ISOLAGEN INC
Form 10-K/A
April 28, 2004

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A

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

For the fiscal year ended December 31, 2003

OR

o 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.)

2500 Wilcrest, 5th Floor
Houston, Texas 77042
(Address of principal executive offices, including zip code)

(713) 780-4754
(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. ý Yes o 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. ý

Indicate by check mark whether the registrant is an accelerated filer (as defined in the Exchange Act Rule 12b-2) o Yes ý No

As of June 30, 2003, 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 $36,059,194.

As of April 28, 2004, issuer had 26,769,718 shares of issued and outstanding common stock, par value $0.001.

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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 product candidates use our proprietary Isolagen Process. Based on our accumulated experience through our retrospective study, clinical trials and treatment of patients in the United Kingdom, we believe that our Isolagen Process utilizes 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.

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 clinical trial for our lead product candidate. We are planning to initiate two additional pivotal Phase III clinical trials for this product candidate during the third quarter of 2004. We expect to file a Biologics License Application, or BLA, for this product candidate during the first quarter of 2005. We completed a Phase I clinical trial for our second product candidate for the treatment of periodontal disease in late 2003, and we are planning to initiate a Phase II clinical trial during the second quarter of 2004. In late 2003, we began limited commercialization for our dermal product in the United Kingdom and Australia.

Our proprietary Isolagen Process is an autologous cellular therapy designed to replenish deficiencies caused by the loss of fibroblast cells as a person ages. Fibroblast cells are found throughout the body and are responsible for producing collagen and elastin, which provide support structures for various tissues in the body such as skin. As a person ages, he or she loses fibroblasts and the ability to produce and replace collagen and elastin leading to normal signs of aging, including both wrinkles and nasolabial folds. Our proprietary Isolagen Process takes the patient's cells from a small skin sample, from which millions of fibroblast cells are extracted, allowed to multiply and then injected into the patient in or around the areas to be treated. Our data indicates that following the injections, the new

fibroblast cells lead to the production of collagen and elastin, which diminish the visible effects of aging. The procedure is minimally invasive and non-surgical.

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 that 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 $2.9 billion in 2003. We believe growth in the aesthetic procedure market is driven by:

- aging of the "baby boomer" population, currently ages 39 to 57, 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, more than 8.3 million surgical and non-surgical procedures were performed in 2003, up 20% from nearly 6.9 million in 2002. According to the ASAPS, consumer demand increased 22% in 2003 for non-surgical cosmetic procedures, exceeding more than 6.4 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 2003:

Procedure	Number
Botox injection	2,272,080
Laser hair removal	923,200
Microdermabrasion	858,312
Chemical peel	722,248
Collagen injections	620,476

Procedures among the 35 to 50 year old age group made up 47% of all non-surgical cosmetic procedures in 2003. The 51 to 64 year old age group made up 24% of all non-surgical cosmetic procedures in 2003, 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. A majority of the population will experience periodontal disease at some point in their lives, and the American Dental Association, or ADA, estimates that, of the 50 million Americans that have periodontal disease, only 7.5 million are receiving treatment. According to the ADA, there were over 155,000 active privately practicing dentists in 2001.

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.

Longer 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 longer-lasting effects, and a permanency claim based on 12-month efficacy data is the subject of the extended portion of our clinical trials.

Less pain associated with the injection. We believe that patients experience less pain with our Isolagen Process because the injected material is less viscous and causes less irritation. A thinner 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 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 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 cultured into tens of millions of cells 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. A total of 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, slow, involves many sterile interventions and is costly.

We are in the final stages of developing our new Automated Cell Expansion, or ACE, System. We believe our ACE System will yield significant improvements in the manufacturing process and reduce costs. Through a collaboration with Applikon Biotechnology, we are developing our ACE System that permits an automated harvesting process in a closed loop sterile environment. The existing process separates cells manually utilizing centrifuge technology. Our ACE System will eliminate several of the steps and materials involved in our current system and will lead to significant cost reductions in both skilled labor and materials and will enable scalable mass production. Our ACE System will incorporate current technology and readily available components common to the pharmaceutical industry, particularly those that have already been well established in facilities operating under cGMP regulations. We currently expect to introduce the ACE System for new patients in our United Kingdom facility in the fourth quarter of 2004.

We have been collaborating with Applikon Biotechnology to patent the manufacturing system improvements beyond Applikon Biotechnology's existing patents. Our ACE System has been successful in the research setting, and we are now undertaking the design fabrication and qualification of the massed-produced single-use, disposable component. Our ACE System will then undergo validation testing prior to incorporation into the manufacturing process. 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.

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 Clinical Trial. In July 2003, we commenced a Phase III clinical trial of our dermal product candidate pursuant to the IND for the treatment of wrinkles and scars. The trial 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. 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 our dermal product candidate observed in our study. 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 Phase III clinical trial, we are currently finalizing the design of two pivotal Phase III clinical trials that we plan to commence during the third quarter of 2004. We had numerous communications throughout 2003 with the FDA with regard to study design. 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 have simplified the study design and added some additional reports or studies. We established a clinical meaningfulness standard through validation using an FDA-recommended 6-point photoguide scale. Furthermore, we established the purity of the fibroblasts produced. The FDA requested that we demonstrate that greater than 99% of the cells were fibroblasts as part of an ongoing discussion with regard to purity testing. The data we submitted to the FDA showed that 99.6% of all cells in the study showed positive for fibroblast antibody. We believe that the remaining study design issues were resolved largely from analysis of the results from the current Phase III clinical trial.

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. We expect the FDA to respond to our request with any comments on our study designs or protocols on or prior to May 21, 2004. To the extent that the FDA has additional comments, we anticipate amending or re-filing the SPA as needed. Successful resolution of any study design issues and data-related questions are critical for the eventual license application. Assuming we are successful in addressing the FDA's concerns, and that there are not delays in the FDA's assessment, such as a referral to an advisory committee for review, we currently plan to complete the two pivotal Phase III clinical trials and file a BLA during the first quarter of 2005.

Phase II Clinical Trial. In January 2003, we commenced a Phase II clinical trial involving two sites. The double-blind clinical trial consisted of 40 patients and four dose regimens ranging in quantity and including a placebo. 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 our previous experience. We then utilized this target dose in our subsequent Phase III trial.

The Phase II study was also used to determine the efficacy of the product candidate using two different scales, the ordinal scale photoguide system, which we refer to as the "5-point scale," which was designated as the "primary" scale, and the visual analog scale. Results did not show a statistically different effect in the treatment and placebo groups using the 5-point scale, designated in the clincial plan as the primary efficacy assessment. In contrast, after four months, patients that used the target dosage experienced a statistically significant change using the visual analog scale.

The difference between the results was explained by the failure of the 5-point scale to capture efficacy data from patients whose baseline value was thought to be more severe than five. If the scale had extended to seven then a proportion of patients who showed improvement but did not move to beyond a five would not have been recorded as "responders." In addition, we realized that a two point shift rather than one was needed to separate responders and false responders on this scale. Lastly, if patient's lesions were minor, they were ranked as two at baseline and this did not allow for sufficient sensitivity in the scale to record efficacy.

The study design for our first Phase III clinical trial was altered to include a 7-point scale with a two point shift to indicate efficacy and a desire to only include patients with lesions 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.

During discussions with the FDA regarding our SPA, the FDA recommended the use of the published and validated 6-point photoguide scale that had been used in previous clinical trials for approved products in this category. As a result, our SPA submission did not include acne or facial scar patients, as these patients may not be adequately assessed using a 6-point photoguide scale.

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 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, the difference between the placebo and therapeutic group was 2.4 millimeters. 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.

Further clinical trials are planned and protocols have been prepared to assess the efficacy and safety of treatment of our dental product candidate for the treatment of the papilla. We are also preparing 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 currently in discussions with the FDA regarding our Phase I clinical trial protocol, and we currently plan to initiate this trial during the second quarter of 2004. 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 repair. We intend to achieve our goal by:

Leveraging our expertise in autologous cell 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. Through our collaboration with Applikon Biotechnology, we are developing our ACE System that will permit an automated cell growth and harvesting process in a closed loop sterile system. 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 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 overseas and building global brand-recognition. We currently sell our dermal product in the United Kingdom and Australia. 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 the 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.

We focused our initial commercialization activities in the United Kingdom in order to establish and develop our 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.

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.

As a result of this increased exposure, we experienced a marked increase in the demand for our dermal product in recent months. In January 2004, our London laboratory received more than a 30% increase in the number of biopsies from patients as compared to the 2003 monthly average. In February 2004, the number of biopsies received increased by more than 100% over January. This increased demand exceeded our existing capacity and we are currently working on improvements to help satisfy this demand, including introducing our new ACE System for new patients in our London facility during the fourth quarter of 2004.

Intellectual Property

We believe that patents, trademarks, copyrights and other proprietary rights are important to our business. We also rely on trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. We seek to protect our intellectual property rights by a variety of means, including 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 April 28, 2004, we had five issued U.S. patents, seven pending U.S. patent applications, 23 issued foreign patents and 19 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 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	Autologen	Collagenesis Corp.
	Dermolagen	Collagenesis Corp.
	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
	Sculptura	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 regulated as medical devices or biologics usually require such 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; 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 one of 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 180 days 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 practice, or cGMP, regulations, 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 good manufacturing practices regulations. 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 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.

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 three manufacturing facilities located in Houston, Texas, London, England and Sydney, Australia. Our manufacturing processes are substantially identical in each facility though different in scale. We use our London and Sydney facilities for commercial production and our Houston facility for research and clinical trials.

Our manufacturing process consists of a traditional cell culture process using sterile plastic flasks processed inside a sterile "biosafety cabinet." All manufacturing practices are strictly controlled under cGMP guidelines, all vendors are audited and all supplies are subject to quality control release criteria. 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.

Through our collaboration with Applikon Biotechnology we are developing our ACE System that permits an automated harvesting process in a closed loop sterile environment. Our ACE System will eliminate several of the steps and materials involved in our current system and will lead to significant cost reductions in both skilled labor and materials and will enable scalable mass production. We

currently expect to introduce our ACE System for new patients in our United Kingdom facility in the fourth quarter of 2004.

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 2003, 2002 and 2001, we incurred research and development expenses of $3.3 million, $1.7 million and $0.9 million, respectively.

Employees

As of March 31, 2004, we employed 55 people on a full-time basis, including 30 in Houston, Texas, 17 in London, England, and eight 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.

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. Our product development efforts may fail for many reasons, including:

failures in pre-clinical studies;

clinical trial data that is insufficient 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 2003, 2002 and 2001 were $446,000, $51,000 and $25,000, respectively. Our net loss for 2003, 2002 and 2001 was $11.3 million, $5.4 million and $1.7 million, respectively. As of December 31, 2003, we had an accumulated deficit of $34.0 million. 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.

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. 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.

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

The process of obtaining FDA and other regulatory approvals is time consuming, expensive, and difficult to design and implement. Clinical trials are required and the marketing and manufacturing of our product candidates are subject to rigorous testing procedures. We have agreed to conduct 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.

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 our business condition could be adversely affected.

Our ability to effectively commercialize our dermal product and our product candidates depends on our ability to implement our ACE System.

We must obtain FDA approval of our 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. 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 ACE System that permits an automated harvesting process in a closed loop sterile environment. We anticipate that improved manufacturing practices as a result of our collaboration with Applikon Biotechnology will allow us to increase our capacity and to reduce many of our variable costs, including our labor costs. However, our ACE System is unproven, and we do not know whether we will be successful in automating the manufacturing process, validating the safety and effectiveness of these processes, obtaining the required scalability or achieving cost savings or obtaining FDA approval of these processes. In addition, 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. 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 to meet increasing demand 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 for our dermal product in the United Kingdom, we will be required to expend significant additional funds to increase the capacity of our U.K. operations, including the addition of personnel, introduction of systems enhancements, automation of our manufacturing process through the implementation of our ACE System and the establishment of new facilities. Our inability to timely expand our operations in the United Kingdom may limit our ability to maximize this market opportunity.

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 Australia, 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 due to the use of our Isolagen Process, 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 was designed or has the capacity to support the full-scale commercialization of our product candidates. Our existing 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 the 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, and is unable to satisfy existing demand. 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 in the United Kingdom even if our ACE System is effectively and timely implemented. We are in the process of planning the establishment of large-scale commercial production facilities in Europe and in the United States. 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 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 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 will 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 payment 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.

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 have agreed to conduct two pivotal Phase III clinical trials related to our lead product candidate. 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 and Australia, 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; and

development of relationships with strategic business partners, including physicians who might use our future products.

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, effectiveness, 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 manfacturing 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 recall;
- delay, interruption or suspension of product manufacturing, distribution, marketing and sale; 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 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 and Australia. 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 an even larger number of 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.

These limitations and interruptions could have a material adverse effect on our business. In addition, 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;
- the effectiveness of our 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. We are currently conducting a search for a Chief Operating Officer, as well as searching for other key personnel. 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.

The ownership of our common stock is highly concentrated, which may prevent our stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause our stock price to decline.

As of April 28, 2004, our officers and directors hold approximately 24.3% of our common stock. As such, they are in a position to influence the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

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. If we are unable to effectively promote our brand and establish a leading position in the marketplace, our operations will suffer. 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.

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 April 28, 2004, we had five issued U.S. patents, seven pending U.S. patent applications, 23 foreign patents, and 19 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, certain future and preexisting intellectual property rights are allocated to us in collaboration and development agreements with Applikon Biotechnology and the University of Texas Health Sciences Center at Houston. 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.

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 a cooperative development agreement with Applikon Biotechnology, 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 Applikon Biotechnology 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; and

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 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 three facilities located in Houston, Texas, London, England, and Sydney, Australia. These facilities could be damaged by fire, floods, power loss, telecommunication and information systems failures and 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 the first quarter of 2004, the per share closing price of our common stock ranged from $4.00 to $11.79. 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.

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 our shares for an indefinite period of time.

Our business is subject to reporting requirements that are currently evolving and, once established, could substantially increase our operating expenses and divert management's attention from the operation of our business.

Because our common stock is publicly traded, we are subject to a variety of rules and regulations of federal, state and financial market exchange entities charged with the protection of investors and the oversight of companies whose securities are publicly traded. These entities, including the SEC, the Public Company Accounting Oversight Board and the American Stock Exchange, have recently issued new requirements and regulations and are currently developing additional regulations and requirements in response to recent laws enacted by Congress, most notably the Sarbanes-Oxley Act of 2002. As certain rules are not yet finalized, we do not know the level of resources we will have to commit in order to be in compliance. Our compliance with current and proposed rules is likely to require the commitment of significant financial and managerial resources. As a result, our management's attention might be diverted from other business concerns, which could negatively affect our business.

Item 2. Properties

We currently lease facilities in three locations: (a) Houston, Texas; (b) London, England, and (c) Sydney, Australia. The Houston facility is located at 2500 Wilcrest, 5th Floor, Houston, Texas 77042 and houses the corporate headquarters as well as laboratory space used for research and development and as the U.S. processing laboratory for cosmetic and dental trials.

In September 2002, we opened our London facility. The facility is located at 59/61 Park Royal, London, NW10 7JJ, England.

In August 2003, we opened our Sydney facility. The facility is located at 2 Lincoln Street, Lane Cove, New South Wales, Australia, 2066.

The following table summarizes the approximate amount of space in square feet utilized by us at each location:

	Administrative	Warehouse	Laboratory	Total
Houston	4,900(1)		3,900(2)	8,800
London	1,300	2,900	5,200	9,400(3)
Sydney	1,100	1,100	4,900	7,100(4)
	7,300	4,000	14,000	25,300

1. Certain officers granted us the use of this office space at no charge until August 2003. Beginning in September 2003, the lease rate is approximately $105,840 annually. We have a month to month lease that may be terminated at our option. The lease is with Axces, Inc., a Delaware corporation, which is owned by Michael Avignon, Michael Macaluso and Timothy Till. Management believes that the leased premises have been made available to us on terms that are superior to those available from arms-length providers of lease space. "See Certain Relationships and Related Transactions."

2. The lease rate is approximately $60,840 annually, and the term of the lease expires on March 31, 2005.

3. The lease rate is approximately $146,640 annually, and the term of the lease expires on March 24, 2010. We have the option to cancel the lease after March 24, 2005.

4. The lease rate is approximately $102,240 annually, and the term of the lease expires on November 19, 2004. We have an option to renew the lease for an additional one year.

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 2003.

Part II

Item 5. Market For Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Since December 11, 2002, our common stock has been traded on the American Stock Exchange under the symbol "ILE." Prior to December 11, 2002, our common stock was quoted on the OTC Bulletin Board under the symbol "ISLG." The market for our common stock is limited and volatile. The following table sets forth the range of high and low bid quotations or high and low closing prices for our common stock for each of the periods indicated as reported by the OTC Bulletin Board or the AMEX. These 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, 2003		December 31, 2002	
	High	Low	High	Low
First Quarter	$ 5.60	$ 4.15	$ 7.25	$ 5.00
Second Quarter	7.70	4.00	6.95	2.90
Third Quarter	11.00	6.35	3.75	2.20
Fourth Quarter	9.13	5.10	5.75	3.00

Holders

As of April 28, 2004, we had 727 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, 2003, which were not registered under the Securities Act of 1933, as amended (the "Securities Act"):

On August 27, 2003, we sold an aggregate of 3,359,331 shares of our common stock at an offering price of $6.00 per share to a group of institutional investors. Legg Mason Wood Walker, Incorporated acted as the sole placement agent for the offering. We relied upon and complied with Regulation D under the Securities Act in connection with the offering, namely, an offering by the issuer not involving a public offering. The securities were sold to a limited number of institutional purchasers who each were, at the time the securities were sold, an "accredited investor" within the meaning of the rules and regulations issued under the Securities Act.

Item 6. Selected Consolidated Financial Data

Our selected historical consolidated financial information presented as of December 31, 1999, 2000, 2001, 2002 and 2003 and for each of the five years ended December 31, 2003 was derived from our audited consolidated financial statements.

This information should be read in conjunction with the historical 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,				
	2003	**2002**	**2001**	**2000**	**1999**
Consolidated Statement of Operations Data					
Revenues	$ 445,689	$ 50,991	$ 25,482	$ 6,584	$ 121,931
License fees		40,000	80,000	40,000	
Total revenues	445,689	90,991	105,482	46,584	121,931
Cost of sales	121,826	35,133	17,891	10,846	84,862
Gross profit	323,863	55,858	87,591	35,738	37,069
Selling, general and administrative expenses	7,980,757	3,994,782	715,468	265,075	1,079,356
Research and development	3,301,341	1,735,244	933,907	463,304	186,178
Operating loss	(10,958,235)	(5,674,168)	(1,561,784)	(692,641)	(1,228,465)
Other income (expense)					
Interest income	40,691	208,692	17	4,891	5,902
Other income	55,663	32,421			
Loss on disposal of asset	(406,413)		(8,222)		
Interest expense			(82,015)	(119,326)	(84,215)
Net loss	$ (11,268,294)	$ (5,433,055)	$ (1,652,004)	$ (807,076)	$ (1,306,778)
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	$ (13,600,374)	$ (16,114,660)	$ (1,652,004)	$ (807,076)	$ (1,306,778)
Per share information					
Net loss basic and diluted	$ (.58)	$ (.36)	$ (.22)	$ (.29)	$ (.49)
Deemed dividend associated with beneficial conversion of preferred stock	(.06)	(.67)			
Preferred stock dividends	(.06)	(.03)			
Net loss attributable to common stockholders	$ (.70)	$ (1.06)	$ (.22)	$ (.29)	$ (.49)
Shares outstanding	19,297,865	15,205,554	7,618,947	2,822,104	2,656,598

	December 31,				
	2003	**2002**	**2001**	**2000**	**1999**
Consolidated Balance Sheet Data					
Cash and cash equivalents	$ 15,935,558	$ 4,244,640	$ 1,380,824	$ 2,574	$ 60,994
Working capital (deficit)	14,367,768	2,811,160	870,377	(1,435,834)	(651,340)
Total assets	19,644,465	7,257,664	1,563,914	62,296	166,703
Total liabilities	2,380,740	2,050,734	511,514	2,290,763	1,590,052

	December 31,				
Total stockholders equity (deficit)	17,263,725	5,206,930	1,052,400	(2,228,467)	(1,423,349)

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

General

We specialize in the development and commercialization of autologous cellular 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 further sources of debt and

equity capital, prompt regulatory approval to sell our products, our ability to automate our manufacturing process and upon our continued expansion. We will require additional capital in the future to expand our operations. No assurance can be given that we will be able to obtain any such additional capital, 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.

As of December 31, 2003, we had a cash balance of $15.9 million. As of March 24, 2004, we had a cash balance of approximately $13.5 million. We believe our existing capital resources are adequate to finance our operations until June 30, 2005, 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. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. On an on-going basis, we evaluate our estimates and assumptions, including but not limited to those related to the impairment of long-lived assets, reserves for doubtful accounts, revenue recognition and certain accrued liabilities. We base our estimates on historical experience and various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Revenue Recognition: We recognize revenue from product sales when goods are shipped and the risk of loss transfers to the customer. Revenue from licenses and other up-front fees are recognized on a ratable basis over the term of the respective agreement. Milestone payments are recognized upon successful completion of a performance milestone event. Any amounts received in advance of performance are recorded as deferred revenue. We recognize revenue over the period the service is performed in accordance with SEC Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" ("SAB 101"). SAB 101 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. We believe that all of these conditions are met at the time of shipment. Currently, three injections are recommended, although the decision to utilize one, two or three injections is between the attending physician and his/her patient. The amount invoiced is fixed and determinable and only varies among customers depending upon the number of injections requested. There is no performance provision under any arrangement with any doctor and there is no right to refund, or returns for unused injections.

Currently the Isolagen Process is delivered through an attending physician to each patient using our recommended regimen of up to three injections. 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. All 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. The amount of the revenue deferral 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.

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.

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.

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.

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 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.

COST OF SALES. Costs of sales increased 247%, or $86,693, to $121,826 in Fiscal 2003, from $35,133 in Fiscal 2002. The increase in cost of sales is primarily related to the increase in revenues generated from the commencement of operations in the UK.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES. Selling, general and administrative expenses increased 100%, or $3,985,975, to $7,980,757 for Fiscal 2003 from $3,994,782 for Fiscal 2002. The major components of the approximate $4.0 million increase in selling, general and administrative expense are as follows: a) consulting expense increased by approximately $0.4 million to $1.1 million for Fiscal 2003 compared to $0.7 million for Fiscal 2002; b) salaries increased by approximately $1.2 million to $1.9 million for Fiscal 2003 compared to $0.7 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; and f) depreciation and amortization increased by approximately $0.7 million to $0.8 million for Fiscal 2003 compared to $0.1 million for Fiscal 2002. 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 $1.6 million during Fiscal 2003 to $3.3 million from $1.7 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 total cumulative cost of research and development incurred through December 31, 2003 is $7.1 million. As of December 31, 2003, we believe a minimum of $3.0 million of additional expenditures will be required to complete this project. That estimate assumes that no further testing requirements are imposed by the FDA, that FDA approval is forthcoming and that FDA approval is received during 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 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 will be if FDA approval is not forthcoming in 2005. We have other research projects currently underway. However, research and development costs related to these projects were not material during the 2003 or 2002 periods. The major components of the approximately $1.6 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 $0.4 million to $0.6 million for Fiscal 2003 compared to $0.2 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.

LOSS ON DISPOSAL OF ASSET. Loss on disposal of asset in Fiscal 2003 of $406,413 primarily consisted of the write-off of software.

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.

Contractual Obligations

The following table summarizes the amounts of payments due under specified contractual obligations as of December 31, 2003:

	Payments Due by Period			
Contractual Obligations	**Less than 1 Year**	**1 3 Years**	**4 5 Years**	**More than 5 Years**
Long-Term Debt Obligations	$	$	$	$
Capital Lease Obligations	$	$	$	$
Operating Lease Obligations	$ 277,799	$ 331,862	$ 331,862	$ 539,276
Purchase Obligations	$	$	$	$
Other Long-Term Liabilities Reflected on the Registrant's Balance Sheet Under GAAP	$	$	$	$
Total	$ 277,799	$ 331,862	$ 331,862	$ 539,276

Off-Balance Sheet Transactions

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

Results of Operations Comparison of Fiscal Years Ending December 31, 2002 and 2001

REVENUES. Revenues decreased 14% or $14,491, to $90,991 for Fiscal 2002, from $105,482 for the year ended December 31, 2001 ("Fiscal 2001"). The decrease in revenues is primarily attributable to a decrease of $40,000 in license fees recognized in Fiscal 2002, partially offset by an increase of $48,473 relating to revenue in the United Kingdom.

COST OF SALES. Costs of sales increased 96%, or $17,242, to $35,133 in Fiscal 2002, from $17,891 in Fiscal 2001. The increase in cost of sales is primarily related to the increase in revenues generated from the commencement of operations in the United Kingdom.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES. Selling, general and administrative expenses increased 458%, or $3,279,314, to $3,994,782 in Fiscal 2002, from $715,468 in Fiscal 2001. The major components of the approximately $3.3 million increase in selling, general and administrative expense are as follows: a) salaries increased by approximately $0.6 million to $0.7 million in Fiscal 2002 compared to $0.1 million in Fiscal 2001 (these amounts include an imputed expense of $400,000 in Fiscal 2002 and $155,556 in Fiscal 2001 relating to the fair market value of services provided by certain officers by which they were not compensated); b) consulting expense increased by approximately $0.6 million to $0.7 million in Fiscal 2002 compared to $0.1 million in Fiscal 2001; c) travel expense increased by approximately $0.3 million to $0.4 million in Fiscal 2002 compared to $0.1 million in Fiscal 2001; d) legal expense increased by approximately $0.2 million to $0.3 million in Fiscal 2002 compared to $0.1 million in Fiscal 2001; e) promotional expense increased by approximately $0.2 million to $0.2 million in Fiscal 2002 compared to $0.0 million in Fiscal 2001; and f) various other expenses, including rent, insurance and other office expense increased by approximately $1.0 million to $1.3 million in Fiscal 2002 compared to $0.3 million in Fiscal 2001. The increase in selling, general and administrative expenses is attributed primarily to: a) higher salaries 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) increase in office locations due to expansion into the United Kingdom and Australia.

RESEARCH AND DEVELOPMENT. Research and development expenses increased by $0.8 million during the twelve months ended December 31, 2002 to $1.7 million from $0.9 million for the same period of 2001. 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, 2002 is $3.8 million. The major components of the approximately $0.8 million increase in research and development expense are as follows: a) consulting expense increased by approximately $0.1 million to $0.7 million in Fiscal 2002 compared to $0.6 million in Fiscal 2001. In Fiscal 2001, we incurred a non-cash consulting expense of $450,000 which represents the issuance of 300,000 common shares as payment for consulting services relating to a potential development of a dental product; b) salaries increased by approximately $0.5 million to $0.9 million in Fiscal 2002 compared to $0.4 million in Fiscal 2001; and c) laboratory expense increased by approximately $0.2 million to $0.2 million in Fiscal 2002 compared to $0.0 million in Fiscal 2001.

INTEREST EXPENSE. Interest expense decreased $82,015 to $0 in Fiscal 2002, from $82,015 in Fiscal 2001. The decrease results from conversion of all of our convertible debt to equity in Fiscal 2001.

INTEREST INCOME. Interest income increased $208,675 to $208,692 in Fiscal 2002, from $17 in Fiscal 2001. The increase is primarily due to an increase in the amount of investable assets representing the net proceeds from the issuance of Series A Preferred Stock.

NET LOSS. Net loss in Fiscal 2002 was $5,433,055, as compared to a net loss of $1,652,004 in Fiscal 2001. This increase in net loss is attributed primarily to salaries, travel, consulting, legal, promotional expenses and bonuses paid to key personnel. Net loss attributable to common stockholders in Fiscal 2002 was $16,114,660, as compared to a net loss of $1,652,004 in Fiscal 2001. These amounts include $10.2 million and $0.0 million of deemed dividend associated with beneficial conversion of preferred stock in Fiscal 2002 and Fiscal 2001, respectively. These amounts include $0.5 million and $0.0 million of preferred stock dividends in Fiscal 2002 and Fiscal 2001, respectively.

Liquidity and Capital Resources

OPERATING ACTIVITIES. Cash used in operating activities during Fiscal 2003 amounted to $9,297,050, as compared to the $3,968,013 of cash used in operating activities during Fiscal 2002. The increase is attributed primarily to salaries, travel, consulting, legal, and promotional expenses. The negative operating cash flows in Fiscal 2003 were financed from our cash balances as of December 31, 2002 and the proceeds of equity placements, as discussed below.

INVESTING ACTIVITIES. Cash used by investing activities during Fiscal 2003 amounted to $1,159,857, as compared to cash used by investing activities of $2,252,368 during Fiscal 2002. This decrease in cash used is due to the purchase of property and equipment for the Houston, Texas, London, England, and Sydney, Australia laboratories in Fiscal 2002.

FINANCING ACTIVITIES. 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, as compared to cash provided by financing activities of $9,070,322 during Fiscal 2002 which consisted of proceeds from the issuance of preferred stock and common stock.

EQUITY TRANSACTIONS. In May 2003, we 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 was convertible into eight shares of 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 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 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,*"Application of Issue No. 98-5 to Certain Convertible Instruments,"* 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 us with a corresponding amount recorded as additional paid-in capital. The deemed dividend associated with the beneficial conversion is calculated as the difference between the fair value of the underlying common stock less the proceeds that have been received for the Series B Preferred Stock limited to the value of the proceeds received.

In August 2003, we sold in a private offering 3,359,331 shares of our common stock at an offering price of $6 per share. After deducting the costs and expenses associated with the sale, we received net cash totaling $18,455,561. In connection with this transaction, all of the holders of the Series A and Series B Preferred Stock converted their preferred shares into common stock. We had a dividend obligation of $1.1 million, which was paid in the third quarter of 2003 to the holders of Series A and Series B Preferred Stock who converted their preferred shares into common stock.

WORKING CAPITAL. As of December 31, 2003, we had a cash balance of $15.9 million. As of March 24, 2004, we had a cash balance of approximately $13.5 million. We do not have any credit facilities with which to fund ongoing working capital needs. Our long-term viability is dependent upon the successful operation of our business and our ability to raise additional debt and equity capital. However, our existing capital resources are adequate to finance our existing operations until June 30, 2005. We will require substantial additional capital to expand our operations and to attain profitability, neither of which can be quantified. We are actively assessing various financing opportunities.

Other

INFLATION. Inflation did not have a significant impact on our results during Fiscal 2003.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to foreign currency exchange rates market risk. Market risk is the potential loss arising from adverse changes in market rates and prices, such as foreign currency exchange rates. We do not enter into derivatives or other financial instruments for trading or speculative purposes.

Substantially all of our revenues for the year ended December 31, 2003 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 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, 13% of our assets at December 31, 2003 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.

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 will also perform a review of the unaudited condensed quarterly financial statements to be included in our quarterly reports on Form 10-Q beginning with the March 31, 2004 Form 10-Q.

Item 9A. Controls and Procedures

As of the end of the period covered by this annual report, we carried out, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer (the "Certifying Officers"), an evaluation of the effectiveness of our "disclosure controls and procedures" (as the term is defined under Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act")). Based on this

evaluation, the Certifying Officers have concluded that our disclosure controls and procedures are effective to ensure that material information is recorded, processed, summarized and reported by management on a timely basis in order to comply with our disclosure obligations under the Exchange Act, and the rules and regulations promulgated thereunder.

Further, there were no changes in our internal controls over financial reporting during the fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Part III

Item 10. Directors and Executive Officers of the Registrant

The following table sets forth the names and ages of all of our directors and executive officers as of April 28, 2004. Our officers are appointed by, and serve at the pleasure of, the Board of Directors.

Name	Age	Title
Frank DeLape	50	Chairman of the Board of Directors
Michael Macaluso	52	Chief Executive Officer, President and Director
Jeffrey W. Tomz	32	Chief Financial Officer and Secretary
Olga Marko	60	Senior Vice President and Director of Research
Vaughan L. Clift, M.D.	42	Vice President of Operations
Nelson Haight	39	Controller
Steven Morrell	48	Director (1)
Henry Y.L. Toh	46	Director (1)
Ralph V. De Martino	49	Director (1)
Marshall G. Webb	61	Director

(1) Messrs. Morrell, Toh and De Martino are members of the Audit, Compensation and Corporate Governance Committees.

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

Frank DeLape. Mr. DeLape was elected to the Board of Directors in June 2001. He was appointed Vice President in August 2001. In August 2001, Mr. DeLape resigned as Vice President and was elected Chairman of the Board. Mr. DeLape is also the Chief Executive Officer of Benchmark Equity Group, Inc., a position he has held since 1994. Benchmark is a boutique merchant banking firm that focuses as facilitators and financial managers for emerging companies. Mr. DeLape is also the Managing Partner of Gemini Growth Fund, LP. Gemini Growth Fund, LP is a Small Business Investment Company licensed by the United States government.

Michael Macaluso. Mr. Macaluso was elected to the Board of Directors in June 2001. He was appointed President in June 2001. In August 2001, Mr. Macaluso resigned as President and was appointed Chief Executive Officer. In June 2003, Mr. Macaluso was re-appointed as President. From October 1998 until June 2001, Mr. Macaluso was the owner of Page International Communications, a manufacturing business. Mr. Macaluso was a founder and principal of International Printing and Publishing, a position Mr. Macaluso held from 1989 until 1997.

Jeffrey W. Tomz. Mr. Tomz was appointed Secretary and Treasurer in June 2001. In August 2001, Mr. Tomz resigned as Treasurer and was appointed Chief Financial Officer. Mr. Tomz is a Principal at Benchmark Equity Group, Inc. Mr. Tomz has served and/or is currently serving on the board of directors of three investee companies, as well as Trident III, L.L.C. and Trident II, L.L.C., which are private investment funds. Mr. Tomz was a Director of InfoHighway Communication Corp., a private communication company from September 1998 to September 2000. Prior to joining Benchmark in the

fall of 1997, Mr. Tomz began his career as a certified public accountant with Arthur Andersen Worldwide.

Olga Marko. Ms. Marko was appointed Vice President in August 2001. She was appointed as Senior Vice President and Director of Research in August 2001. Ms. Marko previously worked for Merck & Co., Inc. in the Department of Molecular Pharmacology, Memorial Sloan Kettering and Advanced Tissue Sciences. Ms. Marko has a BS in Biochemistry/Microbiology.

Vaughan L. Clift, M.D. Dr. Clift was appointed Vice President of Operations in May 2002. He is in charge of the science aspects, regulatory affairs and manufacturing for all product candidates. From January 2001 to May 2002, Dr. Clift researched home oxygen therapy systems while developing an oxygen system for NASA. From July 1997 to January 2001, he was Chief Scientist of DBCD, Inc., a medical device company that manufacturers a range of blood diagnostic products for the human and veterinary market. From May 1992 to June 1997, Dr. Clift was Chief Scientist for the Science Payload Development, Engineering and Operations project at Lockheed Martin's Human Spaceflight. Dr. Clift has received a number of international and federal awards, served as keynote speaker at several international clinical biochemistry conferences, addressed the first combined International Red Cross and WHO meeting in Geneva, and was nominated as one of NASA's top ten inventors in 1995.

Nelson Haight. Mr. Haight was appointed Controller in January 2003. From July 2002 until January 2003, Mr. Haight served as a consultant with Icon Consulting. Prior to that time, Mr. Haight held various finance and accounting positions with Petroleum Geo-Services ASA, a Norwegian oil field services company, from November 1996 to May 2002, and Copano Field Services LLC, an independent oil and gas exploration company, from January 1995 to November 1996. He began his career as a certified public accountant with Arthur Andersen Worldwide.

Steven Morrell. Mr. Morrell was elected to the Board of Directors in May 2002. Since January 2001, Mr. Morrell has been a Partner at Teknoinvest Management AS, a Norwegian venture capital firm investing in Scandinavia and the United States in the life science and information technology sectors with $150 million under management. From January 1999 to January 2001, he was the Managing Director of a Teknoinvest portfolio company, Aquasmart International AS. From January 1998 to February 1999, he was the General Director of Veropharm Co., Ltd. Mr. Morrell has held numerous positions over the previous 14 years including: Managing Director for a Merck & Co., Inc. subsidiary; General Director of Veropharm Co., Ltd., a Russian pharmaceutical company; President of Hafslund Nycomed Pharma AG in Austria, and management consultant in McKinsey & Co., Inc. Mr. Morrell also served in the U.S. Air Force as an officer. Mr. Morrell currently serves as a Member of the Board of AKVAsmart ASA in Norway, Marical, Inc., Optinel Systems, Inc., CyVera Corporation, and OAO Pharmacy Chain 36.6 in Russia. Mr. Morrell holds an MBA from IMD, Switzerland and a B.Sc. degree with a major in Mathematics and a minor in Aerospace Studies from Brigham Young University.

Henry Y.L. Toh. Mr. Toh was appointed to the Board of Directors in January 2004. He is currently serving as a director with four other publicly traded companies. Since 2001, Mr. Toh has served as a director of Teletouch Communications Inc., an AMEX listed company. Since 1992, Mr. Toh has served as an officer and director of Acceris Communications Inc., a publicly held voice-over-IP company. Since December 1998, Mr. Toh has served as a director of National Auto Credit, Inc., a specialized finance and entertainment company. From April 2002 until February 2004, Mr. Toh served as a director of Bigmar, Inc., a Swiss pharmaceuticals company. Since March 2004, Mr. Toh has served as a director of Crown Financial Group, Inc., a registered broker-dealer. Since 1992, Mr. Toh has served as an officer and director of Four M International, Inc., a privately held offshore investment entity. Mr. Toh began his career with KPMG Peat, Marwick from 1980 to 1992, where he specialized in international taxation and mergers and acquisitions. Mr. Toh is a graduate of Rice University.

Ralph V. De Martino. Mr. De Martino was appointed to the Board of Directors in December 2002. Since January 2003, Mr. De Martino has been the managing partner of the Washington, DC office of the law firm Dilworth Paxson LLP and was recently appointed the National Chair of the Securities Department for the firm. Dilworth Paxson LLP provides legal services to Isolagen. From 1983 to December 2002, Mr. De Martino served as the managing principal of the law firm of De Martino Finkelstein Rosen & Virga. Mr. De Martino is a graduate of Bucknell University and the George Washington University National Law Center. Mr. De Martino practices law in the areas of securities and corporate law. From October 1996 through December 2000, Mr. De Martino served on the Board of Directors and Audit Committee of Commodore Cruise Lines.

Marshall G. Webb. Mr. Webb was appointed to the Board of Directors in April 2004. Mr. Webb is President of Polaris Group, an advisory firm he founded in January 1999 to provide financial consulting and merger and acquisition services to public and private companies. Since February 2003, he has served as Chief Executive Officer of HWIGroup, Inc., an early stage company formed to create security services solutions for maritime and land-based facilities including private companies and governmental agencies. Mr. Webb founded BrightStar Information Technology Group, Inc., a global provider of information technology solutions to government and business, and served as its Chief Executive Officer and as a director from 1997 through 1998. Since 2001, Mr. Webb has served as a director of Teletouch Communications, Inc., and is a member of its Audit and Compensation committees. Mr. Webb was appointed to the Board of Directors of Omni Energy Services Corp. in February 2004 and serves on its Audit Committee. Mr. Webb attended Southern Methodist University, is a certified public accountant, and began his career with Peat, Marwick, Mitchell & Co.

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

The Board of Directors currently consists of six members: Michael Macaluso, Frank DeLape, Steve Morrell, Ralph De Martino, Henry L. Toh and Marshall G. Webb. Mr. Morrell's and Mr. Webb's term expires at the 2004 Annual Meeting of Stockholders or until their successors are duly elected and qualified. Mr. Toh's and Mr. De Martino's term expires at the 2005 Annual Meeting of Stockholders or until his successor is duly elected and qualified. Mr. Macaluso's, and Mr. DeLape's term expires at the 2006 Annual Meeting of Stockholders or until his successor is duly elected and qualified.

Audit Committee. We have established an Audit Committee of the Board of Directors consisting of Messrs. De Martino, Morrell and Toh, each of whom is an "independent" director as defined under the rules of the American Stock Exchange. The Board of Directors has determined that Messrs. De Martino and Toh each qualify as an "audit committee financial expert" under federal securities laws.

During 2002, prior to Mr. De Martino's joining the Board of Directors, a firm with which Mr. De Martino was associated received $25,000 in connection with its representation of us in the listing of our shares on AMEX. During 2003, Dilworth Paxon, LLP, a firm with which Mr. De Martino is a partner, received fees in connection with legal services provided to Isolagen.

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 for the fiscal year ended December 31, 2003.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors, executive officers and the persons who beneficially own more than ten percent of our common stock to file reports of ownership and changes in ownership with the Securities and Exchange Commission. Copies of all filed reports are required to be furnished to us. Based solely on the reports received and on the representations of the reporting persons, we believe that these persons have complied with all applicable filing requirements of Section 16(a) of the Exchange Act during the fiscal year ended December 31, 2003.

Item 11. Executive Compensation

The following table sets forth information regarding annual and long-term compensation with respect to the fiscal years ended December 31, 2003, 2002 and 2001, paid or accrued by us to or on behalf of those persons who were, during the fiscal year ended December 31, 2003, our Chief Executive Officer and our most highly compensated executive officers whose compensation was in excess of $100,000 (the "Named Executive Officers").

Summary Compensation Table

		Annual Compensation(1)			Long Term Compensation Awards	
Name and Principal Position	**Year**	**Salary ($)**	**Bonus ($)**	**Other Annual Compensation ($)**	**Restricted Stock Awards ($)(11)**	**Securities Underlying Options (#)**
Michael Macaluso(2)(8)	2003	149,215	78,000			700,000(3)
Chief Executive Officer,	2002		60,500			
President and Director	2001					900,000(3)
Frank DeLape	2003	257,030	100,100			700,000(4)
Chairman of the Board of	2002		236,000			
Directors	2001					650,000(4)
Michael Avignon(2)(8)	2003	102,292	15,000			400,000(5)
Former President and	2002		60,500			
Former Director	2001					900,000(5)
Jeffrey W. Tomz(2)(8)	2003	96,615				120,000(6)
Chief Financial Officer	2002					
and Secretary	2001					150,000(6)
Olga Marko	2003	133,262				
Senior Vice President and	2002	125,402	5,000			
Director of Research	2001	130,000				
Vaughan Clift, M.D.(9)	2003	177,525	5,000			
Vice President Operations	2002	93,549	6,750			250,000(10)
	2001					
Nelson Haight	2003	113,231	5,000			45,000(7)
Controller	2002					
	2001					

(1) Excludes perquisites and other personal benefits unless such compensation was greater than $50,000 or 10% of the total annual salary and bonus of the individual.

(2) We did not pay Messrs. Macaluso, Avignon or Tomz a salary prior to July 14, 2003 pursuant to the terms of our Series A Convertible Preferred Stock. These salary amounts have been foregone by the above individuals and will not be repaid. From July 15, 2003 through September 4, 2003, Messrs. Macaluso, Avignon and Tomz each were paid $21,923. On September 5, 2003, Mr. Macaluso entered into an employment agreement with an annual salary of $300,000. On September 5, 2003, Mr. Avignon's salary was increased to $200,000. On September 5, 2003, Mr. Tomz entered into an employment agreement with an annual salary of $200,000.

(3) Mr. Macaluso was granted 400,000 stock options on February 25, 2003 at $4.50 per share of which 200,000 options vested on February 25, 2004 and 200,000 options vest on February 25, 2005. Mr. Macaluso was also granted 300,000 stock options on September 5, 2003 at $9.81 per share which vest ratably over the last six months of his employment agreement. Mr. Macaluso was granted 900,000 stock options during fiscal year 2001 at $6.00 per share, which are currently exercisable.

(4)

Mr. DeLape was granted 400,000 stock options on February 25, 2003 at $4.50 per share of which 200,000 options vested on February 25, 2004 and 200,000 options vest on February 25, 2005. Mr. DeLape was also granted 300,000 stock options on September 5, 2003 at $9.81 per share which vest ratably over the last six months of his employment agreement. Mr. DeLape was granted 650,000 stock options during fiscal year 2001 at $6.00 per share, which are currently exercisable.

(5)

Mr. Avignon resigned as President in January 2003 and as a director in March 2004. Mr. Avignon was granted 400,000 stock options on February 25, 2003 at $4.50 per share of which 200,000 options vested on February 25, 2004 and 200,000 options vest on February 25, 2005. Mr. Avignon was granted 900,000 stock options during fiscal year 2001 at $6.00 per share, which are currently exercisable.

(6)

Mr. Tomz was granted 120,000 stock options on February 25, 2003 at $4.50 per share of which 60,000 options vested on February 25, 2004 and 60,000 options vest on February 25, 2005. Mr. Tomz was granted 150,000 stock options during fiscal year 2001 at $6.00 per share, which are currently exercisable.

(7)

Mr. Haight received 45,000 stock options on January 8, 2003 at $6.00 per share of which 15,000 options vested on January 7, 2004, 15,000 options vest on January 7, 2005 and 15,000 options vest on January 7, 2006.

(8)

Each of Mr. Macaluso, Mr. Avignon, and Mr. Tomz assumed their respective positions with us on August 24, 2001.

(9)

Dr. Clift assumed his position as Vice President of Operations on May 28, 2002.

(10)

Dr. Clift was granted 250,000 stock options during fiscal year 2002 at $6.00 per share, of which: (a) 40,000 options vested on May 28, 2003, which are currently exercisable, (b) 30,000 options vest on May 28, 2004, (c) 30,000 options vest on May 28, 2005, (d) 50,000 options vest on May 28, 2006, (e) 50,000 options vest on May 28, 2007, and (f) 50,000 options vest on May 28, 2008.

(11)

The number and value of the aggregate restricted stock holdings as of the end of the last fiscal year for each of our Named Executive Officers were as follows: Mr. Macaluso, 1,775,734 shares or $9,944,110 (of which $5,600,000 is held by Mr. Macaluso's spouse); Mr. Delape, 1,355,000 shares or $7,588,000; Mr. Avignon, 1,775,734 shares or $9,944,110 (of which $5,600,000 is held by Mr. Avignon's spouse); Mr. Tomz, 227,200 shares or $1,272,320; Ms. Marko, 1,050,000 shares or $5,880,000; Dr. Clift, 0 shares or $0; and Mr. Haight, 0 shares or $0.

Stock Options

The following table sets forth information concerning individual grants of stock options made during our last fiscal year to our Named Executive Officers. No stock appreciation rights were issued during the fiscal year.

Option Grants in Last Fiscal Year

	Individual Grants				Potential realizable value at assumed annual rates of stock price appreciation for option term (1)	
Name	Number of securities underlying options granted (#)	Percent of total options granted to employees in fiscal year	Exercise or base price ($/Sh)	Expiration date	5% ($)	10% ($)
Michael Macaluso	400,000	17.3%	4.50	12/31/2012	1,822,966	3,930,129
Michael Macaluso	300,000	13.0%	9.81	12/31/2012		1,144,446
Frank DeLape	400,000	17.3%	4.50	12/31/2012	1,822,966	3,930,129
Frank DeLape	300,000	13.0%	9.81	12/31/2012		1,144,446
Michael Avignon	400,000	17.3%	4.50	12/31/2012	1,822,966	3,930,129
Jeffrey W. Tomz	120,000	5.2%	4.50	12/31/2012	546,890	1,179,039
Nelson Haight	45,000	1.9%	6.00	7/10/2011	111,641	296,920

(1) The 5% and 10% assumed annual rates of compounded stock price appreciation are mandated by rules of the SEC. There can be no assurance provided to any executive officer or any other holder of our securities that the actual stock price appreciation over the particular option term will be at the assumed 5% and 10% levels or at any other defined level. Unless the market price of our common stock appreciates over the option term, no value will be realized from the option grants made to the executive officers.

The following table sets forth information concerning option exercises during the fiscal year ended December 31, 2003 and option holdings as of December 31, 2003 with respect to our Named Executive Officers.

Aggregated Option Exercises in Last Fiscal Year and FY-End Option Values

			Number of Securities Underlying Unexercised Options at FY-End (#)		Value of Unexercised In-the-Money Options at FY-End ($)(1)	
Name	Shares Acquired on Exercise (#)	Value Realized ($)	Exercisable	Unexercisable	Exercisable	Unexercisable
Michael Macaluso			900,000	700,000		440,000
Frank DeLape			650,000	700,000		440,000
Michael Avignon			900,000	400,000		440,000
Jeffrey W. Tomz			150,000	120,000		132,000
Vaughan Clift			40,000	210,000		
Nelson Haight				45,000		

(1) Based on the closing price of our common stock on December 31, 2003 of $5.60 per share less the exercise price payable for such shares.

Employment Agreements, Termination of Employment and Change in Control Agreements

We have entered into employment agreements with Olga Marko, William K. Boss, Jr., Vaughan Clift, Frank DeLape, Michael Macaluso and Jeffrey Tomz.

On August 10, 2001, we entered into a five-year employment agreement with Ms. Marko. The agreement provides for an annual base salary of $130,000. The base salary shall increase on an annual basis by the same percentage that the Consumer Price Index has increased during the same time frame or at the direction of the Board of Directors, whichever is higher. Ms. Marko 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, Ms. Marko will be entitled to a twelve month severance payment.

On August 10, 2001, we entered into a five-year employment agreement with Dr. Boss, who served as one of our directors from August 2001 until his resignation in April 2004, which was amended on February 28, 2002. The agreement provides for the following compensation: (a) during the first year of the employment term, Dr. Boss received 60,000 shares of common stock; (b) an annual compensation of $50,000 for 2002; and (c) an annual compensation of $60,000 for 2003. For this compensation, Dr. Boss has agreed to devote 25 mutually agreeable days of service per year as requested by us. If the employment agreement is terminated without cause, Dr. Boss will be entitled to a three-month severance payment.

On May 28, 2002, we entered into a three-year employment agreement with Dr. Clift. The agreement provides for an annual base salary of $150,000, which was later amended to $175,500. Dr. 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, Dr. Clift will be entitled to a two-month severance payment.

On September 5, 2003, we entered into an employment agreement with Mr. DeLape, ending July 31, 2006, that is renewable by mutual agreement on a year-to-year basis. The agreement provides for a base salary of $325,000, subject to the right of the Board of Directors to increase the 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 provided that Mr. DeLape receive employee stock options to purchase 300,000 shares of common stock at an exercise price of $9.81 per share, which was equal to our average closing price on the ten trading days preceding the grant. The option has a term of ten years and will vest and become exercisable ratably over the last six calendar quarters of the 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) a severance payment equal to the greater of: (i) the salary payable over the remaining term of his agreement or (ii) eighteen months salary; and (b) a bonus equal to the greater of: (i) the amount determined under the agreement by the Compensation Committee or (ii) $70,000.

On September 5, 2003, we entered into an employment agreement with Mr. Macaluso, ending July 31, 2006, that is renewable by mutual agreement on a year-to-year basis. The agreement provides for a base salary of $300,000, subject to the right of the Board of Directors to increase the salary from time to time. Mr. Macaluso is entitled to receive an annual bonus in an amount to be determined by the Compensation Committee. If Mr. Macaluso'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. Macaluso will receive employee stock options to purchase 300,000 shares of common stock at an exercise price of $9.81 per share, which was equal to our average closing price on the ten trading days preceding the grant. The option will have 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. Macaluso with disability and life insurance benefits, a car allowance and wireless communications benefits. Mr. Macaluso'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) a severance payment equal to the greater of: (i) the salary payable over the remaining term of his agreement or (ii) eighteen months salary; and (b) a bonus equal to the greater of: (i) the amount determined under the agreement by the Compensation Committee or (ii) $70,000.

On September 5, 2003, we entered into an employment agreement with Mr. Tomz, ending July 15, 2005, that is renewable by mutual agreement on a year-to-year basis. The agreement provides for a base salary of $200,000, subject to the right of the Board of Directors to increase the 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.

Compensation of Directors

Directors who are also employees do not receive compensation for their services as directors. In consideration for our independent directors services, we provided, during the fiscal year ended December 31, 2003, each independent director with a stipend of $15,000 plus options to purchase 100,000 shares of common stock at $6 per share. The options granted to our independent directors vest over a period of three years from the date of grant.

For future fiscal years, we have agreed to compensate our independent directors as follows: (a) a cash stipend of $15,000 per year, (b) meeting fees of $1,500 per Board meeting and $1,000 per Board committee meeting, and (c) an annual option to purchase 20,000 shares of our common stock, which vests one year from the date of grant. New directors will receive an initial appointment grant of an option to purchase 30,000 shares of our common stock, which vests one year from the date of grant. Independent directors who served on the Board prior to April 8, 2004 will not receive an initial grant, and their first option issuance thereafter will occur in January 2005.

Stock Option Plans

We currently have two outstanding stock option plans: (a) our 2001 Stock Option and Appreciation Rights Plan (the "2001 Plan") reserving 5,000,000 shares of common stock for the issuance of options to employees, directors and consultants, and (b) our 2003 Stock Option and Appreciation Rights Plan (the "2003 Plan") reserving 2,250,000 shares of common stock for the issuance of options to employees, directors and consultants. The purposes of the 2001 Plan and 2003 Plan are to promote the interests of the company, and to motivate, attract and retain the services of the people upon whose efforts and contributions our success depends. The 2001 Plan and 2003 Plan provide for grants of non-qualified options, incentive stock options and restricted stock awards, or any combination of the foregoing.

As of December 31, 2003, options to acquire 4,368,100 shares of the common stock have been granted under the 2001 Plan, of which 439,000 options have been exercised, and options to acquire 1,920,000 shares of common stock have been granted under the 2003 Plan, of which none have been

exercised. The options to acquire the shares of common stock granted under the 2001 Plan and 2003 Plan have an exercise price ranging from $1.50 per share to $9.81 per share.

Compensation Committee Interlocks and Insider Participation

Our Compensation Committee consists of Messrs. Morrell, Toh and De Martino. Mr. E. Ashley Smith served on the committee until his resignation effective January 8, 2004, at which time Mr. Toh joined the Board of Directors and assumed Mr. Smith's position on the Compensation Committee. No member of the Compensation Committee has ever been an officer or employee of Isolagen, or any of our subsidiaries or affiliates. None of our executive officers has served on a compensation committee for any other company.

Item 12. Security Ownership of Certain Beneficial Owners and Management

Equity Compensation Plan Information

The following table gives information as of December 31, 2003 about common stock that may be issued upon the exercise of options under our equity compensation plans.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	5,849,100	$ 5.81	961,900
Equity compensation plans not approved by security holders (1)	585,000	$ 3.07	-0-
Total	6,434,100	$ 5.56	961,900

(1) Consists of the following securities: (a) a warrant to purchase 25,000 shares of common stock at an exercise price of $1.50 per share issued to the Lotus Group; (b) a warrant to purchase 350,000 shares of common stock at an exercise price of $2.50 per share issued to the Lotus Group; (c) a warrant to purchase 60,000 shares of common stock at an exercise price of $5.94 per share issued to RCG Capital Markets Group, Inc.; and (d) a warrant to purchase 150,000 shares of common stock at an exercise price of $3.50 per share issued to Equipment Pty, Ltd.

Security Ownership of Certain Beneficial Owners and Management

As of April 28, 2004, 26,769,718 shares of our common stock were outstanding. The following table sets forth information known to us with respect to the beneficial ownership of our common stock as of that date and as adjusted to reflect the sale of common stock offered hereby:

- each stockholder known by us to own beneficially more than 5% of our common stock;
- each of our executive officers;

each of our directors; and

all of our directors and executive officers as a group.

Beneficial ownership has been determined in accordance with rules of the SEC. Under these rules, shares are deemed to be beneficially owned by a person if the person has the right to acquire shares (for example, upon exercise of an option) within 60 days of the date as of which the information is provided. In computing the percentage ownership of any person, the amount of shares is deemed to include the amount of shares beneficially owned by that person by reason of these acquisition rights, but are not deemed outstanding for computing the percentage ownership of any other person. As a result, the percentage of outstanding shares of any person as shown in the following table does not necessarily reflect the person's actual voting power at any particular date.

To our knowledge, except as indicated in the footnotes to this table and pursuant to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them. Unless otherwise indicated in the footnotes, the address of each of the individuals and entities named below is as follows: c/o Isolagen Inc., 2500 Wilcrest, 5th Floor, Houston, Texas 77042.

	Shares Beneficially Owned as of April 28, 2004	
Name and address of beneficial owner	**Number**	**Percent(1)**
Directors & Executive Officers		
Michael Macaluso(2)	2,875,734	10.3%
Frank DeLape(3)	2,205,000	8.0
Olga Marko	1,050,000	3.9
Jeffrey W. Tomz(4)	323,600	1.2
Steven Morrell(5)	78,333	*
Vaughan Clift(6)	70,000	*
Ralph V. De Martino(7)	63,333	*
Nelson Haight(8)	15,000	*
Henry Y.L. Toh(9)	8,333	*
Marshall G. Webb		
All current directors and executive officers as a group (10 persons)(10)	6,689,333	24.3
5% Stockholders		
Michael Avignon(11)		
#7 West River Crest		
Houston, Texas 77042	2,875,734	10.3
Buechel Family Ltd. Partnership(12)		
76 Crest Drive		
So. Orange, New Jersey 07079	2,485,800	9.3
William K. Boss, Jr.	1,614,055	6.0

* Indicates ownership of less than 1%.

(1) Beneficial ownership is determined in accordance with SEC rules, and includes shares of stock underlying outstanding options that are currently exercisable or will become exercisable within 60 days of April 28, 2004.

(2) Includes 1,000,000 shares of common stock beneficially owned by Alyda Macaluso, Mr. Macaluso's wife, and includes options to purchase 1,100,000 shares of common stock held by Mr. Macaluso.

(3) Includes 1,355,000 shares of common stock beneficially owned by Benchmark Equity Group, Inc., which is solely owned by Mr. DeLape, and includes options to purchase 850,000 shares of common stock held by Mr. DeLape. Does not include 736,666 shares of common stock beneficially held by Lighthouse Capital Insurance Company, a Cayman Islands unlimited licensed insurance company,

which has issued a variable universal life insurance contract of which Mr. DeLape and his children are remote contingent beneficiaries. Mr. DeLape disclaims beneficial ownership of such shares held by Lighthouse and does not have voting or dispositive power with respect to such shares.

(4) Includes options to purchase 210,000 shares of common stock.

(5) Consists of options to purchase 78,333 shares of common stock.

(6) Consists of options to purchase 70,000 shares of common stock.

(7) Consists of options to purchase 63,333 shares of common stock.

(8) Consists of options to purchase 15,000 shares of common stock.

(9) Consists of options to purchase 8,333 shares of common stock.

(10) Includes options to purchase 2,394,999 shares of common stock.

(11) Includes 1,000,000 shares of common stock beneficially owned by Laura Avignon, Mr. Avignon's wife, and includes options to purchase 1,100,000 shares of common stock options held by Mr. Avignon.

(12) Includes 826,013 shares of common stock beneficially owned by Buechel Patient Care Research & Education Fund, Inc. Dr. Frederick Buechel exercises voting and dispositive power over the shares held by Buechel Family Ltd. Partnership and by Buechel Patient Care Research & Education Fund, Inc.

Item 13. Certain Relationships and Related Transactions

Certain officers granted us the use of our office space located in Houston, Texas at no charge until August 2003. Beginning in September 2003, the lease rate was approximately $105,840 annually. We have a month to month lease that may be terminated at our option. The lease is with Axces, Inc., a Delaware corporation, which is owned by Michael Avignon, Michael Macaluso and Timothy Till. We believe that the leased premises have been made available to us on terms that are superior to those available from arms-length providers of lease space.

Item 14. Principal Accounting Fees and Services

Aggregate fees for professional services rendered by our principal accountants for the respective services for the fiscal years ended December 31, 2002 and 2003, were as follows:

	2002	2003
Audit Fee	$ 34,500	$ 80,000
Audit-Related Fees		$
Tax Fees	$ 3,000(1)	$ 3,500(1)
All Other Fees		

(1) All of these services were pre-approved by the Audit Committee prior to their performance in fiscal 2003, and by the entire Board of Directors in fiscal 2002.

Audit Fees

Audit fees of $34,500 and $80,000, during fiscal 2002 and fiscal 2003, respectively, represent the aggregate fees billed for professional services rendered by Pannell Kerr Forster of Texas, P.C. for the audit of our annual financial statements, review of financial statements included in our quarterly reports on Form 10-Q or Form 10-QSB, as applicable, review of registration statements or services that

are normally provided in connection with statutory and regulatory filings or engagements for those fiscal years.

Audit-Related Fees

Audit-related fees represent the aggregate fees billed for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements and are not reported under Audit Fees.

Tax Fees

Tax fees of $3,000 and $3,500, during fiscal 2002 and fiscal 2003, respectively, represent the aggregate fees billed for professional services rendered by our principal accountants for tax compliance, tax advice, and tax planning for such years.

All Other Fees

All other fees represent the aggregate fees billed for products and services other than the services reported in the other categories.

Audit Committee Pre-Approval Policies and Procedures

Representatives of the independent auditors normally attend each meeting of the Audit Committee. The Audit Committee on an annual basis reviews audit and non-audit services performed by the independent auditor. All audit and non-audit services are pre-approved by the Audit Committee, which considers, among other things, the possible effect of the performance of such services on the auditors' independence.

Part IV

Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K

(a)

(1) Financial Statements.

Report of Independent Public Accountants

Consolidated Balance Sheets as of December 31, 2003 and 2002

Consolidated Statements of Operations for the years ended December 31, 2003, 2002, and 2001

Consolidated Statements of Stockholders' Equity from inception to December 31, 2003

Consolidated Statements of Cash Flows for the years ended December 31, 2003, 2002 and 2001

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)

Reports on Form 8-K. The following Form 8-Ks were filed during the quarter ended December 31, 2003.

October 27, 2003 We issued a press release on our restatement of financial statements.

November 20, 2003 We issued a press release on our positive results in the U.K.

December 3, 2003 We issued a press release on our positive results in its Dental Study.

December 16, 2003 We issued a press release on our manufacturing system breakthrough.

(c)

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)
10.1	2003 Stock Option and Stock Appreciation Rights Plan(3)*
10.2	2001 Stock Option and Appreciation Rights Plan(4)*
10.3	Employment Agreement dated August 10, 2001 between Isolagen, Inc. and Olga Marko(7)*
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	Employment Agreement dated August 10, 2001 between Isolagen, Inc. and William K. Boss, as amended on February 28, 2002(7)*
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)
14	Code of Ethics(9)
21	List of Subsidiaries(10)
23.1	Pannell Kerr Forster of Texas, P.C. Consent(10)
31.1	Certification pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002(10)
31.2	Certification pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002(10)
32.1	Certification pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002(10)
32.2	Certification pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002(10)

*

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)

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: April 27, 2004

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/ FRANK DELAPE Frank DeLape	Chairman of the Board	April 27, 2004
/s/ MICHAEL MACALUSO Michael Macaluso	Chief Executive Officer, President and Director	April 27, 2004
/s/ JEFFREY W. TOMZ Jeffrey W. Tomz	Chief Financial Officer	April 27, 2004
/s/ STEVEN MORRELL Steven Morrell	Director	April 27, 2004
/s/ HENRY TOH Henry Toh	Director	April 27, 2004
/s/ RALPH DE MARTINO Ralph De Martino	Director	April 27, 2004
/s/ MARSHALL G. WEBB Marshall G. Webb	Director	April 27, 2004

Isolagen, Inc.

(A Development Stage Company)

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

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

We have audited the accompanying consolidated balance sheets of Isolagen, Inc. and Subsidiaries (a Delaware corporation) as of December 31, 2003 and 2002, and the related consolidated statements of operations, shareholders' equity and cash flows for each of the three 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 audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. 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 audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Isolagen, Inc. and Subsidiaries as of December 31, 2003 and 2002 and the results of their operations and their cash flows for each of the three 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, TX
February 17, 2004

Isolagen, Inc.

(A Development Stage Company)

Consolidated Balance Sheets

	December 31,	
	2003	**2002**
Assets		
Current assets		
Cash and cash equivalents	$ 15,935,558	$ 4,244,640
Inventory	259,695	138,910
Accounts receivable, net of allowance for doubtful accounts	207,202	40,204
Other receivables	91,545	153,583
Prepaid expenses	254,508	284,557
Total current assets	16,748,508	4,861,894
Property and equipment, net	2,221,838	2,159,913
Intangible assets	540,000	
Other assets	134,119	235,857
Total assets	$ 19,644,465	$ 7,257,664
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	$ 1,460,478	$ 1,881,236
Accrued expenses	535,975	112,224
Deferred revenue	384,287	57,274
Total current liabilities	2,380,740	2,050,734
Commitments and contingencies		
Shareholders' equity (deficit)		
Preferred stock, $.001 par value; 5,000,000 shares authorized		3,039
Common stock, $.001 par value; 50,000,000 shares authorized	26,672	15,228
Additional paid-in capital	50,862,258	25,573,999
Other comprehensive income	374,380	13,875
Accumulated deficit during development stage	(33,999,585)	(20,399,211)
Total shareholders' equity	17,263,725	5,206,930
Total liabilities and shareholder's equity	$ 19,644,465	$ 7,257,664

The accompanying notes are an integral part of these 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, 2003
	2003	2002	2001	
Revenues				
Sales	$ 445,689	$ 50,991	$ 25,482	$ 1,886,794
License fees		40,000	80,000	260,000
Total revenues	445,689	90,991	105,482	2,146,794
Cost of sales	121,826	35,133	17,891	559,418
Gross profit	323,863	55,858	87,591	1,587,376
Selling, general and administrative expenses	7,980,757	3,994,782	715,468	15,141,416
Research and development	3,301,341	1,735,244	933,907	7,071,461
Operating loss	(10,958,235)	(5,674,168)	(1,561,784)	(20,625,501)
Other income (expense)				
Interest income	40,691	208,692	17	277,780
Other income	55,663	32,421		88,084
Loss on disposal of asset	(406,413)		(8,222)	(414,635)
Interest expense			(82,015)	(311,628)
Net loss	$ (11,268,294)	$ (5,433,055)	$ (1,652,004)	$ (20,985,900)
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	$ (13,600,374)	$ (16,114,660)	$ (1,652,004)	$ (33,999,585)
Per share information				
Net loss basic and diluted	$ (0.58)	$ (0.36)	$ (0.22)	$ (3.06)
Deemed dividend associated with beneficial conversion of preferred stock	(0.06)	(0.67)		(1.67)
Preferred stock dividends	(0.06)	(0.03)		(0.23)
Net loss per common share basic and diluted	$ (0.70)	$ (1.06)	$ (0.22)	$ (4.96)
Weighted average number of basic and diluted common shares outstanding	19,297,865	15,205,554	7,618,947	6,848,333

The accompanying notes are an integral part of these 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	Accumulated Deficit During Development Stage	Other Comprehensive Income	Number of Shares	Amount	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)
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	$ (518,693)	$	2,400	$ (50,280)	$ (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	$ (1,825,471)	$	2,400	$ (50,280)	$ (1,423,349)
Issuance of common stock for					53,583	54	1,869					1,923

	Series A Preferred Stock	Series B Preferred Stock					
cash on 1/18/00							
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)

The accompanying notes are an integral part of these 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	Accumulated Deficit During Development Stage	Other Comprehensive Income	Number of Shares	Amount	Total Shareholders' Equity (Deficit)
Balance, 12/31/00		$		$	2,843,045	$ 2,843	$ 451,517	$ (2,632,547)	$	2,400	$ (50,280)	$ (2,228,467)
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
Uncompensated contribution of services 3rd quarter							55,556					55,556
					145,933	146	218,754					218,900

	Series A Preferred Stock	Series B Preferred Stock			
Issuance of common stock for services on 11/1/01					
Uncompensated contribution of services 4th quarter			100,000		100,000
Net loss				(1,652,004)	(1,652,004)

The accompanying notes are an integral part of these 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	Accumulated Deficit During Development Stage	Other Comprehensive Income	Number of Shares	Amount	Total Shareholders' Equity (Deficit)
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)

Series A Preferred Stock	Series B Preferred Stock	Common Stock	Accumulated Deficit During Development Stage	Treasury Stock

The accompanying notes are an integral part of these 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	Accumulated Deficit During Development Stage	Other Comprehensive Income	Number of Shares	Amount	Total Shareholders' Equity (Deficit)
Balance, 12/31/02	3,038,507	$ 3,039		$	15,227,963	$ 15,228	$ 25,573,999	$ (20,399,211)	$ 13,875		$	$ 5,206,930
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 5/16/02			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 for 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					3,359,331	3,359	18,452,202					18,455,561

	Series A Preferred Stock		Series B Preferred Stock								
for cash on 8/27/03											
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	$ (33,999,585)	$ 374,380		$ $ 17,263,725

The accompanying notes are an integral part of these 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, 2003
	2003	2002	2001	
Cash flows from operating activities				
Net loss	$ (11,268,294)	$ (5,433,055)	$ (1,652,004)	$ (20,985,900)
Adjustments to reconcile net loss to net cash used in operating activities:				
Equity awards issued for services	412,812	157,704	788,970	1,622,595
Uncompensated contribution of services	200,000	400,000	155,556	755,556
Depreciation	835,430	99,812	15,368	1,002,959
Loss on disposal of property and equipment	406,413		8,222	414,635
Change in operating assets and liabilities:				
Decrease (increase) in accounts receivable	(166,998)	(39,137)	1,288	(207,203)
Decrease (increase) in other receivables	62,038	(153,583)		(91,545)
Decrease in inventory	(120,785)	(138,910)		(259,695)
Decrease (increase) in prepaid expenses	30,049	(284,557)		(254,508)
Decrease (increase) in other assets	(17,721)	(115,507)	25,420	(133,228)
Increase (decrease) in accounts payable	(420,758)	1,673,040	59,932	1,460,478
Increase in accrued expenses	423,751	88,906	13,045	535,975
Increase (decrease) in deferred revenue	327,013	(222,726)	(80,000)	384,288
Net cash used in operating activities	(9,297,050)	(3,968,013)	(664,203)	(15,755,593)
Cash flows from investing activities				
Purchase of property and equipment	(1,193,157)	(2,252,368)		(3,529,821)
Proceeds from the sale of property and equipment	33,300		1,000	34,300
Net cash provided by (used in) operating activities	(1,159,857)	(2,252,368)	1,000	(3,495,521)
Cash flows from financing activities				
Proceeds from convertible debt				1,450,000
Proceeds from notes payable to shareholders			30,000	135,667
Proceeds from the issuance of preferred stock	3,919,078	9,012,722		12,931,800
Proceeds from the issuance of common stock	19,137,461	57,600	2,060,000	21,662,871
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)	(48,547)
Repurchase of common stock				(50,280)
Net cash provided by financing activities	21,931,231	9,070,322	2,041,453	34,956,203
Effect of exchange rate changes on cash balances	216,594	13,875		230,469

				Cumulative Period from December 28, 1995 (date of inception) to December 31, 2003
Net increase in cash and cash equivalents	11,690,918	2,863,816	1,378,250	15,935,558
Cash and cash equivalents, beginning of period	4,244,640	1,380,824	2,574	
Cash and cash equivalents, end of period	$ 15,935,558	$ 4,244,640	$ 1,380,824	$ 15,935,558
Supplemental disclosures of cash flow information:				
Cash paid for interest	$	$	$ 1,020	$ 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
Equity awards issued for services	$ 412,812	$ 157,704	$ 788,970	$ 1,622,595
Uncompensated contribution of services	$ 200,000	$ 400,000	$ 155,556	$ 755,556
Common stock issued for Intellectual Property	$ 540,000	$	$	$ 540,000

The accompanying notes are an integral part of these statements.

Isolagen, Inc.

(A Development Stage Company)

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 and wholly-owned subsidiary of Isolagen Technologies ("Isolagen Europe"). Isolagen Technologies is the parent company of Isolagen Australia Pty Limited, a company organized under the laws of Australia and wholly-owned subsidiary of Isolagen Technologies ("Isolagen Australia"). Isolagen Technologies is the parent company of Isolagen International, a company organized under the laws of Switzerland and wholly-owned subsidiary of Isolagen Technologies ("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 is a Houston, Texas based company specializing in the development and commercialization of autologous cellular therapies for soft and hard tissue regeneration. Autologous cells are a patient's own cells taken from a small skin sample. From such sample millions of cells are grown and then injected into the patient to correct and reduce the normal effects of aging like wrinkles, laugh lines, smokers lines, fine lines and all types of depressed scars. The procedure is minimally invasive and non-surgical.

In 1995, Isolagen Technologies began treating a small percentage of patients with the Isolagen Process to correct defects (e.g., wrinkles, depressions and scarring) in the patient's face. Between 1995 and 1999, approximately 200 doctors utilized the Isolagen Process on approximately 963 patients with positive results. In 1997, the FDA began regulating the science of biologics. Biologics, in contrast to drugs that are chemically synthesized, are derived from living sources (such as humans, animals, and microorganisms) like the Isolagen Process. In 1995, when Isolagen Technologies began operations, the FDA had no regulations governing this area of biologics. After reviewing the new regulations and seeking the advice of consultants, Isolagen concluded that the use of the Isolagen Process in cosmetic applications did not require the approval of the FDA. In 1999, Isolagen Technologies filed a request for authorization from the FDA to administer an investigational drug or biological product to humans (referred to herein as an "IND"). Such authorization must be secured prior to commercialization of any new drug or biological product. The FDA placed the IND on clinical hold until Isolagen Technologies' manufacturing processes and procedures were changed to meet these new biologics standards, and FDA approval is obtained. In April 2002, the FDA released Isolagen's IND and clinical trial negotiations are underway.

As a result, a 397 patient retrospective study has been completed. The results demonstrated both safety and efficacy as Phase II data. Using Isolagen Technologies recently completed cGMP laboratory facility in Houston, Texas, several studies are taking place. These include: dosage management, dental application relating to gum and bone, cosmetic correction and scarring. They are operational under currently active INDs with the FDA. The Company anticipates that these INDs are scheduled for License Application (approval) by the FDA in 2005, although there can be no assurance that such approval will be obtained on a timely basis, or at all.

The Company's goal is to become a leading provider of solutions for soft and hard tissue repair. The Company is also pursuing, through Isolagen Europe, commercial operations in the UK and is pursuing commercial operations through subsidiaries, joint ventures or license arrangements in Australia, South Korea, Hong Kong, Brazil, Mexico and elsewhere. The Company is investigating

regulatory and other requirements in these countries and evaluating markets and potential joint venture partners and licensees.

Through December 31, 2003, 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 2004. 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 further sources of debt and equity capital, prompt regulatory approval to sell its products and upon its continued expansion. The Company will require additional capital in the future to expand its operations. No assurance can be given that the Company will be able to obtain any such additional capital, 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 operations and 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, 2003, the Company had a cash balance of $15,935,558. The Company believes its existing cash and cash equivalents will be adequate to meet its anticipated capital and liquidity requirements until June 30, 2005. The long-term viability of the Company is dependent upon successful operation of its business 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 U.S. Food and Drug Administration ("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 at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Statement of cash flows

For purposes of the statements of cash flows, the Company considers all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents.

Concentration of credit risk

The Company maintains its cash with a major U.S. domestic bank. The amounts held in this bank 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.

The Company is subject to risks common to companies in the development stage including, but not limited to, development of new products, development of markets and distribution channels, dependence on key personnel, and the ability to obtain additional capital as needed to fund its business plans. The Company has a limited operating history and has yet to generate any significant revenues from customers. To date, the Company has been funded by private debt and equity financings. The Company's ultimate success is dependent upon its ability to raise additional capital and to successfully develop and market its products.

The products developed by the Company require approvals from the United States FDA or other international regulatory agencies prior to commercial sales. There can be no assurance that all of the Company's products will receive the necessary approvals. If the Company was denied such approvals or such approvals were delayed, it may have a material adverse impact on the Company.

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, leasehold improvements, and office furniture and fixtures is carried at cost less accumulated depreciation. Depreciation for financial reporting purposes is provided by the straight-line method over the estimated useful lives of three to five years subject to half year convention. Leasehold improvements are amortized using the straight-line method over the remaining life of the lease. The cost of repairs and maintenance is charged against income as incurred.

Earnings per share data

Basic earnings (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 and convertible preferred stock (calculated based on the treasury stock method). The Company does not present diluted earnings per share for years in which it incurred net losses as the effect of potentially dilutive shares is antidilutive.

Stock-based compensation

The Company accounts for its stock-based compensation under the provisions of Statement of Financial Accounting Standards ("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. 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.

In December 2002, the Financial Accounting Standards Board ("FASB") issued SFAS No. 148, *"Accounting for Stock-Based Compensation-Transition and Disclosure".* This statement provides guidance for those companies wishing to voluntarily change to the fair value based method of accounting for stock-based compensation. 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 2003, 2002 and 2001 consistent with the provisions of SFAS No. 123, the Company's net loss and net loss per share would have increased to the pro forma amounts indicated below:

	Year ended December 31,		
	2003	2002	2001
Net loss as reported	$ (11,268,294)	$ (5,433,055)	$ (1,652,004)
Less: total stock based employee compensation determined under fair value based method for all awards granted to employees, net of related tax effect	$ (1,540,157)	$ (1,008,562)	$ (149,564)
Net loss pro forma	$ (12,808,451)	$ (6,441,617)	$ (1,801,568)
Net loss per share as reported			
Basic and diluted	$ (0.58)	$ (0.36)	$ (0.22)
Net loss per share pro forma			
Basic and diluted	$ (0.66)	$ (0.42)	$ (0.24)

In computing the pro forma information presented above, the Company used the Black Scholes model with the following weighted average assumptions

	Year ended December 31,		
	2003	2002	2001
Expected life (years)	3 years	6 years	6 years
Interest rate	4%	4%	4%
Dividend yield			
Volatility	71-80%	129%	98%

The weighted average fair value at date of grant for options granted during 2003, 2002 and 2001 was $2.86, $3.96 and $1.12, respectively, per option.

Income taxes

An asset and liability approach is used for financial accounting and reporting for income taxes. Deferred income tax assets and liabilities arise from temporary differences between income tax and financial reporting basis of assets and liabilities and principally relate to recognition of revenue and expenses in different periods for financial and tax accounting purposes. Deferred tax assets and liabilities are measured using currently enacted tax rates and laws. In addition, a deferred tax asset can be generated by net operating loss carryforwards. 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.

Revenue recognition

The Company recognizes revenue from product sales when goods are shipped and the risk of loss transfers to the customer. Revenue from licenses and other upfront fees are recognized on a ratable basis over the term of the respective agreement. Milestone payments are recognized upon successful completion of a performance milestone event. Any amounts received in advance of performance are recorded as deferred revenue. The Company recognizes revenue over the period the service is

performed in accordance with SEC Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" ("SAB 101"). SAB 101 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. We believe that all of these conditions are met at the time of shipment. Currently, three injections are recommended, although the decision to utilize one, two or three injections is between the attending physician and his/her patient. The amount invoiced is fixed and determinable and only varies among customers depending upon the number of injections requested. There is no performance provision under any arrangement with any doctor and there is no right to refund, or returns for unused injections.

Currently the Isolagen Process is delivered through an attending physician to each patient using the Company's recommended regimen of up to three injections. 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. All 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. 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.

Intangible assets

The Company's 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 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.

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 cost to provide such treatments is expensed as incurred. The Company records any discounts granted as a reduction in revenue (i.e., net revenue after discount) from that specific transaction.

Foreign Currency Translation

The financial position and results of operations of the Company's foreign subsidiaries are generally 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 year-end. Income statement accounts are translated at the average rate of exchange prevailing during the year. Adjustments arising from the use of differing exchange rates from period to period are included in other comprehensive income in stockholders' equity. Gains and losses resulting from foreign currency transactions are included in earnings and have not been material in any one year.

Comprehensive income

Comprehensive income encompasses all changes in equity other than those with stockholders and consists of net earnings and foreign currency translation adjustments. 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.

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.

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 $0.1 million for 2003 and $0 for 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 $0.4 million for 2003 and $0 for 2002.

Recent accounting pronouncements

In December 2002, the EITF issued EITF Issue 00-21, "*Accounting for Revenue Arrangements with Multiple Deliverables."* EITF 00-21 provides guidance on determining whether a revenue arrangement contains multiple deliverable items and if so, requires that revenue be allocated amongst the different items based on fair value. EITF 00-21 also requires that revenue or any item in a revenue arrangement with multiple deliverables not delivered completely must be deferred until delivery of the item is

completed. The guidance in EITF 00-21 is effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The Company has applied the requirement of EITF 00-21. The application of EITF 00-21 did not have a material impact on its results of operations or financial position.

In January 2003, the FASB issued FASB Interpretation No. 46 ("FIN 46"), "*Consolidation of Variable Interest Entities"*, which requires the consolidation of variable interest entities. FIN 46 is applicable to variable interest entities created after January 31, 2003. Variable interest entities created prior to February 1, 2003 must be consolidated effective July 1, 2003. The Company adopted FIN 46 in the quarter ended June 30, 2003, and it did not have an impact on the Company's financial position or results of operations.

In April 2003, the FASB issued SFAS No. 149, "*Amendment of Statement 133 on Derivative Instruments and Hedging Activities"*, which amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities under SFAS No. 133. SFAS No. 149 is effective for contracts entered into or modified after June 30, 2003, and for hedging relationships designated after June 30, 2003. The Company adopted SFAS No. 149 effective July 1, 2003, and it did not have an impact on the Company's financial position or results of operations.

In May 2003, the FASB issued SFAS No. 150, "*Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity"*. SFAS No. 150 requires that certain financial instruments, which under previous guidance were accounted for as equity, must now be accounted for as liabilities. The financial instruments affected include mandatory redeemable stock, certain financial instruments that require or may require the issuer to buy back some of its shares in exchange for cash or other assets and certain obligations that can be settled with shares of stock. SFAS No. 150 is effective for all financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. SFAS No. 150 was adopted in the quarter ended June 30, 2003 and it did not have an impact of the Company's financial positions or results of operations.

Note 3 Property and Equipment

Property and equipment is comprised of:

	December 31,	
	2003	**2002**
Lab equipment	$ 1,124,697	$ 682,640
Computer equipment	227,743	333,826
Office furniture and fixtures	41,468	20,536
Leasehold improvements	1,835,236	1,274,146
	3,229,144	2,311,148
Less: Accumulated depreciation	(1,007,306)	(151,235)
Property and equipment, net	$ 2,221,838	$ 2,159,913

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 Federal 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,		
	2003	2002	2001
US	$ 7,494,993	$ 4,069,592	$ 1,652,004
Non-US	$ 3,773,301	$ 1,363,463	$
	$ 11,268,294	$ 5,433,055	$ 1,652,004

The components of the Company's deferred tax assets at December 31, 2003 and 2002 are as follows:

	December 31,	
	2003	2002
Deferred tax assets:		
Loss carryforwards	$ 5,475,308	$ 4,467,456
Deferred tax liabilities:		
Property and equipment	(134,141)	
Deferred revenue	(130,183)	(19,473)
	5,210,984	4,447,983
Less: Valuation allowance	(5,210,984)	(4,447,983)
	$	$

As of December 31, 2003, the Company had generated US net operating loss carryforwards, and net loss carryforwards in certain non-US jurisdictions of approximately $16,100,000 which expire at various dates beginning in 2004. 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, 2003 and 2002. The valuation allowance increased $763,001 during 2003 due to the Company's current period net loss.

Note 6 Commitments and Contingencies

Leases

The Company has entered into leases for office, warehouse and laboratory facilities in London, England and Sydney, Australia under third party non-cancelable operating leases through 2010. Future minimum lease commitments at December 31, 2003 are as follows:

Year Ending December 31	
2004	$ 277,799
2005	165,931
2006	165,931
2007	165,931
2008	165,931
Thereafter	539,276
Total	$ 1,480,799

For the years ended December 31, 2003, 2002 and 2001, rental expense totaled $359,065, $105,206, and $101,988, respectively.

Certain officers of the Company provide 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.

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 years ended December 31, 2003, 2002 and 2001, the Company recognized $0, $40,000, and $80,000, respectively, of contract revenues pursuant to this agreement.

During 2002, the Company began negotiations to revoke the license agreement. As a result, the Company reclassified to a payable the remaining deferred revenue totaling $240,000 and accrued an additional $160,000 in anticipation of a settlement totaling approximately $400,000. Thus, the entire amount of the initial up-front fee of $400,000 has been accrued as management's estimate of the amount necessary to satisfy the Company's obligation under the Agreement.

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 Olga Marko, William K. Boss, Jr., Vaughan Clift, Frank DeLape, Michael Macaluso and Jeffrey Tomz.

Mrs. Marko entered into an employment agreement, dated August 10, 2001, for a term of sixty (60) months at an annual base salary of $130,000. The base salary shall increase on an annual basis by

the same percentage that the Consumer Price Index has increased during the same time frame or at the direction of the Board of Directors, whichever is higher. Mrs. Marko 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, Mrs. Marko will be entitled to a twelve (12) month severance payment.

Dr. Boss entered into an employment agreement, dated August 10, 2001, and later amended on February 28, 2002 as follows: (a) during the first year of the term, Dr. Boss will receive 60,000 shares of Common Stock; (b) an annual compensation of $50,000 for 2002; and (c) an annual compensation of $60,000 for 2003. For this compensation, Dr. Boss agrees to devote 25 mutually agreeable days of service per year as requested by us. If the employment agreement is terminated without cause, Dr. Boss will be entitled to a three (3) month severance payment.

Mr. Clift 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.

Mr. DeLape 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 will have 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 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 is entitled to receive an annual bonus in an amount to be determined by the Compensation Committee. If Mr. Macaluso'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. Macaluso 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. Macaluso on September 5, 2003 with an exercise price of $9.81. The option will have 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. Macaluso with disability and life insurance benefits, a car allowance and wireless communications benefits. Mr. Macaluso'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. Tomz 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.

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 restricted common stock with an assigned value of $200,000 as a retainer fee, which was capitalized as a prepaid expense. As services are rendered, 80% of the invoiced amount is 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 restricted 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 7 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 $200,000, $400,000 and $155,556 for the years ended December 31, 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.

As discussed in Note 1, the Company became a publicly traded enterprise as a result of the Merger. Non cash transactions involving the issuance of equity instruments prior to the Merger were recorded at the fair value of the goods or services received, while transactions occurring after the Merger were recorded at the fair value of the equity instruments issued, which were determined based on quoted market prices.

Common Stock

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.

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 is convertible into two shares of common stock at any time after issuance and accrues 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. 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 was 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.

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

Warrants and Options Issued for Services

During the year ended December 31, 2003, the Company issued 375,000 warrants and options to non-employees, under consulting and distribution agreements. Warrants granted during the year ended December 31, 2003 comprised of 225,000 warrants to acquire common stock at exercise prices ranging from $3.50 to $5.94 per share granted to various third parties under consulting and distribution agreements. The warrants vest over a three year period from the date of grant and are exercisable for a term of 10 years. A total of 50,625 of these warrants had vested as of December 31, 2003. Additionally, during the year ended December 31, 2003, the Company granted 150,000 options to acquire its common stock under the Stock Plan at an exercise price of $3.50 per share to a doctor under an Advisory Board member agreement. The options vest over a three year period from the date of grant and are exercisable for a term of 10 years. None of the options had vested as of December 31, 2003. The value of each warrant and option was calculated on its vesting date using the Black-Scholes pricing model. The weighted average fair value of warrants and options vesting during 2003 was $4.21 per warrant or option. During the year ended December 31, 2003, consulting expense of $412,812 was recorded as the fair value of warrants and options vesting during the year.

Employee Stock Options

In January and February 2003, the Company issued under the Stock Plan a total of 245,000 options to purchase its common stock at an exercise price of $6.00 per share. The options vest ratably over a three year period from the date of grant and are exercisable for a term of 10 years.

Additionally, in February and September 2003, the Company issued under the 2003 Stock Plan 1,320,000 and 600,000 options, respectively, to purchase its common stock to officers and directors with exercise prices of $4.50 and $9.81, respectively, per share. The 1,320,000 options vest over a two year period and are exercisable for a term of 10 years. The 600,000 options vest over a three year period and are exercisable for a term of 10 years.

Information regarding the options and warrants granted in 2003, 2002 and 2001 is as follows:

	Options, Year Ended December 31,			**Warrants, Year Ended December 31,**		
	2003	**2002**	**2001**	**2003**	**2002**	**2001**
Outstanding, beginning of year	4,252,100	3,792,500		1,533,000	450,000	
Granted	2,315,000	698,000	3,792,500	349,600	1,533,000	450,000
Exercised	(400,600)	(38,400)		(422,431)		
Expired or cancelled	(317,400)	(200,000)		(15,000)	(450,000)	
Outstanding, end of year	5,849,100	4,252,100	3,792,500	1,445,169	1,533,000	450,000
Exercisable, end of year	2,999,100	458,017	4,167	985,794	1,243,000	
Available for grant, end of year	961,900	509,500	1,207,500			

The weighted average option and warrant exercise price information for 2003, 2002 and 2001 is as follows:

	Options, Year Ended December 31,			Warrants, Year Ended December 31,		
	2003	2002	2001	2003	2002	2001
Outstanding, beginning of year	$ 5.08	$ 2.70	$	$ 2.05	$ 1.50	$
Granted during the year	$ 5.97	$ 6.07	$ 2.70	$ 4.02	$ 1.93	$ 1.50
Exercised during the year	$ 1.70	$ 1.50	$	$ 1.93	$	$
Expired or cancelled during the year	$ 2.50	$ 1.50	$	$ 5.94	$ 1.50	$
Outstanding at end of year	$ 5.81	$ 5.08	$ 2.70	$ 2.53	$ 2.05	$ 1.50
Exercisable at end of year	$ 5.81	$ 2.08	$ 2.70	$ 2.35	$ 1.94	$ 1.50

Significant option and warrant groups outstanding at December 31, 2003, 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	2,633,500		2,616,500	$ 5.96	7.67
October 2001	140,000		40,000	$ 1.50	7.75
November 2001	78,600		78,600	$ 2.77	7.83
December 2001	40,000		40,000	$ 3.35	7.92
May 2002	362,000		84,000	$ 6.00	8.42
June 2002	40,000		20,000	$ 6.50	8.50
June 2002	20,000		20,000	$ 6.00	8.50
July 2002		735,569	735,569	$ 1.93	3.50
September 2002		375,000	75,000	$ 2.43	9.75
November 2002	100,000		40,000	$ 6.00	8.83
December 2002	120,000		60,000	$ 6.00	8.92
January 2003	45,000			$ 6.00	9.08
February 2003	1,520,000			$ 4.70	9.17
February 2003		60,000	50,625	$ 5.94	9.17
April 2003		150,000		$ 3.50	9.33
May 2003		124,600	124,600	$ 3.50	9.42
May 2003	150,000			$ 3.50	9.42
September 2003	600,000			$ 9.81	9.75

Note 8 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, 2003 and 2002, the Company had accrued in accounts payable $95,891 and $81,514, respectively, for services provided by these related parties. During 2003, the Company incurred total expenses for services provided by these related parties of $319,742.

Note 9 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 reportable segments is as follows:

	Net Sales Year ended December 31,		
	2003	2002	2001
United States	$	$ 42,282	$ 105,482
United Kingdom	$ 399,147	$ 48,709	$
Australia	$ 46,542	$	$
	$ 445,689	$ 90,991	$ 105,482

	Property and Equipment, net As of December 31,		
	2003	2002	2001
United States	$ 605,731	$ 1,090,451	$ 7,357
United Kingdom	$ 834,887	$ 730,589	$
Australia	$ 781,220	$ 338,873	$
	$ 2,221,838	$ 2,159,913	$ 7,357

	Depreciation Year ended December 31,		
	2003	2002	2001
United States	$ 415,783	$ 46,522	$ 15,368
United Kingdom	$ 210,357	$ 53,290	$
Australia	$ 209,290	$	$
	$ 835,430	$ 99,812	$ 15,368

	Capital Expenditures Year ended December 31,		
	2003	2002	2001
United States	$ 328,250	$ 1,129,616	$
United Kingdom	$ 126,380	$ 783,879	$
Australia	$ 738,527	$ 338,873	$
	$ 1,193,157	$ 2,252,368	$

Note 10 Summarized Quarterly Financial Data (unaudited)

For the following three-month periods ended	March 31	June 30	September 30	December 31
2003				
Net revenue	$ 371	$ 79,425	$ 78,575	$ 287,318
Cost of sales	994	47,867	30,300	42,665
Operating loss	(2,252,194)	(2,444,465)	(2,718,217)	(3,543,359)
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)
Range of per share closing prices(a)				
Low	$ 4.20	$ 4.10	$ 6.50	$ 5.15
High	$ 5.55	$ 7.25	$ 10.85	$ 9.03

For the following three-month periods ended	March 31	June 30	September 30	December 31
2002				
Net revenue	$ 22,518	$ 20,000	$	$ 48,473
Cost of sales				35,133
Operating loss	(751,076)	(1,327,869)	(1,498,249)	(2,096,974)
Net loss	(746,538)	(1,280,923)	(1,466,708)	(1,938,886)
Net loss per share	$ (0.05)	$ (0.08)	$ (0.10)	$ (0.13)
Range of per share closing prices(a)				
Low	$ 5.00	$ 2.90	$ 2.20	$ 3.00
High	$ 7.25	$ 6.95	$ 3.75	$ 5.75

(a) Since December 11, 2002, the Company's common stock has been traded on the American Stock Exchange under the symbol "ILE." Prior to December 11, 2002, the Company's common stock was quoted on the OTC Bulletin Board under the symbol "ISLG." The market for the Company's common stock is limited, volatile, and sporadic. The above table sets forth the range of high and low bid quotations or high and low sales prices for the Company's common stock for each of the periods indicated as reported by the OTC Bulletin Board or the AMEX. These 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.