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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, 2004

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

102 Pickering Way
Exton, Pennsylvania 19341
(Address of principal executive offices, including zip code)

(484) 875-3099
(Issuer's telephone number, including area code)

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

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

Indicate by check mark 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 an accelerated filer (as defined in the Exchange Act Rule 12b-2) Yes ☒ No ☐

As of June 30, 2004, 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 $251,550,808.

As of March 14, 2005, issuer had 30,219,899 shares outstanding common stock, par value $0.001.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the 2005 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed within 120 days of the end of the fiscal year ended December 31, 2004, 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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Forward-Looking Information

Some of the information in this report contains forward-looking statements within the meaning of the federal securities laws that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause us or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by the forward-looking statements. You should not rely on forward-looking statements in this report. Forward-looking statements typically are identified by use of terms such as "anticipate," "believe," "plan," "expect," "future," "intend," "may," "will," "should," "estimate," "predict," "potential," "continue," and similar words, although some forward-looking statements are expressed differently. This report also contains forward-looking statements attributed to third parties relating to their estimates regarding the growth of our markets. All forward-looking statements address matters that involve risk and uncertainties, and there are many important risks, uncertainties and other factors that could cause our actual results, as well as those of the markets we serve, levels of activity, performance, achievements and prospects to differ materially from the forward-looking statements contained in this report. You should also consider carefully the statements under "Risk Factors" and other sections of this prospectus, which address additional facts that could cause our actual results to differ from those set forth in the forward-looking statements. We undertake no obligation to publicly update or review any forward-looking statements, whether as a result of new information, future developments or otherwise.

Part I

Item 1. Business

Overview

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

We are developing our lead product candidate for the correction and reduction of the normal effects of aging, such as wrinkles and nasolabial folds. In March 2004, we announced positive results of our first Phase III exploratory clinical trial for our lead product candidate. In July 2004, we announced the commencement of two pivotal Phase III trials, which are being conducted in two different geographic and demographic populations in the United States as two identical trials for the treatment of facial wrinkles. These trials are randomized, double blind and placebo-controlled and are being conducted at various sites in the United States. The trials, which are being conducted simultaneously, each have in excess of 100 patients split evenly between the treatment group and the placebo group. Efficacy will be measured by a two-point improvement on a six-point scale, as evaluated by an independent assessor at four, six, nine and twelve months. The injection phase of both Phase III studies was completed in December 2004 and we expect to file a Biologics License Application, or BLA, for this product candidate during the second half of 2005. In late 2003, we began limited commercialization for our dermal product in the United Kingdom.

We completed a Phase I clinical trial for our second product candidate for the treatment of periodontal disease in late 2003. In the second quarter of 2004, we initiated a Phase II clinical trial for the cosmetic, or "black triangle," application of this product candidate. The enrollment phase of this study is complete and the data from the acute (4-month) phase of the study is currently being analyzed.

We believe our company is still considered to be a "development stage" enterprise since the focus of our efforts has been and will continue to be the development, testing and approval of the aesthetic and dental applications of our process and research into other applications of our process. Since 2002, however, we have made the Isolagen Process available to physicians in the United Kingdom and Australia as a means of developing our marketing, sales and manufacturing processes, as well. Revenues from the sale of these treatments were approximately $4.2 million for Fiscal 2004. These revenues partially offset the costs, included in cost of sales, we are incurring in our manufacturing process.

Our corporate headquarters is located at 102 Pickering Way, Exton, Pennsylvania 19341. Our phone number is (484) 875-3099, and the address of our web site is www.Isolagen.com. Information appearing at our web site is not a part of this Annual Report on Form 10-K. Our web site includes links to our Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments to those reports (SEC Reports). The SEC Reports are available without charge as soon as reasonably practicable following the time that they are filed with or furnished to the SEC. Our fiscal year begins on January 1, and ends on December 31, and references herein to "Fiscal 2004" mean the year ended December 31, 2004, and references to other "Fiscal" years mean the year ending December 31, of the year indicated.

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

The Structure of Skin and Conditions that Affect Appearance

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

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

Our Target Market Opportunity

Aesthetic Market Opportunity

Aesthetic procedures have traditionally been performed by dermatologists, plastic surgeons and other cosmetic surgeons, of which there are approximately 23,000 in the United States, according to the American Society for Aesthetic Plastic Surgery, or ASAPS. According to the ASAPS, the total market for non-surgical cosmetic procedures was approximately $4.7 billion in 2004. We believe growth in the aesthetic procedure market is driven by:

- aging of the "baby boomer" population, currently ages 41 to 59, representing over 27% of the U.S. population;
- increasing desire of many individuals to improve their appearance;

- impact of managed care and reimbursement policies on physician economics, which has motivated physicians to establish or expand the menu of elective, private-pay aesthetic procedures that they offer; and

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

Our lead product candidate is directed primarily at the aesthetic market. According to the ASAPS, nearly 11.9 million surgical and non-surgical cosmetic procedures were performed in 2004, up 44% from nearly 8.3 million in 2003. According to the ASAPS, consumer demand increased 51% in 2004 for non-surgical cosmetic procedures, exceeding more than 9.7 million procedures. 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 2004:

Procedure	Number
Botox injection	2,837,346
Laser hair removal	1,411,899
Chemical peel	1,110,401
Microdermabrasion	1,098,316
Hyaluronic acid	882,469

Procedures among the 35 to 50 year old age group made up 45% of all non-surgical cosmetic procedures in 2004. The 51 to 64 year old age group made up 25% of all non-surgical cosmetic procedures in 2004, while the 19 to 34 year old age group made up 22% of the non-surgical cosmetic procedures. Botox injection was the most popular treatment among the 35 to 50 and 51 to 64 year old age groups.

Dental Market Opportunity

In addition to the aesthetic market, we believe there is an extensive dental market opportunity for an effective therapy for regenerating tissue because a majority of the population will experience periodontal disease at some point in their lives. According to the Department of Labor, Bureau of Labor Statistics, there were over 153,000 active privately practicing dentists in the United States in 2002.

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

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

Limitations of Existing Therapies

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

- *Short duration of effect.* Most of these products last for a short time, as they are reabsorbed by the body over a three to six month period. The need for repeated treatments to maintain an improved appearance makes these options inconvenient and more costly over time for patients.

- *Significant pain associated with the injection.* All of these products are administered through injections directly into the facial tissue. Some competing procedures can be very painful for the patient and require the use of a thicker needle for the injection. For some of these products, physicians will have to anesthetize the area or administer a nerve block in order to complete the procedure. This is both inconvenient for the patient and adds extra time to the procedure for the physician.

- *Irregular correction and lumpiness.* Some of these products eventually cause uneven contours following the injection. Patients may feel unnatural lumps under their skin and experience discomfort where the material has been injected. In some cases, this effect dissipates as the material is reabsorbed by the body over time. In other cases, the effect is permanent.

- *Immunological reactions.* Many of these products are derived from animal sources, such as cow or sheep, or other foreign substances not naturally found in the human body. As a result, the body may react negatively to the material resulting in an allergic reaction. In some cases, the patient must undergo an allergy test to determine whether or not the treatment is suitable for the patient. This is inconvenient for both the patient and the physician because it requires an additional visit to the physician's office.

Our Solution

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

- *Natural mechanism of action.* Our Isolagen Process produces a living cell therapy that is designed to replace the fibroblasts that have deteriorated over time as the patient ages. We believe that the fibroblasts created by our Isolagen Process and injected into the patient's dermis continue to multiply and lead to the production of collagen and elastin. These fibroblast cells are subject to the normal physiological controls of tissue and, therefore, can potentially return the tissue to a more youthful appearance without over-correction or deformity.

- *Long duration of effect.* Fibroblast cells remain viable for many years and, therefore, the effects are likely to last longer. Some patients treated with our Isolagen Process have exhibited positive results for longer than one year. We believe our Isolagen Process will produce long-lasting effects.

- *Minimal pain associated with the injection.* We believe that patients experience minimal pain with our Isolagen Process because the injected material is less viscous and causes less irritation than other synthetic filler products. A thin needle is used, and anesthesia is generally not required for the injection.

- *No immunological reaction.* Our Isolagen Process uses the patient's own cells. As a result, the therapy should not cause a negative immunological response.

- *Broad applications.* Our dermal product candidate may be applicable to virtually every area of the face. We are also exploring the use of our Isolagen Process for the treatment of periodontal disease, vocal cord injury and acne scars.

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

Our Isolagen Process

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

Historically, autologous cell companies have been hampered by manufacturing technologies that use traditional methodology for culturing cells through the utilization of plastic flasks. This methodology is labor intensive, costly and slow, involving many sterile interventions and is costly. The use of this process to produce Isolagen Process injections in commercial quantities would not be profitable.

Since 2002 we have made our Isolagen Process available to physicians in the United Kingdom and Australia. We have been using the commercialization of our process in these markets as a means of researching and developing manufacturing technologies that are more automated and, therefore, we believe could be used to produce commercial quantities of injections on a profitable basis. The existing process separates cells manually utilizing centrifuge technology. Emerging technologies and additional experience from U.K. operations and our clinical trials have allowed us to consider a number of different alternatives for cellular expansion and harvest. We are presently evaluating the technological advantages and commercial viability of several options. We are currently developing an Automated Cell Expansion, or ACE, System. Our ACE System will eliminate several of the steps and materials involved in our current system, which we expect will lead to significant cost reductions in both skilled labor and materials and will enable scalable mass production. These technologies are based on low cost, commercially available cell concentration and washing devices, such as those used in the blood banking industry. We expect the implementation and commercial validation of our ACE System to be completed prior to the filing of our BLA. Additionally, it may be necessary to obtain FDA clearance prior to incorporating our ACE System into our manufacturing process in the United States, which could delay its implementation. There can be no assurance that our efforts to develop and commercialize the ACE System will be successful.

Clinical Trials

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

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

Our Dermal Product Candidate

Phase III Exploratory Clinical Trial. In July 2003, a Phase III exploratory clinical trial for the treatment of wrinkles and scars was conducted at ten sites and included 158 patients in the "Intent To Treat" group. It was a double-blind clinical trial with 75% of the patients receiving the therapeutic dosage and the remaining 25% receiving a placebo. On March 3, 2004, we announced positive results of our four-month clinical endpoint. Of the evaluable population, 77% of treatment group patients were responders, whereas 36% of the placebo group were responders ($p<0.0001$). In this statistically significant result, response was determined by a change of two or more points on a 7-point photoguide scale four months following the first injection. Although the primary endpoint for this study was four-months, evaluations continued for six, nine and twelve-months after first injection. The Isolagen treatment was offered to placebo patients after six-months evaluation. On July 28, 2004, we announced a positive response in 82% of the Isolagen treated patients who were evaluated at six months. This previously disclosed six-month data and new 12-month follow-up data from this trial was the subject of a poster presented at the 63rd Annual Meeting of the American Academy of Dermatology in New Orleans, Louisiana in February 2005. The therapeutic effect of the Isolagen Process compared to placebo was demonstrated at six months (82.2% vs. 38.2%, Fisher's exact, p-value<0.0001). Results of a 12-month follow-up assessment on only the Isolagen treated group demonstrated the therapeutic effect was maintained with a response rate of 82.4% in those patients who were evaluated at 12 months. A p-value is a statistical measure of the probability of drawing an erroneous conclusion from an experimental result. A p-value of less than or equal to 0.05 is generally considered to signify a statistically significant result, which means a result is unlikely to occur by chance. There were no serious adverse events related to the Isolagen Process. There was some mild edema and bruising observed at the injection site in both the placebo and treatment groups, which resolved spontaneously. The FDA has expressed issues concerning the design of this study and stated that additional studies would be necessary to support BLA approval.

Planned Pivotal Phase III Clinical Trials. In view of the FDA's concerns with the completed exploratory Phase III clinical trial, we had numerous communications throughout 2003 with the FDA to finalize the study design for two Phase III pivotal clinical trials. These communications included numerous submissions of data and protocols, meeting requests and annual reports. We had face-to-face meetings in March, September and December 2003 with FDA staff in the Center for Biologics Evaluation and Research.

Following the recommendations of the FDA, we simplified the study design and incorporated the use of an FDA-recommended, 6-point photoguide scale. This published and validated 6-point photoguide scale has been used in previous clinical trials for approved products in this category. The Phase III pivotal studies do not include acne or facial scar patients, as these patients may not be adequately assessed using the 6-point photoguide scale. We believe that the remaining study design issues were resolved.

On April 7, 2004, we submitted a request for a Special Protocol Assessment, or SPA, to the FDA with all the supporting information for our two pivotal Phase III clinical trials. In the SPA process, the FDA reviews the design and size of a proposed Phase III program and provides comments regarding the adequacy of the clinical trial design to support a claim of efficacy in an approvable BLA. The FDA's comments are binding on its review decision, except in limited circumstances, such as when a substantial scientific issue essential to determining the safety and efficacy of a product candidate is identified after the Phase III program commences. On May 21, 2004, the FDA approved our request for an SPA relating to the design of two pivotal Phase III clinical trials to be conducted by us in support of the Isolagen Process for the treatment of nasolabial folds and glabellar lines. The two pivotal Phase III clinical trials were initiated in July 2004. The injection phase of both Phase III studies was completed in December 2004, and Isolagen plans to file the BLA in the second half of 2005.

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

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

UK International Registry. We collected patient response data from 59 patients randomly chosen from a total of the approximately 400 patients treated as of November 2003 in the United Kingdom with our dermal product. This data was analyzed by an independent clinical research organization. The sampling reflects a cross section of all treated patients at all stages of treatment as of November 2003 rather than a summary of patients at some fixed time point.

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

Retrospective Study. In 2002, we conducted a retrospective study of 354 of the approximately 1,000 patients who were treated with a predecessor of our Isolagen Process prior to filing our IND in 1999.

No serious adverse events were reported by any of the 354 patients studied. In fact, less than 10% of those patients reported any adverse events. The majority of the adverse events that were reported were mild edema and bruising at the injection site.

Our Dental Product Candidate

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

Phase II Clinical Trial. In May 2004 we announced the initiation of a Phase II randomized, double-blind, placebo-controlled clinical study to determine the safety and efficacy of Isolagen injections for the treatment of interdental papillary insufficiency. The enrollment phase of this study is completed and the patients are in the follow-up phase of the trial. Analysis of the acute (four-month) phase of the study is planned in the first half of 2005. We plan to prepare protocols for a clinical trial to assess the efficacy and safety of our dental product candidate for the treatment of deep periodontal pockets. These clinical trials will be traditional double blind, internal and placebo controlled studies and are designed to assess the therapeutic efficacy and safety of our dental product candidate.

Other Clinical Trials

We currently have an active IND for vocal cord injury. We are finalizing our Phase I clinical trial protocol, and we currently plan to initiate this trial in 2005. We are also exploring other opportunities for additional product candidates, including for the treatment of acne scars.

Our Strategy

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

- *Leveraging our expertise in autologous cellular therapies to expand into other applications.* We believe that our Isolagen Process is applicable to both aesthetic and medical conditions and can provide meaningful benefits to patients. We plan to pursue additional applications for acne scars and repairing vocal cords. We are also exploring additional opportunities to use our product candidates and technology.

- *Optimizing our manufacturing processes to achieve cost reductions and scalability.* We are developing our ACE System that will permit an automated cell growth and harvesting process. We expect the ACE System to yield significant cost reductions and allow us to implement a platform that enables scalable mass production.

- *Building a direct sales force.* There are approximately 23,000 dermatologists, plastic surgeons and cosmetic surgeons in the United States. We plan to build our own direct sales force focused on calling on a highly targeted segment of these physicians. We believe that by building our own

direct sales force we will be able to maximize the value of our product candidates and provide the required focus to launch our future products successfully.

- *Expanding our international presence.* We believe the size of the international market is comparable to the U.S. market, and we are focused on increasing our market penetration abroad and building global brand-recognition. We currently sell our dermal product in the United Kingdom. We plan to expand sales of our product to other parts of Europe, Asia and the Americas. We intend to add international direct sales employees, distributors and support staff to increase sales and strengthen customer relationships in international markets.

- *Capitalizing on strong direct to consumer response.* In the United Kingdom, we have received strong interest from physicians and patients who have learned about our dermal product through independent news coverage or word of mouth. We may in the future decide to enter into a strategic partnership with a company that has a strong direct to consumer capability.

Sales and Marketing

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

In addition to the United States, we plan to commercialize our future products in other countries. In August 2001, we formed Isolagen Europe Limited, our subsidiary organized under the laws of the United Kingdom, for the purpose of marketing our dermal product to patients in Europe. In August 2003, we received a license from Australia's Therapeutic Goods Administration, or TGA, to begin the manufacture of autologous fibroblast cells. We commenced limited commercialization in the United Kingdom and Australia in late 2003. We are also investigating commercialization opportunities in other foreign countries. In the fourth quarter of 2004, we announced that the anticipated processing enhancements and improved delivery logistics will eliminate the need for an Australian laboratory. Consequently we determined to close our facility in Australia. We expect that closing of the Australian facility will enable us to focus our scientific and management resources on process improvements, increased capacity, reduce cost of goods sold, and enhanced delivery. We reiterate our commitment to the Australian market and anticipate that centralizing production and delivery will benefit Isolagen in a number of areas.

We focused our initial commercialization activities in the United Kingdom in order to establish and develop our processing, sales and marketing capabilities. This consisted of introducing our dermal product to selected leading medical practitioners, primarily plastic surgeons and dermatologists, who could offer the treatment to their patients. Training sessions were given throughout the year in order to train a broader group of physicians, such as general practitioners. In our United Kingdom facility we are using our commercialization activities to study and implement methods by which the processing of cells and the production of injections can be performed on higher volume and more efficient bases.

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

Currently the Isolagen Process is administered by an attending physician to each patient using our recommended regimen of up to three injections. We invoice the attending physician upon that physician submitting his or her patient's tissue sample to us, as a result of which the contractual arrangement is between us and the medical professional. The amount invoiced varies directly with the number of injections requested. Generally, orders are paid in advance by the physician and are not refundable. Revenue is deferred until shipment, provided no significant obligations remain, and is recognized in installments corresponding to the number of injections shipped to the attending physician. 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. Should the physician discontinue the regimen prematurely all remaining deferred revenue is recognized.

We also offer a service whereby we process a patient's cells to expand the cells to the quantity necessary to prepare an injection, but then store the expanded cells for later use in the preparation of injections. The fees charged for both of these services are recognized as revenue rateably over the length of the storage agreement. This service did not result in significant revenue in 2004.

As a result of this increased exposure, we experienced a marked increase in the demand for our dermal product in Fiscal 2004, and revenues for Fiscal 2004 were $4.2 million as compared to revenues of $0.4 million for Fiscal 2003. During 2004, demand for our Isolagen Process in the United Kingdom exceeded the capacity of our London facility. We will be making improvements that we believe will increase the capacity of that facility.

Intellectual Property

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

As of December 31, 2004, we had five issued U.S. patents, seven pending U.S. patent applications, 24 issued foreign patents and 33 pending foreign patent applications. Our issued patents and patent applications primarily cover the method of using autologous cell fibroblasts for the repair-of-skin and soft tissue defects and the use of autologous fibroblast cells for tissue regeneration. We are in the process of pursuing several other patent applications.

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

Our success depends in part on our ability to maintain our proprietary position through effective patent claims and their enforcement against our competitors. Although we believe our patents and patent applications provide a competitive advantage, the patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. We do not know whether any of our patent applications or those patent applications which we have acquired will result in the issuance of any patents. Our issued patents, those that may be issued in the future or those acquired by us, may be challenged, invalidated or circumvented, and the rights granted under any issued patent may not provide us with proprietary protection or competitive advantages against competitors with similar technology. In particular, we do not know if competitors will be able to design variations on our treatment methods to circumvent our current and anticipated patent claims. Furthermore, competitors may independently develop similar technologies or duplicate any technology developed by us. Because

of the extensive time required for the development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized or marketed, any related patent claim may expire or remain in force for only a short period following commercialization, thereby reducing the advantage of the patent.

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

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

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

Competition

We compete with a variety of companies in the dermatology and plastic surgery markets, many of which offer substantially different treatments for similar problems. These include silicone injections, laser procedures, facial surgical procedures, such as facelifts and eyelid surgeries, fat injections, dermabrasion, collagen injections and Botulinum toxin injections. 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.

Patients who might consider using our future products could also consider the following products:

Product Type	Examples	Company
Collagen Implants	Fibrel	Mentor Corp.
	Zyderm/Zyplast	Inamed Corp.
Artificial Implants	Artecoll	Artes Medical, Inc.
	Silicone Droplets	Various
	Softform	Inamed Corp.
	Radiance	BioForm Medical, Inc.
Traditional Medical Devices	Ablative Lasers	Coherent, Inc. and Lumenis Ltd.
	Non-Ablative Lasers	Coherent, Inc. and Lumenis Ltd.
	Microdermabrasion	Various
Other	Alloderm	LifeCell Corp.
	Botox	Allergan, Inc.
	Hylaform	Inamed Corp.
	Restylane	Medicis Corp.
	Lypocytic Dermal Augmentation	Physician manufactured
	Sculptra	Aventis S.A.
	Chemical Peels	Various

We believe that many of our competitors have greater financial and other resources than our company. Although we are not aware of any products similar to our Isolagen Process that have been approved by the FDA, there may be other companies with greater financial resources that are developing or may develop similar products in the future.

Government Regulation

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

Domestic Regulation

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

FDA Approval Process

To obtain approval of a new product from the FDA, we must, among other requirements, submit data demonstrating the product's safety and efficacy as well as detailed information on the manufacture and composition of the product candidate. In most cases, this entails extensive laboratory tests and pre-clinical and clinical trials. This testing and the preparation of necessary applications and processing

of those applications by the FDA are expensive and typically take many years to complete. The FDA may deny our applications or may not act quickly or favorably in reviewing these applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approvals that could delay or preclude us from marketing any products we may develop. The FDA also may require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approvals that could restrict the commercial applications of these products. Regulatory authorities may withdraw product approvals if we fail to comply with regulatory standards or if we encounter problems following initial marketing. With respect to patented products or technologies, delays imposed by the governmental approval process may materially reduce the period during which we will have the exclusive right to exploit the products or technologies.

The FDA does not apply a single regulatory scheme to human tissues and the products derived from human tissue. On a case-by-case basis, the FDA may choose to regulate such products as transplanted human tissue, medical devices or biologics. A fundamental difference in the treatment of products under these classifications is that the FDA generally permits human tissue for transplantation to be commercially distributed without marketing approval. In contrast, products that require manufacturing or processing are regulated as medical devices or biologics and require FDA approval.

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

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

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

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

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

- Phase II: The product is introduced into a limited patient 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 patient population at geographically-dispersed clinical study sites.
- If the FDA does ultimately approve the product, it may require post-marketing testing, including potentially expensive Phase IV studies, to monitor its safety and effectiveness.

Clinical trials must meet requirements for Institutional Review Board, or IRB, oversight, informed consent and the FDA's Good Clinical Practices. Prior to commencement of each clinical trial, the sponsor must submit to the FDA a clinical plan, or protocol, accompanied by the approval of the committee responsible for overseeing clinical trials at the clinical trial sites. The FDA and the IRB at each institution at which a clinical trial is being performed may order the temporary or permanent discontinuation of a clinical trial at any time if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients.

The sponsor must submit to the FDA the results of the pre-clinical and clinical trials, together with, among other things, detailed information on the manufacturing and composition of the product, in the form of an NDA, or, in the case of a biologic, a BLA. The FDA has advised us it is regulating our Isolagen Process as a biologic. Therefore, we will be submitting BLAs to obtain approval of our product candidates. Once the submission has been accepted for filing, the FDA has 12 months to review the application and respond to the applicant. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved, but the FDA is not bound by the recommendation of an advisory committee.

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

The FDA may, during its review of an NDA or BLA, ask for additional test data. If the FDA does ultimately approve the product, it may require post-marketing testing, including potentially expensive Phase IV studies, to monitor the safety and effectiveness of the product. In addition, the FDA may, in some circumstances, impose restrictions on the use of the product, which may be difficult and expensive to administer and may require prior approval of promotional materials.

Ongoing FDA Requirements

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

The labeling, advertising, promotion, marketing and distribution of a drug or biologic product also must be in compliance with FDA and FTC requirements which include, among others, standards and regulations for direct-to-consumer advertising, industry-sponsored scientific and educational activities, and promotional activities involving the internet. The FDA and FTC have very broad enforcement authority, and failure to abide by these regulations can result in penalties, including the issuance of a Warning Letter directing the company to correct deviations from regulatory standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA and enforcement actions that can include seizures, injunctions and criminal prosecution.

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

HIPAA Requirements

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

HIPAA requirements, covered entities conducting clinical trials for us may not be able to share with us any results from clinical trials that include such health information.

International Regulation

The regulation of our products outside of the United States varies by country. Certain countries regulate human tissue products as a pharmaceutical product, which would require us to make extensive filings and obtain regulatory approvals before selling our products. Certain other countries classify our products as human tissue for transplantation but may restrict its import or sale. Other countries have no application regulations regarding the import or sale of products similar to our products, creating uncertainty as to what standards we may be required to meet. Management made inquiry to the Medicines Control Agency with respect to our proposed use of our Isolagen Process in cosmetic applications in the United Kingdom. Based on the written responses received from the Medicines Control Agency, we believe that the proposed use of our Isolagen Process in cosmetic applications in the United Kingdom does not currently require regulatory approval. We began limited commercialization of our dermal product in the United Kingdom in late 2003.

Our marketing communications are governed by the UK advertising rules, based on voluntary code and statutory provisions. In June 2004, the Medicines and Healthcare products Regulatory Agency (MHRA) informed Isolagen that they had received inquiries about the Isolagen product. Accordingly, the MHRA requested copies of all the material used to advertise and/or promote Isolagen within the United Kingdom to determine if any action was required. Based on our discussions with the agency, we agreed to modify our advertising and promotional materials to address agency concerns, including clarifying the regulatory status of the product in the United Kingdom. We do not believe these modifications will seriously affect our ability to generate future sales. However, it is possible that further questions could be forthcoming from the agency requiring further revisions to promotional material. Such revisions could negatively impact our ability to promote the product.

In August 2003, we received a license from the Therapeutic Goods Administration, the agency that regulates medical drugs and devices in Australia, to begin the manufacture of autologous fibroblasts, including the initiation of primary cultures of fibroblasts, the propagation of fibroblasts, the harvesting of cultured fibroblasts, the storage of cultured fibroblasts and release for supply of cultured fibroblasts. We commenced limited commercialization of our dermal product in Australia in late 2003. In addition, we are assessing commercialization of our dermal product in other foreign countries.

Manufacturing

We currently have two facilities located in Houston, Texas and London, England. We use our London facility for commercial production to supply United Kingdom and other non-US markets and our Houston facility for research and clinical trials. As discussed above, the increase in the demand for our dermal product in Fiscal 2004 produced demand on our London facility that exceeded its capacity. We are currently working on improvements to increase the quality systems and capacity of our U.K. operations.

Our manufacturing process consists of a traditional cell culture process using sterile plastic flasks processed inside a sterile "biosafety cabinet." We have a system in place for timely and effective corrective and preventive action to manage non-conformities reported by our customers or detected within our operations.

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

Research and Development

In addition to our clinical development activities, our research and development activities include improving our manufacturing processes and reducing costs. Fibroblasts are a general support cell for the tissue and, in addition to their direct production of collagen and elastin, produce endocrine factors, which we believe may assist in the growth or repair of surrounding tissues, such as the epidermis. We believe this effect is responsible for some of the positive results that physicians have observed when treating patients with severe scarring. We continue to explore additional opportunities for our Isolagen Process for other applications, such as vocal cord injury, acne scarring, gastrointestinal and urological disorders and bone growth. We expense research and development costs as they are incurred. For the Fiscal years 2004, 2003 and 2002, we incurred research and development expenses of $5.1 million, $3.3 million and $1.5 million, respectively.

Employees

As of March 14, 2005, we employed 125 people on a full-time basis, including 33 in Houston, Texas, 13 in Exton, Pennsylvania, 78 in London, England, and one in Sydney, Australia. We anticipate hiring additional employees in the areas of executive management, sales and marketing, quality assurance, manufacturing and research and development as the need arises. None of our employees are covered by a collective bargaining agreement, and we consider our relationship with our employees to be good. We may also employ consultants on an as needed basis to supplement existing staff.

Segment Information

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

Corporate History

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

Investment Considerations

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

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

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

- conduct substantial additional research and development;
- successfully complete lengthy and expensive pre-clinical and clinical testing, including two pivotal Phase III clinical trials for our lead product candidate;
- successfully automate our manufacturing process through the implementation of our Automated Cell Expansion, or ACE, System; and
- obtain U.S. Food and Drug Administration, or FDA, approvals.

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

- failures in pre-clinical studies;
- insufficient clinical trial data to support the safety or efficacy of our product candidates;
- failure to successfully implement our ACE System; or
- failure to obtain the required FDA approvals.

Even if our product development efforts are successful, we cannot assure you that we will be able to commercialize our Isolagen Process or any of our product candidates currently under development. In that event, we will be unable to generate significant revenues, 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 revenues.

We are focused on product development and have not generated significant revenue from commercial sales of our products to date. We have incurred operating losses since our inception. Our revenues for the years ended December 31, 2004, 2003 and 2002 were $4.2 million, $446,000, and $51,000, respectively. Our net loss for the years ended December 31, 2004, 2003 and 2002 was $21.5 million, $11.3 million, and $5.4 million, respectively. As of December 31, 2004, we had an accumulated development stage deficit of $55.5 million.

We currently have no product candidates for sale in the United States, and we cannot guarantee that we will ever have marketable products in the United States. We must demonstrate that our product candidates satisfy rigorous standards of safety and efficacy before the FDA and other regulatory authorities in the United States and abroad will approve the products for commercial marketing. We will need to conduct significant additional research, preclinical testing and clinical testing before we can file applications with the FDA for approval of our product candidates. We must also develop, validate and obtain FDA approval of our ACE manufacturing process. In addition, to compete effectively, our future products must be easy to use, cost-effective and economical to manufacture on a commercial scale. We may not achieve any of these objectives.

We expect to continue to incur losses as we research, develop and seek regulatory approvals for our product candidates. If our product candidates fail in clinical trials or do not gain regulatory approval, or if our product candidates do not achieve market acceptance, we will not be profitable. If we fail to become and remain profitable, or if we are unable to fund our continuing losses, our business may fail.

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

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

- delays in obtaining regulatory approvals to commence a study;

- delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;
- delays in the enrollment of patients;
- lack of efficacy during clinical trials; or
- unforeseen safety issues.

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

Even if marketing approval from the FDA is received, the FDA may impose post-marketing requirements, such as:

- labeling and advertising requirements, restrictions or limitations, including the inclusion of warnings, precautions, contra-indications or use limitations that could have a material impact on the future profitability of our product candidates;
- testing and surveillance to monitor our future products and their continued compliance with regulatory requirements;
- submitting products for inspection and, if any inspection reveals that the product is not in compliance, prohibiting the sale of all products;
- suspending manufacturing; or
- withdrawing marketing clearance.

Our ability to effectively commercialize our dermal product and our product candidates depends on our ability to implement our ACE System, and/or to satisfactorily validate the cellular expansion and harvesting process.

We must obtain FDA approval of our validated manufacturing process before we can commercially manufacture our product candidates. In addition, we must pass a pre-approval inspection of our manufacturing facility before we can obtain marketing approval for our product candidates. We intend to seek FDA approval of our automated cellular expansion manufacturing process as a component of the BLA application and approval process. In order to obtain approval, all of our manufacturing methods, equipment and processes must comply with the FDA's current Good Manufacturing Practices, or cGMP, requirements. We will also need to perform extensive audits of our suppliers, vendors and contract laboratories. The cGMP requirements govern all areas of recordkeeping, production processes and controls, personnel and quality control. To ensure that we meet these requirements, we will expend significant time, money and effort. Due to the unique nature of our Isolagen Process, we cannot predict the likelihood that the FDA will approve our facility as compliant with cGMP requirements even if we believe that we have taken the steps necessary to achieve compliance.

Large-scale improvements in capacity and operating margins depend on the successful implementation of our Automated Cell Expansion, or ACE, System that permits an automated harvesting process. Our ACE System will eliminate several of the steps and materials involved in our current system, which we expect will lead to significant cost reductions in both skilled labor and materials and will enable scalable mass production. These technologies are based on low cost, commercially available cell concentration and washing devices, such as those used in the blood banking industry. However, the commercial viability of the automation techniques under consideration are uncertain, and we do not know whether we will be successful in implementing our ACE System, validating the safety and efficacy of these processes, obtaining the required scalability, achieving cost savings or obtaining FDA approval of these processes. Our previous and current clinical trials, including

our two pivotal Phase III trials for our lead product candidate, are being conducted using a manual process, rather than using the ACE System.

The FDA, in its regulatory discretion, may require us to undergo additional clinical trials with respect to our ACE System or any other new manufacturing process we develop or utilize. This could delay or prevent approval of our product candidates. If we fail to comply with cGMP requirements, pass an FDA pre-approval inspection or obtain FDA approval of our ACE System, we would not receive FDA approval and would be subject to possible regulatory action. The failure to successfully implement our ACE System may delay or prevent our future profitability.

Our inability to increase capacity in the United Kingdom will limit or delay our ability to attain profitability.

We began limited commercialization of our dermal product in the United Kingdom in late 2003. Our facilities in the United Kingdom were primarily designed to demonstrate the efficacy of our Isolagen Process, and have limited capacity. In light of increasing demand and regulatory requirements, specifically the new European Directive 2004/23/EC which is due to become effective in the U.K. April 7, 2006, we will be required to expend significant additional funds to increase the quality systems and capacity of our U.K. operations. This includes the addition of personnel, introduction of systems enhancements, automation of our manufacturing process and possibly the establishment of new facilities. Our inability to timely expand our operations in the United Kingdom and to improve our level of quality compliance may limit our ability to supply product and to maximize this market opportunity. In order to implement the changes in the facility needed to comply with the new Directive, it may be necessary for Isolagen to decrease capacity, or stop production from the U.K. facility.

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

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

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

None of our facilities were designed or have the capacity to support the full-scale commercialization of our product candidates. Our facility in Houston, Texas was constructed to support our clinical trial efforts and does not have the capacity to support commercialization of the Isolagen Process in the United States. Our manufacturing facilities in the United Kingdom and Australia were designed primarily to enable us to demonstrate the efficacy of our Isolagen Process, and to provide a platform for the future development of our manufacturing processes and our information and other support systems. Our U.K. facility is currently operating at capacity. While we are expanding our capacity at that facility, the limited size of that facility represents an inherent limitation of our capacity. The U.K. facility may not be able to meet the ongoing demand for our dermal product in the United Kingdom, even if our efforts to automate the manufacturing process are effectively and timely implemented. We recently announced our intention to discontinue operations at our Australian facility. We are in the process of planning the establishment of large-scale commercial production facilities in

the United States and Europe. If we encounter delays in establishing those facilities, the commercialization of our Isolagen Process will also be delayed. The failure to timely establish commercial manufacturing facilities in the United States and Europe may delay or prevent our future profitability.

We plan to operate a single manufacturing facility in the United States. As a result, if we obtain FDA approval of our lead product candidate, all of the manufacturing for the U.S. market will take place at a single U.S. facility. If regulatory, manufacturing or other problems require us to discontinue production at that facility, we will not be able to supply product in the United States, which would adversely impact our business.

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

We recently completed a note offering in which we issued $90 million of indebtedness pursuant to an indenture. We may incur additional indebtedness in the future, and the indenture does not restrict our future incurrence of indebtedness. Our level of indebtedness will have several significant effects on our future operations, including the following:

- we will be required to use a portion of our cash flow from operations for the payment of any principal or interest due on our outstanding indebtedness, including the recently issued notes;
- our outstanding indebtedness and leverage will increase the impact of negative changes in general economic and industry conditions, as well as competitive pressures; and
- the level of our outstanding debt may affect our ability to obtain additional financing for working capital, capital expenditures or general corporate purposes.

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

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

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

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

We believe our cash resources will be sufficient to fund our planned operations for at least 24 months. We are focused on research and development, are incurring losses from operations, have limited capital resources, and do not have access to a line of credit or other debt facility. We may need additional capital in the future to execute our business strategy, and if we are unsuccessful in raising such additional capital we may be unable to fully execute our business strategy on a timely basis, if at all. If we raise additional capital through the issuance of debt securities, the interests of our stockholders would be subordinated to the interests of our debt holders and any interest payments

would reduce the amount of cash available to operate and grow our business. If we raise additional capital through the sale of equity securities, the ownership of our current stockholders would be diluted. Additionally, we do not know whether any financing, if obtained, will be adequate to meet our capital needs and to support our growth. If adequate capital cannot be obtained on satisfactory terms, we may terminate or delay regulatory approval of one or more of our product candidates, curtail or delay the implementation of our ACE System or delay the expansion of our sales and marketing capabilities. If we terminate or delay regulatory approval, curtail or delay the implementation of our ACE System or delay the expansion of our sales and marketing capabilities, our business may fail.

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

We have a limited operating history, and because of the emerging nature of the markets in which we compete, our historical financial data is of limited value in estimating future operating expenses. Our budgeted expense levels are based in part on our expectations concerning future revenues. However, the size of these future revenues depends on the choices and demand of individuals, which are difficult to forecast accurately. We may be unable to adjust our operations in a timely manner to compensate for any unexpected shortfall in revenues. Accordingly, a significant shortfall in demand for our products could have an immediate and material adverse effect on our business, results of operations and financial condition. Further, our fixed manufacturing costs and business development and marketing expenses will increase significantly as we expand our operations. To the extent that expenses precede or are not rapidly followed by increased revenue, our business, results of operations and financial condition may be materially adversely affected.

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

Prior to receiving approval to commercialize any of our product candidates, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA and other regulatory authorities in the United States and abroad, that our product candidates are both safe and effective. We will need to demonstrate our product candidates' efficacy and monitor their safety throughout the process. We are conducting two pivotal Phase III clinical trials related to our lead product candidate. The success of prior pre-clinical or clinical trials does not ensure the success of these trials, which are being conducted in populations with different racial and ethnic demographics than our previous trials. If these trials or future clinical trials are unsuccessful, our business and reputation would be harmed and our stock price would be adversely affected.

All of our product candidates are prone to the risks of failure inherent in biologic development. The results of early-stage clinical trials of our product candidates do not necessarily predict the results of later-stage clinical trials. Product candidates in later-stage clinical trials may fail to show desired safety and efficacy traits despite having progressed through initial clinical testing. Even if we believe the data collected from clinical trials of our product candidates is promising, this data may not be sufficient to support approval by the FDA or any other U.S. or foreign regulatory approval. Preclinical and clinical data can be interpreted in different ways. Accordingly, FDA officials could interpret such data in different ways than we do, which could delay, limit or prevent regulatory approval. The FDA, other regulatory authorities, our Institutional Review Boards or we may suspend or terminate clinical trials at any time. Any failure or significant delay in completing clinical trials for our product candidates, or in receiving regulatory approval for the sale of any products resulting from our product candidates, may severely harm our business and reputation.

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

Our operating results may fluctuate significantly in the future as a result of a variety of factors, many of which are outside of our control. These factors include:

- the level of demand for our Isolagen Process and future products that we may develop;
- the timely and successful implementation of our ACE System;
- 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;
- the amount and timing of capital expenditures and other costs relating to the expansion of our operations;
- government regulation and legal developments regarding our Isolagen Process in the United States and in the foreign countries in which we operate; and
- general economic conditions.

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

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

We have expended significant resources on hiring of personnel, research and development, advertising and expansion, and we expect these costs to continue to rise in the future. As a result, we have incurred losses since our inception and expect to experience operating losses and negative cash flow as we expand our operations. As we have had insignificant revenues to date and we are in the process of expanding our limited operations in the United Kingdom, we expect to continue to incur significant additional costs and expenses related to:

- FDA clinical trials and regulatory approvals;
- expansion of laboratory and manufacturing operations;
- research and development;
- promotional and marketing activities;
- brand development;
- personnel costs;
- development of relationships with strategic business partners, including physicians who might use our future products; and
- interest expense related to the notes we recently offered.

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

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

Even if we obtain regulatory approval for our product candidates, we will continue to be subject to extensive requirements by a number of foreign, national, state and local agencies. These regulations will impact many aspects of our operations, including testing, research and development, manufacturing, safety, efficacy, labeling, storage, quality control, adverse event reporting, record keeping, approval, advertising and promotion of our future products. The FDA enforces post-marketing regulatory requirements, including the cGMP requirements, through periodic unannounced inspections. We do not know whether we will pass any future FDA inspections. Failure to pass an inspection could disrupt, delay or shut down our manufacturing operations. Failure to comply with applicable regulatory requirements could, among other things, result in:

- fines;
- changes to advertising;
- failure to obtain marketing approvals for our product candidates;
- revocation or suspension of regulatory approvals of products;
- product seizures or recalls;
- delay, interruption or suspension of product manufacturing, distribution, marketing and sales; or
- civil or criminal sanctions.

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

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

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

If we become subject to any of the above requirements, it could be damaging to our reputation and restrict our ability to sell or market our future products, and our business condition could be adversely affected.

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

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

In both the United States and a number of foreign jurisdictions, there have been legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our future products profitably. The FDA's policies may change and additional government regulations may be enacted, which could prevent or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we might not be permitted to market our future products and our business could suffer.

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

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

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

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

- unexpected changes in regulatory requirements;
- export and import restrictions, tariffs and other trade barriers;
- difficulties in staffing and managing foreign operations;
- longer payment cycles and problems in collecting accounts receivable;
- potential adverse tax consequences;
- exchange rate fluctuations;

- increased risks of piracy and limits on our ability to enforce our intellectual property rights;
- limits on repatriation of funds; and
- political risks that may limit or disrupt international sales.

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

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

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

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

- labeling requirements or limitations;
- market acceptance by practitioners and their patients;
- our ability to successfully automate our manufacturing process through implementation of our ACE System to allow us to more cost-effectively produce our future products, thereby reducing the price at which we can offer our future products;
- the effectiveness of our sales efforts and marketing activities; and
- the success of competitive products.

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

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

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

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

If we achieve growth in our operations in the next few years, such growth could place a strain on our management, and our administrative, operational and financial infrastructure. Our ability to manage our operations and growth requires the continued improvement of operational, financial and management controls, reporting systems and procedures. In addition, we will need to hire additional

management, financial and sales and marketing personnel to manage our operations. If we are unable to manage our growth effectively or if we are unable to attract additional highly qualified personnel, our business, operating results and financial condition may be materially adversely affected.

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

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

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

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

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

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

Our ability to achieve commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our technology and future products, as well as successfully defending these patents against third party challenges. If we are unable to obtain and maintain protection for our intellectual property and proprietary technology, the value of our technology and future products will be adversely affected, and we will not be able to protect our technology from unauthorized use by third parties.

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

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

As of December 31, 2004, we had five issued U.S. patents, seven pending U.S. patent applications, 24 foreign patents and 33 pending foreign patent applications. If we fail to obtain or maintain these protections, we may not be able to prevent third parties from using our proprietary rights. We will be

able to protect our proprietary rights from unauthorized use only to the extent that these rights are covered by valid and enforceable patents or are effectively maintained as trade secrets.

The patent situation in the markets in which we compete is highly uncertain and involves complex legal and scientific questions. It may be difficult to obtain additional patents relating to our technology. Furthermore, any changes in, or unexpected interpretations of, the patent laws may adversely affect our ability to enforce our patent position.

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

- the inventors of the inventions covered by each of our pending patent applications might not have been the first to make such inventions;
- because the information contained in patent applications is generally not publicly available, we might not have been the first to file patent applications for these inventions or similar technology;
- the future and pending applications we will file or have filed, or to which we will or do have exclusive rights, may not result in issued patents or may take longer than we expect to result in issued patents;
- the claims of any patents that are issued may not provide meaningful protection;
- our issued patents may not provide a basis for commercially viable products or may not be valid or enforceable;
- we might not be able to develop additional proprietary technologies that are patentable;
- the patents licensed or issued to us may not provide a competitive advantage;
- patents issued to other companies, universities or research institutions may harm our ability to do business;
- other companies, universities or research institutions may independently develop similar or alternative technologies or duplicate our technologies and commercialize discoveries that we attempt to patent;
- other companies, universities or research institutions may design around technologies we have licensed, patented or developed; and
- many of our patent claims are method, rather than composition of matter, claims. Generally, composition of matter claims are easier to enforce and are more difficult to circumvent.

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

The rights to some of our patent applications were obtained in a purchase agreement with a third party. If this purchase agreement is found invalid or there are otherwise disputes regarding the invention and corresponding ownership rights in the invention, we may not be able to market future products covered by the license. Additionally, if we select the Applikon Biotechnology technology for cell harvesting, then certain future and preexisting intellectual property rights are, or are expected to be, allocated to us in collaboration and development agreements with Applikon Biotechnology. If we select an alternative technology, it is reasonably anticipated that certain intellectual property may be allocated to us in collaboration and development agreements with the manufacturer. If the provisions of these agreements are found invalid or otherwise do not operate as we anticipate, there may be disputes as to inventorship and the corresponding rights in know-how and inventions resulting from the joint creation or use of intellectual property by us and our collaborators. We may not be able to use

and claim proprietary rights to the technology resulting from these collaboration and cooperation agreements, which may adversely affect our business.

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

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

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

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

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

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

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

Through internal research and cooperative development agreements with industry partners, we are seeking to develop a commercially viable design and production system for our future products, as well as new areas of application for our Isolagen Process. If we, or our industry partners, are unable to develop suitable techniques to produce and manufacture our technology for the commercial market or additional areas of application for our Isolagen Process, our business prospects will suffer.

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

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

- diversion of management's time and attention;

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

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

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

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

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

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

We conduct operations in two facilities located in Houston, Texas and London, England and we plan to open commercial manufacturing facilities in Pennsylvania and mainland Europe. We recently announced our intention to discontinue operations at a third facility located in Sydney, Australia. Our facilities could be damaged by fire, floods, power loss, telecommunication and information systems failures or similar events. Our insurance policies have limited coverage levels for loss or damages in these events and may not adequately compensate us for any losses that may occur. In addition, terrorist acts or acts of war may cause harm to our employees or damage our facilities. The potential for future terrorist attacks, the national and international responses to terrorist attacks or perceived threats to national security, and other acts of war or hostility have created many economic and political uncertainties that could adversely affect our business and results of operations in ways that we cannot predict, and could cause our stock price to fluctuate or decline. We are uninsured for these types of losses.

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

The market price of our common stock has experienced, and may continue to experience, significant volatility. During 2003 and 2004, the per share closing price of our common stock ranged

from $4.10 to $12.04 per share. The value of our common stock may decline regardless of our operating performance or prospects. Factors affecting our market price include:

- the success or failure of our product development efforts, especially those related to obtaining regulatory approvals domestically and internationally;
- the implementation of our ACE System;
- 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; and
- market reaction to any acquisitions or joint ventures announced by us or our competitors.

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. A securities class action suit against us could result in potential liabilities, substantial costs and the diversion of management's attention and resources, regardless of whether we win or lose.

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

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

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

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

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

The use of a staggered Board of Directors and the ability to issue "blank check" preferred stock are traditional anti-takeover measures. These provisions in our charter documents make it difficult for a majority stockholder to gain control of the Board of Directors and of our company. These provisions may be beneficial to our management and our Board of Directors in a hostile tender offer and may

have an adverse impact on stockholders who may want to participate in such a tender offer, or who may want to replace some or all of the members of our Board of Directors.

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

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

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

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market, or as a result of the perception that these sales could occur. In addition, these factors could make it more difficult for us to raise funds through future offerings of common stock. As of December 31, 2004, there are 34,194,899 shares of common stock issued and 30,194,899 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, which may limit your ability to sell shares of common stock.

There is a limited public trading market for our common stock. Without an active trading market, there can be no assurance of any liquidity or resale value of our common stock, and stockholders may be required to hold shares of our common stock for an indefinite period of time.

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

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

As directed by Section 404 of the Sarbanes-Oxley Act, the SEC adopted rules requiring public companies to include a report of management on the company's internal controls over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of the company's internal controls over financial reporting. In addition, the public accounting firm auditing the company's financial statements must attest to and report on management's assessment of the effectiveness of the company's internal controls over financial reporting. This requirement is applicable to our current annual report on Form 10-K and for all future annual reports.

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

We have determined that we do not have effective internal controls over financial reporting. In view of the foregoing we expect that our independent auditors will be unable to provide us with an unqualified report as to the effectiveness of our internal controls over financial reporting as of December 31, 2004 required by Section 404. As a consequence, our investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our securities.

Item 2. Properties

Our principal executive offices are located in Exton, Pennsylvania. This facility occupies a total of approximately 2,000 square feet. This lease is month to month. We are currently conducting feasibility studies for a new location for our principal executive offices in Exton, Pennsylvania.

Our manufacturing and research and development facility is located in Houston, Texas. This facility occupies a total of approximately 11,200 square feet, including 7,300 square feet under a month-to-month lease. We have terminated our lease effective March 31, 2005 and moved into a new facility on March 1, 2005. The new facility occupies a total of approximately 14,800 square feet under a lease that expires April 30, 2008.

We also maintain a cellular laboratory in London, England. Our London, England facility consists of approximately 11,800 square feet under a lease that expires in March 2010, but for which we have an option to cancel after March 24, 2005. We have also leased 2,000 square feet of office space in London for our selling and administrative personnel. We signed a two year lease effective January 1, 2005 with an option to cancel after one year.

Our Sydney, Australia facility consists of approximately 7,100 square feet under a lease that expires in May 2005. As discussed above, in September, 2004 we decided to close this facility and service the Australia market from our London facility.

The increase in the demand for our dermal product in Fiscal 2004, and our decision to close our Australia facility and service that market from our London facility produced demand on our London facility that exceeded our existing capacity. We are currently working on improvements to our quality systems and capacity of our U.K. operations.

Item 3. Legal Proceedings

We are not currently subject to any legal proceedings, threatened or pending. We may from time to time become a party to various legal proceedings arising in the ordinary course of our business.

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 2004.

Part II

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

Market Information

Since December 11, 2002, our common stock has been traded on the American Stock Exchange under the symbol "ILE." Prior to December 11, 2002, our common stock was quoted on the OTC Bulletin Board under the symbol "ISLG." The market for our common stock is limited and volatile. The following table sets forth the range of high and low bid quotations or high and low closing prices, as applicable, for our common stock for each of the periods indicated as reported by the OTC Bulletin Board or the AMEX. The prices for the OTC Bulletin Board reflect inter-dealer prices, without retail mark-up, mark-down or commissions. The OTC Bulletin Board and AMEX prices listed below may not represent actual transaction prices.

	December 31, 2004		December 31, 2003	
	High	Low	High	Low
First Quarter	$ 11.79	$ 5.40	$ 5.55	$ 4.20
Second Quarter	12.04	8.40	7.25	4.10
Third Quarter	10.24	7.09	10.85	6.50
Fourth Quarter	9.89	6.65	9.03	5.15

Holders

As of March 14, 2005, we had 586 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 earnings 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

The following information relates to our securities sold during the twelve months ended December 31, 2004, which were not registered under the Securities Act of 1933, as amended (the "Securities Act"), and which have not been previously disclosed:

In the fourth quarter of 2004, we issued 185,000 options to purchase our common stock with exercise prices ranging from $6.76 to $9.75 per share to various new employees. The options vest over a three year period from the date of grant.

We relied upon Section 4(2) and/or Regulation D under the Securities Act in connection with these sales. The securities were sold to a limited number of "accredited investors" within the meaning of the rules and regulations issued under the Securities Act, or to sophisticated persons that had such knowledge and experience in financial and business matters that they were able to evaluate the merits and risks of an investment in Isolagen.

Stock Repurchases

Period	(a) Total Number of Shares Purchased	(b) Average Price Paid per Share
Month #1 (October 1 through October 31)	—	—
Month #2 (November 1 through November 30)	4,000,000	$ 6.49
Month #3 (December 1 through December 31)	—	—

Of the foregoing repurchases, 2,000,000 shares were repurchased from certain of our affiliates and former affiliates at a purchase price of $6.33 per share, which represented a 5% discount from the closing price of our common stock on the American Stock Exchange on the date we entered into agreements to repurchase the shares. The purchase of the shares was approved by a special committee of independent directors in partial reliance on a fairness opinion issued by an investment bank.

We did not make any repurchases as part of a publicly announced plan or program, and we do not currently have any such plans or programs outstanding.

Item 6. Selected Financial Data

Our selected historical consolidated financial information presented as of December 31, 2004, 2003, 2002, 2001 and 2000 and for each of the five years ended December 31, 2004 was derived from our audited consolidated financial statements.

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

	For the Year Ended December 31,				
	2004	2003	2002	2001	2000
Consolidated Statement of Operations Data					
Revenues	$ 4,179,247	$ 445,689	$ 50,991	$ 25,482	$ 6,584
License fees	—	—	40,000	80,000	40,000
Total revenues	4,179,247	445,689	90,991	105,482	46,584
Cost of sales(a)	5,491,008	2,197,222	481,153	17,891	10,846
Selling, general and administrative expenses(a)(b)	15,127,365	6,311,774	3,764,187	723,690	265,075
Research and development(a)	5,057,149	3,301,341	1,519,819	933,907	463,304
Operating loss	(21,496,275)	(11,364,648)	(5,674,168)	(1,570,006)	(692,641)
Other income (expense)					
Interest income	566,526	40,691	208,692	17	4,891
Other income	91,956	55,663	32,421	—	—
Interest expense	(636,676)	—	—	(82,015)	(119,326)
Net loss	$ (21,474,469)	$ (11,268,294)	$ (5,433,055)	$ (1,652,004)	$ (807,076)
Deemed dividend associated with beneficial conversion of preferred stock	—	(1,244,880)	(10,178,944)	—	—
Preferred stock dividends	—	(1,087,200)	(502,661)	—	—
Net loss attributable to common stockholders	$ (21,474,469)	$ (13,600,374)	$ (16,114,660)	$ (1,652,004)	$ (807,076)
Per share information					
Net loss—basic and diluted	$ (.71)	$ (.58)	$ (.36)	$ (.22)	$ (.29)
Deemed dividend associated with beneficial conversion of preferred stock	—	(.06)	(.67)	—	—
Preferred stock dividends	—	(.06)	(.03)	—	—
Net loss attributable to common stockholders	$ (.71)	$ (.70)	$ (1.06)	$ (.22)	$ (.29)
Weighted Average Shares outstanding	30,116,827	19,297,865	15,205,554	7,618,947	2,822,104

	December 31,				
	2004	2003	2002	2001	2000
Consolidated Balance Sheet Data					
Cash and cash equivalents and short-term investments	$ 116,139,016	$ 15,935,558	$ 4,244,640	$ 1,380,824	$ 2,574
Working capital (deficit)	111,061,724	14,367,768	2,811,160	870,377	(1,435,834)
Total assets	128,121,138	19,644,465	7,257,664	1,563,914	62,296
Total liabilities	99,135,713	2,380,740	2,050,734	511,514	2,290,763
Total stockholders equity (deficit)	28,985,425	17,263,725	5,206,930	1,052,400	(2,228,467)

(a) The classification of certain costs between costs of sales and selling, general and administrative expenses and research and development changed from that reflected in the financial statements previously issued for Fiscal 2003 and 2002, and the first three quarters of Fiscal 2004 to reflect the classifications adopted by the Company in the fourth quarter of Fiscal 2004. See "Managements Discussion and Analysis of Financial Condition and results of Operations—Critical Accounting Policies" and Notes 2 and 11 of Notes to Consolidated Financial Statements.

(b) The classification of losses on disposal of assets changed from that reflected in the financial statement previously issued for Fiscal 2003 and 2002, and the first three quarters of Fiscal 2004 to reflect the classifications adopted by the Comapny in the fourth quarter of Fiscal 2004. See "Managements Discussion and Analysis of Financial Condition and results of Operations—Critical Accounting Policies" and Notes 2 and 11 of Notes to Consolidated Financial Statements.

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

Certain statements contained herein are not based on historical facts, but are forward-looking statements that are based upon numerous assumptions about future conditions that could prove not to be accurate. "Forward-looking statements" include statements regarding our expectations, hopes, intentions, or strategies regarding the future. Forward looking statements include: statements regarding future products or products or product development; statements regarding our implementation of the ACE system; statements regarding future selling, general and administrative costs and research and development spending and our product development strategy; statements regarding future capital expenditures and financing requirements; and similar forward-looking statements. Actual events, transactions and results may materially differ from the anticipated events, transactions or results described in such statements. Our ability to consummate such transactions and achieve such events or results is subject to numerous risks and uncertainties. Such risks and uncertainties include, but are not limited to, the existence of demand for and acceptance of our products and services, regulatory approvals and developments, economic conditions, the impact of competition and pricing, results of financing efforts and other factors affecting our business that are beyond our control.

Although we believe that our expectations are based on reasonable assumptions, we can give no assurance that our expectations will materialize. Many factors including those contained in "Business—Investment Considerations" could cause actual results to differ materially from our forward-looking statements. We are under no obligation to and do not intend to update, revise or otherwise publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of any unanticipated events.

General

We specialize in the development and commercialization of autologous cellular technology that has specific applications in cosmetic dermatology and are exploring applications for periodontal disease, reconstructive dentistry and other health-related markets. Our ability to operate profitably under our current business plan is largely contingent upon our success in obtaining regulatory approval to sell our products and upon our successful development of markets for our products and profitable manufacturing processes. We may be required to obtain additional capital in the future to support these efforts or expand our operations. No assurance can be given that we will be able to obtain such regulatory approvals, successfully develop the markets for our products or profitable manufacturing methods, or obtain such additional capital as we might need, either through equity or debt financing, on satisfactory terms or at all. Additionally, no assurance can be given that any such financing, if obtained, will be adequate to meet our ultimate capital needs and to support our growth. If adequate capital cannot be obtained on satisfactory terms, our operations could be negatively impacted.

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

Although the focus of our efforts has been and will continue to be the development, testing and approval of the aesthetic and dental applications of our process, and research into other applications of our process, as a result of which our company is still considered to be a "development stage" enterprise, we have, since 2002, made Isolagen Process injections available to physicians in the United Kingdom and Australia as a means of developing our marketing, sales and manufacturing processes. Revenues from the sale of these treatments were approximately $4.2 million for Fiscal 2004. These

revenues partially offset the costs we are incurring in our developing marketing, sales and manufacturing.

As of December 31, 2004, we had cash, cash equivalents and short-term investments of $116.1 million. As of February 28, 2005, we had cash, cash equivalents and short-term investments of approximately $112.2 million. We believe our existing capital resources are adequate to finance our operations until June 30, 2007, however our long-term viability is dependent upon successful operation of our business, our ability to automate our manufacturing process, the approval of our products and the ability to raise additional debt and equity to meet our business objectives.

Critical Accounting Policies

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

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

Currently the Isolagen Process is administered by an attending physician to each patient using our recommended regimen of up to three injections. Due to the short shelf life, each injection is cultured on an as needed bases and shipped prior to the individual injection being administered by the physician. We believe each injection has stand alone value to the patient. We invoice the attending physician upon that physician submitting his or her patient's tissue sample to us; as a result of which the contractual arrangement is between us and the medical professional. The amount invoiced varies directly with the number of injections requested. Generally, orders are paid in advance by the physician prior to the first injection and are not refundable and there is no performance provision under any arrangement with any doctor, and there is no right to refund, or returns for unused injections.

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

Revenue from licenses and other upfront fees are recognized on a ratable basis over the term of the respective agreement.

We also offer a service whereby we store a patient's cells for later use in the preparation of injections, and a service whereby we process a patient's cells to expand the cells to the mass necessary to prepare an injection, but then store the expanded cells for later use in the preparation of injections. In accordance with EITF 00-21, the fees charged for both of these services are recognized as revenue rateably over the length of the storage agreement. No separate revenue is recognized for the initial cell expansion service, as we do not offer this service separately and the process of cell expansion has no value without either the subsequent preparation of an injection or the storage of the expanded cells for later use in the preparation of injections. This service did not result in significant revenue in 2004.

Cost of Sales and Selling,General and Administrative Expenses and Research and Development Expenses: In the fourth quarter of Fiscal 2004 we changed the manner by which we classify the costs incurred in our London and Australia facilities as either costs of sales or selling, general and administrative expenses or research and development expenses. We believe that the new classifications better reflect the primary purpose and functions of each of these facilities, as described below. The new manner of classifying these costs is reflected in the accompanying consolidated statements of operations for all periods presented, as well as in the unaudited summarized quarterly financial data presented in Note 11 of Notes to the Consolidated Financial Statements. The reclassifications did not have any effect on net loss or net loss per share.

As described under "Business—Overview", the primary purpose of our Houston, Texas facility is to conduct research on the development, testing and approval of the aesthetic and dental applications of our process, including the required clinical trials, and research into other applications of our process, while our London and Australia (being closed in the first quarter of Fiscal 2005) facilities were engaged in the commercialization of our process (for which they earned revenues from the sale of Isolagen Process Injections) in these markets as a means of improving manufacturing technologies that are more automated and therefore can be used to produce commercial quantities of injections on a profitable basis. Therefore, we have classified as cost of sales the costs (except for costs related to marketing, sales and general corporate administration) incurred in operating our London and Australia facilities as cost of sales, while the costs incurred in operating our Houston, Texas facility (except for costs related to general corporate administration) have been classified as research and development expenses. Previously some of the costs of operating our London and Australia facilities now included in cost of sales had been included in selling, general and administrative expenses and research and development expenses.

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

As discussed under "Business—Our Solution," historically, autologous cell companies have been hampered by manufacturing technologies that use traditional methodology for culturing cells through the utilization of plastic flasks. This methodology is labor intensive, slow, involves many sterile interventions and is costly. The use of this process to produce Isolagen Process injections in commercial quantities would not, over time, be profitable. We have been using the commercialization of our process in these markets as a means of researching and developing manufacturing technologies that are more automated and therefore can be used to produce commercial quantities of injections on a profitable basis. Through the end of Fiscal 2004 our cost of sales has exceeded our revenues. This reflects the fact that the level of our sales from our commercialization efforts in the United Kingdom and Australia, while increasing, have not yet reached the levels necessary for profitable operations, and the development and implementation of our automated processes has not yet achieved all of the cost efficiencies we hope to achieve.

If, in the future, the purposes for which we operate our Houston, Texas, or London facilities, or any new facilities we open, changes, the allocation of the costs incurred in operating that facility

between cost of sales and research and development expenses could change to reflect such operational changes.

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

Intangible Assets: Our intangible assets represent patent applications which are recorded at cost. We have filed applications for patents in connection with technologies being developed. The patent applications and any patents issued as a result of these applications are important to the protection of our technologies that may result from our research and development efforts. Costs associated with patent applications and maintaining patents are capitalized and will be amortized over the life of the patents. We review the value recorded for intangibles to assess recoverability from future operations using undiscounted cash flows. Impairments are recognized in operating results to the extent the carrying value exceeds fair value determined based on the net present value of estimated future cash flows. The projection of future cash flows requires us to make estimates about the when product approvals may be obtained, and the amount of future revenues. The actual future results could differ significantly from these estimates, and resulting changes in the estimates of future cash flows could be significant and could affect the recoverability of intangible assets.

Stock-Based Compensation: We account for our stock-based compensation under the provisions of Statement of Financial Accounting Standards ("SFAS") No. 123—"Accounting for Stock Based Compensation." Under SFAS No. 123, we are permitted to either record expenses for stock options and other employee compensation plans based on their fair value at the date of grant or to continue to apply the provisions of Accounting Principles Board Opinion No. 25 "Accounting for Stock Issued to Employees," ("APB No. 25"), and recognize compensation expense, if any, based on the intrinsic value of the equity instrument at the measurement date. We have elected to continue following the provisions of APB No. 25. Stock options issued to other than employees or directors are recorded on the basis of their fair value as required by SFAS No. 123.

Beginning in the quarter beginning July 1, 2005, we will be required to adopt SFAS No. 123 (Revised 2004), *"Share Based Payment,"* which eliminates the use of APB Opinion No. 25 and we will be required to measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost will be recognized over the period during which an employee is required to provide service in exchange for the reward—the requisite service period. No compensation cost will be recognized for equity instruments for which employees do not render the requisite service. The grant-date fair value of employee share options and similar instruments will be estimated using option-pricing models adjusted for the unique characteristics of those instruments. SFAS No. 123 (Revised 2004) must be applied to all options granted or modified after its effective date and also to recognize the cost associated with the portion of any option awards made before its effective date for with the associated service has not been rendered as of its effective date. We are still studying the requirements of SFAS No. 123 (Revised 2004) and have not yet determined what impact it will have on our results of operations and financial position.

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

REVENUES. Revenues increased 838% or $3,733,558, to $4,179,247 for Fiscal 2004, from $445,689 for Fiscal 2003. The increase in revenues is primarily attributable to the continuation of operations in the United Kingdom.

The Isolagen Process involves a patient's physician obtaining an approximately three millimeter punch skin sample from the patient. The skin sample is packed in a container provided by us and shipped overnight to our laboratory. We invoice the physician upon receipt of the skin sample. The specimen is then cultured utilizing our Isolagen Process. Approximately six weeks later, the patient's cells are sent to the doctor for treatment. Additional amounts are available for re-injection every two to three weeks. We recognize one-third of the revenue associated with each treatment upon the shipment of the first injection to the patient's physician, an additional one-third of revenue associated with each treatment is recognized upon shipment of the second injection to the patient's physician, and the remaining one-third is recognized upon the shipment of the last injection to the patient's physician.

The revenues which we did recognize during Fiscal 2003 and Fiscal 2004 from our United Kingdom operations were in part reduced by the effects of promotional incentives provided to doctors utilizing the Isolagen Process. We expect to continue providing such promotional incentives to doctors during the introduction phase of the Isolagen Process in the United Kingdom.

We also offers a service whereby we store a patient's cells for later use in the preparation of injections, and a service whereby we processes a patient's cells to expand the cells to the mass necessary to prepare an injection, but then store the expanded cells for later use in the preparation of injections. The fees charged for both of these services are recognized as revenue rateably over the length of the storage agreement. Revenues from these services were approximately $12,355 in Fiscal 2004 and $0 in Fiscal 2003.

COST OF SALES. Costs of sales increased 150%, or $3,293,786, to $5,491,008 in Fiscal 2004, from $2,197,222 in Fiscal 2003. The increase in cost of sales is primarily related to the increase in activities of our London and Australia facilities. The increase resulted from increases in essentially all categories of costs as these facilities increased their commercialization of our process. Cost of sales exceeded revenues as the development and implementation of our automated processes has not yet achieved all of the cost efficiencies we hope to achieve.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES. Selling, general and administrative expenses increased 140%, or $8,815,591, to $15,127,365 for Fiscal 2004 from $6,311,774 for Fiscal 2003. The major components of the approximate $8.8 million increase in selling, general and administrative expense are as follows:

a) Consulting expense increased by approximately $2.1 million to $2.8 million for Fiscal 2004 compared to $0.7 million for Fiscal 2003. The increase included $1.5 million of stock based expenses related to options and warrants issued under consulting and distribution agreements, and $0.4 million of stock compensation related to stock options issued to directors and officers. There was an $0.4 million stock based expense for Fiscal 2003. The level of the expense recorded for the warrants issued under consulting and distribution contracts can vary from quarter to quarter based on changes in the market price of our common stock.

b) Salaries increased by approximately $2.9 million to $4.0 million for Fiscal 2004 compared to $1.1 million for Fiscal 2003 due to an increase in our number of employees. The expense for Fiscal 2004 included $1.1 million related to employee severances. Of this $1.1 million, $0.9 million results from the severance of two employees who are entitled, under their contracts, to receive salary payments through July 2006 and $0.2 million results from our decision to close our facility in Australia and serve the Australian market through our existing facility in Europe (see Note 2 of Notes to Consolidated Financial Statements). Fiscal 2003 expense included an imputed expense

of $200,000 for the fair market value of services provided by certain officers for which they will not be compensated.

c) Travel expense increased by approximately $0.2 million to $1.0 million for Fiscal 2004 compared to $0.8 million for Fiscal 2003.

d) Legal expense increased by approximately $0.1 million to $0.6 million for Fiscal 2004 compared to $0.5 million for Fiscal 2003.

e) Promotional expense increased by approximately $0.7 million to $1.3 million for Fiscal 2004 compared to $0.6 million for Fiscal 2003 due to increased marketing and promotional efforts related to the expansion of our operations in the United Kingdom.

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

g) Office and other costs increased by approximately $2.3 million to $4.5 million for Fiscal 2004 compared to $2.2 million for Fiscal 2003, which increase is primarily related to the commencement of our operations in the United Kingdom and the completion of our U.S. laboratory. There was an $0.2 million loss on disposal of an asset, primarily consisting of assets in Australia for Fiscal 2004. There was an $0.4 million loss on disposal of an asset, primarily consisting of the write-off of software for Fiscal 2003.

RESEARCH AND DEVELOPMENT. Research and development expenses increased by approximately $1.8 million during Fiscal 2004 to $5,057,149 from $3,301,341 for Fiscal 2003. Research and development costs are composed primarily of costs related to our efforts to gain FDA approval for our products in the United States. These costs include those personnel and laboratory costs related to the current FDA trials and certain consulting costs. This project is still under development. The total cumulative cost of research and development incurred through December 31, 2004 is $11.9 million. As of December 31, 2004, we believe a minimum of $1.0 million of additional expenditures will be required to complete this project. That estimate assumes that no further testing requirements for the initial dermal applications are imposed by the FDA, that we file our BLA during the second half of 2005. The FDA approval process is extremely complicated and is dependent upon our study protocols and the results of our studies. In the event that the FDA requires additional studies for dermal applications or requires changes in our study protocols or in the event that the results of the studies are not consistent with our expectations the process will be more expensive and time consuming. Due to the vagaries of the FDA approval process we are unable to predict what the cost of obtaining approval for the initial dermal applications will be if the BLA is not filed during the second half of 2005. We have other research projects currently underway. However, research and development costs related to these projects were not material during the 2004 or 2003 periods. The major components of the approximately $1.8 million increase in research and development expense are as follows: a) consulting expense increased by approximately $1.2 million to $2.8 million in Fiscal 2004 compared to $1.6 million in Fiscal 2003; b) salaries and payroll taxes increased by approximately $0.7 million to $1.8 million for Fiscal 2004 compared to $1.1 million for Fiscal 2003; and c) laboratory expense decreased by approximately $0.1 million to $0.5 million for Fiscal 2004 compared to $0.6 million for Fiscal 2003.

INTEREST INCOME. Interest income increased 1,292%, or $525,835, to $566,526 for Fiscal 2004, from $40,691 for Fiscal 2003. The increase in interest income resulted principally from an increase in the amount of cash held in interest bearing accounts, and our investment in marketable debt securities, as the result of our receipt of the proceeds of $56.8 million from the issuance of

common stock in the second quarter of fiscal 2004 and the issuance of $90 million of 3.5% Convertible Subordinated Notes in the fourth quarter of Fiscal 2004.

INTEREST EXPENSE. Interest expense increased $636,676, to $636,676 for Fiscal 2004, from $0 for Fiscal 2003. The increase in interest expense resulted principally from the issuance of $90 million in principal amount of 3.5% Convertible Subordinated Notes due November 1, 2004.

NET LOSS. Net loss for Fiscal 2004 was $21,474,469, as compared to a net loss of $11,268,294 for Fiscal 2003. This increase in net loss is attributed primarily to the increases in our selling, general and administrative expenses and research and development expenses discussed above. We compute our net loss per share on the basis of net loss attributable to common stockholders, which included the effects of certain items not included in the determination of net income. Net loss attributable to common stockholders for Fiscal 2004 was $21,474,469 as compared to a net loss attributable to common stockholders of $13,600,374 for Fiscal 2003. These amounts include $1.2 million of deemed dividend associated with beneficial conversion of preferred stock for Fiscal 2003. These amounts include $1.1 million of preferred stock dividends for Fiscal 2003.

Contractual Obligations

The following table summarizes the amounts of payments due under specified contractual obligations as of December 31, 2004:

	Payments Due by Period			
Contractual Obligations	Less than 1 Year	1 - 3Years	4 - 5 Years	More than 5 Years
Long-Term Debt Obligations, excluding interest	$ —	$ —	$ 90,000,000	$ —
Capital Lease Obligations	$ 80,617	$ 73,899	$ —	$ —
Operating Lease Obligations	$ 794,631	$ 1,011,859	$ 406,863	$ 14,849
Purchase Obligations	$ —	$ —	$ —	$ —
Other Long-Term Liabilities Reflected on the Registrant's Balance Sheet Under GAAP	$ —	$ 336,318	$ —	$ —
Total	$ 875,248	$ 1,422,076	$ 90,406,863	$ 14,849

Off-Balance Sheet Transactions

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

Results of Operations—Comparison of Fiscal Years Ending December 31, 2003 and 2002

REVENUES. Revenues increased 390% or $354,698, to $445,689 for the year ended December 31, 2003 ("Fiscal 2003"), from $90,991 for the year ended December 31, 2002 ("Fiscal 2002"). The increase in revenues is primarily attributable to the commencement of operations in the United Kingdom. Included in Fiscal 2002 was $40,000 in license fees recognized which did not recur in Fiscal 2003.

COST OF SALES. Costs of sales increased 357%, or $1,716,069, to $2,197,222 in Fiscal 2003, from $481,153 in Fiscal 2002. The increase in cost of sales is primarily related to the increase in activities of our London, United Kingdom and Australia facilities. The increase resulted from increases in essentially all categories of costs as these facilities increased their commercialization of our process. Cost of sales exceeded revenues as sales have not yet reached the levels necessary for profitable operations, and the development and implementation of our automated processes has not yet achieved all of the cost efficiencies we hope to achieve.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES. Selling, general and administrative expenses increased 68%, or $2,547,587, to $6,311,774 for Fiscal 2003 from $3,764,187 for Fiscal 2002. The major components of the approximate $2.5 million increase in selling, general and administrative expense are as follows: a) consulting expense stayed constant at approximately $0.7 million for Fiscal 2003 compared to $0.7 million for Fiscal 2002; b) salaries increased by approximately $0.5 million to $1.1 million for Fiscal 2003 compared to $0.6 million for Fiscal 2002 (these amounts include an imputed expense of $200,000 in Fiscal 2003 and an imputed expense of $400,000 in Fiscal 2002 relating to the fair market value of services provided by certain officers for which they will not be compensated); c) travel expense increased by approximately $0.4 million to $0.8 million for Fiscal 2003 compared to $0.4 million for Fiscal 2002; d) legal expense increased by approximately $0.2 million to $0.5 million for Fiscal 2003 compared to $0.3 million for Fiscal 2002; e) promotional expense increased by approximately $0.4 million to $0.6 million for Fiscal 2003 compared to $0.2 million for Fiscal 2002; f) depreciation and amortization increased by approximately $0.3 million to $0.4 million for Fiscal 2003 compared to $0.1 million for Fiscal 2002 and g) there was an $0.4 million loss on disposal of an asset, primarily consisting of the write-off of software for fiscal 2003. The increase in selling, general and administrative expenses is attributed primarily to: a) higher salaries expense due to an increase in the number of employees; b) increased travel expenses related to our expansion into the United Kingdom and Australia; c) higher legal fees related to patent and business development issues; d) increased marketing and promotion efforts related to the commencement of operations in the United Kingdom; and e) depreciation and amortization of assets placed into service during 2003 with the commencement of operations in the United Kingdom and Australia and the completion of the U.S. laboratory.

RESEARCH AND DEVELOPMENT. Research and development expenses increased by approximately $1.8 million during Fiscal 2003 to $3.3 million from $1.5 million for Fiscal 2002. Research and development costs are composed primarily of costs related to our efforts to gain FDA approval for our products in the United States. These costs include those personnel and laboratory costs related to the current FDA trials and certain consulting costs. This project is still under development. The major components of the approximately $1.8 million increase in research and development expense are as follows: a) consulting expense increased by approximately $0.9 million to $1.6 million in Fiscal 2003 compared to $0.7 million in Fiscal 2002; b) salaries increased by approximately $0.2 million to $1.1 million for Fiscal 2003 compared to $0.9 million for Fiscal 2002; and b) laboratory expense increased by approximately $0.6 million to $0.6 million for Fiscal 2003 compared to $0.0 million for Fiscal 2002.

INTEREST INCOME. Interest income decreased 81%, or $168,001, to $40,691 for Fiscal 2003, from $208,692 for Fiscal 2002. The decrease in interest income resulted from, among other things, a decrease in our average cash balances in Fiscal 2003, and a decrease in interest rates paid on our deposits.

NET LOSS. Net loss for Fiscal 2003 was $11,268,294, as compared to a net loss of $5,433,055 for Fiscal 2002. This increase in net loss is attributed primarily to salaries, travel, consulting, legal and promotional expenses. Net loss attributable to common stockholders for Fiscal 2003 was $13,600,374 as compared to a net loss of $16,114,660 for Fiscal 2002. These amounts include $1.2 million and $10.2 million of deemed dividend associated with beneficial conversion of preferred stock for Fiscal 2003 and Fiscal 2002, respectively. These amounts include $1.1 million and $0.5 million of preferred stock dividends for Fiscal 2003 and Fiscal 2002, respectively.

Liquidity and Capital Resources

OPERATING ACTIVITIES. Cash used in operating activities during Fiscal 2004 amounted to $14,840,662, as compared to the $9,297,050 of cash used in operating activities during Fiscal 2003. The increase is attributed primarily to salaries, travel, consulting, legal, and promotional expenses. The

negative operating cash flows in Fiscal 2004 were financed from our cash balances as of December 31, 2003 and the proceeds of debt and equity placements, as discussed below.

INVESTING ACTIVITIES. Cash used by investing activities during Fiscal 2004 amounted to $54,611,715, as compared to cash used by investing activities of $1,159,857 during Fiscal 2003. This increase in cash used is due to the purchase of property and equipment for the Houston, Texas, London, England, and Sydney, Australia laboratories of $2,811,715 in Fiscal 2004 and the net purchase of short-term investments of $51,800,000 in Fiscal 2004.

FINANCING ACTIVITIES. Cash provided by financing activities was $117,449,656 during Fiscal 2004, which consisted substantially of a) the proceeds from the sale of 7,200,000 shares of common stock in a public offering in June 2004 for cash totaling $56,817,434, after deducting the costs and expenses associated with the sale and b) the proceeds from the sale of $90 million in principal amount of 3.5% Convertible Subordinated Notes due November 1, 2024, netting $60,279,807, after deducting the costs and expenses associated with the sale and the 4,000,000 share purchase of treasury stock. Cash provided by financing activities during Fiscal 2003 amounted to $21,931,231 consisting primarily of a) $3,919,078 raised from the issuance of preferred stock; b) $19,137,461 raised from the issuance of common stock; and c) $1,087,200 in cash dividends paid on preferred stock.

In May 2003, we sold in a private offering 155,750 shares of Series B Convertible Preferred Stock at an offering price of $28 per share. Each share of Series B preferred stock was convertible into 8 shares of our common stock at any time after issuance and accrued 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, we received cash totaling $3,919,078. In conjunction with the private offering, we 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 was offset from the proceeds received from the sale of the Series B Preferred Stock and recorded as additional paid in capital.

As stated above, the price of the Series B Preferred Stock sold was $28 per share. The market value of our 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 $1,244,880 was recorded with a corresponding amount recorded as additional paid-in capital. The deemed dividend associated with the beneficial conversion was calculated as the difference between the fair value of the underlying common stock less the proceeds that were received for the Series B Preferred Stock limited to the value of the proceeds received.

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 cash totaling $18,455,561.

In November 2004, we issued $90 million in principal amount of 3.5% Convertible Subordinated Notes due November 1, 2024. The 3.5% Convertible Subordinated Notes are convertible at the option of the holder into our common stock at an initial conversion rate (subject to adjustment) of 109.2001 shares of common stock per $1,000 principal amount of 3.5% Convertible Subordinated Notes, which is equivalent to an initial conversion price of approximately $9.16 per share, at any time prior to the stated maturity. In the event of certain fundamental changes that occur prior to November 1, 2009, we are required to pay a make-whole premium to the holders of the 3.5% Convertible Subordinated Notes that convert their 3.5% Convertible Subordinated Notes into our common stock on or after the date on which notice of such fundamental change is given. The net proceeds from the 3.5% Convertible Subordinated Notes were approximately $86.2 million. We used approximately $26 million of the

proceeds to repurchase 4,000,000 shares of common stock, and intend to use the remainder for general corporate purposes. See Note 5 of Notes to Consolidated Financial Statements.

WORKING CAPITAL. As of December 31, 2004, we had cash, cash equivalents and short-term investments of $116.1 million. As of February 28, 2005, we had cash, cash equivalents and short-term investments of approximately $112.2 million. We believe our existing capital resources are adequate to finance our operations until June 30, 2007, however our long-term viability is dependent upon successful operation of our business, our ability to automate our manufacturing process, the approval of our products and the ability to raise additional debt and equity to meet our business objectives.

Recent Accounting Pronouncements

In November 2004, the FASB issued SFAS No. 151, *"Inventory Costs, an Amendment of ARB No. 43, Chapter 4."* SFAS No. 151 retains the general principle of ARB No. 43, Chapter 4, "Inventory Pricing," that inventories are presumed to be stated at cost; however, it amends ARB No. 43 to clarify that abnormal amounts of idle facilities, freight, handling costs and spoilage should be recognized as current period expenses. Also, SFAS No. 151 requires fixed overhead costs be allocated to inventories based on normal production capacity. The guidance of SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. We believe that implementing SFAS No. 151 should not have a material impact on our financial condition or results of operations.

In December 2004, the FASB issued SFAS No. 123 (Revised 2004), *"Share Based Payment,"* which eliminates the use of APB Opinion No. 25 and will require us to measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost will be recognized over the period during which an employee is required to provide service in exchange for the reward—the requisite service period. No compensation cost is recognized for equity instruments for which employees do not render the requisite service. The grant-date fair value of employee share options and similar instruments will be estimated using option-pricing models adjusted for the unique characteristics of those instruments. SFAS No. 123 (Revised 2004) is effective for the first interim or annual reporting period that begins after June 15, 2005 (the quarter beginning July 1, 2005 for us) and must be applied to all options granted or modified after its effective date and also to recognize the cost associated with the portion of any option awards made before its effective date for with the associated service has not been rendered as of its effective date. We are still studying the requirements of SFAS No. 123 (Revised 2004) and have not yet determined what impact it will have on our results of operations and financial position.

In December, 2004 the FASB issued SFAS No. 153, *"Exchanges of Nonmonetary Assets—an amendment of APB Opinion No. 29."* APB Opinion No. 29 provided an exception to the basic measurement principle (fair value) for exchanges of similar productive assets. That exception required that some nonmonetary exchanges, although commercially substantive, be recorded on a carryover basis. SFAS No. 153 amends APB Opinion No. 29 to eliminate the exception to fair value for exchanges of similar productive assets and replace it with a general exception for exchange transactions that do not have commercial substance, which are defined as transactions that are not expected to result in significant changes in the cash flows of the reporting entity. SFAS No. 153 is effective for nonmonetary exchanges occurring in fiscal periods beginning after June 15, 2005. We do not expect that SFAS No. 153 will have a material affect on our financial statements.

Other

INFLATION. Inflation did not have a significant impact on our results during Fiscal 2004.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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

Substantially all of our revenues for the year ended December 31, 2004 were derived from operations in the United Kingdom. We commenced operations in Australia in the fourth quarter of 2003. The results of operations and financial position of our foreign operations were principally measured in their respective functional currencies and translated into U.S. dollars. The effect of U.S. dollar currency fluctuations against the foreign currency in these countries is somewhat mitigated by the fact that expenses are generally incurred in the same currencies in which the revenue is generated. Our income will be higher or lower depending on the weakening or strengthening of the U.S. dollar against the respective foreign currency. Additionally, approximately 4% of our assets at December 31, 2004 were based in our foreign operations and translated into U.S. dollars at the foreign currency exchange rate in effect as of the end of each accounting period, with the effect of such translation reflected as a separate component of consolidated stockholders' equity. Accordingly, our consolidated stockholders' equity will fluctuate depending on the weakening or strengthening of the U.S. dollar against the respective foreign currency.

At December 31, 2004 we had approximately $51.8 million invested in short-term investment, comprised of marketable debt securities (see Note 2 of Notes to Consolidated Financial Statements). These investments subject us to interest rate risk, in that increases in interest rates would cause the market value of the investments to decline and decreases in interest rates would cause the market value of the investments to increase. Additionally, approximately $42.8 million of such investments are in the form of Auction Rate Securities ("ARS"), for which the interest rate is reset periodically through a Dutch auction process. As a result, the interest rate we earn on those investments in future periods could decline if market interest rates decline, and could increase if market interest rates increase. However, it should be noted that these investments represent the temporary investment of the proceeds of our Fiscal 2004 equity and debt placements until these funds are needed for operating purposes. Accordingly, it is not anticipated that the December 31, 2004 level of investments will be held throughout Fiscal 2005 and beyond, and as a result our exposure to interest rate risk must be judged accordingly.

Our principle interest bearing debt, our 3.5% Convertible Subordinated Notes, pay interest at a fixed rate, and accordingly we are not exposed to interest rate risk as a result of this debt.

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

Item 8. Financial Statements and Supplementary Data

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

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

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

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

In accordance with Rule 13a-15(b) of the Securities Exchange Act of 1934 (the "Exchange Act"), as of the end of the period covered by this Annual Report on Form 10-K, our management evaluated, with the participation of our President and Chief Executive Officer and our Chief Financial Officer, the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act). Based upon their evaluation of these disclosure controls and procedures, our President and Chief Executive Officer and our Chief Financial Officer have concluded that the disclosure controls and procedures were not effective as of the date of such evaluation to ensure that material information relating to us, including our consolidated subsidiaries, was made known to them by others within those entities, particularly during the period in which this Annual Report on Form 10-K was being prepared.

Management's Report on Internal Control over Financial Reporting

Under Section 404 of the Sarbanes-Oxley Act, we are required to evaluate and test our internal controls over financial reporting in order to satisfy the requirements of Section 404, which requires the inclusion in our Annual Report on Form 10-K of management's report of the effectiveness of our internal controls over financial reporting and the inclusion of a report of our Independent Registered Public Accounting Firm attesting to management's report on internal controls over financial reporting. We are evaluating our internal controls over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework in accordance with the standards of the Public Company Accounting Oversight Board (United States) (the "PCAOB").

The Company is eligible for the 45 day extension of time allowed by the SEC for companies of a certain size to file these reports. We are currently in the process of completing our evaluation of our internal controls over financial reporting, and we have elected to utilize this 45 day extension, and therefore, this Form 10-K does not include these reports. We anticipate completing this process and filing these reports in an amended Form 10-K, which we expect to file in April 2005.

As of the date of the filing of this Annual Report on Form 10-K, management has made certain preliminary conclusions, which it has communicated to both the Audit Committee and our Independent Registered Public Accounting Firm, that there existed at December 31, 2004 certain material weaknesses in the internal controls over financial reporting as well as certain significant deficiencies in the internal controls over financial reporting that may in the aggregate, constitute material weaknesses. Under the auditing standards of the PCAOB, a significant deficiency represent a deficiency in the design or operation of internal control, which could adversely affect the organization's ability to initiate, record, process, and report financial data consistent with the assertions of management in the financial statements. A material weakness is a significant deficiency, or a combination of significant deficiencies, that results in there being more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis by management or employees in the normal course of performing their assigned functions.

Those significant deficiencies or material weaknesses are as follows:

(i) The failure to perform certain closing procedures on a timely basis, to timely identify certain accounting and financial statement disclosure issues, as discussed below, and the lack of an adequate internal audit function, each of which result from inadequate staffing of the accounting and financial reporting function and a lack of certain needed financial reporting expertises. As a result of this, (a) the Company did not identify certain required changes in the classification of expenses between selling, general and administrative expenses and cost of

sales, as described in Notes 2 and 11 of Notes to Consolidated Financial Statements, (b) the Company did not identify that approximately $51.8 million of marketable debt securities were improperly included in cash and cash equivalents instead of being separately presented as short term investments, (c) the Company under accrued the costs relating to the closure of the Australian facility by approximately $135,000, and (d) the Company made certain errors in the preparation of the disclosures about its deferred tax assets and liabilities (see Note 6 of Notes to Consolidated Financial Statements), although this had no effect of the company's results of operations or financial position as all of the Company's net deferred tax assets have been fully reserved.

(ii) The failure to provide clear, continual and easily accessible information to employees concerning the Company's code of ethics and policies, including information on the methods available to report suspected violations of the Company ethics or policies, and to obtain acknowledgements from employees that they have read, understood and complied with the Company's code of ethics.

(iii) The execution of certain contracts without the approval of the board of directors, or without the review of the contracts by counsel, as the company's policies require for contracts of those types or amounts.

(iv) The failure to provide controls within the information systems area and to effectively test them including segregation of duties within the information technology department and the potential impact of that situation on the consistency of systems processing and access security.

Due to the number of controls being examined, the complexity of the process, as well as the difficult judgments and subjectivity involved in determining the effectiveness of controls, we cannot be certain that additional significant deficiencies or material weaknesses will not be identified as we complete our evaluation of our internal controls over financial reporting. Additionally, we cannot predict whether, in the completion of our evaluation of our internal controls, we might conclude that some of the deficiencies listed above are not significant deficiencies, or are compensated for by other internal controls over financial reporting.

Attestation Report of Independent Registered Public Accounting Firm

The attestation report of our Independent Registered Public Accounting Firm required under this Item 9A will be included when we file the amended Annual Report on Form 10-K, as discussed above.

Changes in Internal Controls

During the quarter ended December 31, 2004, the Company completed its implementation of a new internal control framework, including a) improved segregation of duties in the United Kingdom; b) formalized the documentation of certain procedures; and c) daily reconciliation of cash received to the general ledger, that was designed to remediate previously identified deficiencies in internal controls and comply with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002.

Item 9B. Other Information

None.

Part III

Item 10. Directors and Executive Officers of the Registrant

The information required by this Item 10 will be included in the Company's Proxy Statement for the 2005 Annual Meeting of Stockholders which will be filed with the Securities and Exchange Commission no later than May 2, 2005 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. A copy of the code of ethics has been filed as an exhibit to our annual report.

Item 11. Executive Compensation

The information required by this Item 11 will be included in the Company's Proxy Statement for the 2005 Annual Meeting of Stockholders which will be filed with the Securities and Exchange Commission no later than May 2, 2005 and is incorporated into this Item 11 by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management

The information required by this Item 12 will be included in the Company's Proxy Statement for the 2005 Annual Meeting of Stockholders which will be filed with the Securities and Exchange Commission no later than May 2, 2005 and is incorporated into this Item 12 by reference.

Item 13. Certain Relationships and Related Transactions

The information required by this Item 13 will be included in the Company's Proxy Statement for the 2005 Annual Meeting of Stockholders which will be filed with the Securities and Exchange Commission no later than May 2, 2005 and is incorporated into this Item 13 by reference.

Item 14. Principal Accounting Fees and Services

The information required by this Item 14 will be included in the Company's Proxy Statement for the 2005 Annual Meeting of Stockholders which will be filed with the Securities and Exchange Commission no later than May 2, 2005 and is incorporated into this Item 14 by reference.

Part IV

Item 15. Exhibits and Financial Statement Schedules

(a)(1) Financial Statements.

- Reports of Independent Registered Public Accounting Firms
- Consolidated Balance Sheets as of December 31, 2004 and 2003
- Consolidated Statements of Operations for the years ended December 31, 2004, 2003, and 2002 and inception to December 31, 2004
- Consolidated Statements of Stockholders' Equity from inception to December 31, 2004
- Consolidated Statements of Cash Flows for the years ended December 31, 2004, 2003 and 2002 and inception to December 31, 2004
- Notes to Consolidated Financial Statements

(a)(2) Financial Statement Schedule.

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

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

(b) Exhibits.

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

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(7)
3(ii)	Bylaws(10)
4.1	Specimen of Common Stock certificate(2)
4.2	Certificate of Designations of Series A Convertible Preferred Stock(7)
4.3	Certificate of Designations of Series B Convertible Preferred Stock(5)
4.4	Indenture, dated November 3, 2004, between the Company and The Bank of New York Trust Company, N.A., as trustee(11)
10.1	2003 Stock Option and Stock Appreciation Rights Plan(3)*
10.2	2001 Stock Option and Appreciation Rights Plan(4)*
10.3	Reserved
10.4	Employment Agreement dated May 28, 2002 between Isolagen, Inc. and Vaughan Clift(7)*
10.5	Employment Agreement dated September 5, 2003 between Isolagen, Inc. and Frank DeLape(7)*

10.6	Employment Agreement dated September 5, 2003 between Isolagen, Inc. and Michael Macaluso(7)*
10.7	Employment Agreement dated September 5, 2003 between Isolagen, Inc. and Jeffrey W. Tomz(7)*
10.8	Reserved
10.9	Lease Agreement dated March 24, 2002 by and between the Registrant as Lessee and Claire O Aceti Gbmh as Lessor(7)
10.10	Lease Agreement dated November 20, 2002 by and between the Registrant as Lessee and Lego Australia Pty Limited as Lessor(7)
10.11	Intellectual Property Purchase Agreement between Isolagen Technologies, Inc., Gregory M. Keller, and PacGen Partners(8)
10.12	Employment Agreement effective September 1, 2004 between Isolagen, Inc. and Robert Bitterman(12)
10.13	Employment Agreement effective September 13, 2004 between Isolagen, Inc. and Dr. Kimberley Forbes-McKean(12)
10.14	Employment Agreement effective September 27, 2004 between Isolagen, Inc. and Dennis L. Bevan(12)
10.15	Purchase Agreement among CIBC World Market Corp., UBS Securities LLC, and Adams, Harkness & Hill, Inc. dated October 28, 2004(11)
10.16	Registration Rights Agreement among CIBC World Market Corp., UBS Securities LLC, and Adams, Harkness & Hill, Inc. dated November 3, 2004(11)
14	Code of Ethics(9)
21	List of Subsidiaries(10)
23.1	Pannell Kerr Forster of Texas, P.C. Consent(12)
23.2	BDO Seidman, LLP Consent(12)
31.1	Certification pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002(12)
31.2	Certification pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002(12)
32.1	Certification pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002(12)
32.2	Certification pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002(12)

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

(1) Previously filed as an exhibit to the company's Form 8-K, filed on August 22, 2001, and is incorporated by reference hereto.

(2) Previously filed as an exhibit to the company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2001, and is incorporated by reference hereto.

(3) Previously filed as an appendix to the company's Definitive Proxy Statement, as filed on May 6, 2003, in connection with the 2003 Annual Stockholder Meeting, and is incorporated by reference hereto.

(4) Previously filed as an appendix to the company's Definitive Proxy Statement, as filed on October 23, 2001, in connection with the 2001 Annual Stockholder Meeting, and is incorporated by reference hereto.

(5) Previously filed as an exhibit to the company's Form 10-Q for the fiscal quarter ended March 31, 2003, as filed on May 15, 2003, and is incorporated by reference hereto.

(6) Previously filed as an exhibit to the company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2002, and is incorporated by reference hereto.

(7) Previously filed as an exhibit to the company's Form S-1, as filed on September 12, 2003, and is incorporated by reference hereto.

(8) Previously filed as an exhibit to the company's amended Form S-1, as filed on October 24, 2003, and is incorporated by reference hereto.

(9) Previously filed as an exhibit to the company's Annual Report on Form 10-K for the fiscal year ended December 31, 2003, and is incorporated by reference hereto.

(10) Previously filed as an exhibit to the company's Annual Report on Form 10-K/A for the fiscal year ended December 31, 2003, and is incorporated by reference hereto.

(11) Previously filed as an exhibit to the company's Current Report on Form 8-K dated November 4, 2004, and is incorporated by reference hereto.

(12) 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/ JEFFREY W. TOMZ

Jeffrey W. Tomz, Chief Financial Officer and
Principal Accounting Officer

Date: March 14, 2005

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

Signature	Title	Date
/s/ ROBERT BITTERMAN	President, Chief Executive Officer and Director	March 14, 2005
Robert Bitterman		
/s/ FRANK DELAPE	Chairman of the Board and Director	March 14, 2005
Frank DeLape		
/s/ JEFFREY W. TOMZ	Chief Financial Officer and Accounting Officer and Secretary	March 14, 2005
Jeffrey W. Tomz		
/s/ MICHAEL MACALUSO	Director	March 14, 2005
Michael Macaluso		
/s/ STEVEN MORRELL	Director	March 14, 2005
Steven Morrell		
/s/ HENRY TOH	Director	March 14, 2005
Henry Toh		
/s/ RALPH DE MARTINO	Director	March 14, 2005
Ralph De Martino		
/s/ MARSHALL G. WEBB	Director	March 14, 2005
Marshall G. Webb		

Isolagen, Inc.
(A Development Stage Company)

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheet of Isolagen, Inc. (a Delaware corporation in the development stage) as of December 31, 2004, and the related consolidated statements of operations, shareholders' equity and cash flows for the year then ended and the related statements of operations and cash flows for the period from inception (December 28, 1995) to December 31, 2004. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We did not audit the consolidated financial statements of Isolagen, Inc. for the period from inception (December 28, 1995) to December 31, 2003. Such statements are included in the cumulative inception to December 31, 2004 totals of the consolidated statements of operations and cash flows and reflect a net loss of 49.4% and total revenues of 33.9% of the related cumulative totals. Those consolidated statements were audited by other auditors whose report has been furnished to us and our opinion, insofar as it relates to amounts for the period from inception (December 28, 1995) to December 31, 2003 included in the cumulative totals, is based solely upon the report of the other auditors.

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

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

/s/ BDO SEIDMAN, LLP

Houston, Texas
March 14, 2005

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheet of Isolagen, Inc. and Subsidiaries (a Delaware corporation) as of December 31, 2003 and the related consolidated statements of operations, shareholders' equity and cash flows for each of the two years in the period ended December 31, 2003 and the cumulative amounts during the development stage (inception December 28, 1995 to December 31, 2003). These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Isolagen, Inc. and Subsidiaries as of December 31, 2003 and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2003 and the cumulative amounts for the period from inception to December 31, 2003 in conformity with accounting principles generally accepted in the United States of America.

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

Houston, Texas
February 17, 2004

Isolagen, Inc.
(A Development Stage Company)

Consolidated Balance Sheets

	December 31,	
	2004	2003
Assets		
Current assets		
Cash and cash equivalents	$ 64,329,356	$ 15,935,558
Short-term investments	51,809,660	—
Accounts receivable, net of allowance for doubtful accounts of $50,533 and $0, respectively	1,516,591	207,202
Inventory	1,010,768	259,695
Other receivables	350,861	91,545
Prepaid expenses	769,984	254,508
Total current assets	119,787,220	16,748,508
Property and equipment, net	3,634,992	2,221,838
Intangible assets	540,000	540,000
Other assets, net of amortization of $124,873 and $0, respectively	4,158,926	134,119
Total assets	$ 128,121,138	$ 19,644,465
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	$ 2,360,363	$ 1,460,478
Accrued expenses	3,441,805	535,975
Deferred revenue	2,923,328	384,287
Total current liabilities	8,725,496	2,380,740
Long term debt	90,000,000	—
Other long term liabilities	410,217	—
Total liabilities	99,135,713	2,380,740
Commitments and contingencies		
Shareholders' equity		
Preferred stock, $.001 par value; 5,000,000 shares authorized	—	—
Common stock, $.001 par value; 50,000,000 shares authorized	34,195	26,672
Additional paid-in capital	109,935,174	50,862,258
Treasury stock, at cost, 4,000,000 shares	(25,974,000)	—
Accumulated other comprehensive income	464,110	374,380
Accumulated deficit during development stage	(55,474,054)	(33,999,585)
Total shareholders' equity	28,985,425	17,263,725
Total liabilities and shareholder's equity	$ 128,121,138	$ 19,644,465

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 December 28, 1995 (date of inception) to December 31, 2004
	2004	2003	2002	
Revenues				
Product sales	$ 4,179,247	$ 445,689	$ 50,991	$ 6,066,041
License fees	—	—	40,000	260,000
Total revenues	4,179,247	445,689	90,991	6,326,041
Cost of sales	5,491,008	2,197,222	481,153	8,571,842
Selling, general and administrative expenses	15,127,365	6,311,774	3,764,187	28,377,425
Research and development	5,057,149	3,301,341	1,519,819	11,913,185
Operating loss	(21,496,275)	(11,364,648)	(5,674,168)	(42,536,411)
Other income (expense)				
Interest income	566,526	40,691	208,692	844,306
Other income	91,956	55,663	32,421	180,040
Interest expense	(636,676)	—	—	(948,304)
Net loss	$ (21,474,469)	$ (11,268,294)	$ (5,433,055)	$ (42,460,369)
Deemed dividend associated with beneficial conversion of preferred stock	—	(1,244,880)	(10,178,944)	(11,423,824)
Preferred stock dividends	—	(1,087,200)	(502,661)	(1,589,861)
Net loss attributable to common shareholders	$ (21,474,469)	$ (13,600,374)	$ (16,114,660)	$ (55,474,054)
Per share information				
Net loss—basic and diluted	$ (0.71)	$ (0.58)	$ (0.36)	$ (4.50)
Deemed dividend associated with beneficial conversion of preferred stock	—	(0.06)	(0.67)	(1.21)
Preferred stock dividends	—	(0.06)	(0.03)	(0.17)
Net loss per common share—basic and diluted	$ (0.71)	$ (0.70)	$ (1.06)	$ (5.88)
Weighted average number of basic and diluted common shares outstanding	30,116,827	19,297,865	15,205,554	9,436,522

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

Isolagen, Inc.
(A Development Stage Company)

Consolidated Statements of Shareholders' Equity

	Series A Preferred Stock		Series B Preferred Stock		Common Stock			Treasury Stock				
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Number of Shares	Amount	Accumulated Other Comprehensive Shares	Accumulated During Development Stage Income	Total Shareholders' Equity (Deficit)
Issuance of common stock for cash on 12/28/95	—	$ —	—	$ —	2,285,291	$ 2,285	$ (1,465)	—	$ —	$ —	$ —	$ 820
Issuance of common stock for cash on 11/7/96	—	—	—	—	11,149	11	49,989	—	—	—	—	50,000
Issuance of common stock for cash on 11/29/96	—	—	—	—	2,230	2	9,998	—	—	—	—	10,000
Issuance of common stock for cash on 12/19/96	—	—	—	—	6,690	7	29,993	—	—	—	—	30,000
Issuance of common stock for cash on 12/26/96	—	—	—	—	11,148	11	49,989	—	—	—	—	50,000
Net loss	—	—	—	—	—	—	—	—	—	—	(270,468)	(270,468)
Balance, 12/31/96	—	$ —	—	$ —	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.

Isolagen, Inc.
(A Development Stage Company)

Consolidated Statements of Shareholders' Equity (Continued)

	Series A Preferred Stock		Series B Preferred Stock		Common Stock			Treasury Stock			Accumulated Deficit During Development Stage	Total Shareholders' Equity (Deficit)
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Number of Shares	Amount	Accumulated Other Comprehensive Income		
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.

Isolagen, Inc.
(A Development Stage Company)

Consolidated Statements of Shareholders' Equity (Continued)

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

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

Isolagen, Inc.
(A Development Stage Company)

Consolidated Statements of Shareholders' Equity (Continued)

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

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

Isolagen, Inc.
(A Development Stage Company)

Consolidated Statements of Shareholders' Equity (Continued)

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

Isolagen, Inc.
(A Development Stage Company)

Consolidated Statements of Shareholders' Equity (Continued)

	Series A Preferred Stock		Series B Preferred Stock		Common Stock			Treasury Stock				
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Number of Shares	Amount	Accumulated Other Comprehensive Income	Accumulated Deficit During Development Stage	Total Shareholders' Equity (Deficit)
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 securities	—	—	—	—	—	—	—	—	—	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.

Isolagen, Inc.
(A Development Stage Company)

Consolidated Statements of Cash Flows

	For the Year Ended December 31,			Cumulative Period from December 28, 1995 (date of inception) to December 31, 2004
	2004	2003	2002	
Cash flows from operating activities				
Net loss	$ (21,474,469)	$ (11,268,294)	$ (5,433,055)	$ (42,460,369)
Adjustments to reconcile net loss to net cash used in operating activities:				
Equity awards issued for services	1,910,590	412,812	157,704	3,533,185
Uncompensated contribution of services	—	200,000	400,000	755,556
Depreciation	1,303,298	835,430	99,812	2,306,257
Provision for doubtful accounts	50,533	—	—	50,533
Amortization of debt issue costs	124,873	—	—	124,873
Loss on disposal or impairment of property and equipment	161,226	406,413	—	575,861
Change in operating assets and liabilities:				
Increase in accounts receivable	(1,285,925)	(166,998)	(39,137)	(1,493,128)
Decrease (increase) in other receivables	(237,883)	62,038	(153,583)	(329,428)
Increase in inventory	(727,411)	(120,785)	(138,910)	(987,106)
Decrease (increase) in prepaid expenses	(490,315)	30,049	(284,557)	(744,823)
Increase in other assets	(155,573)	(17,721)	(115,507)	(288,801)
Increase (decrease) in accounts payable	840,432	(420,758)	1,673,040	2,300,910
Increase in accrued expenses	2,731,782	423,751	88,906	3,267,757
Increase (decrease) in deferred revenue	2,408,180	327,013	(222,726)	2,792,468
Net cash used in operating activities	(14,840,662)	(9,297,050)	(3,968,013)	(30,596,255)
Cash flows from investing activities				
Purchase of property and equipment	(2,811,715)	(1,193,157)	(2,252,368)	(6,341,536)
Proceeds from the sale of property and equipment	—	33,300	—	34,300
Purchase of investments	(72,800,000)	—	—	(72,800,000)
Proceeds from sales and maturities of investments	21,000,000	—	—	21,000,000
Net cash used in investing activities	(54,611,715)	(1,159,857)	(2,252,368)	(58,107,236)
Cash flows from financing activities				
Proceeds from convertible debt	90,000,000	—	—	91,450,000
Offering costs associated with the issuance of convertible debt	(3,746,193)	—	—	(3,746,193)
Proceeds from notes payable to shareholders, net	—	—	—	135,667
Proceeds from the issuance of preferred stock, net	—	3,919,078	9,012,722	12,931,800
Proceeds from the issuance of common stock, net	57,169,849	19,137,461	57,600	78,832,720
Cash dividends paid on preferred stock	—	(1,087,200)	—	(1,087,200)
Cash paid for fractional shares of preferred stock	—	(38,108)	—	(38,108)
Merger and acquisition expenses	—	—	—	(48,547)
Repurchase of common stock	(25,974,000)	—	—	(26,024,280)
Net cash provided by financing activities	117,449,656	21,931,231	9,070,322	152,405,859
Effect of exchange rate changes on cash balances	396,519	216,594	13,875	626,988
Net increase in cash and cash equivalents	48,393,798	11,690,918	2,863,816	64,329,356
Cash and cash equivalents, beginning of period	15,935,558	4,244,640	1,380,824	—
Cash and cash equivalents, end of period	$ 64,329,356	$ 15,935,558	$ 4,244,640	$ 64,329,356
Supplemental disclosures of cash flow information:				
Cash paid for interest	$ —	$ —	$ —	$ 150,283
Deemed dividend associated with beneficial conversion of preferred stock	$ —	$ 1,244,880	$ 10,178,944	$ 11,423,824
Preferred stock dividend	$ —	$ 1,087,200	$ 502,661	$ 1,589,861
Uncompensated contribution of services	$ —	$ 200,000	$ 400,000	$ 755,556
Common stock issued for Intellectual Property	$ —	$ 540,000	$ —	$ 540,000
Equipment acquired through capital lease	$ 167,154	$ —	$ —	$ 167,154

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

Notes to Consolidated Financial Statements

Note 1—Basis of Presentation, Business and Organization

Isolagen, Inc. f/k/a American Financial Holding, Inc., a Delaware corporation ("Isolagen" or the "Company") is the parent company of Isolagen Technologies, Inc., a Delaware corporation ("Isolagen Technologies"). Isolagen Technologies is the parent company of Isolagen Europe Limited, a company organized under the laws of the United Kingdom ("Isolagen Europe"). Isolagen Technologies is the parent company of Isolagen Australia Pty Limited, a company organized under the laws of Australia ("Isolagen Australia"). Isolagen Technologies is the parent company of Isolagen International, 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 American Stock Exchange ("AMEX") under the symbol "ILE."

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

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

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

On April 7, 2004, the Company submitted a request for a Special Protocol Assessment, or SPA, to the FDA with all the supporting information for its two pivotal Phase III clinical trials for specific dermal applications. In the SPA process, the FDA reviewed the design and size of a proposed Phase III program and provided comments regarding the adequacy of the clinical trial design to support a claim of efficacy in an approvable Biologics License Application, or BLA. The FDA's comments are binding on its review decision, except in limited circumstances, such as when a substantial scientific issue essential to determining the safety and efficacy of a product candidate is identified after the Phase III program commences. In May 2004, the FDA approved the Company's request for an SPA relating to the design of two pivotal Phase III clinical trials to be conducted by Isolagen in support of registration of the Isolagen Process for the treatment of nasolabial folds and glabellar lines. The Company believes that the FDA's action will significantly reduce the risks associated with conducting its pivotal Phase III clinical trials to provide evidence of efficacy and safety sufficient for license application. In July 2004, the Company announced the commencement of two pivotal Phase III trials, which are being conducted in two different geographic and demographic populations in the United States as two identical trials for

the treatment of facial wrinkles. These trials are randomized, double blind and placebo-controlled and are being conducted at various sites in the United States. The trials, which are being conducted simultaneously, each have in excess of 100 patients split evenly between the treatment group and the placebo group. Efficacy will be measured by a two-point improvements on a six-point scale, as evaluated by an independent assessor at four, six, nine and twelve months. The Company expects to file a BLA for this product candidate during the second half of 2005. The Company completed Phase I clinical trial for its second candidate for the treatment of periodontal disease in late 2003. In the second quarter of 2004, the Company initiated a Phase II clinical trial for the cosmetic, or "black triangle," application of this product candidate.

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

Through December 31, 2004, the Company has been primarily engaged in developing its initial product technology, recruiting personnel, commencing its UK operations and raising capital. In the course of its development activities, the Company has sustained losses and expects such losses to continue through at least 2005. The Company will finance its operations primarily through its existing cash and future financing.

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

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

As of December 31, 2004, the Company had cash and cash equivalents and short-term investments of $116.1 million. The Company believes that its existing capital resources are adequate to finance its operations until June 30, 2007, however its long-term viability is dependent upon successful operation of its business, its ability to automate its manufacturing process, the approval of its products and the ability to raise additional debt and equity to meet its business objectives.

Acquisition and merger and basis of presentation

On August 10, 2001, 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 3,942,000 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 Process. AFH was a non-operating, public shell company with limited assets. Gemini was a non-operating private company with limited assets and was unaffiliated with AFH.

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

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

The financial statements presented include Isolagen, Inc. and its wholly-owned subsidiaries. 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.

Note 2—Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Examples include provisions for bad debts and inventory obsolescence, useful lives of property

and equipment and intangible assets, impairment of property and equipment and intangible assets, deferred taxes, and the provision for and disclosure of litigation and loss contingencies. Actual results may differ materially from those estimates.

Foreign Currency Translation

The financial position and results of operations of the Company's foreign subsidiaries are determined using the local currency as the functional currency. Assets and liabilities of these subsidiaries are translated at the exchange rate in effect at each period-end. Income statement accounts are translated at the average rate of exchange prevailing during the period. Adjustments arising from the use of differing exchange rates from period to period are included in accumulated other comprehensive income in shareholders' equity. Gains and losses resulting from foreign currency transactions are included in earnings and have not been material in any one period.

Balances of related after-tax components comprising accumulated other comprehensive income included in stockholders' equity, at December 31, 2004 and December 31, 2003 are as follows:

	December 31	
	2004	2003
Unrealized gains on available-for-sale securities	$ 10,005	$ —
Foreign currency translation adjustment	454,105	374,380
Accumulated other comprehensive income	$ 464,110	$ 374,380

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.

Concentration of credit risk

The Company maintains its cash primarily with major U.S. domestic banks. The amounts held in these banks exceed the insured limit of $100,000 from time to time. 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 Fannie Mae and government securities.

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

Short-Term Investments

At December 31, 2004 the Company held certain investments in marketable debt securities as a means of temporarily investing the proceeds from its issuance of shares of common stock and 3.5% Convertible Subordinated Notes until the funds are needed for operating purposes. These investments are being accounted for as "available-for-sale" securities under Statement of Financial Accounting Standards ("SFAS") No. 115," *Accounting for Certain Investments in Debt and Equity Securities."* As a result, the investments are reflected at their fair value, based on quoted market prices, with unrealized gains and losses recorded in accumulated other comprehensive income until the investments are sold, at which time the realized gains and losses are included in the results of operations.

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

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

The Company's investments in state and local government and corporate issues are principally investments in Auction Rate Securities ("ARS"), for which the interest rates are reset periodically through a Dutch auction process.

The following sets forth the aggregate maturities of the Company's investments in marketable debt securities without regard to the dates at which the interest rates for ARS investments reset:

Maturity	Cost	Fair Value
2005	$ 8,999,655	$ 9,009,660
2006-2010	—	—
2011-2015	1,950,000	1,950,000
2016 and after	40,850,000	40,850,000
	$ 51,799,655	$ 51,809,660

Proceeds from the sale of available-for-sale marketable debt securities were $21 million for Fiscal 2004, and no realized gains and losses based on specific identification, were included in the results of operations upon those sales.

Allowance for Doubtful Accounts

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

The Company did not have an allowance for doubtful accounts for years ended December 31, 2003 and 2002. The following is a rollforward of the allowance for doubtful accounts for Fiscal 2004:

Balance, as of December 31, 2003	$ —
Provision during 2004	50,533
Changes	—
Balance, as of December 31, 2004	$ 50,533

Inventory

Inventory primarily consists of raw materials used in the Isolagen Process. Inventory is stated at the lower of cost or market and cost is determined by the weighted average method.

Property and equipment

Property and equipment, consisting primarily of lab equipment, computer equipment, software, leasehold improvements, and office furniture and fixtures is carried at cost less accumulated depreciation and amortization. Depreciation and amortization for financial reporting purposes is provided by the straight-line method over the estimated useful lives of three to five years. Leasehold improvements are amortized using the straight-line method over the remaining lease term or the life of the asset, whichever is shorter. The cost of repairs and maintenance is charged as an expense as incurred.

Intangible assets

The Company's intangible assets represent patent applications which are recorded at cost. The Company has filed applications for patents in connection with technologies being developed. The patent applications and any patents issued as a result of these applications are important to the protection of the Company's technologies that may result from its research and development efforts. Costs associated with patent applications and maintaining patents are capitalized and will be amortized over the life of the patents. The Company reviews the value recorded for intangibles to assess recoverability from future operations using undiscounted cash flows. Impairments are recognized in operating results to the extent the carrying value exceeds fair value determined based on the net present value of estimated future cash flows.

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. The amount of costs capitalized during the year ended December 31, 2004 was approximately $3,746,000.

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.

Currently the Isolagen Process is delivered through an attending physician to each patient using the Company's recommended regimen of up to three injections. Due to the short shelf life, each injection is cultured on an as needed basis and shipped prior to the individual injection being administered by the physician. The Company believes each injection has stand alone value to the patient. The Company invoices the attending physician upon that physician submitting his or her patient's tissue sample to the Company, as a result of which the contractual arrangement is between

the Company and the medical professional. The amount invoiced varies directly with the number of injections requested. Generally, all orders are paid in advance by the physician prior to the first injection and are not refundable and there is no performance provision under any arrangement with any doctor, and there is no right to refund, or returns for unused injections.

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

Revenue from licenses and other upfront fees are recognized on a ratable basis over the term of the respective agreement.

The Company also offers a service whereby it stores a patient's cells for later use in the preparation of injections, and a service whereby it processes a patient's cells to expand the cells to the mass necessary to prepare an injection, but then store the expanded cells for later use in the preparation of injections. In accordance with EITF 00-21, the fees charged for both of these services are recognized as revenue ratably over the length of the storage agreement. No separate revenue is recognized for the initial cell expansion service, as the Company does not offer this service separately and the process of cell expansion has no value without either the subsequent preparation of an injection or the storage of the expanded cells for later use in the preparation of injections.

Promotional incentives

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

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

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. The Company accrues the costs of services rendered in connection with third-party contractor activities based on its estimate of management fees, site management and monitoring costs and data management costs. Actual clinical trial costs may differ from estimated clinical trial costs and are adjusted for in the period in which they become known.

Costs of Exit Activities

In September, 2004, the Company approved a plan for the closure of its Australian facilities and the servicing of Australia from the Company's London, England facility. The Company adopted this plan because it believed that anticipated processing enhancements and improved delivery logistics will eliminate the need for an Australian laboratory. The Company expects that the closure of the Australian facility will be completed by March, 2005.

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

The following sets forth information about the major components of the exit costs for the year ended December 31, 2004:

	Accrued liability at December 31, 2003	Costs charged to expense	Costs paid or settled	Accrued liability at December 31, 2004
Employee severance	$ —	$ 204,894	$ 204,894	$ —
Contract termination	—	361,625	—	361,625
Total	$ —	$ 566,519	$ 204,894	$ 361,625

The Company expects the total costs to be incurred in the closure of the Australian facility, including amounts to be recognized in future periods, to approximate $0.7 million.

Additionally, pursuant to SFAS 144 *"Accounting for the Impairment or Disposal of Long-Lived Assets,"* the Company recorded a $0.1 million charge to reduce the carrying value of the Australian laboratory and office equipment to the estimate of its net realizable value.

The exit costs and impairment of long-lived assets charged to expense are included in selling, general and administrative expenses in the consolidated statements of operations.

Shipping and handling costs

The Company typically does not charge customers for shipping and handling costs. These costs are included in selling, general and administrative expenses and totaled $0.4 million for Fiscal 2004, $0.1 million for Fiscal 2003 and $0.0 million for Fiscal 2002.

Advertising cost

Advertising costs are expensed as incurred and include the costs of public relations activities in Europe and Australia. These costs are included in selling, general and administrative expenses and totaled $0.3 million for Fiscal 2004, $0.4 million for Fiscal 2003 and $0.0 million for Fiscal 2002.

Stock-based compensation

The Company accounts for its stock-based compensation under the provisions of SFAS No. 123 *"Accounting for Stock Based Compensation."* Under SFAS No. 123, the Company is permitted to either

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

The Company from time to time issues common stock, stock options or common stock warrants to acquire services or goods from non-employees. Common stock, stock options and common stock warrants issued to other than employees or directors are recorded on the basis of their fair value, as required by SFAS No. 123, which is measured as of the date required by EITF Issue 96-18, *"Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services"*. In accordance with EITF 96-18, the stock options or common stock warrants are valued using the Black-Scholes model on the basis of the market price of the underlying common stock on the "valuation date", which for options and warrants related to contracts that have substantial disincentives to non-performance is the date of the contract, and for all other contracts is the vesting date. Expense related to the options and warrants is recognized on a straight-line basis over the shorter of the period over which services are to be received or the vesting period. Where expense must be recognized prior to a valuation date, the expense is computed under the Black-Scholes model on the basis of the market price of the underlying common stock at the end of the period, and any subsequent changes in the market price of the underlying common stock up through the valuation date is reflected in the expense recorded in the subsequent period in which that change occurs. See Note 8.

In December 2002, the Financial Accounting Standards Board ("FASB") issued SFAS No. 148, *"Accounting for Stock-Based Compensation-Transition and Disclosure"*. SFAS No. 148 also amends the disclosure requirements of SFAS No. 123, requiring prominent disclosure in annual and interim financial statements regarding a company's method for accounting for stock-based employee compensation and the effect of the method on reported results. While Isolagen continues to utilize the disclosure-only provisions of SFAS No. 123, the Company has modified its disclosures to comply with SFAS No. 148.

Had compensation costs for the Company's stock option plan been determined based on the fair value at the grant date in 2004, 2003 and 2002 consistent with the provisions of SFAS No. 123 and SFAS 148, the Company's net loss and net loss per share would have increased to the pro forma amounts indicated below:

	Year ended December 31,		
	2004	2003	2002
Net loss—as reported	$ (21,474,469)	$ (11,268,294)	$ (5,433,055)
Plus: stock-based employee compensation expense (gain) included in reported net loss, net of related tax effects of $0	373,147	—	—
Less: total stock based employee compensation determined under fair value based method for all awards granted to employees, net of related tax effect of $0	(4,665,753)	(13,678,048)	(1,679,158)
Net loss—pro forma	$ (25,767,075)	$ (24,946,342)	$ (7,112,213)
Net loss per share—as reported			
Basic and diluted	$ (0.71)	$ (0.58)	$ (0.36)
Net loss per share—pro forma			
Basic and diluted	$ (0.86)	$ (1.29)	$ (0.47)

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

	Year ended December 31,		
	2004	2003	2002
Expected life (years)	5 years	3 years	6 years
Interest rate	4%	4%	4%
Dividend yield	—	—	—
Volatility	71%	71-80%	129%

Income taxes

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

Loss per share data

Basic loss per share is calculated based on the weighted average common shares outstanding during the period, after giving effect to the manner in which the merger was accounted for as described in Note 1. Diluted earnings per share also gives effect to the dilutive effect of stock options, warrants (calculated based on the treasury stock method) and convertible notes and convertible preferred stock. The Company does not present diluted earnings per share for years in which it incurred net losses as the effect is antidilutive.

At December 31, 2004, options and warrants to purchase 8,302,356 shares of common stock at exercise prices ranging from $1.50 to $11.38 per share were outstanding, but were not included in the computation of diluted earnings per share as their effect would be antidilutive, and 9,828,009 shares issuable upon the conversion of the Company's convertible notes, at a conversion price of approximately $9.16, were not included as their effect would be antidilutive.

Comprehensive loss

Comprehensive loss encompasses all changes in equity other than those with shareholders and consists of net loss and foreign currency translation adjustments and unrealized gains and losses on available-for-sale marketable debt securities. The Company does not provide for U.S. income taxes on foreign currency translation adjustments since it does not provide for such taxes on undistributed earnings of foreign subsidiaries.

Fair Value of Financial Instruments

The Company's financial instruments consist of accounts receivable, marketable debt securities, accounts payable and convertible subordinated debentures. The fair values of the Company's accounts receivable, accounts payable, and convertible subordinated debentures approximate, in the Company's opinion, their respective carrying amounts. The Company's marketable debt securities are carried at fair value.

Reclassifications

In the fourth quarter of Fiscal 2004 the Company changed the manner by which it classifies the costs incurred in its London and Australia facilities as either costs of sales or selling, general and administrative expenses. The Company believes that the new classifications better reflect the primary purpose and functions of each of these facilities. The new manner of classifying these costs is reflected in the accompanying consolidated statements of operations for all periods presented, as well as in the unaudited summarized quarterly financial data presented in Note 11. The reclassifications did not have any effect on net loss or net loss per share.

In the fourth quarter of Fiscal 2004 the Company changed the manner by which it classifies losses on disposal of assets and includes these amounts in selling, general and administrative expenses. The new manner of classifying these costs is reflected in the summarized quarterly financial data. The reclassifications did not have any effect on net loss or net loss per share.

Recent accounting pronouncements

In November 2004, the FASB issued SFAS No. 151, *"Inventory Costs, an Amendment of ARB No. 43, Chapter 4."* SFAS No. 151 retains the general principle of ARB No. 43, Chapter 4, "Inventory Pricing," that inventories are presumed to be stated at cost; however, it amends ARB No. 43 to clarify that abnormal amounts of idle facilities, freight, handling costs and spoilage should be recognized as current period expenses. Also, SFAS No. 151 requires fixed overhead costs be allocated to inventories based on normal production capacity. The guidance of SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The Company believes that implementing SFAS No. 151 should not have a material impact on its financial condition.

In December 2004, the FASB issued SFAS No. 123 (Revised 2004), *"Share Based Payment,"* which eliminates the use of APB Opinion No. 25 and will require the Company to measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost will be recognized over the period during which an employee is required to provide service in exchange for the reward—the requisite service period. No compensation cost is recognized for equity instruments for which employees do not render the requisite service. The grant-date fair value of employee share options and similar instruments will be estimated using option-pricing models adjusted for the unique characteristics of those instruments. SFAS No. 123 (Revised 2004) is effective for the first interim or annual reporting period that begins after June 15, 2005 (the quarter beginning July 1, 2005 for the Company) and must be applied to all options granted or modified after its effective date and also to recognize the cost associated with the portion of any option awards made before its effective date for with the associated service has not been rendered as of its effective date. The Company is still studying the requirements of SFAS No. 123 (Revised 2004) and has not yet determined what impact it will have on the Company's results of operations and financial position.

In December, 2004 the FASB issued SFAS No. 153, *"Exchanges of Nonmonetary Assets—an amendment of APB Opinion No. 29."* APB Opinion No. 29 provided an exception to the basic measurement principle (fair value) for exchanges of similar productive assets. That exception required that some nonmonetary exchanges, although commercially substantive, be recorded on a carryover basis. SFAS No. 153 amends APB Opinion No. 29 to eliminate the exception to fair value for exchanges of similar productive assets and replace it with a general exception for exchange transactions that do not have commercial substance, which are defined as transactions that are not expected to result in significant changes in the cash flows of the reporting entity. SFAS No. 153 is effective for nonmonetary exchanges occurring in fiscal periods beginning after June 15, 2005. The Company does not expect that SFAS No. 153 will have a material affect on our financial statements.

Note 3—Property and Equipment

Property and equipment is comprised of:

	December 31,	
	2004	2003
Lab equipment	$ 1,788,159	$ 1,124,697
Computer equipment and software	1,975,502	227,743
Office furniture and fixtures	42,232	41,468
Leasehold improvements	2,250,921	1,835,236
	6,056,814	3,229,144
Less: Accumulated depreciation	(2,421,822)	(1,007,306)
Property and equipment, net	$ 3,634,992	$ 2,221,838

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

	Year ended December 31,		
	2004	2003	2002
Cost of sales	$ 399,644	$ 387,951	$ 41,057
Selling, general and administrative expenses	903,654	447,479	58,755
Total depreciation expense	$ 1,303,298	$ 835,430	$ 99,812

Note 4—Intangible Assets

Effective January 31, 2003, the Company entered into an Intellectual Property Purchase Agreement to acquire two pending patent applications titled "Augmentation and Repair of Vocal Cord Tissue Defects" and "A Method of Using Autologous Fibroblasts to Promote Healing of Wounds and Fistulas." As consideration, the Company issued the seller, on March 31, 2003, 100,000 shares of its Common Stock and royalty equal to (a) 5% of all revenues recognized by the Company or its Affiliates from commercial application of the Intellectual Property made, provided, distributed, sold or manufactured directly by the Company or its Affiliates, or (b) 25% of all revenues recognized by the Company or its Affiliates from licensing, sublicensing, transferring or selling the Intellectual Property to a third party, without offset or deduction for general and administrative or operating costs, subject to a total maximum royalty of $2 million. The Company has recorded an intangible asset of $540,000 related to the acquisition of the Intellectual Property and intends to amortize this cost over the life of any future patent granted.

Note 5—Convertible Subordinated Notes

On November 3, 2004 the Company completed the private placement of $75,000,000 aggregate principal amount of 3.5% Convertible Subordinated Notes Due 2024 (the "3.5% Subordinated Notes"). 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 $15,000,000 of additional 3.5% Subordinated Notes through December 2, 2004. On November 5, 2004 the Company completed the private placement of the additional $15,000,000 aggregate principal amount of 3.5% Subordinated Notes. The Company received net proceeds of approximately $14.5 million after the deduction of discounts, commissions and offering expenses. The total net proceeds to the Company were approximately $86.2 million after the deduction of commissions and offering expenses.

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

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

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

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

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

In the event a change in control occurs on or before November 9, 2009, the holders of the 3.5% Subordinated Notes may require the Company to purchase all or a portion of their notes at a purchase price equal to 100% of the principal amount of the 3.5% Subordinated Notes to be purchased plus accrued and unpaid interest and the payment of a "make-whole" payment which is based on the date on which the change in control occurs and the price per share paid for the Company's common stock in such change in control transaction. The Company will be allowed to pay for the repurchase of the 3.5% Subordinated Notes and accrued and unpaid interest in cash or, at its option, shares of its common stock, and the Company will be allowed to make the make-whole payment in cash or, at its option, such other form of consideration as is paid to its common stockholders in the change of control transaction. In addition, in the event a change in control occurs on or before November 9, 2009, the holders of the 3.5% Subordinated Notes that convert their 3.5% Subordinated Notes into shares of the Company's common stock in connection with such change of control transaction will also be entitled to receive the make-whole payment.

The 3.5% Subordinated Notes were issued in an offering not registered under the Securities Act of 1933, as amended ("the Securities Act'). However, the Company is obligated to file with the SEC, on or prior to 90 days following the date the 3.5% Subordinated Notes were originally issued, a shelf

registration statement covering resales of the 3.5% Subordinated Notes and the shares of the Company's common stock issuable upon the conversion of the 3.5% Subordinated Notes, and to use its reasonable best efforts to cause the shelf registration statement to be declared effective under the Securities Act on or prior to 180 days following the date the 3.5% Subordinated Notes were originally issued. If the Company should fail to meet the registration obligations described above, the interest rate payable of the 3.5% Subordinated Notes will increase by 0.5% per annum for the period the Company is not in compliance with the registration obligations.

Note 6—Income Taxes

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

	Year ended December 31,		
	2004	2003	2002
US	$ 14,353,454	$ 7,494,993	$ 4,069,592
Non-US	$ 7,121,015	$ 3,773,301	$ 1,363,463
	$ 21,474,469	$ 11,268,294	$ 5,433,055

The components of the Company's deferred tax assets (liabilities) at December 31, 2004 and 2003 are as follows:

	December 31,	
	2004	2003
Deferred tax assets and liabilities:		
Loss carryforwards	$ 12,918,221	$ 5,475,308
Accrued expenses and other	1,317,536	—
Property and equipment	(40,282)	(134,141)
Deferred revenue	—	(130,183)
	14,195,475	5,210,984
Less: Valuation allowance	(14,195,475)	(5,210,984)
	$ —	$ —

As of December 31, 2004, the Company had generated US net operating loss carryforwards of approximately $26.0 million which expire from 2005 to 2019 and net loss carryforwards in certain non-US jurisdictions of approximately $12.7 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 expirations 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, 2004 and 2003. The valuation allowance increased $9.0 million, $0.8 million and $1.5 million during 2004, 2003 and 2002, respectively due to the Company's current period 2004, 2003 and 2002 net loss, respectively.

Note 7—Commitments and Contingencies

Leases

The Company has entered into leases for office, warehouse and laboratory facilities in Houston, Texas, London, England and Sydney, Australia under third party non-cancelable operating leases through 2010. Future minimum lease commitments at December 31, 2004 are as follows:

Year Ending December 31		
2005	$	794,631
2006		685,180
2007		326,679
2008		228,675
2009		178,188
Thereafter		14,849
Total	$	2,228,202

For the years ended December 31, 2004, 2003 and 2002, rental expense totaled $537,668, $359,065, and $105,206, respectively.

Certain officers of the Company provided office space and laboratory facilities in Houston, Texas at no charge until August 2003. Beginning September 2003, the lease rate is approximately $1.80 per month per square foot.

As discussed in Note 2, in September, 2004 the Company adopted a plan to close its Australia facilities. The lease on the Company's Australia facilities was originally due to expire on December, 31, 2004. In the fourth quarter of 2004 the Company negotiated an expansion on that lease through May 31, 2005. The Company does not expect to incur any material costs in connection with the restoration of the leased property.

License agreement

In 2000, the Company granted exclusive rights to develop and market its technologies and products within Japan. Should the development efforts result in a marketable product, the Company will receive royalties based on product sales. Upon execution of the license agreement, the Company received an initial up-front fee of $400,000 which was deferred and will be recognized on a ratable basis over the five year term of the agreement in accordance with the terms of the agreement. For the year ended December 31, 2002, the Company recognized $40,000 of contract revenues pursuant to this agreement (no revenue was recognized in Fiscal 2004 or Fiscal 2003).

During 2002, the Company began negotiations to revoke the license agreement. As a result, the Company reclassified to a payable the remaining deferred revenue totaling $240,000 and accrued an additional $160,000 in anticipation of a settlement totaling approximately $400,000. The $400,000 was settled for a payment of $375,000 in the fourth quarter 2004.

Distribution agreement

In April 2003, the Company entered into a distribution agreement with Equipmed Pty. Ltd ("Equipmed"). Equipmed has the exclusive right as the Company's distributor in Australia and New Zealand of services utilizing the Company's technology for its autologous cellular system for soft tissue regeneration and other therapies in the cosmetic dermatological surgery markets (i.e., exclusively for wrinkle and acne reduction) within Australia and New Zealand.

Employment agreements

The Company has entered into employment agreements with Vaughan Clift, Frank DeLape, Michael Macaluso, Jeffrey Tomz, Robert Bitterman, Kimberley Forbes-McKean and Dennis Bevan.

Mr. Clift, Vice President of Operations, entered into an employment agreement, dated May 28, 2002, for a term of thirty-six (36) months at an annual base salary of $175,500. Mr. Clift is eligible for an annual bonus to be determined by the Board of Directors in its sole discretion. If the employment agreement is terminated without cause, Mr. Clift will be entitled to a two (2) month severance payment. In the fourth quarter of 2004, Mr. Clift's annual base salary was increased to $250,000.

Mr. DeLape, Chairman of the Board, entered into an employment agreement dated September 5, 2003, with an initial term ending July 31, 2006 and providing for a base salary of $325,000, subject to the right of the Board of Directors to increase his salary from time to time. Mr. DeLape is entitled to receive an annual bonus in an amount to be determined by the Compensation Committee. If Mr. DeLape's performance satisfies criteria to be established by the Compensation Committee, his target bonus will be 40% of his annual salary. The agreement also provides that Mr. DeLape will receive employee stock options to purchase 300,000 shares of common stock at an exercise price equal to the average closing transaction price on the ten trading days preceding the grant. 300,000 options were granted to Mr. DeLape on September 5, 2003 with an exercise price of $9.81. The option has a term of ten years and will vest and become exercisable ratably over the last six calendar quarters of his employment agreement. The vesting of the option will accelerate in the event of a change in control of the Company, the sale of substantially all of the assets of the Company or the merger out of existence of the Company. The agreement also provides Mr. DeLape with disability and life insurance benefits, a car allowance and wireless communications benefits. Mr. DeLape's employment may be terminated at any time, provided that if his employment is terminated without "Cause" or if he terminates his employment for "Good Reason" as those terms are defined in the agreement, he will be entitled to receive a severance payment equal to the greater of (i) the salary payable over the remaining term of his agreement or (ii) eighteen months salary, as well as a bonus computed on the basis of the greater of (a) the amount determined under the agreement by the Compensation Committee or (b) $70,000.

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

Mr. Tomz, Chief Financial Officer and Secretary, entered into an employment agreement dated September 5, 2003 with an initial term ending July 15, 2005 and providing for a base salary of $200,000, subject to the right of the Board of Directors to increase his salary from time to time. Mr. Tomz is entitled to receive an annual bonus in an amount to be determined by the Compensation Committee. If Mr. Tomz's performance satisfies criteria to be established by the Compensation Committee, his target bonus will be 30% of his annual salary. Mr. Tomz's employment may be terminated at any time, provided that if his employment is terminated without "Cause" or if he terminates his employment for "Good Reason" as those terms are defined in the agreement, he will be entitled to a six month severance payment. In the event of a change in control of the Company, the sale of substantially all of the assets of the Company, a merger of the Company in which the Company is not the surviving entity, or the termination of his employment (other than for Cause) the vesting of any options owned by him shall accelerate.

Mr. Bitterman, Chief Executive Officer and President, entered into an employment agreement dated September 1, 2004 with an initial term ending December 31, 2007 and providing for a base salary of $400,000, subject to the right of the Board of Directors to increase his salary from time to time.

Mr. Bitterman is entitled to receive an annual bonus in an amount to be determined by the Compensation Committee. If Mr. Bitterman's performance satisfies criteria to be established by the Compensation Committee, his target bonus will be 50% of his annual salary. The agreement also provides that Mr. Bitterman will receive employee stock options to purchase 500,000 shares of common stock at an exercise price equal to the average closing transaction price on the ten trading days preceding the grant. 500,000 options were granted to Mr. Bitterman on September 1, 2004 with an exercise price of $8.10. If Mr. Bitterman achieves certain criteria during the term of the Agreement, then prior to September 30, 2005, he will be eligible to earn an additional option to purchase 166,666 shares of Isolagen common stock at an exercise price equal to the average market value of the common stock during the ten days preceding any such additional issuance. The options granted, and any additional options that may be granted as described above, have a term of ten years and vest ratably on a monthly basis over three years. The vesting provisions of each of these options would accelerate and Mr. Bitterman would be entitled to a severance payment equal to his base salary plus a pro rata portion of his bonus, if any, for the greater of twelve months or the remainder of the term of the Agreement, if Mr. Bitterman were terminated without "cause," or if Mr. Bitterman were to terminate his employment with Isolagen for "good reason" (each of the terms as defined in the Agreement). During any period in which severance payments are being made, Mr. Bitterman has agreed not to compete with Isolagen.

Dr. Forbes-McKean, Senior Vice President and Chief Technical Science Officer, entered into an employment agreement dated September 13, 2004 with an initial term ending September 30, 2005 and providing for a base salary of $260,000, subject to the right of the Board of Directors to increase her salary from time to time. Dr. Forbes-McKean is entitled to receive an annual bonus in an amount to be determined by the Compensation Committee. If Dr. Forbes-McKean's performance satisfies criteria to be established by the Compensation Committee, her target bonus will be 40% of his annual salary. The agreement also provides that Dr. Forbes-McKean will receive employee stock options to purchase 175,000 shares of common stock at an exercise price equal to the average closing transaction price on the ten trading days preceding the grant. 175,000 options were granted to Dr. Forbes-McKean on September 13, 2004 with an exercise price of $8.53. The option has a term of ten years and vest ratably on an annual basis over three years. The vesting provisions of the option would accelerate and Dr. Forbes-McKean would be entitled to a severance payment equal to her base salary for the greater of twelve months or the remainder of the term of the Agreement, if Dr. Forbes-McKean were terminated without "cause," or if Dr. Forbes-McKean were to terminate her employment with Isolagen for "good reason" (each of the terms as defined in the Agreement). During any period in which severance payments are being made, Dr. Forbes-McKean has agreed not to compete with Isolagen.

Mr. Bevan, Vice President International Commercial Operations, entered into an employment agreement dated September 27, 2004 with an initial term ending September 30, 2005 and providing for a base salary of $200,000, subject to the right of the Board of Directors to increase his salary from time to time. Mr. Bevan is entitled to receive an annual bonus in an amount to be determined by the Compensation Committee. If Mr. Bevan's performance satisfies criteria to be established by the Compensation Committee, his target bonus will be 37.5% of his annual salary. The agreement also provides that Mr. Bevan will receive employee stock options to purchase 150,000 shares of common stock at an exercise price equal to the average closing transaction price on the ten trading days preceding the grant. 150,000 options were granted to Mr. Bevan on September 27, 2004 with an exercise price of $9.64. The option has a term of ten years and vest ratably on an annual basis over three years. The vesting provisions of the option would accelerate and Mr. Bevan would be entitled to a severance payment equal to his base salary for the greater of twelve months or the remainder of the term of the Agreement, if Mr. Bevan were terminated without "cause," or if Mr. Bevan were to terminate his employment with Isolagen for "good reason" (each of the terms as defined in the Agreement). During any period in which severance payments are being made, Mr. Bevan has agreed not to compete with Isolagen.

Consulting agreement

Effective August 20, 2001, the Company entered into an agreement with Cato Research Ltd. to provide drug development, regulatory advisory and other services. Pursuant to the terms of the agreement, the Company issued 133,333 shares of common stock with an assigned value of $200,000 as a retainer fee, which was capitalized as a prepaid expense. As services were rendered, 80% of the invoiced amount was payable in cash with the remaining 20% payable through a reduction in the retainer fee. At December 31, 2002, $120,350 was capitalized as other assets related to this agreement. On March 31, 2003, the agreement with Cato Research Ltd. was terminated and 79,382 shares of common stock were cancelled.

SEC Enforcement

On October 9, 1996, the Company was advised by the Enforcement Division of the Securities and Exchange Commission (the "Commission") that it is considering recommending that the Commission bring an enforcement action, which could include a civil penalty, against the Company in U.S. District Court for failing to file timely periodic reports in violation of Section 13(a) of the Securities and Exchange Act of 1934 and the rules thereunder.

In October 1996, the Company also received a request for the voluntary production of information to the Enforcement Division of the Commission related to the resignation of Coopers & Lybrand LLP and the termination of Arthur Andersen LLP and the appointment of Jones, Jensen & Company as the Company's independent public accountants and the reasons therefore. In addition, the Company was requested to provide certain information respecting its previous sales of securities. The Company cooperated in providing information in response to these inquiries in early 1997. The Company has not been advised of the outcome of the foregoing, and has had no further contact by the Enforcement Division of the Commission.

Note 8—Equity, Stock Plan and Warrants

Uncompensated contributed services

From the date of the Merger through July 15, 2003, the Company did not pay compensation to certain officers and directors. Accordingly, the Company recorded imputed compensation expense for the estimated fair value of these services. The uncompensated contributed services recorded totaled $0, $200,000, $400,000 and $155,556 for the years ended December 31, 2004, 2003, 2002 and 2001, respectively. The value of the contributed services was based upon the Company's estimate of their fair market value. This contribution of services was recorded as an increase to compensation expense and increase in additional paid in capital.

Equity instruments issued to non-employees

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

Common Stock

During the year ended December 31, 2002, the Company issued 38,400 shares of common stock upon the exercise of stock options for cash exercise proceeds totaling $57,600.

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 $18,455,561.

During the year ended December 31, 2003, the Company issued 400,600 shares of common stock upon the exercise of stock options for cash exercise proceeds totaling $681,900 and issued 327,825 shares of common stock in a cashless exercise of warrants.

During the three months ended March 31, 2004, the Company issued 19,000 shares of common stock for cash totaling $102,720 in connection with the exercise of stock options and warrants and issued 78,526 shares of common stock in exchange for cashless exercise of warrants.

During the three months ended June 30, 2004, the Company issued a) 7,200,000 shares of common stock, at $8.50 per share, for cash totaling net $56.8 million in connection with the secondary offering completed in June 2004; and b) 51,828 shares of common stock in exchange for cashless exercise of warrants. During the three month ended June 30, 2004, there were no shares of common stock issued for cash in connection with the exercise of stock options or warrants.

During the three months ended September 30, 2004, the Company issued a) 138,270 shares of common stock for cash totaling $249,695 in connection with exercise of stock options and warrants; and b) issued 7,431 shares of common stock in exchange for cashless exercise of warrants.

During the three months ended December 31, 2004, the Company issued 27,652 shares of common stock in exchange for cashless exercise of warrants.

Treasury Stock

As discussed in Note 5, in November, 2004 the Company repurchased 4,000,000 shares of its common stock for an aggregate of $25,974,000, of which 2,000,000 shares were repurchased from Frank DeLape, the Chairman of the Board of Directors, Michael Macaluso, a 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.

Series A 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 the 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 are 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 has been 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 $502,661.

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 $10,178,944 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.

Series B Convertible Preferred Stock

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 $3,919,078. 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 $1,244,880 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.

Conversion of Preferred Stock

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

2001 Stock Option and Stock Appreciation Rights Plan

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

In January 2004, the Company issued under the Stock Plan a total of 300,000 options to purchase its common stock with an exercise price of $6.00 per share to three independent board members. The options vest over a three year period and expire in January 2014. Compensation expense for these options of $0.4 million was recorded in the three months ended March 31, 2004 as these options had a cashless exercise provision. Compensation gain for these options of $0.1 million was recorded in the three months ended June 30, 2004. The cashless exercise provision for these options were eliminated on May 10, 2004, thus an expense (income) will no longer be recorded subsequent to that date.

In the second quarter of 2004, the Company issued a total of 265,000 options to purchase its common stock with an exercise price ranging from $8.54 to $11.38 per share to various employees. The

options vest over a three year period from the date of grant. In the second quarter of 2004, the Company issued 30,000 options to purchase its common stock with an exercise price of $9.00 to one independent board member. The options vest after twelve months from the date of grant.

In the fourth quarter of 2004, the Company issued a total of 40,000 options to purchase its common stock with an exercise price of ranging from $7.20 to $8.83 per share to various employees. 35,000 of these options vest on April 29, 2005. 5,000 of these options vest over a three year period from the date of grant.

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

In January 2004, the Company issued 160,000 options to purchase its common stock with an exercise price of $6.00 per share to a consultant. The options vest over a three year period, subject to certain acceleration clauses. In February 2004, the Company issued 100,000 options to purchase its common stock with an exercise price of $10.49 per share to a consultant. The options vest over a three year period from the date of grant.

In the second quarter of 2004, an employee retired 300,000 options to purchase common stock.

In the fourth quarter of 2004, the Company issued a total of 190,000 options to purchase its common stock with an exercise price ranging from $6.98 to $8.75 to various employees. The options vest over a three year period from the date of grant.

Other Stock Options

In September 2004, the Company issued 920,000 options to purchase its common stock with an exercise price ranging from $8.10 to $10.11 per share to various new employees. The options vest over a three year period from the date of grant. 825,000 of these options were granted at exercised prices that were from $0.06 to $0.54 less than the market price of the common stock on the date of grant. Total stock compensation expense of $308,750 is being charged to expense on a straight line basis over the three year vesting periods.

In the fourth quarter of 2004, the Company issued 185,000 options to purchase its common stock with an exercise price ranging from $6.76 to $9.75 per share to various new employees. The options vest over a three year period from the date of grant.

Warrants and Options Issued for Services

As of December 31, 2004, the Company has outstanding 653,600 warrants and options issued to non-employees under consulting and distribution agreements. The following sets forth certain information concerning these warrants and options:

	Vested	Unvested
Warrants and options outstanding	371,100	282,500
Vesting period	n/a	3 to 36 months
Range of exercise prices	$1.50 to $10.49	$6.00 to $10.49
Weighted average exercise price	$4.71	$6.11
Expiration dates	2007 to 2013	2007 to 2013

Expense related to these contracts was $1.5 million, 0.4 million and 0.2 million for the years ended December 31, 2004, 2003, 2002, respectively.

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

	2004	2003	2002
Expected life (years)	5 years	10 years	10 years
Interest rate	4%	4%	4%
Dividend yield	—	—	—
Volatility	83%	83%	83%

Summary Stock Option and Warrant Information

Information regarding the options and warrants granted in 2004, 2003 and 2002 is as follows:

	Options Year Ended December 31,			Warrants Year Ended December 31,		
	2004	2003	2002	2004	2003	2002
Outstanding, beginning of year	5,849,100	4,252,100	3,792,500	1,445,169	1,533,000	450,000
Granted	2,190,000	2,315,000	698,000	—	349,600	1,533,000
Exercised	(125,000)	(400,600)	(38,400)	(246,913)	(422,431)	—
Expired or cancelled	(360,000)	(317,400)	(200,000)	(450,000)	(15,000)	(450,000)
Outstanding, end of year	7,554,100	5,849,100	4,252,100	748,256	1,445,169	1,533,000
Exercisable, end of year	4,097,156	2,999,100	458,017	748,256	985,794	1,243,000
Available for grant, end of year	431,900	961,900	509,500			

The weighted average fair value of options granted for the years ended December 31, 2004, 2003, and 2002 is $5.08, $4.21 and $3.96, respectively.

The weighted average option and warrant exercise price information for 2004, 2003 and 2002 is as follows:

	Options Year Ended December 31,			Warrants Year Ended December 31,		
	2004	2003	2002	2004	2003	2002
Outstanding, beginning of year	$ 5.81	$ 5.08	$ 2.70	$ 2.53	$ 2.05	$ 1.50
Granted during the year	$ 8.36	$ 5.97	$ 6.07	$ —	$ 4.02	$ 1.93
Exercised during the year	$ 2.28	$ 1.70	$ 1.50	$ 2.11	$ 1.93	$ —
Expired or cancelled during the year	$ 9.18	$ 2.50	$ 1.50	$ 2.83	$ 5.94	$ 1.50
Outstanding at end of year	$ 6.44	$ 5.81	$ 5.08	$ 2.48	$ 2.53	$ 2.05
Exercisable at end of year	$ 5.65	$ 5.81	$ 2.08	$ 2.48	$ 2.35	$ 1.94

Significant option and warrant groups outstanding at December 31, 2004, and related weighted average exercise price and life information is as follows:

Grant date	Options Outstanding	Warrants Outstanding	Exercisable	Weighted Exercise Price	Remaining Life (Years)
September 2001	2,600,000	—	2,600,000	$ 6.00	6.67
September 2001	33,500	—	33,500	$ 3.00	6.67
October 2001	40,000	—	40,000	$ 1.50	6.75
November 2001	38,600	—	38,600	$ 1.50	6.83
November 2001	40,000	—	40,000	$ 4.00	6.83
December 2001	10,000	—	10,000	$ 4.00	6.92
December 2001	20,000	—	20,000	$ 2.70	6.92
May 2002	362,000	—	148,000	$ 6.00	7.33
June 2002	20,000	—	20,000	$ 6.00	7.41
June 2002	30,000	—	20,000	$ 6.50	7.41
July 2002	—	211,015	211,015	$ 1.93	2.50
August 2002	—	11,580	11,580	$ 1.93	2.58
October 2002	—	357,415	357,415	$ 1.93	2.75
November 2002	40,000	—	40,000	$ 6.00	7.83
December 2002	115,000	—	87,500	$ 6.00	7.92
January 2003	45,000	—	15,000	$ 6.00	8.00
February 2003	200,000	—	66,500	$ 6.00	8.08
February 2003	1,320,000	—	660,000	$ 4.50	8.08
February 2003	—	60,000	60,000	$ 5.94	8.08
May 2003	—	108,246	108,246	$ 3.50	3.33
May 2003	150,000	—	50,000	$ 3.50	8.33
September 2003	300,000	—	—	$ 9.81	8.67
January 2004	460,000	—	115,000	$ 6.00	9.00
February 2004	100,000	—	37,500	$ 10.49	9.08
April 2004	215,000	—	—	$ 11.38	9.25
April 2004	30,000	—	—	$ 9.00	9.25
May 2004	10,000	—	—	$ 8.90	9.33
May 2004	5,000	—	—	$ 8.54	9.33
June 2004	35,000	—	—	$ 9.61	9.42
September 2004	500,000	—	55,556	$ 8.10	9.67
September 2004	175,000	—	—	$ 8.53	9.67
September 2004	95,000	—	—	$ 10.11	9.67
September 2004	150,000	—	—	$ 9.64	9.67
October 2004	55,000	—	—	$ 9.75	9.75
October 2004	80,000	—	—	$ 8.75	9.75
October 2004	35,000	—	—	$ 8.70	9.75
October 2004	35,000	—	—	$ 8.83	9.75
November 2004	45,000	—	—	$ 6.76	9.84
November 2004	50,000	—	—	$ 6.98	9.84
November 2004	35,000	—	—	$ 7.20	9.84
December 2004	80,000	—	—	$ 7.74	9.92
Total	7,554,100	748,256	4,845,412		

Note 9—Certain Relationships and Related Transactions

Certain officers of the Company, through affiliated companies, provide services to the Company. During 2003, these services consisted primarily of the following: (i) office space and laboratory facilities in Houston, Texas, a portion of which was provided at no charge to the Company through August 2003 (beginning in September 2003, the Company began paying a lease rate of approximately $1.80 per month per square foot), (ii) printing services, and (iii) and computer and information technology systems support.

At December 31, 2004 and 2003, the Company had accrued in accounts payable $14,833 and $95,891, respectively, for services provided by these related parties. During Fiscal 2004 and Fiscal 2003, the Company incurred total expenses for services provided by these related parties of $63,172 and $319,742, respectively.

As discussed in Notes 5 and 8, in November 2004 the Company repurchased 2,000,000 shares of its common stock from Frank DeLape, the Chairman of the Board of Directors, Michael Macaluso, a 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.

Note 10—Segment Information

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

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

	Revenues Year ended December 31,		
	2004	2003	2002
United States	$ —	$ —	$ 42,282
United Kingdom	$ 3,746,806	$ 399,147	$ 48,709
Australia	$ 432,441	$ 46,542	$ —
	$ 4,179,247	$ 445,689	$ 90,991

	Property and Equipment, net As of December 31,		
	2004	2003	2002
United States	$ 1,824,296	$ 605,731	$ 1,090,451
United Kingdom	$ 1,574,077	$ 834,887	$ 730,589
Australia	$ 236,619	$ 781,220	$ 338,873
	$ 3,634,992	$ 2,221,838	$ 2,159,913

	Depreciation Year ended December 31,		
	2004	2003	2002
United States	$ 571,986	$ 415,783	$ 46,522
United Kingdom	$ 294,771	$ 210,357	$ 53,290
Australia	$ 436,541	$ 209,290	$ —
	$ 1,303,298	$ 835,430	$ 99,812

	Capital Expenditures Year ended December 31,		
	2004	2003	2002
United States	$ 1,840,601	$ 328,250	$ 1,129,616
United Kingdom	$ 964,053	$ 126,380	$ 783,879
Australia	$ 7,061	$ 738,527	$ 338,873
	$ 2,811,715	$ 1,193,157	$ 2,252,368

Note 11—Summarized Quarterly Financial Data (unaudited)

For the following three-month periods ended	March 31(a)(b)	June 30(a)(b)	September 30(a)(b)	December 31
2004				
Revenues	$ 289,357	$ 544,246	$ 1,342,804	$ 2,002,840
Cost of sales	742,440	1,013,991	1,753,172	1,981,405
Operating loss	(4,884,849)	(3,880,835)	(6,637,202)	(6,093,389)
Net loss	(4,866,744)	(3,859,319)	(6,435,414)	(6,312,992)
Net loss per share	$ (0.18)	$ (0.14)	$ (0.19)	$ (0.20)

For the following three-month periods ended	March 31(a)(b)	June 30(a)(b)	September 30(a)(b)	December 31(a)(b)
2003				
Revenues	$ 371	$ 79,425	$ 78,575	$ 287,318
Cost of sales	434,486	444,663	550,911	767,162
Operating loss	(2,252,194)	(2,444,465)	(2,763,578)	(3,904,411)
Net loss	(2,189,101)	(2,441,275)	(2,709,433)	(3,928,485)
Net loss per share	$ (0.14)	$ (0.16)	$ (0.14)	$ (0.14)

(a) In the fourth quarter of Fiscal 2004 the Company changed the manner by which it classifies the costs incurred in our Houston, Texas, London and Australia facilities as either costs of sales or selling, general and administrative expenses. The new manner of classifying these costs is reflected in the summarized quarterly financial data. The reclassifications did not have any effect on operating loss, net loss or net loss per share. See Note 2.

(b) In the fourth quarter of Fiscal 2004 the Company changed the manner by which it classifies losses on disposal of assets and includes these amounts in selling, general and administrative expenses. The new manner of classifying these costs is reflected in the summarized quarterly financial data. The reclassifications did not have any effect on net loss or net loss per share.

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Exhibit 10.12

EMPLOYMENT AGREEMENT

THIS EXECUTIVE EMPLOYMENT AGREEMENT (this "Agreement") dated as of September 1, 2004, is by and between Isolagen, Inc., a Delaware corporation (together with its subsidiaries, the "Company" or "Isolagen"), and Robert Bitterman, an individual residing in Radnor Township, Pennsylvania (the "Executive").

W I T N E S S E T H:

WHEREAS, the Executive desires to serve the Company as its President and Chief Executive Officer; and

WHEREAS, the Company desires to employ Executive as its President and Chief Executive Officer;

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

1. *Term of Employment; Office and Duties.*

(a) Commencing on September 1, 2004 (the "Employment Date"), and for an initial term ending December 31, 2007, the Company shall employ the Executive as a senior executive of the Company with the title of President and Chief Executive Officer, with the duties and responsibilities prescribed for such offices in the Bylaws of the Company and such additional duties and responsibilities consistent with such positions as may from time to time be assigned to the Executive by the Board of Directors. Specifically included in the Executive's responsibilities shall be the identification, recruitment and retention of the members of the senior management team of the Company, with the advice and consent of the Board of Directors. Executive agrees to perform such duties and discharge such responsibilities in accordance with the terms of this Agreement. This Agreement shall be renewed for an additional one (1) year term, by the mutual written agreement of the Executive and the Company at least thirty (30) days prior to its expiration.

(b) The Executive shall devote substantially all of his working time to the business and affairs of the Company other than during vacations of four weeks per year and periods of illness or incapacity; provided, however, that nothing in this Agreement shall preclude the Executive from devoting time required: (i) for serving as a director or officer of any organization or entity not in a competing business with the Company, and any other businesses in which the Company becomes involved; (ii) delivering lectures, writing articles or books, or fulfilling speaking engagements; or (iii) engaging in charitable and community activities provided that such activities do not interfere with the performance of his duties hereunder.

(c) The Board of Directors shall appoint Executive to serve on the Board of directors within thirty (30) days of the employment Date.

(d) The Company agrees that Executive may move to promptly establish executive offices of the Company for a senior management team in the Philadelphia, Pennsylvania, area, at a location to be approved by the Board of Directors.

2. *Compensation and Benefits.*

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

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

(a) *Base Salary.* The Company shall pay the Executive a fixed salary ("Base Salary") at a rate of Four Hundred Thousand Dollars ($400,000) per year. The Board of Directors may periodically review the Executive's Base Salary and may determine to increase (but not decrease) the Executive's salary, in accordance with such policies as the Company may hereafter adopt from time to time, if it deems appropriate. Base Salary will be payable in accordance with the customary payroll practices of the Company.

(b) *Bonus.* Executive shall be entitled to a one-time bonus in the amount of $50,000, payable to Executive within thirty (30) days of his commencement of service as President and Chief Executive Officer. Beginning in fiscal year 2005, Executive will also be entitled to receive an annual bonus (the "Annual Bonus"), payable each year subsequent to the issuance of final audited financial statements, but in no case later than 120 days after the end of the Company's most recently completed fiscal year. The final determination on the amount of the Annual Bonus will be made by the Compensation Committee of the Board of Directors, based primarily on mutually agreed upon criteria, established with respect to the ensuing fiscal year, within thirty (30) days of the end of each fiscal year. The Compensation Committee may also consider other more subjective factors in making its determination. The targeted amount of the Annual Bonus shall be 50% of the Executive's base salary. The actual Annual Bonus for any given period may be higher or lower than 50%.

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

(i) The Executive shall be entitled to participate in such disability, health and life insurance and other fringe benefit plans or programs offered to all employees of the Company, as well as to the key executive employees of Company, including a Section 401(k) and retirement plan of the Company as may be established from time to time by the Board of Directors, subject to the rules and regulations applicable thereto. In addition, the Executive shall be entitled to the following benefits.

(ii) Contemporaneous with the execution of this Agreement, the Executive will be granted a non-qualified stock option (the "Employment Option") to purchase 500,000 shares of the Company's Common Stock, par value $.001 per share (the "Common Stock") with an exercise price per share equal to the average closing transaction price on the ten trading days preceding the grant. In the Company's discretion, the Employment Option may be issued pursuant to the Company's existing stock option plans or apart from those plans. The term of the Employment Option will be for a period of five (5) years from the date of grant. The shares eligible for purchase under the Employment Option grant vest ratably, on a monthly basis over the three years following the Employment Date; provided, however, that if Executive's employment with the Company is terminated (i) without "Cause" or (ii) "For Good Reason," all unvested portions of the Employment Option shall vest immediately upon such termination.

(iii) On or before September 1, 2005, the Company will grant to Executive an additional non-qualified stock option (the "Additional Employment Option") to purchase 166,666 shares of the Company's Common Stock with an exercise price per share equal to the average closing transaction price on the ten trading days preceding the grant, provided that Executive has satisfied the conditions that will be agreed to by the Company and Executive in writing on or before March 31, 2005. In the Company's discretion, the Additional Employment Option may be issued pursuant to the Company's existing stock option plans or apart from those plans. To the extent eligible and available, the Additional Employment Option will be Incentive Stock Options. The term of the Additional Employment Option will be for a period of five (5) years

from the date of grant. The shares eligible for purchase under the Employment Option grant vest ratably, on a monthly basis over the three years following the date of grant of the Additional Employment Option; provided, however, that if Executive's employment with the Company is terminated (i) without "Cause" or (ii) "For Good Reason," all unvested portions of the Additional Employment Option, once granted, shall vest immediately upon such termination.

(iv) The vesting of the Employment Option and the Additional Employment Option shall accelerate and vest immediately upon a change in control of the Company as defined in Rule 405 of the Securities Act of 1933 or upon sale of substantially all of the assets of the Company or the merger out of existence of the Company.

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

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

(f) *Death.* The Company shall provide the Executive with a policy of life insurance benefits in the amount of at least Two Million Dollars ($2,000,000). To the extent permitted by the Company's existing life insurance policy, the Executive's life insurance policy will be a portable policy. The Executive agrees to pay for any additional premium payments resulting from providing a portable policy (in comparison to a group policy) and further agrees to have the additional premium payments deducted from his pay. In the event of the Executive's death, the Executive's family shall continue to be covered by all of the Company's medical, health and dental plans, at the Company's expense, to the extent such benefits can be obtained at a reasonable cost, for eighteen (18) months following the Executive's death in accordance with the terms of such plans.

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

(h) *Relocation.* The Company shall reimburse Executive for all reasonable costs incident to relocating Executive and Executive's family (and their household), and provided that they are deductible by the Company against its taxable income, if at any time during the term of employee's employment by the Company the parties shall agree to a relocation to an area greater than fifty miles from the Executive's current residence. These costs shall include, but not be limited to, the costs of packing and moving the household goods, the closing costs and realtor fees associated with the sale of the Executive's residence in Pennsylvania, as well as unpacking of the household goods and all closing costs on Executive's residence at the new location.

(i) *Temporary Living.* In the event of a relocation as described above, the Company will provide up to 6 months of temporary living accommodations for Executive and his family. These accommodations will be appropriate to Executive's needs and the demands of the business.

(j) *Travel.* It is anticipated that Executive will be engaged in regular travel between Philadelphia and Houston. The Company agrees to reimburse all expenses related to such travel

for all members of Executive's family (air travel shall be via coach class) for up to a 6-month period from the Date of Employment.

3. *Business Expenses.*

The Company shall pay or reimburse all reasonable travel and entertainment expenses incurred by the Executive in connection with the performance of his duties under this Agreement, including travel between Executive's current domicile in the Philadelphia, Pennsylvania metropolitan area, travel to the Company's various offices and facilities in the United States and abroad, reimbursement for attending out-of-town meetings of the Board of Directors, and such other travel as may be required or appropriate in Executive's discretion, consistent with duly approved Company budgets, to fulfill the responsibilities of his office, all in accordance with such policies and procedures as the Company may from time to time establish for senior officers and as required to preserve any deductions for federal income taxation purposes to which the Company may be entitled and subject to the Company's normal requirements with respect to reporting and documentation of such expenses. The Company shall provide the Executive with the use of a suitable lodgings during the times he is in Houston, as well as with suitable transportation. The Company shall pay to Executive a non-accountable automobile allowance of one thousand dollars ($1,000) per month for all expenses incurred by the Executive for Executive's automobile (including lease payments, insurance, maintenance, and gasoline). The Company shall also pay or reimburse Executive for all membership fees and dues in appropriate professional associations and organizations utilized by Executive in the course of his service for the Company, as well as all expenses incurred by the Executive for Executive's cellular telephone including monthly service charges, equipment maintenance and all other ancillary charges including, but not limited to, text messaging, paging, and wireless communications.

4. *Termination of Employment.*

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

(a) By the Company, in the event of the Executive's death or Disability (as hereinafter defined) or for Cause (as hereinafter defined). For purposes of this Agreement, "Cause" shall mean either: (i) the indictment of, or the bringing of formal charges against Executive on charges involving criminal fraud or embezzlement; (ii) the conviction of Executive of a crime involving an act or acts of dishonesty, fraud or moral turpitude by the Executive, which act or acts constitute a felony; (iii) Executive having caused the Company to violate the Company's Bylaws; (iv) Executive having committed acts or omissions constituting gross negligence or willful misconduct with respect to the Company including with respect to any valid contract to which the Company is a party; (v) Executive having committed acts or omissions constituting a material breach of Executive's obligations under this Agreement or of Executive's duty of loyalty or fiduciary duty to the Company or any material act of dishonesty or fraud with respect to the Company which are not cured in a reasonable time, which time shall be 30 days from receipt of written notice from the Company of such material breach; or (vi) Executive having committed acts or omissions constituting a material breach of this Agreement which are not cured in a reasonable time, which time shall be 30 days from receipt of written notice from the Company setting forth with specificity the particulars of any such material breach as well as the corrective actions required. A determination that Cause exists as defined in clauses (iv), (v), or (vi) (as to this Agreement) of the preceding sentence shall be made by at least a majority of the members of the Board of Directors. For purposes of this Agreement, "Disability" shall mean the inability of Executive, in the reasonable judgment of a physician jointly appointed by the Executive and Board of Directors, to perform, even with reasonable accommodation, his duties of employment for the Company or any of its subsidiaries because of any physical or mental disability or incapacity, where such disability

shall exist for an aggregate period of more than 120 days in any 365-day period or for any period of 90 consecutive days. The Company shall by written notice to the Executive specify the event relied upon for termination pursuant to this Section 4(a), and Executive's employment hereunder shall be deemed terminated as of the date of such notice. In the event of any termination under this Subsection 4(a), the Company shall pay all amounts then due to the Executive under Section 2(a) of this Agreement for any portion of the payroll period worked but for which payment has not yet been made up to the date of termination, and, if such termination was for Cause, the Company shall have no further obligations to Executive under this Agreement, and any and all options granted hereunder shall terminate according to their terms. In the event of a termination due to Executive's Disability or death, the Company shall comply with its obligations under Sections 2(e) and 2(f).

(b) By the Company, in the absence of Cause, for any reason and in its sole and absolute discretion, provided that in such event the Company shall, as liquidated damages or severance pay, or both, continue to pay to Executive the Base Salary (at a monthly rate equal to the rate in effect immediately prior to such termination) for the longer of the remaining term through December 31, 2007 or twelve months from the date of termination (the "Termination Payments"), when, as and if such payments would have been made in the absence of Executive's termination. The Termination Payments shall be made regardless of Executive's subsequent re-employment as long as any new employment is not in violation of Sections 5 or 6 of this Agreement.

(c) By the Executive for "Good Reason," (as the Executive shall reasonably determine in good faith) which shall be deemed to exist: (i) if the Company's Board of Directors or that of any successor entity of Company, fails to appoint or reappoint the Executive or removes the Executive from the title and/or office of President, or the title and/or office of CEO, of the Company or from any successor entity operating the Company; (ii) if Executive is assigned any duties materially inconsistent with the duties or responsibilities of the President and CEO of the Company as contemplated by this Agreement or any other action by the Company that results in a material diminution in such position, authority, duties, or responsibilities, excluding an isolated, insubstantial, and inadvertent action not taken in bad faith and which is remedied by the Company promptly after receipt of notice thereof given by Executive (but not excluding changes resulting from a sale of the Company, whether by merger, tender offer or otherwise) provided that Executive shall act within 30 days of any such diminution in the scope of his duties, responsibilities, authority or position; (iii) if the Company shall breach or shall have continued to fail to comply with any material provision of this Agreement after a 30-day period to cure (if such failure is curable) following written notice to the Company of such non-compliance; (iv) if the Board of Directors requires Executive without his express written consent to relocate to Houston, Texas, or to any other area outside a thirty (30) mile radius of Radnor Township, Pennsylvania, (v) upon a change in control of the Company, or within twelve (12) months of any such change in control (for these purposes the term "change in control" shall have the meaning set forth in Rule 405 of the Securities Act of 1933) or within twelve (12) months of a sale of substantially all of the assets of the Company or the merger out of existence of the Company. In the event of any termination for "Good Reason" under this Section 4(c), the Company shall, as liquidated damages or severance pay, or both, pay the Termination Payments, as defined in (b) of this Section 4, to Executive, when, as and if such payments would have been made in the absence of Executive's termination.

(d) During any period in which Executive is obligated not to compete with the Company pursuant to Section 5 hereof (unless Executive was terminated for Cause as defined herein), Executive and his family shall continue to be covered by the Company's life, medical, health and death plans. Such coverage shall be at the Company's life, medical, health and death plans. Such coverage shall be at the Company's expense to the same extent as if Executive were still employed

by the Company. In the event of a termination pursuant to Sections 4(b) or 4(c), the Company shall provide to Executive the pro-rata share of his annual bonus, to the extent one is awarded by the Compensation Committee the consideration of which shall be taken in good faith, giving a full month's credit for any partial month worked in that bonus year. Additionally, in the event of a termination pursuant to Sections 4(b) or 4(c), the Company shall provide to Executive, at the Company's expense, outplacement services of a nature customarily provided to a senior executive. Notwithstanding the foregoing, the obligations of the Company pursuant to this Section 4(d) shall remain in effect no longer than the term of the Termination Payments.

5. *Non-Competition.*

During the period of Executive's employment hereunder and during the period, if any, during which payments are required to be made to the Executive by the Company pursuant to Sections 4(b) or 4(c), the Executive shall not, within any state or foreign jurisdiction in which the Company or any subsidiary of the Company is then providing services or products or marketing its services or products (or engaged in active discussions to provide such services), or within a fifty (50) mile radius of any such state, directly or indirectly own any interest in, manage, control, participate in, consult with, render services for, or in any manner engage in any business engaged in by the Company (unless the Board of Directors shall have authorized such activity and the Company shall have consented thereto in writing). The term "business engaged in by the Company" shall mean the development and commercialization of autologous fibroblast system technology for application in, among other therapies, dermatology, surgical and post-traumatic scarring, skin ulcers, cosmetic surgery, periodontal disease, reconstructive dentistry, vocal chord injuries, urinary incontinence, and digestive and gastroenterological disorders and other applications relating to the market for autologous fibroblast or UMC cells and the five derivative cell lines: osteoblast, chondroblast, fibroblast, adipocyte, and neutroectoderm. Investments in less than five percent of the outstanding securities of any class of a corporation subject to the reporting requirements of Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended, shall not be prohibited by this Section 5. At the option of Executive, Executive's obligations under this Section 5 arising after the termination of Executive shall be suspended during any period in which the Company fails to pay to him Termination Payments required to be paid to him pursuant to this Agreement. The provisions of this Section 5 are subject to the provisions of Section 14 of this Agreement.

6. *Inventions and Confidential Information.*

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

provisions of Section 14 hereof, the Executive hereby agrees as follows, recognizing that the Company is relying on these agreements in entering into this Agreement:

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

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

7. *Indemnification.*

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

8. *Litigation Expenses.*

In the event of any litigation or other proceeding between the Company and the Executive with respect to the subject matter of this Agreement and the enforcement of the rights hereunder and such litigation or proceeding results in final judgment or order in favor of the Executive, the Company shall reimburse the Executive for all of his reasonable costs and expenses relating to such litigation or other proceeding, including, without limitation, his reasonable attorney's fees and expenses.

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

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

10. *Survival of Obligations.*

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

11. *Executive's Representations.*

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

12. *Company's Representations.*

The Company hereby represents and warrants to the Executive that (i) the execution, delivery and performance of this Agreement by the Company do not and shall not conflict with, breach, violate or cause a default under any contract, agreement, instrument, order, judgment or decree to which the Company is a party or by which it is bound; (ii) upon the execution and delivery of this Agreement by the Executive, this Agreement shall be the valid and binding obligation of the Company, enforceable in accordance with its terms; and (iii) the Company's representations made by the Board of Directors and members of senior management prior to the execution of this Agreement regarding the science, business or fiscal propriety of the Company are accurate in all material respects.

13. *Enforcement.*

Because the Executive's services are unique and because the Executive has access to confidential information concerning the Company, the parties hereto agree that money damages would not be an adequate remedy for any breach of this Agreement. Therefore, in the event of a breach of this Agreement, the Company may, in addition to other rights and remedies existing in its favor, apply to

any court of competent jurisdiction for specific performance and/or injunctive or other relief in order to enforce, or prevent any violations of, the provisions hereof (without posting a bond or other security).

14. *Severability.*

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

15. *Entire Agreement; Amendment.*

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

16. *Notices.*

All notices, requests, demands and other communications hereunder shall be in writing and shall be deemed to have been duly given if physically delivered, delivered by express mail or other expedited

service or upon receipt if mailed, postage prepaid, via registered mail, return receipt requested, addressed as follows:

(a) To the Company:

Isolagen Technologies, Inc.,
700 Gemini
Suite 100
Houston, TX 77058

and to:

Dilworth Paxson, LLP
3200 Mellon Bank Center
1735 Market Street
Philadelphia, PA 19103-7595
Attn: Susan Stranahan Ciallella,
Esquire

(b) To the Executive:

Robert Bitterman
783 Woodlea Road
Rosemont, PA 19010

Copy to:

Robin Bond, Esq.
88 Militia Hill Drive
Wayne, PA 19087

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

17. *Assignability*.

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

18. *Governing Law*.

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

19. Waiver and Further Agreement.

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

20. Headings of No Effect.

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

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

COMPANY:

ISOLAGEN, INC.

By: /s/ STEVE MORRELL /s/ HENRY TOH

Steve Morrell
Director

Henry Toh
Director

EXECUTIVE:

/s/ ROBERT BITTERMAN

Robert Bitterman

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Exhibit 10.13

EMPLOYMENT AGREEMENT

THIS EXECUTIVE EMPLOYMENT AGREEMENT (the "Agreement") dated as of September 7, 2004, is by and between Isolagen, Inc., a Delaware corporation (together with its subsidiaries, the "Company" or "Isolagen"), and Dr. Kim Forbes-McKean, an individual residing in Chester Springs, Pennsylvania (the "Executive").

W I T N E S S E T H:

WHEREAS, the Executive desires to serve the Company as its Senior Vice President, Chief Technical Science Officer; and

WHEREAS, the Company desires to employ Executive as its Senior Vice President, Chief Technical Science Officer;

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

55398. *Term of Employment; Office and Duties*.

(a) Commencing on September 20, 2004 (the "Employment Date"), and for an initial term ending September 30, 2005, the Company shall employ the Executive as a senior executive of the Company with the title of Senior Vice President, Chief Technical Science Officer, with the duties and responsibilities prescribed for such offices in the Bylaws of the Company and such additional duties and responsibilities consistent with such positions as may from time to time be assigned to the Executive by the President and Chief Executive Officer and the Board of Directors. Executive agrees to perform such duties and discharge such responsibilities in accordance with the terms of the Agreement. The Agreement shall be renewed for an additional one (1) year term, by the mutual written agreement of the Executive and the Company at least thirty (30) days prior to its expiration.

(b) The Executive shall devote substantially all of her working time to the business and affairs of the Company other than during vacations of four weeks per year and periods of illness or incapacity; provided, however, that nothing in the Agreement shall preclude the Executive from devoting time required: (i) for serving as a director or officer of any organization or entity not in a competing business with the Company, and any other businesses in which the Company becomes involved; (ii) delivering lectures, writing articles or books, or fulfilling speaking engagements; or (iii) engaging in charitable and community activities provided that such activities do not interfere with the performance of her duties hereunder.

2. *Compensation and Benefits*.

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

(a) *Base Salary*. The Company shall pay the Executive a fixed salary ("Base Salary") at a rate of Two Hundred Sixty Thousand Dollars ($260,000) per year. The Board of Directors may periodically review the Executive's Base Salary and may determine to increase (but not decrease) the Executive's salary, in accordance with such policies as the Company may hereafter adopt from time to time, if it deems appropriate. Base Salary will be payable in accordance with the customary payroll practices of the Company.

(b) *Bonus*. Executive shall be entitled to a one-time bonus in the amount of $15,000, payable to Executive within thirty (30) days of her commencement of service as Senior Vice President, Chief Technical Science Officer. Beginning in fiscal year 2005, Executive will also be entitled to receive an annual bonus (the "Annual Bonus"), payable each year subsequent to the issuance of

final audited financial statements, but in no case later than 120 days after the end of the Company's most recently completed fiscal year. The final determination on the amount of the Annual Bonus will be made by the Compensation Committee of the Board of Directors, based primarily on mutually agreed upon criteria, established with respect to the ensuing fiscal year, within thirty (30) days of the end of each fiscal year. The Compensation Committee may also consider other more subjective factors in making its determination. The targeted amount of the Annual Bonus shall be 40% of the Executive's base salary. The actual Annual Bonus for any given period may be higher or lower than 40%.

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

(i) Thirty days following the date of Executive's employment, the Executive shall be entitled to participate in such disability, health and life insurance and other fringe benefit plans or programs offered to all employees of the Company, as well as to the key executive employees of Company, including a Section 401(k) and retirement plan of the Company as may be established from time to time by the Board of Directors, subject to the rules and regulations applicable thereto. In addition, the Executive shall be entitled to the following benefits:

(ii) Contemporaneous with the execution of the Agreement, the Executive will be granted a non-qualified stock option (the "Employment Option") to purchase 175,000 shares of the Company's Common Stock, par value $.001 per share (the "Common Stock") with an exercise price per share equal to the average closing transaction price on the ten trading days preceding the grant. In the Company's discretion, the Employment Option may be issued pursuant to the Company's existing stock option plans or apart from those plans. The term of the Employment Option will be for a period of five (5) years from the date of grant. The shares eligible for purchase under the Employment Option grant vest as follows: one-third of the shares vest on the one year anniversary of your Employment Date, one-third of the shares vest on the two year anniversary of your Employment Date, and one-third of the shares vest on the third year anniversary of your Employment Date; provided, however, that if Executive's employment with the Company is terminated (i) without "Cause" or (ii) "For Good Reason," all unvested portions of the Employment Option shall vest immediately upon such termination.

(iii) The vesting of the Employment Option shall accelerate and vest immediately upon a change in control of the Company as defined in Rule 405 of the Securities Act of 1933 in the event that Executive does not continue to be employed by the Company or upon sale of substantially all of the assets of the Company or the merger out of existence of the Company in the event that Executive does not continue to be employed by the successor of the Company or the purchaser of the Company's assets.

(iv) Executive will be eligible for additional grants of options based upon criteria set forth by the Compensation Committee in the third year of her employment. The Compensation Committee may also determine to grant additional options to Executive prior to the third year of her employment, if in consultation with the President and Chief Executive Officer the Compensation Committee in its sole discretion deems such additional grants to be advisable.

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

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

(h) *Travel*. It is anticipated that Executive will be engaged in regular travel including between Philadelphia and Houston. The Company agrees to reimburse all expenses related to such travel (air travel shall be via coach class).

3. *Business Expenses*.

The Company shall pay or reimburse all reasonable travel and entertainment expenses incurred by the Executive in connection with the performance of her duties under the Agreement, including travel between Executive's current domicile in the Philadelphia, Pennsylvania metropolitan area, travel to the Company's various offices and facilities in the United States outside of the Philadelphia metropolitan area and abroad, and such other travel as may be required or appropriate, consistent with duly approved Company budgets, to fulfill the responsibilities of her office, all in accordance with such policies and procedures as the Company may from time to time establish for senior officers and as required to preserve any deductions for federal income taxation purposes to which the Company may be entitled and subject to the Company's normal requirements with respect to reporting and documentation of such expenses. The Company shall provide the Executive with the use of suitable lodgings during the times she is in Houston, as well as with suitable transportation. The Company shall also pay or reimburse Executive for all expenses incurred by the Executive for Executive's cellular telephone including monthly service charges, equipment maintenance and all other ancillary charges including, but not limited to, text messaging, paging, and wireless communications.

4. *Termination of Employment*.

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

(a) By the Company, in the event of the Executive's death or Disability (as hereinafter defined) or for Cause (as hereinafter defined). For purposes of the Agreement, "Cause" shall mean either: (i) the indictment of, or the bringing of formal charges against Executive on charges involving criminal fraud or embezzlement; (ii) the conviction of Executive of a crime involving an act or acts of dishonesty, fraud or moral turpitude by the Executive, which act or acts constitute a felony; (iii) Executive having caused the Company to violate the Company's Bylaws; (iv) Executive having committed acts or omissions constituting gross negligence or willful misconduct with respect to the Company including with respect to any valid contract to which the Company is a party; (v) Executive having committed acts or omissions constituting a material breach of Executive's obligations under the Agreement or of Executive's duty of loyalty or fiduciary duty to the Company or any material act of dishonesty or fraud with respect to the Company which are not cured in a reasonable time, which time shall be 30 days from receipt of written notice from the Company of such material breach; (vi) Executive having committed acts or omissions constituting a material breach of the Agreement which are not cured in a reasonable time, which time shall be 30 days from receipt of written notice from the Company setting forth with specificity the particulars of any such material breach as well as the corrective actions required; or (vii) a failure to observe the policies of the Company or the direction of the Board of Directors or of the President and CEO. A determination that Cause exists as defined in clauses (iv), (v), (vi) (as to the Agreement) or (vii) of the preceding sentence shall be made by at least a majority of the members of the Board of Directors. For purposes of the Agreement, "Disability" shall mean the inability of Executive, in the reasonable judgment of a physician jointly appointed by the Executive and Board of Directors, to perform, even with reasonable accommodation, her duties of employment for the Company or any of its subsidiaries because of any physical or mental disability or incapacity, where such disability shall exist for an aggregate period of more than 120 days in any 365-day period or for any period of 90 consecutive days. The Company shall by written notice to the Executive specify the event relied upon for termination pursuant to the Section 4(a), and

Executive's employment hereunder shall be deemed terminated as of the date of such notice. In the event of any termination under the Subsection 4(a), the Company shall pay all amounts then due to the Executive under Section 2(a) of the Agreement for any portion of the payroll period worked but for which payment had not yet been made up to the date of termination, and, if such termination was for Cause, the Company shall have no further obligations to Executive under the Agreement, and any and all options granted hereunder shall terminate according to their terms. In the event of a termination due to Executive's Disability or death, the Company shall comply with its obligations under Sections 2(e) and 2(f).

(b) By the Company, in the absence of Cause, for any reason and in its sole and absolute discretion, provided that in such event the Company shall, as liquidated damages or severance pay, or both, continue to pay to Executive the Base Salary (at a monthly rate equal to the rate in effect immediately prior to such termination) for the longer of the remaining term through September 30, 2005 or twelve months from the date of termination (the "Termination Payments"), when, as and if such payments would have been made in the absence of Executive's termination. The Termination Payments shall be made regardless of Executive's subsequent re-employment as long as any new employment is not in violation of Sections 5 or 6 of the Agreement.

(c) By the Executive for "Good Reason," (as the Executive shall reasonably determine in good faith) which shall be deemed to exist: (i) if the Company's Board of Directors or that of any successor entity of Company, fails to appoint or reappoint the Executive or removes the Executive from the title and/or office of Senior Vice President, Chief Technical Science Officer of the Company or from any successor entity operating the Company; (ii) if Executive is assigned any duties materially inconsistent with the duties or responsibilities of the Senior Vice President, Chief Technical Science Officer of the Company as contemplated by the Agreement or any other action by the Company that results in a material diminution in such position, authority, duties, or responsibilities, excluding an isolated, insubstantial, and inadvertent action not taken in bad faith and which is remedied by the Company promptly after receipt of notice thereof given by Executive (but not excluding changes resulting from a sale of the Company, whether by merger, tender offer or otherwise) provided that Executive shall act promptly upon any such diminution in the scope of her duties, responsibilities, authority or position; (iii) if the Company shall breach or shall have continued to fail to comply with any material provision of the Agreement after a 30-day period to cure (if such failure is curable) following written notice to the Company of such non-compliance; (iv) if the Board of Directors requires Executive without her express written consent to relocate to Houston, Texas, or to any other area outside a thirty (30) mile radius of Chester Springs, Pennsylvania, (v) upon a change in control of the Company, or within twelve (12) months of any such change in control (for these purposes the term "change in control" shall have the meaning set forth in Rule 405 of the Securities Act of 1933) or within twelve (12) months of a sale of substantially all of the assets of the Company or the merger out of existence of the Company. In the event of any termination for "Good Reason" under the Section 4(c), the Company shall, as liquidated damages or severance pay, or both, pay the Termination Payments, as defined in (b) of the Section 4, to Executive, when, as and if such payments would have been made in the absence of Executive's termination.

(d) During any period in which Executive is obligated not to compete with the Company pursuant to Section 5 hereof (unless Executive was terminated for Cause as defined herein), Executive and her family shall continue to be covered by the Company's life, medical, health and death plans. Such coverage shall be at the Company's expense to the same extent as if Executive were still employed by the Company. In the event of a termination pursuant to Sections 4(b) or 4(c), the Company shall provide to Executive the pro-rata share of her annual bonus, to the extent one is awarded by the Compensation Committee the consideration of which shall be taken in good faith, giving a full month's credit for any partial month worked in that bonus year. Additionally, in

the event of a termination pursuant to Sections 4(b) or 4(c), the Company shall provide to Executive, at the Company's expense, outplacement services of a nature customarily provided to a senior executive. Notwithstanding the foregoing, the obligations of the Company pursuant to the Section 4(d) shall remain in effect no longer than the term of the Termination Payments.

5. *Non-Competition*.

During the period of Executive's employment hereunder and during the period, if any, during which payments are required to be made to the Executive by the Company pursuant to Sections 4(b) or 4(c), the Executive shall not, within any state or foreign jurisdiction in which the Company or any subsidiary of the Company is then providing services or products or marketing its services or products (or engaged in active discussions to provide such services), or within a fifty (50) mile radius of any such state, directly or indirectly own any interest in, manage, control, participate in, consult with, render services for, or in any manner engage in any business engaged in by the Company (unless the Board of Directors shall have authorized such activity and the Company shall have consented thereto in writing). The term "business engaged in by the Company" shall mean the development and commercialization of autologous fibroblast system technology for application in, among other therapies, dermatology, surgical and post-traumatic scarring, skin ulcers, cosmetic surgery, periodontal disease, reconstructive dentistry, vocal chord injuries, urinary incontinence, and digestive and gastroenterological disorders and other applications relating to the market for autologous fibroblast or UMC cells and the five derivative cell lines: osteoblast, chondroblast, fibroblast, adipocyte, and neuroectoderm. Investments in less than five percent of the outstanding securities of any class of a corporation subject to the reporting requirements of Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended, shall not be prohibited by the Section 5. At the option of Executive, Executive's obligations under the Section 5 arising after the termination of Executive shall be suspended during any period in which the Company fails to pay to her Termination Payments required to be paid to her pursuant to the Agreement. The provisions of the Section 5 are subject to the provisions of Section 14 of the Agreement.

6. *Inventions and Confidential Information*

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

(i) During the period of Executive's employment with the Company and thereafter, the Executive will not use, disclose to others, or publish or otherwise make available to any other party any inventions or any confidential business information about the affairs of the Company, including but not limited to confidential information concerning the Company's products. "Confidential

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

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

7. *Indemnification*.

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

8. *Litigation Expenses*.

In the event of any litigation or other proceeding between the Company and the Executive with respect to the subject matter of the Agreement and the enforcement of the rights hereunder and such litigation or proceeding results in final judgment or order in favor of the Executive, the Company shall reimburse the Executive for all of her reasonable costs and expenses relating to such litigation or other proceeding, including, without limitation, her reasonable attorneys' fees and expenses.

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

Nothing in the Agreement shall preclude the Company from combining, consolidating or merging with or into, transferring all or substantially all of its assets to, or entering into a partnership or joint venture with, another corporation or other entity, or effecting any other kind of corporate combination provided that the corporation resulting from or surviving such combination, consolidation or merger, or to which such assets are transferred, or such partnership or joint venture assumes the Agreement and all obligations and undertakings of the Company hereunder. Upon such a consolidation, merger, transfer of assets or formation of such partnership or joint venture, the Agreement shall inure to the benefit of, be assumed by, and be binding upon such resulting or surviving transferee corporation or such partnership or joint venture, and the term "Company," as used in the Agreement, shall mean such

corporation, partnership or joint venture or other entity, and the Agreement shall continue in full force and effect and shall entitle the Executive and her heirs, beneficiaries and representatives to exactly the same compensation, benefits, perquisites, payments and other rights as would have been their entitlement had such combination, consolidation, merger, transfer of assets or formation of such partnership or joint venture not occurred.

10. *Survival of Obligations*.

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

11. *Executive's Representations*.

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

12. *Company's Representations*.

The Company hereby represents and warrants to the Executive that (i) the execution, delivery and performance of the Agreement by the Company do not and shall not conflict with, breach, violate or cause a default under any contract, agreement, instrument, order, judgment or decree to which the Company is a party or by which it is bound; (ii) upon the execution and delivery of the Agreement by the Executive, the Agreement shall be the valid and binding obligation of the Company, enforceable in accordance with its terms.

13. *Enforcement*.

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

14. *Severability*.

In case any one or more of the provisions or part of a provision contained in the Agreement shall for any reason be held to be invalid, illegal or unenforceable in any respect in any jurisdiction, such invalidity, illegality or unenforceability shall be deemed not to affect any other jurisdiction or any other provision or part of a provision of the Agreement, nor shall such invalidity, illegality or unenforceability affect the validity, legality or enforceability of the Agreement or any provision or provisions hereof in any other jurisdiction; and the Agreement shall be reformed and construed in such jurisdiction as if

such provision or part of a provision held to be invalid or illegal or unenforceable had never been contained herein and such provision or part reformed so that it would be valid, legal and enforceable in such jurisdiction to the maximum extent possible. In furtherance and not in limitation of the foregoing, the Company and the Executive each intend that the covenants contained in Sections 5 and 6 shall be deemed to be a series of separate covenants, one for each and every state of the United States and any foreign country set forth therein. If, in any judicial proceeding, a court shall refuse to enforce any of such separate covenants, then such unenforceable covenants shall be deemed eliminated from the provisions hereof for the purpose of such proceedings to the extent necessary to permit the remaining separate covenants to be enforced in such proceedings. If, in any judicial proceeding, a court shall refuse to enforce any one or more of such separate covenants because the total time, scope or area thereof is deemed to be excessive or unreasonable, then it is the intent of the parties hereto that such covenants, which would otherwise be unenforceable due to such excessive or unreasonable period of time, scope or area, be enforced for such lesser period of time, scope or area as shall be deemed reasonable and not excessive by such court.

15. *Entire Agreement; Amendment*.

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

16. *Notices*.

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

(a) To the Company:

Isolagen Technologies, Inc.,
700 Gemini Suite 100
Houston, TX 77058

and to:

Dilworth Paxson, LLP.
3200 Mellon Bank Center
1735 Market Street
Philadelphia, PA 19103-7595
Attn: Susan Stranahan Ciallella,
Esquire

(b) To the Executive:

Dr. Kim Forbes-McKean
16 Houndstooth Lane
Chester Springs, PA 19425

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

17. *Assignability*.

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

then the Agreement shall be binding on the transferee of the business of the Company whether or not the Agreement is expressly assigned to the transferee.

18. *Governing Law*.

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

19. *Waiver and Further Agreement*.

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

20. *Headings of No Effect*.

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

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

COMPANY:

ISOLAGEN, INC.

By: _____

Robert Bitterman, President and Chief Executive Officer

EXECUTIVE:

_____

Dr. Kim Forbes-McKean

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Exhibit 10.14

EMPLOYMENT AGREEMENT

THER EXECUTIVE EMPLOYMENT AGREEMENT (the "Agreement") dated as of September , 2004, is by and between Isolagen, Inc., a Delaware corporation (together with its subsidiaries, the "Company" or "Isolagen"), and Dennis L. Bevan, an individual residing in Phoenixville, Pennsylvania (the "Executive").

WITNESSETH:

WHEREAS, the Executive desires to serve the Company as its Vice President, International Commercial Operations; and

WHEREAS, the Company desires to employ Executive as its Vice President, International Commercial Operations;

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

1. *Term of Employment; Office and Duties*.

(a) Commencing on September , 2004 (the "Employment Date"), and for an initial term ending September 30, 2005, the Company shall employ the Executive as a senior executive of the Company with the title of Vice President, International Commercial Operations, with the duties and responsibilities prescribed for such office in the Bylaws of the Company and such additional duties and responsibilities consistent with such positions as may from time to time be assigned to the Executive by the President and Chief Executive Officer and the Board of Directors. Executive agrees to perform such duties and discharge such responsibilities in accordance with the terms of the Agreement. The Agreement may be renewed for an additional one (1) year term, by the mutual written agreement of the Executive and the Company at least thirty (30) days prior to its expiration.

(b) The Executive shall devote substantially all of his working time to the business and affairs of the Company other than during vacations of four weeks per year and periods of illness or incapacity; provided, however, that nothing in the Agreement shall preclude the Executive from devoting time required: (i) for serving as a director or officer of any organization or entity not in a competing business with the Company, and any other businesses in which the Company becomes involved; (ii) delivering lectures, writing articles or books, or fulfilling speaking engagements; or (iii) engaging in charitable and community activities provided that such activities do not interfere with the performance of his duties hereunder.

2. *Compensation and Benefits*.

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

(a) *Base Salary*. The Company shall pay the Executive a fixed salary ("Base Salary") at a rate of Two Hundred Thousand Dollars ($200,000) per year. The Board of Directors may periodically review the Executive's Base Salary and may determine to increase (but not decrease) the Executive's salary, in accordance with such policies as the Company may hereafter adopt from time to time, if it deems appropriate. Base Salary will be payable in accordance with the customary payroll practices of the Company.

(b) *Bonus*. Executive shall be entitled to a one-time bonus in the amount of $10,000, payable to Executive within thirty (30) days of his commencement of service as Vice President, International Commercial Operations. Beginning in fiscal year 2005, Executive will also be entitled

to receive an annual bonus (the "Annual Bonus"), payable each year subsequent to the issuance of final audited financial statements, but in no case later than 120 days after the end of the Company's most recently completed fiscal year. The final determination on the amount of the Annual Bonus will be made by the Compensation Committee of the Board of Directors, based primarily on mutually agreed upon criteria, established with respect to the ensuing fiscal year, within thirty (30) days of the end of each fiscal year. The Compensation Committee may also consider other more subjective factors in making its determination. The targeted amount of the Annual Bonus shall be 37.5% of the Executive's base salary. The actual Annual Bonus for any given period may be higher or lower than 37.5%.

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

(i) Thirty days following the date of Executive's employment, the Executive shall be entitled to participate in such disability, health and life insurance and other fringe benefit plans or programs offered to all employees of the Company, as well as to the key executive employees of Company, including a Section 401(k) and retirement plan of the Company as may be established from time to time by the Board of Directors, subject to the rules and regulations applicable thereto. In addition, the Executive shall be entitled to the following benefits:

(ii) Contemporaneous with the execution of the Agreement, the Executive will be granted a non-qualified stock option (the "Employment Option") to purchase 150,000 shares of the Company's Common Stock, par value $.001 per share (the "Common Stock") with an exercise price per share equal to the average closing transaction price on the ten trading days preceding the grant. In the Company's discretion, the Employment Option may be issued pursuant to the Company's existing stock option plans or apart from those plans. The term of the Employment Option will be for a period of five (5) years from the date of grant. The shares eligible for purchase under the Employment Option grant vest as follows: one-third of the shares vest on the one year anniversary of the Employment Date, one-third of the shares vest on the two year anniversary of the Employment Date, and one-third of the shares vest on the third year anniversary of the Employment Date; provided, however, that if Executive's employment with the Company is terminated (i) without "Cause" or (ii) "For Good Reason," all unvested portions of the Employment Option shall vest immediately upon such termination.

(iii) The vesting of the Employment Option shall accelerate and vest immediately upon a change in control of the Company as defined in Rule 405 of the Securities Act of 1933 in the event that Executive does not continue to be employed by the Company or upon sale of substantially all of the assets of the Company or the merger out of existence of the Company in the event that Executive does not continue to be employed by the successor of the Company or the purchaser of the Company's assets.

(iv) Executive will be eligible for additional grants of options based upon criteria set forth by the Compensation Committee in the third year of his employment. The Compensation Committee may also determine to grant additional options to Executive prior to the third year of his employment, if in consultation with the President and Chief Executive Officer the Compensation Committee in its sole discretion deems such additional grants to be advisable.

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

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

(f) *Travel*. It is anticipated that Executive will be engaged in regular travel including between Philadelphia and Houston. The Company agrees to reimburse all expenses related to such travel (air travel shall be via coach class).

3. *Business Expenses*.

The Company shall pay or reimburse all reasonable travel and entertainment expenses incurred by the Executive in connection with the performance of his duties under the Agreement, including travel between Executive's current domicile in the Philadelphia, Pennsylvania metropolitan area, travel to the Company's various offices and facilities in the United States outside of the Philadelphia metropolitan area and abroad, and such other travel as may be required or appropriate, consistent with duly approved Company budgets, to fulfill the responsibilities of his office, all in accordance with such policies and procedures as the Company may from time to time establish for senior officers and as required to preserve any deductions for federal income taxation purposes to which the Company may be entitled and subject to the Company's normal requirements with respect to reporting and documentation of such expenses. The Company shall provide the Executive with the use of suitable lodgings during the times he is in Houston, as well as with suitable transportation. The Company shall also pay or reimburse Executive for all expenses incurred by the Executive for Executive's cellular telephone including monthly service charges, equipment maintenance and all other ancillary charges including, but not limited to, text messaging, paging, and wireless communications.

4. *Termination of Employment*.

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

(a) By the Company, in the event of the Executive's death or Disability (as hereinafter defined) or for Cause (as hereinafter defined). For purposes of the Agreement, "Cause" shall mean either: (i) the indictment of, or the bringing of formal charges against Executive on charges involving criminal fraud or embezzlement; (ii) the conviction of Executive of a crime involving an act or acts of dishonesty, fraud or moral turpitude by the Executive, which act or acts constitute a felony; (iii) Executive having caused the Company to violate the Company's Bylaws; (iv) Executive having committed acts or omissions constituting gross negligence or willful misconduct with respect to the Company including with respect to any valid contract to which the Company is a party; (v) Executive having committed acts or omissions constituting a material breach of Executive's obligations under the Agreement or of Executive's duty of loyalty or fiduciary duty to the Company or any material act of dishonesty or fraud with respect to the Company which are not cured in a reasonable time, which time shall be 30 days from receipt of written notice from the Company of such material breach; (vi) Executive having committed acts or omissions constituting a material breach of the Agreement which are not cured in a reasonable time, which time shall be 30 days from receipt of written notice from the Company setting forth with specificity the particulars of any such material breach as well as the corrective actions required; or (vii) a failure to observe the policies of the Company or the direction of the Board of Directors or of the President and CEO. A determination that Cause exists as defined in clauses (iv), (v), (vi) (as to the Agreement) or (vii) of the preceding sentence shall be made by at least a majority of the members of the Board of Directors. For purposes of the Agreement, "Disability" shall mean the inability of Executive, in the reasonable judgment of a physician jointly appointed by the Executive and Board of Directors, to perform, even with reasonable accommodation, his duties of employment for the Company or any of its subsidiaries because of any physical or mental disability or incapacity, where such disability shall exist for an aggregate period of more than 120 days in any 365-day period or for any period of 90 consecutive days. The Company shall by written notice to the Executive specify the event relied upon for termination pursuant to this Section 4(a), and

Executive's employment hereunder shall be deemed terminated as of the date of such notice. In the event of any termination under this Section 4(a), the Company shall pay all amounts then due to the Executive under Section 2(a) of the Agreement for any portion of the payroll period worked but for which payment had not yet been made up to the date of termination, and, if such termination was for Cause, the Company shall have no further obligations to Executive under the Agreement, and any and all options granted hereunder shall terminate according to their terms.

(b) By the Company, in the absence of Cause, for any reason and in its sole and absolute discretion, provided that in such event the Company shall, as liquidated damages or severance pay, or both, continue to pay to Executive the Base Salary (at a monthly rate equal to the rate in effect immediately prior to such termination) for the longer of the remaining term through September 30, 2005 or twelve months from the date of termination (the "Termination Payments"), when, as and if such payments would have been made in the absence of Executive's termination. The Termination Payments shall be made regardless of Executive's subsequent re-employment as long as any new employment is not in violation of Sections 5 or 6 of the Agreement.

(c) By the Executive for "Good Reason," (as the Executive shall reasonably determine in good faith) which shall be deemed to exist: (i) if the Company's Board of Directors or that of any successor entity of Company, fails to appoint or reappoint the Executive or removes the Executive from the title and/or office of Vice President of the Company or from any successor entity operating the Company; (ii) if Executive is assigned any duties materially inconsistent with the duties or responsibilities of the Vice President, International Commercial Operations of the Company as contemplated by the Agreement or any other action by the Company that results in a material diminution in such position, authority, duties, or responsibilities, excluding an isolated, insubstantial, and inadvertent action not taken in bad faith and which is remedied by the Company promptly after receipt of notice thereof given by Executive (but not excluding changes resulting from a sale of the Company, whether by merger, tender offer or otherwise) provided that Executive shall act promptly upon any such diminution in the scope of his duties, responsibilities, authority or position; (iii) if the Company shall breach or shall have continued to fail to comply with any material provision of the Agreement after a 30-day period to cure (if such failure is curable) following written notice to the Company of such non-compliance; (iv) if the Board of Directors requires Executive without his written consent to relocate to Houston, Texas, or to any other area outside a fifty (50) mile radius of the Company's initial office in the Philadelphia, Pennsylvania metropolitan area, (v) upon a change in control of the Company, or within twelve (12) months of any such change in control (for these purposes the term "change in control" shall have the meaning set forth in Rule 405 of the Securities Act of 1933) or within twelve (12) months of a sale of substantially all of the assets of the Company or the merger out of existence of the Company. In the event of any termination for "Good Reason" under the Section 4(c), the Company shall, as liquidated damages or severance pay, or both, pay the Termination Payments, as defined in (b) of the Section 4, to Executive, when, as and if such payments would have been made in the absence of Executive's termination.

(d) During any period in which Executive is obligated not to compete with the Company pursuant to Section 5 hereof (unless Executive was terminated for Cause as defined herein), Executive and his family shall continue to be covered by the Company's life, medical, health and death plans. Such coverage shall be at the Company's expense to the same extent as if Executive were still employed by the Company. In the event of a termination pursuant to Sections 4(b) or 4(c), the Company shall provide to Executive the pro-rata share of his annual bonus, to the extent one is awarded by the Compensation Committee the consideration of which shall be taken in good faith, giving a full month's credit for any partial month worked in that bonus year. Additionally, in the event of a termination pursuant to Sections 4(b) or 4(c), the Company shall provide to Executive, at the Company's expense, outplacement services of a nature customarily provided to a

senior executive. Notwithstanding the foregoing, the obligations of the Company pursuant to the Section 4(d) shall remain in effect no longer than the term of the Termination Payments.

5. *Non-Competition*.

During the period of Executive's employment hereunder and during the period, if any, during which payments are required to be made to the Executive by the Company pursuant to Sections 4(b) or 4(c), the Executive shall not, within any state or foreign jurisdiction in which the Company or any subsidiary of the Company is then providing services or products or marketing its services or products (or engaged in active discussions to provide such services), or within a fifty (50) mile radius of any such state or foreign jurisdiction, directly or indirectly own any interest in, manage, control, participate in, consult with, render services for, or in any manner engage in any business engaged in by the Company (unless the Board of Directors shall have authorized such activity and the Company shall have consented thereto in writing). The term "business engaged in by the Company" shall mean the development and commercialization of autologous fibroblast system technology for application in, among other therapies, dermatology, surgical and post-traumatic scarring, skin ulcers, cosmetic surgery, periodontal disease, reconstructive dentistry, vocal chord injuries, urinary incontinence, and digestive and gastroenterological disorders and other applications relating to the market for autologous fibroblast or UMC cells and the five derivative cell lines: osteoblast, chondroblast, fibroblast, adipocyte, and neuroectoderm. Investments in less than five percent of the outstanding securities of any class of a corporation subject to the reporting requirements of Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended, shall not be prohibited by this Section 5. At the option of Executive, Executive's obligations under this Section 5 arising after the termination of Executive shall be suspended during any period in which the Company fails to pay the Termination Payments required to be paid to him pursuant to the Agreement. The provisions of the Section 5 are subject to the provisions of Section 14 of the Agreement.

6. *Inventions and Confidential Information*.

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

(i) During the period of Executive's employment with the Company and thereafter, the Executive will not use, disclose to others, or publish or otherwise make available to any other party any inventions or any confidential business information about the affairs of the Company, including but not limited to confidential information concerning the Company's products. "Confidential Information" shall include commercial or trade secrets about Company's products, methods,

engineering designs and standards, analytical techniques, technical information, customer information, employee information, or financial and business records, any of which contains proprietary information created or acquired by the Company and which information is held in confidence by Company. Confidential Information does not include information which: (i) becomes generally available to the public, unless said Confidential Information was disclosed in violation of a confidentiality agreement; or (ii) becomes available to Executive on a non-confidential basis from a source other than the Company or its agents, provided that such source is not bound by a confidentiality agreement with the Company.

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

7. *Indemnification*.

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

8. *Litigation Expenses*.

In the event of any litigation or other proceeding between the Company and the Executive with respect to the subject matter of the Agreement and the enforcement of the rights hereunder and such litigation or proceeding results in final judgment or order in favor of the Executive, the Company shall reimburse the Executive for all of his reasonable costs and expenses relating to such litigation or other proceeding, including, without limitation, his reasonable attorneys' fees and expenses.

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

Nothing in the Agreement shall preclude the Company from combining, consolidating or merging with or into, transferring all or substantially all of its assets to, or entering into a partnership or joint venture with, another corporation or other entity, or effecting any other kind of corporate combination provided that the corporation resulting from or surviving such combination, consolidation or merger, or to which such assets are transferred, or such partnership or joint venture assumes the Agreement and all obligations and undertakings of the Company hereunder. Upon such a consolidation, merger, transfer of assets or formation of such partnership or joint venture, the Agreement shall inure to the benefit of, be assumed by, and be binding upon such resulting or surviving transferee corporation or such partnership or joint venture, and the term "Company," as used in the Agreement, shall mean such corporation, partnership or joint venture or other entity, and the Agreement shall continue in full force

and effect and shall entitle the Executive and his heirs, beneficiaries and representatives to exactly the same compensation, benefits, perquisites, payments and other rights as would have been their entitlement had such combination, consolidation, merger, transfer of assets or formation of such partnership or joint venture not occurred.

10. *Survival of Obligations*.

Sections 4, 5, 6, 7, 8, 9, 11, 12, 13 and 14 shall survive the termination for any reason of the Agreement (whether such termination is by the Company, by the Executive, upon the expiration of the Agreement or otherwise).

11. *Executive's Representations*.

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

12. *Company's Representations*.

The Company hereby represents and warrants to the Executive that (i) the execution, delivery and performance of the Agreement by the Company do not and shall not conflict with, breach, violate or cause a default under any contract, agreement, instrument, order, judgment or decree to which the Company is a party or by which it is bound; (ii) upon the execution and delivery of the Agreement by the Executive, the Agreement shall be the valid and binding obligation of the Company, enforceable in accordance with its terms.

13. *Enforcement*.

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

14. *Severability*.

In case any one or more of the provisions or part of a provision contained in the Agreement shall for any reason be held to be invalid, illegal or unenforceable in any respect in any jurisdiction, such invalidity, illegality or unenforceability shall be deemed not to affect any other jurisdiction or any other provision or part of a provision of the Agreement, nor shall such invalidity, illegality or unenforceability affect the validity, legality or enforceability of the Agreement or any provision or provisions hereof in any other jurisdiction; and the Agreement shall be reformed and construed in such jurisdiction as if such provision or part of a provision held to be invalid or illegal or unenforceable had never been

contained herein and such provision or part reformed so that it would be valid, legal and enforceable in such jurisdiction to the maximum extent possible. In furtherance and not in limitation of the foregoing, the Company and the Executive each intend that the covenants contained in Sections 5 and 6 shall be deemed to be a series of separate covenants, one for each and every state of the United States and any foreign country set forth therein. If, in any judicial proceeding, a court shall refuse to enforce any of such separate covenants, then such unenforceable covenants shall be deemed eliminated from the provisions hereof for the purpose of such proceedings to the extent necessary to permit the remaining separate covenants to be enforced in such proceedings. If, in any judicial proceeding, a court shall refuse to enforce any one or more of such separate covenants because the total time, scope or area thereof is deemed to be excessive or unreasonable, then it is the intent of the parties hereto that such covenants, which would otherwise be unenforceable due to such excessive or unreasonable period of time, scope or area, be enforced for such lesser period of time, scope or area as shall be deemed reasonable and not excessive by such court.

15. *Entire Agreement; Amendment*.

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

16. *Notices*.

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

(a) To the Company:

Isolagen Technologies, Inc.,
700 Gemini
Suite 100
Houston, TX 77058

and to:

Dilworth Paxson, LLP.
3200 Mellon Bank Center
1735 Market Street
Philadelphia, PA 19103-7595
Attn: Susan Stranahan Ciallella,
Esquire

(b) To the Executive:

Dennis L. Bevan
20 Dorchester Way
Phoenixville, PA 19460

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

17. *Assignability*.

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

then the Agreement shall be binding on the transferee of the business of the Company whether or not the Agreement is expressly assigned to the transferee.

18. *Governing Law*.

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

19. *Waiver and Further Agreement*.

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

20. *Headings of No Effect*.

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

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

COMPANY:

ISOLAGEN, INC.

By: _____

Robert Bitterman, President and Chief Executive Officer

EXECUTIVE:

_____

Dennis L. Bevan

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EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of Isolagen, Inc. on Forms S-3 and S-8 (Registration Nos. 333-108769 and 333-108219) of our report dated February 17, 2004 relating to the financial statements which appear in Isolagen, Inc.'s Form 10-K/A for the year ended December 31, 2003, which report is also included in the December 31, 2004 Annual Report on Form 10-K of Isolagen, Inc. We also consent to the references to us under the heading "Experts" in such Registration Statements.

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

March 15, 2005

EXHIBIT 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Isolagen, Inc.
Exton, Pennsylvania

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-108769) and Form S-8 (No. 333-108219) of Isolagen, Inc. of our report dated March 14, 2005, relating to the consolidated financial statements which appears in this Form 10-K.

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

March 15, 2005

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Exhibit 31.1

CERTIFICATION

I, Robert Bitterman, President and Chief Executive Officer of Isolagen, Inc., certify that:

1. I have reviewed this Annual Report on Form 10-K of Isolagen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a - 15(e) and 15d - 15(e)) 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. 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

   c. 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 reasonable likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Dated: March 14, 2005

By: /s/ ROBERT BITTERMAN

Robert Bitterman
President and Chief Executive Officer
Isolagen, Inc.

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Exhibit 31.2

CERTIFICATION

I, Jeffrey W. Tomz, Chief Financial Officer of Isolagen, Inc., certify that:

1. I have reviewed this Annual Report on Form 10-K of Isolagen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a - 15(e) and 15d - 15(e)) 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. 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

   c. 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 reasonable likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Dated: March 14, 2005

By: /s/ JEFFREY W. TOMZ

Jeffrey W. Tomz
Chief Financial Officer
Isolagen, Inc.

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Exhibit 32.1

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

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

i. the Annual Report on Form 10-K of the Company for the year ended December 31, 2004, as filed with the Securities and Exchange Commission on the date hereof (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Commission Act of 1934; and

ii. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 14, 2005

By: /s/ ROBERT BITTERMAN

Robert Bitterman
President and Chief Executive Officer
Isolagen, Inc.

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

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Exhibit 32.2

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

For purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned, Jeffrey W. Tomz, the Chief Financial 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, 2004, as filed with the Securities and Exchange Commission on the date hereof (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Commission Act of 1934; and

ii. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 14, 2005

By: /s/ JEFFREY W. TOMZ

Jeffrey W. Tomz
Chief Financial Officer
Isolagen, Inc.

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