Commission on the date hereof (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Commission Act of 1934; and
- ii. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: April 14, 2009

By: /s/ Declan Daly
Declan Daly
Chief Executive Officer
Isolagen, Inc.

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

For purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned, Declan Daly, Chief 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, 2008, as filed with the Securities and Exchange Commission on the date hereof (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Commission Act of 1934; and
- ii. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: April 14, 2009

By: /s/ Todd J. Greenspan
Todd J. Greenspan
Chief Financial Officer
Isolagen, Inc.