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

# FORM 10-K

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

**For the fiscal year ended December 31, 2003**

**OR**

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

## Isolagen, Inc.
(Exact name of registrant as specified in its Charter.)

| **Delaware** | **0-12666** | **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. ☒ Yes ☐ No

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

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

As of March 24, 2004, the aggregate market value of the issuer's common stock held by non-affiliates of the issuer based upon the price of at which such common stock was sold on the American Stock Exchange as of such date was $185,917,466.

As of March 24, 2004, issuer had 26,768,893 shares of issued and outstanding common stock, par value $0.001.

Documents Incorporated by Reference: Portions of the information set forth in the definitive proxy statement to be filed by the registrant within 120 days of the close of the fiscal year are incorporated by reference in Part III hereof.

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**Forward-Looking Information**

This report contains forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause Isolagen, Inc.'s or its 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.

In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential," or the negative of these terms or other comparable terminology. These statements are only predictions. Actual events or results may differ materially.

Although Isolagen, Inc. believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee future results, levels of activity, performance, or achievements. Moreover, neither Isolagen, Inc. nor any other person assumes responsibility for the accuracy and completeness of these forward-looking statements. Isolagen, Inc. is under no duty to update any of the forward-looking statements after the date of this report to conform its prior statements to actual results. Isolagen Inc.'s actual results could differ materially from its historical operating results and from those anticipated in these forward-looking statements as a result of certain factors, including, without limitation, those set forth under "Business—Risk Factors" of this Form 10-K and those set forth under "Management's Discussion and Analysis of Financial Condition and Results of Operation."

We are under no obligation to and do not intend to update, revise or otherwise publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of any unanticipated events.

## Part I

### Item 1. Business

**Overview**

Isolagen Technologies, Inc. is a biopharmaceutical company located in Houston, Texas that specializes in the development and commercialization of autologous cellular therapy for hard and soft tissue regeneration. Our lead product candidate is in Phase III clinical development and has applications in cosmetic dermatology to correct and reduce the normal effects of aging, such as wrinkles, laugh lines, smokers' lines, fine lines and all types of depressed scars. We expect to file a Biologics License Application ("BLA") for this product in late 2004. Our second product candidate, which is being developed to treat periodontal disease, completed a Phase I clinical trial in late 2003.

Autologous cellular therapy is the process whereby a patient's own cells are extracted, processed, and then reintroduced to the patient. The Isolagen Process is an autologous cellular therapy designed to replenish deficiencies caused through the loss of fibroblast cells. As the body ages, it loses approximately 1% of its fibroblast cells each year. Fibroblast cells are responsible for producing collagen and elastin, which support the skin. By the time a person is 40 years old, his or her body has lost approximately 40% of its fibroblast cells, leading to dermal depressions and wrinkles. In the Isolagen Process, the patient's cells are taken from a small skin sample from which millions of fibroblast cells are separated and reproduced and then injected into the patient in or around the areas to be treated. Following injection, the new fibroblast cells lead to the production of collagen and elastin, which diminish the depressions and wrinkles. The procedure is minimally invasive and non-surgical.

Currently, there are multiple competitive alternatives to reduce the signs of aging. In this market area there have been a number of products developed over the years designed to treat the symptoms of



this pathology. These products include various collagen formulations fabricated from animal and human cadaver, hyaluronic acid from animal and synthetic sources, plastic beads, and calcium, hydroxyapatite. Other therapies include paralysis of the underlying superficial musculature with *Botulinum* toxin and transplantation of autologous fat. These products are associated with clinical problems which vary from the one product to the other product such as short duration of action for collagen and *Botulinum* toxin products (3-6 months), immunological reactions, irregular correction of contour, and significant pain associated with the injection. Isolagen's process is designed to address many of these issues. As the cells used in the Isolagen process are derived from the patient's own skin, they express identical antigens to those of the cells in the treatment area, and therefore do not stimulate immune rejection.

In addition to the United States, we plan to commercialize the Isolagen Process 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 the Isolagen Process to patients located in Europe. We began commercialization in the United Kingdom in the first quarter of 2003. In August 2003, we received a license from Australia's Therapeutic Goods Administration ("TGA") to begin the manufacture of autologous fibroblast cells. Consequently, we commenced commercialization in Australia in the fourth quarter of 2003. We are also investigating commercialization in South Korea, Hong Kong, Italy and Mexico.

Throughout 2003, Isolagen focused its market introduction activities in the UK and European markets on establishing a solid foundation for future growth. This consisted of introducing the Isolagen Process to selected leading medical practitioners, primarily plastic surgeons and dermatologists to the Isolagen Process who could offer the treatment to their patients. Periodically, training sessions were given throughout the year as well to train a broader group of practitioners.

During this initial phase, Isolagen also gradually exposed potential patients to the therapy through articles in health and beauty journals. In the beginning of 2004 the landscape was sufficiently covered with trained physicians such that the public relations activities could be increased. An additional public relations firm was hired that had extensive contacts in broadcast media. Additionally, an agreement was reached with Emma Samms, the actress who played Falon on Dynasty, to represent Isolagen for 2004.

As a result of this increased exposure, a marked increase in demand for Isolagen's dermal therapy was experienced in recent months. In January 2004, the 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. . In the last week of February a major public relations campaign was started.. Isolagen was featured on a UK television talk show, in an article in which the actress Emma Samms was interviewed about her experience with Isolagen and in a feature story in the most widely read newspaper in the UK. The resultant increased demand far exceeded Isolagen's capacity.

As part of Isolagen's continued marketing efforts, the Company is in negotiations with several British national medical clinics that are interested in providing enough patients that could increase the monthly demand substantially. The recent sharp increase in demand has outstripped the supply to such an extent that the Company, in March 2004, is scheduling patients as far out as August 2004. Additionally, the Company has had to suspend marketing and sales efforts in all European countries except the UK.

Because of tremendous demand, the Company is expanding its European production facilities. With the introduction of the new more automated and scalable manufacturing system as well as the increase in capacity, the Company expects to be able to meet the increasing demand, not only from the UK but also from the other European countries.



**Market Opportunity**

*Cosmetic*

The Isolagen Process is directed primarily at the dermatological and plastic surgery markets. Options to ameliorate the signs of aging or to delay or avoid invasive surgery are becoming increasingly popular. According to statistics released in March 2004 by the American Society of Plastic Surgeons ("ASPS"), consumer demand jumped 41% in 2003 for minimally invasive plastic surgery, exceeding more than 6.9 million

procedures. More than 8.7 million procedures were performed on people who took action to proactively manage signs of aging or enhance their appearance by choosing cosmetic plastic surgery in 2003, according to the statistics released in March 2004 by the ASPS, up 32% from nearly 6.6 million in 2002. Ultimately, the concept of cosmetic injectables has become more mainstream and accepted.

The following table shows the top five minimally invasive cosmetic procedures in 2003:

| | |
|---|---|
| Botox injections* | 2,891,390 |
| Chemical Peel | 995,238 |
| Microdermabrasion | 935,984 |
| Laser hair removal | 523,297 |
| Collagen injections | 576,255 |

* most popular with both genders

The 35-50 age group made up 46% of all minimally invasive procedures in 2003. The 51-64 age group made up 26% of the population receiving these procedures, while patients 19 to 34 made up 19% of the minimally invasive procedures. Botox was the most popular treatment among all three age groups.

ASPS offers the most comprehensive, reliable statistics on plastic surgery procedures. For 2003, the ASPS statistics were collected through the first online national database for plastic surgery procedures called Tracking Operations and Outcomes for Plastic Surgeons ("TOPS"). This data combined with an annual survey sent to more than 17,000 board certified physicians in specialties most likely to perform plastic surgery procedures resulted in the most comprehensive report on plastic surgery procedures to date.

*Dental*

In addition to the dermatological market, there is an extensive dental market opportunity. The Company's research shows that, in the United States, there are approximately 33,000 practitioners performing cosmetic procedures, whereas there are approximately 150,000 dentists.

As our population has aged and conservative dentistry has improved, there has been an increasing demand for therapeutic options that preserve and replace teeth. The single greatest cause of bone and tooth loss in the mouth is periodontal disease. As the periodontal pockets deepen, the amount of debris and infection trapped leads to increasing inflammation and bone loss around the tooth. Any process which could lessen the depth of the pockets or reverse the progression of the disease would greatly decrease the root damage and tooth loss. Recent studies have shown that the Isolagen Process has the ability to decrease the size of pockets greater than 4 mm by as much as 2.4 mm (see below) providing a therapeutic tool to the family dentist that can be simply administered in the dental chair in a few brief sessions.

While there have been dramatic improvements in restorative dentistry allowing us to maintain good dentition, there have not been corresponding improvements in the preservation of gum and soft tissue. The Isolagen Process can be used therapeutically for those patients with symptoms of



periodontal disease such as deep pocket disease, papillary recession, and gingival recession in other areas.

Papillary recession, also known as black triangles, is part of the progression of periodontal disease, and involves the recession of the triangular section of gum tissue between two teeth. To date, the Company is not aware of any documented effective treatment for this condition. In cases where the recession of the gum has progressed to an advanced stage, the accepted treatment is to surgically transfer a skin graft from the palate to the site of recession. This process is painful and can potentially create donor site defects. The results of this procedure have been varied and are not fully embraced by periodontists due to the donor site morbidity associated with the skin graft extraction.

The vast majority of the population will experience periodontal disease at some point in their lives. Others will have a need for a tooth extraction or have a dry or contracted socket. Only a small percentage of the population, however, will elect to undergo a cosmetic procedure. For these reasons, we consider the Isolagen Process to be a viable solution for the dental market.

**Our Solution**

*The Isolagen Process*

The Isolagen Process begins when the patient's doctor obtains a 3mm punch biopsy from behind the patient's ear. In the case of the dental product, a 1mm biopsy is taken from the patient's gingiva. The biopsy is then packed in an Isolagen-provided container at the doctor's office and is shipped overnight to the Isolagen laboratory. Upon arrival at the laboratory, the specimen is initiated into culture. Through a series of plastic culture vessels and growth media over a period of approximately six weeks, the fibroblasts within the specimen are cultured to tens of millions of cells. The fibroblasts are then harvested and put into a transport vial. After completion of a series of quality control tests, the cells are released to the physician and are shipped to the physician's office overnight. A total of three injections are supplied and administered to the patient over approximately one month. A patient may elect for Isolagen to cryogenically store a fibroblast culture for future treatments.

Isolagen has developed a new cell culturing system and is in the final stages of a significant improvement in the manufacturing process as part of its cost reduction efforts. Through a collaboration with Applikon Biotechnology, the Company has developed a new system that permits an automated harvesting process in a closed loop sterile environment. The existing process separates cells manually utilizing centrifuge technology. This new harvesting process is expected to yield significant cost reductions and is a key component of a platform for scalable mass production.

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 and slow and involves many sterile interventions and therefore is costly. Our focus over the past 27 months has been to automate the culturing technology incorporating newer technology and concepts common to the pharmaceutical industry particularly those that have already been well established in cGMP facilities.

We have been collaborating with Applikon under a Joint Intellectual Property Collaboration that will allow Isolagen to patent the manufacturing system improvements beyond Applikon's existing patents. The system has been successful in research setting and we are now undertaking the design and fabrication of the massed-produced single-use (disposable) component. The production unit will then undergo validation testing prior to incorporation into the manufacturing process. The functioning unit, combined with novel application of existing manufacturing systems, should permit significant cost reduction.



*Dermal Application*

The primary application of the Isolagen Process is to repair dermal defects. Some of the advantages of the Isolagen Process are as follows:

- The Isolagen product is a living cell therapy. Therefore, the fibroblasts in the dermis continue to multiply and produce matrix until the tissue reaches its optimal repair.
- The cells are subject to the normal physiological controls of tissue and therefore can return the tissue to its youthful appearance but do not overcorrect or cause deformity to the area.
- As it is autologous, it is devoid of immune rejection complications.
- It is applicable to virtually every area of the face, unlike many competitor products, which, because of their mechanism of action, are restricted as to where they can be applied.

- Fibroblast cells remain viable for many years and therefore the effects are likely to be long-lasting. A permanency claim is the subject of the extended portion of our clinical trials.

- Fibroblasts are a general support cell for the tissue, and in addition to their direct production of collagen and matrix, produce endocrine factors which may assist in the growth or repair of surrounding tissues such as the overlying epithelium.

Under prior management, William K. Boss, Jr., M.D., currently a director of the Company and a board certified plastic surgeon, began treating patients with the Isolagen Process to correct facial defects (e.g., wrinkles, depressions, and scars) in 1995. Dr. Boss, along with 200 other doctors, utilized the Isolagen Process on approximately 950 patients with positive results. Of these patients, totaling 2,000 procedures, the participating physicians documented no significant adverse reactions. The FDA notified Isolagen Technologies in 1999 that the Isolagen Process would require FDA approval as a regulated biologic product. Isolagen Technologies filed an investigational new drug application ("IND"), which was accepted by the FDA and commenced the FDA process.

In January 2003, we commenced a two site Phase II study. The double blind trial consisted of forty patients and four dose regimens. The trial confirmed the therapeutic dosage used previously in the UK and produced significant information used in the design of the subsequent Phase III study.

In July 2003, Isolagen commenced a Phase III clinical trial for dermal defects 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 study with 75% of the patients receiving the therapeutic dosage and the remaining 25% receiving a placebo. Of the evaluable population, 77% of treatment group patients were responders whereas 36% of the placebo group were responders (Fisher's Exact test $p < 0.0001$). In this statistically significant result, response was determined by a change of two or more on a seven point photo guide scale. There were few adverse events related to Isolagen and none were classified as serious adverse events. The results confirmed statistically the early efficacy of the Isolagen process at 4 months. Most "fillers" have an immediate response but are then actively cleared by the body. In a recently reported study 73.3% of the patients treated with Hyalform® returned to baseline by 12 weeks. The Isolagen process is based on an approach of "curing the disease" rather than "covering the symptoms". The cells are instilled into the area and begin the reparative process. The cumulative injury causing the depletion of the fibroblasts may have taken several decades to occur. The cohort study conducted on UK patients demonstrated that the process shows 75% response rate by 2-4 months and a 100% response rate at 6 months. This response rate is still present at 12 months for the patients studied. We hope to confirm this ongoing improvement in the present and anticipated clinical trials.

Isolagen has had numerous communications throughout 2003 with the FDA with regard to the IND. These communications include numerous submissions of data and protocols, meeting requests and



annual reports. We had face to face meetings in April, September and December 2003 with senior FDA staff in the Center for Biologics Evaluation and Research and the review committee following the IND. Though this is the normal process for license application, we believe Isolagen has had a disproportionate degree of attention and level of interest reflecting the unique nature of the process as well as a great deal of support and encouragement from the FDA during this process.

Some of the remaining issues stem from the fact that the product is not easily classified as a biologic as it so closely resembles a tissue graft and is inherently safe. Numerous issues have and are being resolved that may affect study design and the license application itself. Successful resolution of any study design issues and data related questions are critical for the eventual license application. The majority of issues are resolved simply by analysis of data from the existing trials.

The discussions to date have been very productive. Following the recommendations of the FDA, Isolagen has simplified the study design and added some additional reports or studies including, establishing the "Clinical Meaningfullness" of the process and establishing the purity of the fibroblasts produced. In the latter case, the FDA requested that Isolagen demonstrate that greater than 98% of the cells were fibroblasts as part of an ongoing discussion with regard to purity testing. Data submitted to the FDA showed that 99.6% of all cells in the study showed positive for fibroblast antibody.

Remaining study design issues will be determined largely from analysis of the results from the present Phase III trial. Such matters as to whether it is better to use the physician investigators or independent assessors can be evaluated from this data. The decisions will be presented with the supporting data to the FDA. In essence, most of the queries from the FDA relate to provision of supportive data for claims made by Isolagen. Objective supporting data is now available because of the successful completion of the acute phase of the trials.

*Dental Application*

Isolagen has completed a Phase I clinical trial of twenty-one patients for dental applications treating gingival recession and deep periodontal pockets. The trial is a 12-month double blind clinical study conducted at the University of Texas Health Science Center (UTHSC) Dental Branch. In February 2004, we reported that the Isolagen Process demonstrated significant improvement in the oral therapeutic treatment of periodontal disease by reducing deep pocket areas in a majority of sites, whereas placebo treated sites showed only a nominal improvement. For pockets greater than 5 mm in depth the difference between placebo and therapeutic group was 2.4 mm. The study included areas with gingival recession between teeth, showing improvement at 20 of 21 Isolagen-treated sites, with deterioration of the gum height recorded at most placebo sites (14 of 21). Furthermore, no adverse event was related to the Isolagen Process**.**

The Isolagen Dental Product also potentially provides a solution for problems that may develop when teeth are removed, such as dry socket or contracted socket. The accepted treatment by oral surgeons is to implant a cellular material to prevent these defects. Treatment often requires a follow-up surgical procedure for correction and to prevent additional soft tissue problems.

Further studies are planned and protocols have been prepared to assess the efficacy and safety of treatment of the papilla and deep pockets. These studies are traditional placebo controlled double blinded studies on a statistically larger population and are designed to establish the therapeutic efficacy and safety of the Isolagen process. A smaller study to explore variations on the injection technique used with the papilla, is also anticipated. A second confirmatory study will probably be needed for license application in each area.



**Our Strategy**

Our goal is to become the industry leader in the research, development and commercialization of autologous cellular therapy for dermatological and dental applications. We will endeavor to increase and strengthen our market position in the following ways:

- Working with regulatory agencies, on a country-by-country basis, to obtain the approval of the Isolagen Process and any future products. We are currently in late-stage clinical development in the United States. We have begun commercialization in the United Kingdom and Australia.

- Expanding and solidifying our relationship with the approximately 200 physicians who have treated their patients with the Isolagen Process, as well as marketing our processes and products to other doctors (e.g., plastic surgeons, facial plastic surgeons, dermatologists and aestheticians). Currently, we are not approved to market our products in the United States.

- Optimizing our manufacturing processes to achieve cost reductions and scalability. Through the Company's collaboration with Applikon Biotechnology, the Company has developed a new system that permits an automated cell harvesting process in a closed loop sterile system compared to the existing process of separating cells utilizing centrifuge technology. This new harvesting process is expected to yield significant cost reductions and allow the Company to move toward a platform that enables scalable mass production.

- Developing new applications for the Isolagen Process beyond repair of facial dermal defects. The research capability that has produced the Isolagen Process could be applicable to other areas, such as gum rejuvenation and other dental applications, urology, bone marrow and other pigment-related maladies.

- Investigating additional foreign countries to market the Isolagen Process and any future products. We are currently assessing the commencement of operations in Italy, South Korea, Hong Kong, Brazil, and Mexico. We are investigating regulatory and other requirements in these countries and evaluating potential joint venture partners and licensees.

- Establishing strategic partnering relationships to enhance application-specific sales and distribution of our products.

- Continuing our current research into the science of autologous cellular therapy.



**Intellectual Property**

Protecting our proprietary technology is vitally important to our competitive position. We currently hold the following patents:

| Number | Business Line | Title | Filing Date | Patent Date | Term |
|---|---|---|---|---|---|
| 5,591,444 United States | Cosmetic | Use of autologous dermal fibroblasts for the repair of skin and soft tissue Defects | July 28, 1995 | Jan. 7, 1997 | 20 Years |
| 5,660,850 United States | Cosmetic | Use of autologous dermal fibroblasts for the repair of skin and soft tissue defects | June 6, 1996 | Aug. 26, 1997 | 20 Years |
| 5,665,372 United States | Cosmetic | Autologous dermal fibroblasts for the repair of skin and soft tissue defects | June 6, 1996 | Sept. 9, 1997 | 20 Years |
| 5,858,390 United States | Cosmetic | Use of autologous undifferentiated mesenchylmal cells for the repair of skin and soft tissue defects | Sept. 8, 1997 | Jan. 12, 1999 | 20 Years |
| 698440 Australia | Cosmetic | Use of autologous dermal fibroblasts for the repair of skin and soft tissue defects | July 28, 1995 | Feb. 11, 1999 | 20 Years |
| 312548 New Zealand | Dental | Use of autologous dermal fibroblasts for the repair of skin and soft tissue defects | July 3, 1996 | March 9, 2000 | 20 Years |
| 206136 | Cosmetic | Use of autologous dermal fibroblasts for the repair of skin and soft tissue defects | July 3, 1996 | Jan. 24, 2002 | 20 Years |
| 9,083,618 United States | Dental | Compositions for regenerating tissue that has deteriorated and methods for using such compositions | May 2, 1998 | Aug. 13, 2002 | 20 Years |
| 0845963 Europe | Cosmetic | Use of autologous dermal fibroblasts for the repair of skin and soft tissue defects | July 3, 1996 | Sept. 24, 2003 | 20 Years |
| 123077 Israel | Cosmetic | Use of autologous dermal fibroblasts for the repair of skin and soft tissue defects | July 3, 1996 | Oct. 7, 2003 | 20 Years |

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.

We are in the process of pursuing several other patent applications. We continue to seek ways to protect our proprietary technology and trade secrets, including entering into confidentiality or license agreements with our employees, consultants and corporate partners, and controlling access to and distribution of our technologies and other proprietary information.



**Competition**

Tissue regeneration companies compete in the dermatology and plastic surgery markets with substantially different treatments. These include silicone injections, laser procedures, facial surgical procedures (e.g., facelifts and eyelid surgeries), fat injections, dermabrasion, collagen injections, and botulisum toxin injections. Indirect competition comes from facial care treatment products. Items catering to the growing demand for therapeutic skin care products are facial scrubs, anti-aging treatments, tonics, astringents and skin-restoration formulas.

The standard treatment for tissue regeneration has been bovine collagen, a foreign protein derived from cows, which is generally fully reabsorbed by a patient's body within a few months after application, leaving the patient with no visible signs of correction. As additional treatments with bovine collagen are performed, there may be an immune response that could compromise the treatment's effectiveness. Combined with the expense and the continued intrusiveness of ongoing treatments, we believe the value and benefit of bovine collagen injections are diminished.

We believe that the benefits of the Isolagen Process counters the drawbacks of bovine collagen treatments, thereby extending the market potential for soft tissue regeneration to a broader population of patients. This broader population includes those who have tried and discontinued use of bovine collagen and those that never considered treatments due to potential drawbacks.

Patients who might consider using the Isolagen Process could also consider the following products:

| Product Type | Examples | Company |
|---|---|---|
| Collagen Implants | Autologen<br>Dermolagen<br>Fibrel<br>Zyderm/Zyplast | Collagenesis Corp.<br>Collagenesis Corp.<br>Mentor<br>Inamed Aesthetics |
| Artificial Implants | Artecoll<br>Silicone Droplets<br>Softform<br>Radiance | Artecoll<br>Silicone Droplets<br>Collagen Corp.<br>BioForm |
| Medical Devices | Ablative Lasers<br>Non-Ablative Lasers<br>Microdermabrasion | Coherent and Luminesse<br>Coherent and Luminesse<br>Microdermex, Parisian Peel and Dermaglow |

| | | |
|---|---|---|
| Other | Alloderm | Lifecell Corp. |
| | Botox | Allergan |
| | Hylaform | Biomatrix |
| | Restylane | Medicis |
| | Lypocytic Dermal Augmentation | Physician manufactured |
| | Sculptura | Aventis |
| | Chemical Peels | TCA, Pharmacist fumulated Phenol chemicals |

We believe that many of our competitors have greater financial and other resources than we have. Although we are not aware of any similar products to the Isolagen Process that have received pre-market approval from 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 certain foreign countries. Governmental authorities in the United States and other countries extensively regulate the preclinical and clinical testing, manufacturing, labeling, storage, record-keeping, advertising, promotion, export, marketing and distribution, among other things, of pharmaceutical products.

*Domestic Regulation*

In the United States, the FDA under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal statutes and regulations subjects pharmaceutical and biologic products to rigorous review. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or allow us to manufacture or market our product candidates, and we may be criminally prosecuted. The FDA also has the authority to 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 supporting 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 preclinical 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 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 pre-market 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 preclinical laboratory testing;
- submission of an IND, 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 Biologics License Application, or BLA, for a biologic.



The sponsor typically conducts human clinical trials in three sequential phases, but the phases may overlap:

- In Phase I clinical trials, the product is tested in a small number of patients or healthy volunteers, primarily for safety at one or more doses.
- In Phase II, in addition to safety, the sponsor evaluates the efficacy of the product on targeted indications, and identifies possible adverse effects and safety risks, in a patient population somewhat larger than Phase I clinical trials.
- Phase III clinical trials typically involve additional testing for safety and clinical efficacy in an expanded population at geographically-dispersed test sites.

Clinical trials must be conducted in accordance with the FDA's Good Clinical Practices requirements. 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 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 Institutional Review Board, or IRB, at each clinical site may also require the clinical trial at that site to be halted, either temporarily or permanently for the same reasons.

The sponsor must submit to the FDA the results of the preclinical and clinical trials, together with, among other things, detailed information on the manufacture and composition of the product, in the form of a new drug application, or NDA, or, in the case of a biologic, a BLA. The FDA has advised the Company it is regulating the Isolagen Process as a biologic. Therefore, we will be submitting BLAs to obtain approval of our product candidate. In a process that may take from several months to several years, the FDA reviews these applications and, when and if it decides that adequate data are available to show that the new compound is both safe and effective and that other applicable requirements have been met, approves the drug or biologic for marketing. The amount of time taken for this approval process is a function of a number of variables, including whether the product has received a fast track designation, the quality of the submission and studies presented, the potential contribution that the compound will make in improving the treatment of a condition in question, and the workload at the FDA. 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, during its review of a 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 drug. In addition, the FDA may, in some circumstances, impose restrictions on the use of the drug, 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 FDA's good manufacturing practice regulations which govern the manufacture, holding and distribution of a product. Manufacturers of biologics also must comply with 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 and quality control and 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, or voluntary recall of product. 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 Federal Trade Commission, or FTC, requirements which include, among others, standards and regulations for direct-to-consumer advertising, off-label promotion, 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 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 these areas, as above, 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.

*International Regulation*

The regulation of our products, including the Isolagen Process, 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, including the Isolagen Process, 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 the Isolagen Process in cosmetic applications in the United Kingdom. Based on the written responses received from the Medicines Control Agency, management believes that the proposed use of the Isolagen Process in cosmetic applications in the United Kingdom does not require regulatory approval. We began commercialization of the Isolagen Process in the United Kingdom in the first quarter of 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. Consequently, we have commenced commercialization in Australia in the fourth quarter of 2004.

In addition, we are assessing commercialization in Italy, South Korea, Hong Kong, Brazil and Mexico.

**Corporate History**

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



**Research and Development**

Our research and development focus is not just limited to the dermal and dental product developments, but includes extensive activities for improved process science, manufacturing and cost reduction. Furthermore, we continue to explore applications for the Isolagen Process like therapies to regrow hair, to repair damaged nerves, and to heal burned skin. We expense research and development costs as they are incurred. For the years ending December 31, 2003, 2002 and 2001, we incurred research and development expenses of $3.3 million, $1.7 million, and $0.9 million, respectively.

**Employees**

We presently employ fifty-five (55) people on a full-time basis including, thirty (30) in Houston, Texas, seventeen (17) in London, England, and eight (8) in Sydney, Australia. We anticipate hiring additional employees in the areas of quality assurance, manufacturing, marketing and research and development as the need arises. None of these individuals are covered by a collective bargaining agreement and management considers its relations with the company's employees to be good. We may also employ consultants on an as needed basis to supplement existing staff.

**Risk Factors**

**We Will Need to Raise Substantial Additional Capital To Fund Our Operations Over the Course of the Next Two Years. 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.** Although we believe our current cash resources will be sufficient to fund our planned operations until June 30, 2005, we will require substantial additional capital to meet our long-term needs. Subsequent to June 30, 2005 we will require approximately $20 million of additional capital to bring our product to market in the United States and expand operations in the United Kingdom and Australia. This 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 recently commenced operations, are suffering losses from operations, have limited capital resources, do not have access to a line of credit or other debt facility, and will be unable to sustain operations absent substantial infusions of capital. We are actively assessing various financing opportunities. There can be no assurance that we will be successful in raising the necessary capital; or that we will be able to raise capital on acceptable terms. 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 materially and adversely impacted.

**The Need To Raise Additional Capital Will Expose Existing Shareholders To The Risk Of Substantial Dilution**. In the event that we sell equity securities or securities convertible into our equity securities to raise additional capital, such sales will dilute the public ownership of the Company.

**Isolagen Has Not Demonstrated An Ability To Generate Significant Revenue, And There Is No Assurance That We Will Produce Any Material Revenues.** Isolagen is a development stage company with a limited operating history and no significant revenues to date. Isolagen has not yet demonstrated its ability to generate significant revenue, and there is no assurance that we will produce any material revenues, or that we will ever operate on a profitable basis.

**As A Result Of Our Limited Operating History And Because Of The Emerging Nature Of The Markets In Which We Will Compete, Our Financial Data Is Of Limited Value In Planning Future Operating Expenses. Our operating Expenses Are Difficult To Forecast Accurately. To The Extent That Such Expenses Precede Or Are Not Rapidly Followed By Increased Revenue, Our Business, Results Of Operations And Financial Condition May Be Materially Adversely Affected.** As a result of our limited operating history and because of the emerging nature of the markets in which we will compete, our financial data is of limited value in planning future operating expenses. Our expense levels will be based in part on our expectations concerning future revenues. A significant portion of our revenue is anticipated to be derived from the Isolagen Process; however, the size and extent of such revenues are wholly dependent upon 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 the Isolagen Process could have an immediate and material adverse effect on our business, results of operations and financial condition. Further, business development and marketing expenses may increase significantly as we expand our operations. To the extent that such expenses precede or are not rapidly followed by increased revenue, our business, results of operations and financial condition may be materially adversely affected.

**The Development of the Isolagen Process and the Company's Other Products Involves a Lengthy and Complex Process, and the Company May be Unable to Commercialize the Isolagen Process or any of its Other Processes or Products Currently Under Development.** Before the Company can commercialize the Isolagen Process or any other of its development-stage products or processes in the U.S., the Company will need to conduct substantial research and development; undertake preclinical and clinical testing; and pursue regulatory approvals, including but not limited to FDA approval of its IND for the Isolagen Process. This process involves a high degree of risk and may take several years. The Company's process and product development efforts may fail for many reasons, including: failure of the process or product in preclinical studies; clinical trial data that is insufficient to support the safety or effectiveness of the process or product; or the failure to obtain the required regulatory approvals. Specifically, the FDA may withhold approval of the IND for several years or reject the IND outright. For these reasons, and others, the Company may not successfully commercialize the Isolagen Process or any of its other processes or products currently under development. We are unable to determine whether or when the Isolagen Dental Process will prove to be medically effective or commercially viable, and whether or when FDA approval will occur.

**Obtaining FDA and Other Regulatory Approvals is Time Consuming and Expensive, And The Respective Outcomes Are Uncertain.** The process of obtaining FDA and other regulatory approvals is time consuming and expensive. Clinical trials are required and the marketing and manufacturing of Company's products and services are subject to rigorous testing procedures. The Company may not be able to obtain FDA approval or other regulatory approval to conduct clinical trials or to manufacture and market any of the products it develops, acquires or licenses. Moreover, the costs to obtain approvals could be considerable and the failure to obtain or delays in obtaining an approval could significantly harm the Company's business performance and financial results. Even if pre-marketing approval from the FDA is received, the FDA is authorized to impose post-marketing requirements such as: (i) testing and surveillance to monitor a product and its continued compliance with regulatory requirements; (ii) submitting products for inspection and, if any inspection reveals that the product is not in compliance, prohibiting the sale of all products; (iii) suspending manufacturing; and (iv) withdrawing marketing clearance. In their regulation of advertising, the FDA and Federal Trade Commission (the "FTC") from time to time issue correspondence alleging that some advertising or promotional practices are false, misleading or deceptive. The FDA has the power to impose a wide array of sanctions on companies for such advertising practices, and the receipt of correspondence from the FDA alleging these practices could result in the following: (i) incurring substantial expenses, including fines, penalties, legal fees and costs to comply with the FDA's requirements; (ii) changes in



the methods of marketing and selling products; (iii) taking FDA-mandated corrective action, which may include placing advertisements or sending letters to physicians, rescinding previous advertisements or promotions; and (iv) disruption in the distribution of products and loss of sales until compliance with the FDA's position is obtained.

**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. Our Operating Results May Fall Below The Expectations Of Securities Analysts, Stockholders And Investors In Any Future Period.** 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 the Isolagen Process and other services and products that we may develop; 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 customers; the amount and timing of capital expenditures and other costs relating to the expansion of our operations; government regulation and legal developments regarding the use of the Isolagen Process; and general economic conditions. As a strategic response to changes in the competitive environment, we may from time to time make certain pricing, service, technology or marketing decisions or business or technology acquisitions that could have a material adverse effect on our quarterly results. Due to all of these factors, our operating results may fall below the expectations of securities analysts, stockholders and investors in any future period.

**We Anticipate That Losses Will Continue To Increase From Current Levels And That We Will Experience Negative Cash Flow, Which May Limit Or Delay Ability To Become Profitable.** The Company expects to expend significant resources on consultants, technology, advertising, hiring of personnel and startup costs. As a result, the Company has incurred losses since its inception and expects to experience operating losses and negative cash flow for the foreseeable future. The Company anticipates its losses will continue to increase from current levels because it expects to incur additional costs and expenses related to brand development, consulting costs, laboratory development costs, FDA clinical trials, marketing and other promotional activities, the addition of customer service personnel, the continued development of its website, its computer network, and development of relationships with strategic business partners, including but not limited to doctors who might use the Isolagen Process. For the years ending December 31, 2003, 2002 and 2001, we incurred losses of $11.3 million, $5.4 million and $1.7 million, respectively. Since inception we have incurred losses of $20.9 million.

**Our Ability to Become Profitable May Be Limited or Delayed by a Number of Factors.** Inasmuch as we are still in the development stage, our operations are subject to all of the risks inherent in the establishment of a new business enterprise, the development of new processes, and the marketing of new products. As we have had virtually no sales or revenues to date and are in the process of developing initial operations in the UK related to our first product, we expect to continue to incur significant additional costs and expenses related to:

- brand development;
- consulting costs;
- laboratory and manufacturing development and operation costs;
- FDA clinical trials and regulatory approvals;
- promotional and marketing activities;



- customer service and other personnel;
- development of our website, computer network; and
- development of relationships with strategic business partners, including doctors who might use the Isolagen Process.

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

**Our Inability to Increase Capacity in our UK Operations to Meet Increasing Demand in the UK Will Limit or Delay our Ability to Attain Profitability.** We began commercialization of the Isolagen Process in cosmetic applications in the UK in the first quarter of 2003. However, our facilities in the UK were designed to demonstrate the efficacy of the Isolagen Process. In light of increasing demand for the Isolagen Process in the UK, we will be required to expend additional funds to increase the capacity of the operation, including addition of personnel, introduction of systems enhancements and the establishment of new facilities. Large scale improvements in capacity and operating margins are largely dependent upon our successful completion of our ongoing efforts to automate the Isolagen Process. We anticipate that improved manufacturing practices as a result of our collaboration with Applikon Biotechnology will allow the Company's laboratories to have significantly greater through-put and reduce many of the Company's variable costs; however, there can be no assurance we will be successful in establishing suitable operations, automating the manufacturing process, obtaining the required scalability or achieving significant cost savings or profitable operations.

**We Are Subject to Extensive Governmental Regulation That May Significantly Affect Our Operating Results.** Human healthcare products and services companies are subject to significant regulation by a number of national, foreign, state and local agencies. The FDA has jurisdiction covering testing, manufacturing, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of the Company's products. Failure to comply with applicable regulatory requirements could, among other things, result in: (i) fines; (ii) changes to advertising; (iii) suspensions of regulatory approvals of products; (iv) delays in product distribution, marketing and sale; and (iv) civil or criminal sanctions. The Company's products receive FDA review regarding their safety and effectiveness. However, the FDA is permitted to revisit and change its prior determinations. The Company cannot be sure that the FDA will not change its position with regard to the safety or effectiveness of its products. If the FDA's position changes, the Company may be required to change its labeling or cease to manufacture and market the challenged products. Even prior to any formal regulatory action, the Company could voluntarily decide to cease distribution and sale or recall any of its products if concerns about the safety or effectiveness develop.

**We Are Also Subject To A Variety Of Other Regulations In Various Foreign Markets That Could Have A Material Adverse Effect On Our Business In A Particular Market Or In General.** The Company is also subject to a variety of other regulations in various foreign markets. The Company's failure to comply, or assertions that the Company fails to comply, with these regulations could have a material adverse effect on the Company's business in a particular market or in general. To the extent the Company decides 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. In addition, the Company may introduce additional products into the foreign markets. However, government regulations in both the Company's domestic and international markets can delay or prevent the introduction, or require the reformulation or withdrawal, of some of the Company's products.

**Our Foreign Operations are Exposed to Risks Associated with Foreign Regulations, Exchange Rate Fluctuations, Trade Restrictions and Political, Economic and Social Instability.** A foreign government may impose trade or foreign exchange restrictions or increased tariffs, which could adversely affect our operations. We are also exposed to risks associated with foreign currency fluctuations. Our operations in some markets also may be adversely affected by political, economic and social instability in foreign countries. As we continue to focus on expanding our existing international operations, these and other risks associated with international operations may increase. We are also 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, problems in collecting accounts receivable, potential adverse tax consequences, exchange rate fluctuations, increased risks of piracy, 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. Such limitations and interruptions could have a material adverse effect on our business, financial condition and results of operations. 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.

**Terrorist Attacks or Acts of War May Seriously Harm the Company's Business.** Terrorist attacks or acts of war may cause damage or disruption to the Company, its employees, its facilities and its customers, which could impact the Company's revenues, costs and expenses, and financial condition. The terrorist attacks that took place in the United States on September 11, 2001 were unprecedented events that have created many economic and political uncertainties, some of which may materially adversely affect the Company's business, results of operations, and financial condition. The potential for future terrorist attacks, the national and international responses to terrorist attacks, and other acts of war or hostility have created many economic and political uncertainties, which could materially adversely affect the Company's business, results of operations, and financial condition in ways that management currently cannot predict.

**Any Marketable Processes or Products that the Company Develops May Not be Commercially Successful.** Even if the Company obtains regulatory approval for the Isolagen Process or any of its other development-stage processes or products in the U.S. and other countries, those processes or products may not be accepted by the market. A number of factors may affect the rate and level of market acceptance of the Isolagen Process or our other processes or products, including: regulation by the FDA and other government authorities; market acceptance by doctors and hospital administrators; the effectiveness of the Company's sales force; the effectiveness of the Company's production and marketing capabilities; the success of competitive products; and the availability and extent of reimbursement from third-party payers. If the Isolagen Process or any other Company processes or products fail to achieve market acceptance, the Company's profitability and financial condition will suffer.

**Our Competitors in the Biotechnology and Pharmaceutical Industries May Have Superior Products, Manufacturing Capabilities or Marketing Position.** The human healthcare products and services industry is extremely competitive. The Company's competitors include major pharmaceutical companies and other biotechnology companies. Most of these competitors have more extensive research and development, marketing and production capabilities and greater financial resources than the Company. The Company's future success will depend on its ability to develop and market effectively its



processes and products against those of its competitors. If the Company's processes and products receive marketing approval but cannot compete effectively in the marketplace, the Company's profitability and financial position will suffer.

**Difficulties Managing Growth Could Adversely Affect Our Business, Operating Results And Financial Condition.** 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 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.

**We Are Dependent On Our Key Officers and Employees.** The Company is dependent on the efforts of Frank DeLape (Chairman of the Board of Directors), William K. Boss, Jr. (Vice Chairman of the Board of Directors), Michael Macaluso, (Chief Executive Officer, President and Director), Jeffrey Tomz, (Chief Financial Officer and Secretary), Olga Marko (Senior Vice President and Director of Research), and Vaughan Clift, (Vice President of Operations). The loss of any of these officers or employees or our inability to recruit and train additional key service personnel in a timely manner, could materially and adversely affect our business and our future prospects. While no assurances can be given that the Company's current management resources will enable it to succeed as planned, a loss of one or more of its current officers or key employees could severely and negatively impact its operations. No assurances can be given that the Company will not suffer the loss of key human resources for one reason or another. The Company has employment agreements with certain of its officers, but some of its key management personnel are employed "at-will" and may elect to pursue other opportunities at any time. Specifically, the loss of Michael Macaluso, the Chief Executive Officer of the Company, or Frank DeLape, Chairman of the Board, could significantly harm the Company's business. The Company has no present intention of obtaining key man life insurance on any of the executive officers or management. We have had no difficulty hiring and retaining the necessary management and personnel in the recent past.

**We Will Need To Attract, Train Or Retain Additional Highly Qualified Technical And Managerial Personnel In The Future. Our Inability To Do So Could Have A Material Adverse Affect On Our Business, Operating Results And Financial Condition.** There can be no assurance that we will be able to attract, train or retain additional highly qualified technical and managerial personnel in the future, which could have a material adverse effect on the our business, financial condition and results of operations.

**Our Officers And Directors Have Effective Voting Control Of The Common Stock. Therefore, Our Other Stockholders Will Have Limited Participation In Our Affairs.** As of December 31, 2003, our present executive officers, directors and controlling stockholders beneficially hold 51.2% of the outstanding shares of Common Stock. Our officers, directors and controlling stockholders currently are, and in the foreseeable future will continue to be, in a position to control Isolagen by being able to nominate and elect a majority of our Board of Directors. The Board of Directors establishes corporate policies and has the sole authority to nominate and elect our officers to carry out those policies. Other stockholders therefore will have limited participation in our affairs.

**We Have Not Declared Any Dividends On Our Common Stock To Date And We Have No Intention Of Declaring Dividends In The Foreseeable Future. Investors In Our Common Stock Cannot Rely On Dividend Income.** The future payment by the Company of cash dividends on the Common Stock rests within the discretion of its Board of Directors and will depend, among other things, upon the Company's earnings, its "unencumbered cash," its capital requirements and its financial condition, as



well as other relevant factors. The Company does not anticipate making any cash distributions on the Common Stock in the foreseeable future. Investors in our common stock cannot rely on dividend income.

**If We Are Unable To Effectively Promote Our Brand And Establish A Leading Position In The Biotechnology Marketplace, Results Of Operation And Financial Condition Will Suffer.** The Company's brand name is new and unproven. If the Company is unable to effectively promote its brand and establish a leading position in the biotechnology marketplace, our results of operations and financial condition will suffer. Company management believes that the importance of brand recognition will increase over time. In order to gain brand recognition, the Company may increase its marketing and advertising budgets to create and maintain brand loyalty.

**We May Fail to Protect Adequately Our Proprietary Technology, Which Would Allow Competitors to Take Advantage of Its Research and Development Efforts.** The Company's long-term success largely depends on its ability to market technologically competitive processes and products. If the Company fails to obtain or maintain these protections it may not be able to prevent third parties from using its proprietary rights. The Company's currently pending or future patent applications may not result in issued patents. In the United States, patent applications are confidential until patents issue, and because third parties may have filed patent applications for technology covered by its pending patent applications without the Company being aware of those applications, the Company's patent applications may not have priority over any patent applications of others. In addition, the Company's issued patents may not contain claims sufficiently broad to protect the Company against third parties with similar technologies or products or provide the Company with any competitive advantage. If a third party initiates litigation regarding the Company's patents, and is successful, a court could revoke the Company's patents or limit the scope of coverage for those patents.

The U.S. Patent and Trademark Office, commonly referred to as the USPTO, and the courts have not consistently treated the breadth of claims allowed in biotechnology patents. If the USPTO or the courts begin to allow broader claims, the incidence and cost of patent interference proceedings and the risk of infringement litigation will likely increase. On the other hand, if the USPTO or the courts begin to allow narrower claims, the value of the Company's proprietary rights may be limited. Any changes in, or unexpected interpretations of, the patent laws may adversely affect the Company's ability to enforce its patent position.

The Company also relies upon trade secrets, proprietary know-how and continuing technological innovation to remain competitive. The Company protects this information with reasonable security measures, including the use of confidentiality agreements with its employees, consultants and corporate collaborators. It is possible that these individuals will breach these agreements and that any remedies for a breach will be insufficient to allow the Company to recover its costs. Furthermore, the Company's trade secrets, know-how and other technology may otherwise become known or be independently discovered by its competitors.

**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 sue us, one of our subsidiaries or one of our strategic collaborators for infringing a third-party's patent rights. Likewise, we may need to resort to litigation to enforce our patent rights or to determine the scope and validity of third-party proprietary rights.

The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in the our favor, could be substantial, and the litigation would divert management's efforts. 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 resources. If we do not prevail in this type of litigation, we or our strategic collaborators may be required to: pay monetary damages; stop



commercial activities relating to the affected products or services; obtain a license in order to continue manufacturing or marketing the affected products or services; or compete in the market with a substantially similar product.

Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue some of our operations. In addition, a court may require that we pay expenses or damages and litigation could disrupt the Company's commercial activities.

**We May be Liable for Product Liability Claims Not Covered by Insurance.** Doctors who use the Company's processes and products, including but not limited to the Isolagen Process, and patients who have been treated by the Isolagen Process or any other process or products of the Company may bring product liability claims against the Company or its subsidiaries. While the Company has taken, and continues to take, what the Company believes are appropriate precautions, the Company may be unable to avoid significant liability exposure. The Company intends to obtain and keep in force product liability insurance sufficient to protect it from claims; however, the Company may be unable to obtain insurance in the future, or the Company may be unable to do so on acceptable terms. Any additional insurance the Company obtains 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 the Company's products and services; and injury to the Company's reputation. At present, we believe we carry reasonably adequate insurance coverage against product liability claims.

**If We Are Unable To Keep Up With Rapid Technological Changes, Our Processes, Products Or Services May Become Obsolete And Unmarketable.** The field of biotechnology 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 processes, products or services 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, Adversely Impacting Our Business, Results Of Operations and Financial Condition.** In the near future, the Company 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. Management may be unable to maintain and improve upon the uniform standards, controls, procedures and policies of the Company if it fails in this integration. Acquisitions may cause disruptions in operations and divert management's attention from day-to-day operations, which could impair the Company's relationships with current employees, customers and strategic partners. The Company 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 the Company's stockholders' holdings. In addition, profitability of the Company may suffer because of such acquisition-related costs or amortization costs for acquired goodwill and other intangible assets. If management is unable to fully integrate acquired businesses, products, technologies or personnel with existing operations, the Company may not receive the intended benefits of such acquisitions. We are not party to any agreements, written or oral, for the acquisition of any company, product or technology.

**Provisions in Our Bylaws Provide for Indemnification of Officers and Directors, Which Could Require Us to Direct Funds Away**

**From Our Business and Products.** Our Bylaws provide for indemnification of officers and directors. We may be required 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 such officers and directors are involved by reason of being or having been an officer or director. 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 products, thereby affecting our ability to attain profitability. This could cause our stock price to drop.

**There Is A Limited Public Trading Market For The Common Stock That May Limit Or Preclude Your Ability To Sell Shares Of Common Stock.** There is a limited public trading market for the Common Stock, and there is no assurance that any established public trading market will develop for any of the Company's securities. Without such an active or public trading market, there can be no assurance of any liquidity or resale value of the Common Stock. The Common Stock may be illiquid for indefinite periods of time.

**Our Stock Price Is Highly Volatile, And Represents Significant Market Risk To An Investment In Our Common Stock.** The market price of the Common Stock is likely to be highly volatile due to risks and uncertainties described in this report, as well as other factors, including sales of substantial amounts of our stock by existing stockholders and price and volume fluctuations in the stock market which do not relate to our operating performance. During 2002, our common stock traded from $2.20 to $7.25. During 2003, our common stock traded from $4.00 to $11.00.

**Our Common Stock is Vulnerable to Pricing and Purchasing Actions That are Beyond Our Control And, Therefore, Persons Acquiring Our Shares May be Unable to Resell Their Shares At a Profit as a Result of This Volatility.** The securities markets have from time to time experienced significant price and volume fluctuations that may be unrelated to the operating performance of particular companies. Announcements of delays in our testing, development or regulatory approval schedules, technological innovations or new products developed by us or our competitors and developments or disputes concerning patents or proprietary rights could have a significant and adverse impact on such market prices. Regulatory developments in the United States and foreign countries, economic and other external factors, all affect the market price of our securities. In addition, the realization of any of the risks described in these Risk Factors could have a significant and adverse impact on such market prices.

**Future Sales of Our Common Stock May Cause Our Stock Price to Decline. Therefore, Present Stock Prices May Not Be Indicative Of The Prices At Which You Will Be Able To Sell Shares Of Common Stock.** Our stock price may decline as a result of future sales of our shares or the perception that such sales may occur. We are unable to estimate the amount, timing, or nature of future sales of outstanding common stock. Sales of substantial amounts of our common stock in the public market may cause the stock's market price to decline.

**Item 2. Properties**

The Company currently leases 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 cellular laboratory to demonstrate the efficacy of the Isolagen Process in the U. K. market. The new cellular facility, located at 59/61 Park Royal, London, NW10 7JJ, England began operations in the fourth quarter of 2002. In light of increasing demand for the Isolagen Process, we will be required to expend additional funds to increase the capacity of the operation, including addition of personnel, introduction of systems enhancements, the establishment of new facilities, and the like. While we believe that suitable facilities will be available or can be developed to suit our requirements, we are unable to estimate the cost of suitable facilities at the present time.



In August 2003, we opened our Australia cellular laboratory in the city of Sydney to serve the Australian market, and various markets in the Pacific Rim if required regulatory approvals are received. The new cellular facility, located at 2 Lincoln Street, Lane Cove, New South Wales, Australia, 2066, began operations in August 2003.

Our laboratories are designed as cGMP laboratories to process autologous cultured fibroblast cells for therapeutic injections used in our procedures and clinical and pivotal trials. We believe our laboratories meet FDA facilities requirements under Center for Biologics Evaluation and Research ("CBER"). 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 and we have the option to cancel after March 24, 2005.

4. The lease rate is approximately $102,240 annually and the term of the lease expires on November 19, 2004 and we have an option to renew 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 fiscal year 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, volatile, and sporadic. The following table sets forth the range of high and low bid quotations or high and low sales 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 March 24, 2004, we had 717 shareholders of record and approximately 1,500 beneficial owners.

**Dividends**

We have never paid dividends on Common Stock. Currently, we anticipate that we will retain earnings, if any, to support operations and to finance the growth and development of our business and do not anticipate paying cash dividends on the Common Stock in the foreseeable future. We are obligated to pay $1.1 million, which was paid in the third quarter of 2003, to the former holders of the Series A Convertible Preferred Stock and Series B Convertible Preferred Stock, respectively, who converted their respective holdings into Common Stock shares in August 2003.

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

The following table provides information as of December 31, 2003, with respect to securities authorized for issuance under equity compensation plans.

| Plan Category | Number of Securities to be Issued Upon Exercise of Outstanding Options | Weighted-Average Exercise Price of Outstanding Options | Number of Securities Remaining Available for Future Issuance |
|---|---|---|---|
| Equity compensation plans approved by security holders | 5,849,100 | $ 5.81 | 961,900 |
| Equity compensation plans not approved by security holders | 585,000 | $ 3.07 | NA |



**Recent Sales of Unregistered Securities**

The following information relates to securities of the Company issued or 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, the Company sold an aggregate of 3,359,331 shares of its Common Stock, par value $0.001 per share, at an offering price of $6.00 per share, to a group of institutional investors. Legg Mason Wood Walker, Inc. acted as the sole placement agent for the offering. The Company relied upon and complied with Regulation D under the Securities Act of 1933 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 of 1933, as amended.

**Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

**None.**

**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 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 |
| 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**

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

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

**General**

Isolagen is a Houston, Texas based emerging pharmaceutical bioscience company which has focused its efforts in the development and commercialization of autologous cellular technology that has specific applications in cosmetic dermatology and is exploring applications for periodontal disease, reconstructive dentistry and other health-related markets. Autologous cellular therapy is a process whereby a patient's own cells are extracted, reproduced and then reintroduced to the patient for specific cosmetic and medical applications. Unlike other applications for the treatment of dermal defects, Isolagen utilizes only the patient's unique, living cells to produce the patient's own collagen. There is no foreign substance utilized in this treatment protocol. Isolagen's goal is to become the industry leader in the research, development and commercialization of autologous cellular therapy which stimulate a patient's own collagen production.

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 $15.9 million. As of March 24, 2004, the Company had a cash balance of approximately $13.5 million. Our existing capital resources are adequate to finance our operations until June 30, 2005, however 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 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 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 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. 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.

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.

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 doctor obtaining an approximately 3 mm punch skin sample from the patient. The skin sample is packed in a container provided by us and shipped overnight to our laboratory. The Company invoices the doctor upon receipt of the skin sample. The specimen is then cultured utilizing our patented Isolagen Process. This process separates the cell, called a fibroblast, from the rest of the tissue then multiplies these fibroblasts. Approximately six (6) weeks later, approximately 1 ml of the patient's cells is sent to the doctor for treatment. Additional amounts of approximately 1 ml are available for re-injection every two (2) to three (3) weeks. We recognize one-third of the revenue associated with each treatment upon the shipment of the first injection to the patient's doctor, an additional one-third of revenue associated with each treatment is recognized upon shipment of the second injection to the patient's doctor, and the remaining one-third is recognized upon the shipment of the last injection to the patient's doctor.

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 the Fiscal 2003 to $3.3 million from $1.7 million for Fiscal 2002. Research and development costs are composed primarily of costs related to the Company's efforts to gain FDA approval for the Isolagen Process 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 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. The Company has other research projects currently underway, including those related to repairing damaged nerves and therapies to regrow

hair and to heal burned skin. 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 the Company's average cash balances in Fiscal 2003, and a decrease in interest rates paid on the Company's 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 Isolagen Process revenue in the UK.

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 UK.

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 UK 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 UK; 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 the Company's efforts to gain FDA approval for the Isolagen Process 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. As of December 31, 2002, we believe at a minimum it will cost $4.2 million 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. The Company has other research projects currently underway, including those related to repairing damaged nerves and therapies to regrow hair and to heal burned skin. However, research and development costs related to these projects were not material during the 2002 or 2001 periods. 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, the Company 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 the Company's 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, 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 was convertible into 8 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, 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 Series B 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, *"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 the Company with a corresponding amount recorded as additional paid-in capital. The deemed dividend associated with the beneficial conversion is calculated as the difference between the fair value of the underlying common stock less the proceeds that have been received for the Series B Preferred Stock limited to the value of the proceeds received.

In 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. 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, the Company had a cash balance of $15.9 million. As of March 24, 2004, the Company had a cash balance of approximately $13.5 million. The Company does not have any credit facilities with which to fund ongoing working capital needs. The long-term viability of the Company is dependent upon successful operation of its business and the 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 UK. We commenced operations in Australia in the 4th 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. The reported income of these subsidiaries 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 shareholders' equity. Accordingly, our consolidated shareholders' 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 of the Company, including the notes thereto and report of the independent auditors thereon, are included in this report as set forth in the "Index to Financial Statements." See F-1 for Index to Consolidated Financial Statements.

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

None.

**Item 9A. Controls and Procedures**

As of the end of the period covered by this annual report, the Company carried out, under the supervision and with the participation of the Company's management, including the company's Chief Executive Officer and Chief Financial Officer (the "Certifying Officers"), an evaluation of the effectiveness of its "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 the Company's disclosure controls and procedures are effective to ensure that material information is recorded, processed, summarized and reported by management of the Company on a timely basis in order to comply with

the Company's disclosure obligations under the Exchange Act, and the rules and regulations promulgated thereunder.

Further, there were no changes in the Company's internal controls over financial reporting during the fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's 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 the directors and executive officers of Isolagen and the positions held by each such person as of March 24, 2004. 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 |
| William K. Boss, Jr. | 54 | Vice Chairman of the Board of Directors |
| Michael Macaluso | 52 | Chief Executive Officer, President, and Director |
| Jeffrey W. Tomz | 32 | Chief Financial Officer and Secretary |
| Steven Morrell | 48 | Director(1) |
| Henry Y.L. Toh | 46 | Director(1) |
| Ralph V. De Martino | 49 | Director(1) |
| Olga Marko | 60 | Senior Vice President and Director of Research |
| Vaughan Clift | 42 | Vice President of Operations |
| Nelson Haight | 39 | Controller |

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

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

*Frank DeLape.* Mr. DeLape was appointed as a director to the Board of Directors on June 18, 2001. He was elected Vice President on August 10, 2001. On August 24, 2001, Mr. DeLape resigned as Vice President and was elected Chairman of the Board. Mr. DeLape is also the Chief Executive Officer at 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.

*William K. Boss, Jr.* Mr. Boss was appointed to the Board of Directors on August 10, 2001. He was elected Vice Chairman of the Board of Directors on August 24, 2001. Dr. Boss has been the founder, Chief Executive Officer and Chairman of the Board of Isolagen Technologies since its inception in 1995. Dr. Boss is a Board Certified Plastic Surgeon and serves the Hackensack Medical Center as Vice Chairman of Plastic Surgery. Dr. Boss also serves as an Assistant Clinical Professor at the University of Medicine and Dentistry in New Jersey.

*Michael Macaluso.* Mr. Macaluso was appointed to the Board of Directors on June 18, 2001. He was elected President of the Company on June 21, 2001. On August 24, 2001, Mr. Macaluso resigned as President of the Company and he was appointed Chief Executive Officer. On June 18, 2003, Mr. Macaluso was appointed and President. Mr. Macaluso is a founder and principal of International Printing and Publishing ("IPP"), a position Mr. Macaluso has held since 1990. Over the past seventeen



(17) years, Mr. Macaluso has bought, managed and sold numerous companies. In 1990, he was instrumental in the financial transaction with Touche Ross' venture fund to acquire three companies, resulting in the creation of IPP. As a result of the merger of Touche Ross and Deloitte, Mr. Macaluso became a partner with Deloitte Touche. Subsequent to the merger, Mr. Macaluso negotiated the buyout of Deloitte Touche's interest and subsequently sold IPP to a large consolidator.

*Jeffrey W. Tomz.* Mr. Tomz was appointed Secretary and Treasurer of the Company on June 21, 2001. He was appointed Chief Financial Officer on August 24, 2001. Mr. Tomz is also a Principal at Benchmark Equity Group, Inc. Benchmark is a boutique merchant banking firm that focuses as facilitators and financial managers for emerging companies. Mr. Tomz has served and/or is currently serving on the board of directors of 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.

*Steven Morrell.* Mr. Morrell was appointed to the Board of Directors on May 22, 2002. Since January 2001, Mr. Morrell is a Partner at Teknoinvest Management AS, which is the oldest and largest Norwegian venture capital firm investing in Scandinavia and the US in the Life Science and Information Technology sectors with $150 million under management. From February 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 fourteen years including Managing Director for Merck & Co., Inc.'s subsidiary in Russia, Central Asia and Caucasia; General Director of Veropharm Co., Ltd (Russia) which is one of the largest Russian pharmaceutical companies; President of Hafslund Nycomed Pharma AG (Austria) and management consultant in McKinsey & Co., Inc. (Scandinavia). Mr. Morrell has extensive experience in pharmaceutical company management including licensing technology and products; marketing and sales; production and quality control management; as well as mergers and acquisitions. Mr. Morrell also served in the U.S. Air Force as an officer and an F-15 fighter pilot (Japan). He also currently serves as a Member of the Board of AKVAsmart ASA (Norway), Marical, Inc. (USA), Optinel Systems, Inc. (USA), CyVera Corporation (USA), and OAO Pharmacy Chain 36.6 (Russia) as well as an Observer to the Board of Cidra Corporation (USA). Mr. Morrell is fluent in English, Norwegian and German as well as conversational in Russian, and holds an MBA (with Honors) from IMD, Switzerland and a B.Sc. degree with a major in Mathematics and a minor in Aerospace Studies from Brigham Young University, USA.

*Henry Y.L Toh.* Mr. Toh was appointed to the Board of Directors on January 8, 2004. He is currently serving as a director with four other publicly traded companies: He has served since 2001as a director of Teletouch Communications Inc., an AMEX listed company. He has served since 1992 as an officer and director of Acceris Communications Inc. (a publicly held Voice over IP Company). He has served as a director of National Auto Credit, Inc. (a specialized finance and entertainment company) from December 1998 to the present; and became a director and of Bigmar, Inc. (a Swiss pharmaceuticals company) from 2002 through February 2004; and he became a director of Crown Financial Group, Inc. (a registered broker-dealer in March 2004). He has also served since 1992 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 in December 2002. Since January 2003, Mr. De Martino is 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 Paxon, LLP provides legal services to the Company.) 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 attended Bucknell University (Bachelor of Science in Business Administration, cum laude, 1976, Accounting, with departmental honors) and the George Washington University National Law Center (Juris Doctor, with honors, 1979). Mr. De Martino practices in the areas of securities and corporate law. From 1999 through 2001, Mr. De Martino served on the Board of Directors and Audit Committee of Commodore Cruise Lines.

*Olga Marko.* Ms. Marko was appointed Vice President of the Company on August 10, 2001. She assumed the role of Senior Vice President and Director of Research on August 24, 2001. Ms. Marko has served as Vice President and Director of Research at Isolagen Technologies since its inception in 1995. Prior to incorporating Isolagen Technologies with Dr. Boss, Ms. Marko worked for Merck and Company in the Department of Molecular Pharmacology, Memorial Sloan Kettering and Advanced Tissue Sciences. Her focus, at Merck, involved new drug development, as well as mentoring a group of more than 45 scientists, in the area of tissue culture. During this time, she developed a number of new techniques which improved transfections and receptor expression. In addition, she also developed unique stem cell lines from bone marrow, which were related to animal and human origin. While at Advanced Tissue Sciences, she was instrumental in developing "in vitro", full thickness skin. She was the first to successfully cultivate melanocytes in culture while she was at Memorial Sloan Kettering research institution in New York. Ms. Marko's basic research in academic institutions included cancer research, onco-virology, metastatic involvement, skin cells biology, and wound/burn treatment. The research in wound/burn treatment was done in collaboration with the Cornell University Burn Unit and Rockefeller University. Her industrial experience also included validating the effect of drugs for AIDS treatment and its immuno responses. Ms. Marko established a number of very unique cell lines and holds a number of patents as a result of her work. Ms. Marko has been published in such prestigious, internationally, multi-faceted journals as Science, Nature and the Proceedings of the National Academy, as well as many "niche" publications. She has also co-authored a number of chapters in books relating to tissue culture and medical sciences. Ms. Marko has over thirty-six (36) years in basic research uncovering numerous opportunities for the development of cell lines for specific applications. Ms. Marko has a BS in Biochemistry/Microbiology with graduate work and extensive commercial experience in cell biology. Her experience involves diverse, yet related, fields including cell biology, transplantation, immunology, biochemistry, molecular biology and virology.

*Vaughan L Clift, M.D.* Dr. Clift was appointed Vice President of Operations on May 28, 2002. He is in charge of the science aspects, regulatory affairs and manufacturing performance of the Company for all products. From January 2001 to May 2002, Dr. Clift did various research on 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 NASA spin-off medical device company that mass-produced a range of blood diagnostic products for the human and veterinary market. From May 1992 to June 1997, Dr. Clift was Chief Scientist for Lockheed Martin's Human Spaceflight SPDEO contract. 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, was recognized as one of NASA's top ten scientists and was the subject of a television documentary "NASA Man". He has clinical, manufacturing and FDA experience in integrating automated scaled manufacturing processes.

*Nelson Haight.* Mr. Haight was appointed Controller of the Company on January 8, 2003. Prior to joining the Company, Mr. Haight held various finance and accounting positions with Petroleum Geo-Services ASA, a Norwegian oilfield services company, from November 1996 to May 2002, as well as 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.

The information in the sections entitled "Election of Directors," "Information Regarding the Board of Directors," "Section 16(a) Beneficial Ownership Reporting Compliance," and "Code of Business Conduct and Ethics" in the Proxy Statement to be filed by us with the Securities and Exchange Commission no later than 120 days after the close of our fiscal year ended December 31, 2003 (the "Proxy Statement") is incorporated herein by reference.



**Item 11. Executive Compensation**

The Company incorporates herein by reference the applicable information regarding executive compensation from the Company's definitive proxy statement to be filed by the registrant within 120 days of the close of the fiscal year.

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

The Company incorporates herein by reference the applicable information regarding security ownership of certain beneficial owners and management from the Company's definitive proxy statement to be filed by the registrant within 120 days of the close of the fiscal year.

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

The Company incorporates herein by reference the applicable information regarding certain relationships and related transactions from the Company's definitive proxy statement to be filed by the registrant within 120 days of the close of the fiscal year.

**Item 14. Principal Accountant Fees and Services**

The Company incorporates herein by reference the applicable information regarding principal accountant fees and services from the Company's definitive proxy statement to be filed by the registrant within 120 days of the close of the fiscal year.

**Part IV**

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

**(a) The following financial statements and those financial statements schedules required by Item 8 hereof are filed as part of this report:**

**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 for the years ended December 31, 2003, 2002 and 2001
- Consolidated Statements of Cash Flows for the years ended December 31, 2003, 2002 and 2001
- Notes to Consolidated Financial Statements

**2. Financial Statement Schedules:**

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.



**(b) Exhibits required by Item 601 of Regulation S-K:**

| 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(8) |
| 3(ii) | Bylaws(2) |
| 4.1 | Specimen of Common Stock certificate(3) |
| 4.2 | Certificate of Designations of Series A Convertible Preferred Stock(8) |
| 4.3 | Certificate of Designations of Series B Convertible Preferred Stock(6) |
| 4.4 | Letter of Transmittal for holders of promissory notes of Isolagen Technologies, Inc.(1) |
| 4.5 | Letter of Transmittal for stockholders of Isolagen Technologies, Inc.(1) |
| 4.6 | Letter of Transmittal for stockholders of Gemini IX, Inc.(1) |
| 10.1 | 2003 Stock Option and Stock Appreciation Rights Plan(4) |
| 10.2 | 2001 Stock Option and Appreciation Rights Plan(5) |
| 10.3 | Employment Agreement dated August 10, 2001 between Isolagen, Inc. and Olga Marko(8) |
| 10.4 | "Intentionally Blank" |
| 10.5 | Employment Agreement dated May 28, 2002 between Isolagen, Inc. and Vaughan Clift(8) |
| 10.6 | Employment Agreement dated September 5, 2003 between Isolagen, Inc. and Frank DeLape(8) |
| 10.7 | Employment Agreement dated September 5, 2003 between Isolagen, Inc. and Michael Macaluso(8) |
| 10.8 | Employment Agreement dated September 5, 2003 between Isolagen, Inc. and Jeffrey W. Tomz(8) |
| 10.9 | Employment Agreement dated August 10, 2001 between Isolagen, Inc. and William K. Boss, as amended on February 28, 2002(8) |
| 10.10 | "Intentionally Blank" |
| 10.11 | Lease Agreement dated March 24, 2002 by and between the Registrant as Lessee and Claire O Aceti Gbmh as Lessor(8) |
| 10.12 | Lease Agreement dated November 20, 2002 by and between the Registrant as Lessee and Lego Australia Pty Limited as Lessor(8) |
| 10.13 | Intellectual Property Purchase Agreement between Isolagen Technologies, Inc., Gregory M. Keller, and PacGen Partners(9) |
| 14 | Code of Ethics(10) |
| 21 | List of Subsidiaries(7) |
| 23.1 | Consent of Pannell Kerr Forster of Texas, P.C. |



| | |
|---|---|
| 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). |

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

(2) Previously filed as exhibit to the Registrant's Annual Report on Form 10-KSB for the fiscal year ended December 31, 1991 and is incorporated by reference hereto.

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

(4) Previously filed as appendix to the Registrant's Definitive Proxy Statement (DEF14A) filed with the SEC in connection with the 2003 Annual Stockholder Meeting and is incorporated by reference hereto.

(5) Previously filed as appendix to the Registrant's Definitive Proxy Statement (DEF14A) filed with the SEC in connection with the 2001 Annual Stockholder Meeting and is incorporated by reference hereto.

(6) Previously filed as appendix to the Registrant's Form 10-Q as filed on May 15, 2003 and is incorporated by reference hereto.

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

(8) Previously filed as appendix to the Registrant's Form S-1 as filed as filed on September 12, 2003 and is incorporated by reference hereto.

(9) Previously filed as appendix to the Registrant's amended Form S-1 as filed as filed on October 24, 2003 and is incorporated by reference hereto.

(10) Filed herewith.

**(c) Reports on Form 8-K.**

During the quarter ended December 31, 2003, the Company filed four reports on Form 8-K:

- October 27, 2003—The Company issued a press release on its restatement of financial statements
- November 20, 2003—The Company issued a press release on its positive results in the U.K.

- December 3, 2003—The Company issues a press release on its positive results in its Dental Study.
- December 16, 2003—The Company issued a press release on its manufacturing system breakthrough.



**SIGNATURES**

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

*Isolagen, Inc.*

By: /s/ JEFFREY W. TOMZ

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

Date: March 26, 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 | Chairman of the Board | March 26, 2004 |
| Frank DeLape | | |
| /s/ WILLIAM K. BOSS, JR. | Vice Chairman of the Board | March 26, 2004 |
| William K. Boss, Jr. | | |
| /s/ MICHAEL MACALUSO | Chief Executive Officer, President and Director | March 26, 2004 |
| Michael Macaluso | | |
| /s/ JEFFREY W. TOMZ | Chief Financial Officer | March 26, 2004 |
| Jeffrey W. Tomz | | |
| /s/ STEVEN MORRELL | Director | March 26, 2004 |
| Steven Morrell | | |
| /s/ HENRY TOH | Director | March 26, 2004 |
| Henry Toh | | |
| /s/ RALPH DE MARTINO | Director | March 26, 2004 |
| Ralph De Martino | | |



**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 | | | | | Treasur |
|---|---|---|---|---|---|---|---|---|---|---|
| | 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 |
| Issuance of common stock for cash on 12/28/95 | — | $ — | — | $ — | 2,285,291 | $ 2,285 | $ (1,465) | $ — | $ — | — |
| Issuance of common stock for cash on 11/7/96 | — | — | — | — | 11,149 | 11 | 49,989 | — | — | — |
| Issuance of common stock for cash on 11/29/96 | — | — | — | — | 2,230 | 2 | 9,998 | — | — | — |
| Issuance of common stock for cash on 12/19/96 | — | — | — | — | 6,690 | 7 | 29,993 | — | — | — |
| Issuance of common stock for cash on 12/26/96 | — | — | — | — | 11,148 | 11 | 49,989 | — | — | — |
| Net loss | — | — | — | — | — | — | — | (270,468) | — | — |
| Balance, 12/31/96 | — | $ — | — | $ — | 2,316,508 | $ 2,316 | $ 138,504 | $ (270,468) | $ — | — |
| Issuance of common stock for cash on 12/27/97 | — | — | — | — | 21,182 | 21 | 94,979 | — | — | — |
| Issuance of common stock for Services on 9/1/97 | — | — | — | — | 11,148 | 11 | 36,249 | — | — | — |
| Issuance of common stock for Services on 12/28/97 | — | — | — | — | 287,193 | 287 | 9,968 | — | — | — |
| Net loss | — | — | — | — | — | — | — | (52,550) | — | — |
| Balance, 12/31/97 | — | $ — | — | $ — | 2,636,031 | $ 2,635 | $ 279,700 | $ (323,018) | $ — | — |
| Issuance of common stock for cash on 8/23/98 | — | $ — | — | $ — | 4,459 | $ 4 | $ 20,063 | $ — | $ — | — |
| Repurchase of common stock on 9/29/98 | — | — | — | — | — | — | — | — | — | 2,400 |
| Net loss | — | — | — | — | — | — | — | (195,675) | — | — |
| Balance, 12/31/98 | — | $ — | — | $ — | 2,640,490 | $ 2,639 | $ 299,763 | $ (518,693) | $ — | 2,400 |
| Issuance of common stock for cash on 9/10/99 | — | — | — | — | 52,506 | 53 | 149,947 | — | — | — |
| Net loss | — | — | — | — | — | — | — | (1,306,778) | — | — |
| Balance, 12/31/99 | — | $ — | — | $ — | 2,692,996 | $ 2,692 | $ 449,710 | $ (1,825,471) | $ — | 2,400 |
| Issuance of common stock for cash on 1/18/00 | — | — | — | — | 53,583 | 54 | 1,869 | — | — | — |
| Issuance of common stock for Services on 3/1/00 | — | — | — | — | 68,698 | 69 | (44) | — | — | — |
| Issuance of common stock for Services on 4/4/00 | — | — | — | — | 27,768 | 28 | (18) | — | — | — |
| Net loss | — | — | — | — | — | — | — | (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 | | | | | Treasur |
|---|---|---|---|---|---|---|---|---|---|---|
| | 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 |
| Balance, 12/31/00 | — | $ — | — | $ — | 2,843,045 | $ 2,843 | $ 451,517 | $ (2,632,547) | $ — | 2,400 |
| Issuance of common stock for services on 7/1/01 | — | — | — | — | 156,960 | 157 | (101) | — | — | — |
| Issuance of common stock for services on 7/1/01 | — | — | — | — | 125,000 | 125 | (80) | — | — | — |
| Issuance of common stock for capitalization of accrued salaries on 8/10/01 | — | — | — | — | 70,000 | 70 | 328,055 | — | — | — |
| Issuance of common stock for conversion of convertible debt on 8/10/01 | — | — | — | — | 1,750,000 | 1,750 | 1,609,596 | — | — | — |
| Issuance of common stock for conversion of convertible shareholder notes payable on 8/10/01 | — | — | — | — | 208,972 | 209 | 135,458 | — | — | — |
| Issuance of common stock for bridge financing on 8/10/01 | — | — | — | — | 300,000 | 300 | (192) | — | — | — |
| Retirement of treasury stock on 8/10/01 | — | — | — | — | — | — | (50,280) | — | — | (2,400) |
| 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 | — | — | — |
| Transaction and fund raising expenses on 8/10/01 | — | — | — | — | — | — | (48,547) | — | — | — |
| Issuance of common stock for services on 8/10/01 | — | — | — | — | 60,000 | 60 | — | — | — | — |
| Issuance of common stock for cash on 8/28/01 | — | — | — | — | 26,667 | 27 | 39,973 | — | — | — |
| Issuance of common stock for services on 9/30/01 | — | — | — | — | 314,370 | 314 | 471,241 | — | — | — |
| Uncompensated contribution of services—3rd quarter | — | — | — | — | — | — | 55,556 | — | — | — |
| Issuance of common stock for services on 11/1/01 | — | — | — | — | 145,933 | 146 | 218,754 | — | — | — |
| Uncompensated contribution of services—4th quarter | — | — | — | — | — | — | 100,000 | — | — | — |
| Net loss | — | — | — | — | — | — | — | (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 | | | | | Trea |
|---|---|---|---|---|---|---|---|---|---|---|
| | 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 |
| Balance, 12/31/01 | — | $ — | — | $ — | 15,189,563 | $ 15,190 | $ 5,321,761 | $ (4,284,551) | $ — | — |
| Uncompensated contribution of services—1st quarter | — | — | — | — | — | — | 100,000 | — | — | — |
| Issuance of preferred stock for cash on 4/26/02 | 905,000 | 905 | — | — | — | — | 2,817,331 | — | — | — |
| Issuance of preferred stock for cash on 5/16/02 | 890,250 | 890 | — | — | — | — | 2,772,239 | — | — | — |
| Issuance of preferred stock for cash on 5/31/02 | 795,000 | 795 | — | — | — | — | 2,473,380 | — | — | — |
| Issuance of preferred stock for cash on 6/28/02 | 229,642 | 230 | — | — | — | — | 712,991 | — | — | — |
| Uncompensated contribution of services—2nd quarter | — | — | — | — | — | — | 100,000 | — | — | — |
| Issuance of preferred stock for cash on 7/15/02 | 75,108 | 75 | — | — | — | — | 233,886 | — | — | — |
| Issuance of common stock for cash on 8/1/02 | — | — | — | — | 38,400 | 38 | 57,562 | — | — | — |
| Issuance of warrants for services on 9/06/02 | — | — | — | — | — | — | 103,388 | — | — | — |
| Uncompensated contribution of services—3rd quarter | — | — | — | — | — | — | 100,000 | — | — | — |
| Uncompensated contribution of services—4th quarter | — | — | — | — | — | — | 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) | — | — |
| Other comprehensive income, foreign currency translation adjustment | — | — | — | — | — | — | — | — | 13,875 | — |
| Comprehensive loss | — | — | — | — | — | — | — | — | — | — |

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 | | | | | Trea |
|---|---|---|---|---|---|---|---|---|---|---|
| | 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 |
| Balance, 12/31/02 | 3,038,507 | $ 3,039 | — | $ — | 15,227,963 | $ 15,228 | $ 25,573,999 | $ (20,399,211) | $ 13,875 | — |
| Issuance of common stock for cash on 1/7/03 | — | — | — | — | 61,600 | 62 | 92,338 | — | — | — |
| Issuance of common stock for patent pending acquisition on 3/31/03 | — | — | — | — | 100,000 | 100 | 539,900 | — | — | — |
| Cancellation of common stock on 3/31/03 | — | — | — | — | (79,382) | (79) | (119,380) | — | — | — |
| Uncompensated contribution of services—1st quarter | — | — | — | — | — | — | 100,000 | — | — | — |
| Issuance of preferred stock for cash on 5/9/03 | — | — | 110,250 | 110 | — | — | 2,773,218 | — | — | — |
| Issuance of preferred stock for cash on 5/16/02 | — | — | 45,500 | 46 | — | — | 1,145,704 | — | — | — |
| Conversion of preferred stock into common stock- 2nd qtr | (70,954) | (72) | — | — | 147,062 | 147 | 40,626 | — | — | — |
| Conversion of warrants into common stock- 2nd qtr | — | — | — | — | 114,598 | 114 | (114) | — | — | — |
| Uncompensated contribution of services—2nd quarter | — | — | — | — | — | — | 100,000 | — | — | — |
| Issuance of preferred stock for dividends | — | — | — | — | — | — | — | (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 | — | — | — |
| Issuance of common stock for cash on 8/27/03 | — | — | — | — | 3,359,331 | 3,359 | 18,452,202 | — | — | — |
| Conversion of preferred stock into common stock—3rd qtr | (2,967,553) | (2,967) | (155,750) | (156) | 7,188,793 | 7,189 | (82,875) | — | — | — |
| Conversion of warrants into Common stock—3rd qtr | — | — | — | — | 212,834 | 213 | (213) | — | — | — |
| Compensation expense on warrants issued to non-employees | — | — | — | — | — | — | 412,812 | — | — | — |
| Issuance of common stock for cash—4th qtr | — | — | — | — | 136,500 | 137 | 279,363 | — | — | — |
| Conversion of warrants into Common stock—4th qtr | — | — | — | — | 393 | — | — | — | — | — |
| Comprehensive income: | | | | | | | | | | |
| Net loss | — | — | — | — | — | — | — | (11,268,294) | — | — |
| Other comprehensive income, foreign currency translation adjustment | — | — | — | — | — | — | — | — | 360,505 | — |
| Comprehensive loss | — | — | — | — | — | — | — | — | — | — |
| Balance, 12/31/03 | — | $ — | — | $ — | 26,672,192 | $ 26,672 | $ 50,862,258 | $ (33,999,585) | $ 374,380 | — |

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 |
| 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 biotechnology company which has developed a patented process for the propagation of autologous cells to be used to stimulate a patient's own collagen and elastin production (the "Isolagen Process"). 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 or obtained on a timely basis.

The Company's goal is to become the industry leader in the research, development and commercialization of the Isolagen Process and the use of autologous cellular systems ("ACS") which stimulate a patient's own collagen production. 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 38.5% 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.

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**Exhibit 14**

**ISOLAGEN, INC.**

**CODE OF ETHICS**

Isolagen, Inc. and its subsidiaries (collectively referred to as "Isolagen" or the "Company") are committed to conducting the Company's business in accordance with all applicable federal, state and local laws, honesty in our business dealings, prudent use of our assets and resources, sound growth and achievement of business objectives and fair treatment of our employees. We are committed to achieving and maintaining the highest level of integrity and ethics in our dealings with our employees, customers, suppliers, shareholders and the public. For the purposes of these business and ethical conduct standards ("Standards"), the Company considers its officers, directors, employees, agents and consultants to be "Employees" and each an "Employee."

As Employees we are responsible for fully implementing the business practices and corporate policies of Isolagen. These Standards are presented to govern the conduct of all our Employees. The Standards are directed to all Isolagen Employees as well as our business alliance partners.

***CONFLICTS OF INTEREST***

It is very important that every Employee avoid any situation which involves a conflict with his/her duty to the Company and the interests of the Company and its shareholders. We expect our Employees to exercise good judgment, honesty and high ethical standards at all times. Adherence to these Standards should prevent the occurrence of conflicts of interest. Employees should be particularly sensitive to possible conflicts with suppliers, brokers or any vendors which could arise from engaging in business dealings with, or accepting gifts or compensation from, others. If the Employee is in doubt, the Ethics Officer should be consulted. The transmittal letter accompanying the copy of this Code of Ethics delivered to you identifies the Ethics Officer and the Chairman of the Audit Committee of the Board of Directors. Should questions arise regarding the appropriate handling of your responsibilities under this Code of Ethics, please contact either of these persons; and, definitely, contact the Chairman of the Audit Committee if and whenever you have concerns about the prompt and responsive handling of any matter of concern to you.

Playing "favorites" or having conflicts of interest, in practice or appearance, runs counter to the fair treatment to which we are all entitled. Each Employee should avoid any relationship, influence or activity that might impair, or have the appearance of impairing, his/her ability to make objective and fair decisions when performing his/her job. Conflict of interest laws and regulations must be fully and carefully observed. When in doubt, review Company policies and procedures, and share the facts of the situation with the Ethics Officer.

Here are some ways a conflict of interest could arise:

- Employment by a competitor or potential competitor, regardless of the nature of the employment, while employed by the Company.
- Acceptance of gifts, cash or in kind from those seeking to do business with the Company.
- Placement of business with a firm owned or controlled by an Employee or his/her family.
- Ownership of, or substantial interest in, a company which is a competitor of or a supplier to the Company.
- Acting as a consultant to a Company customer or supplier without the Company's express prior written approval. Approval is required for any Employee's services as director, officer, employee, or consultant to any company which is a supplier or a customer having business dealings with Isolagen.

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In order to preserve the Company's reputation for honesty and integrity, the management of our Company must be advised of any matters which might be considered sensitive. Any such notification should be addressed to the Ethics Officer. Each Employee has a duty to ensure that proprietary information relating to the Company or any entity or person with which the Company does business is not disclosed to anyone without proper authorization. Every Employee has a duty to keep proprietary documents protected and secure, particularly when dealing with suppliers, customers and competitors.

***FINANCIAL REPORTING***

The Company's senior financial officers (e.g., principal financial officer, comptroller, principal accounting officer and any person performing similar functions) as well as any person whose responsibilities include financial reporting duties ("Finance Personnel") have a heightened obligation to perform their duties in a diligent, honest and ethical manner. This duty of honesty extends to the full, fair, accurate, timely and understandable disclosure of information relating to the Company's financial condition and results of operation in its periodic reports and compliance with all applicable government rules and regulations. The primary responsibility for financial reporting, internal control, and compliance with laws, regulation, and ethics rests with executive management.

If Finance Personnel discover, or have reason to believe, that there is an actual or potential conflict of interest between their personal and professional relationships, they must report this information in a prompt fashion to the Ethics Officer or the Company's Audit Committee. Examples of information which should be reported include but are not limited to: (i) internal control deficiencies such as failure to conduct quarterly reviews of those controls, or control overrides (such as situations in which Company officials responsible for a certain function have avoided performing such function or their decisions are overridden); (ii) fraud by management or by Employees with significant roles in financial reporting or internal controls (regardless of materiality); (iii) utilization of proprietary Company information by non-Company personnel for the benefit of persons or entities other than the Company; and (iv) provision of non-auditing services by the Company's auditors without the prior consent of the

Company's Audit Committee.

The Company's Audit Committee has important oversight responsibilities that relate to the Company's financial reporting, internal controls, compliance with applicable laws and regulations and Company ethics. In this capacity, the Audit Committee has the power to authorize investigations that are within the scope of its responsibilities, including conducting interviews or discussions with Employees and other persons whose views may be helpful to them. In its oversight capacity, the Audit Committee also monitors internal control processes by reviewing reports issued by external auditors and other information to gain reasonable assurance that the Company is in compliance with pertinent laws and regulations, is conducting its affairs ethically, and is maintaining effective controls against conflict of interest and fraud. If you have any concerns regarding the Company's financial reporting, internal controls, compliance with applicable laws and regulations and compliance of Company Employees with this Code of Ethics, you should contact the Chairman of the Audit Committee directly.

***GIFTS, GRATUITIES AND ENTERTAINMENT***

*Customer and Supplier Personnel*

The purchase of supplies, materials and services from vendors, suppliers and subcontractors must be accomplished in a fair and nondiscriminatory process based solely on quality, performance, price and customer criteria (in cases where purchases are made for customers).

Isolagen specifically prohibits offering, attempting to give, soliciting or receiving any form of bribe or kickback. These are criminal acts. Since the mere receipt of a request to engage in such activity may be a reportable event under the law, all Employees should immediately seek advice from the Ethics Officer if any such request is received. Similarly, any dealings with affiliated persons of the Company or



of any officer of the Company must be reviewed by the Ethics Officer. No transaction may be effected with an affiliated person or entity absent the written approval of the Audit Committee.

*Government Personnel*

No Employee may give federal, state or local government employees any meal, beverage, gift or form of entertainment regardless of value with the following exceptions:

- Promotional items which have a retail value of less than $25.00 and which contain the Company's name or logo may be offered without violating this Code of Ethics;
- Employees may also provide (i) modest items of food and refreshments offered other than as part of a meal (such as soft drinks, coffee and doughnuts) to employees of federal executive agencies other than uniformed services; and (ii) greeting cards and items with little intrinsic value such as plaques, certificates and trophies, which are intended solely for presentation.
- Employees may socially entertain relatives or personal friends employed by government agencies. It should be clear, however, that such entertainment is not related to the Company's business. Expenditures for such non-business entertainment are not reimbursable by the Company to the Employee.
- Employees may not make loans, guarantee loans or make payments to or on behalf of federal, state or local government employees.

Anyone with questions regarding this section should contact the Ethics Officer. The making of gifts that exceed these limits is a violation of the Code of Ethics and other policies.

*Non-Government Personnel*

Furnishing meals, refreshments, modest gifts/honorariums (see below) and entertainment in conjunction with business discussions with non-government personnel is a commonly accepted business practice. Isolagen permits its Employees, within reason, to engage in such practices. The furnishing of meals, refreshments or entertainment and the making of modest gifts/honorariums, however, should not violate good common sense and the standards of conduct of the recipient's organization, and must be consistent with past practices and standards established from time to time by the Company.

Employees who make, and supervisors who approve, expenditures for meals, refreshments or entertainment, must use discretion and care to ensure that such expenditures are in the proper course of business and cannot reasonably be construed as bribes or improper inducements.

Modest gifts/honorariums should only be given in order to commemorate a specific holiday or special event. In no event should the value of such individual items exceed $50.00 without the prior approval of the Chief Financial Officer. Detailed records of all such gifts and their business purpose should be maintained for at least three years. Employees should at all times be mindful of the need to avoid the appearance of gift giving for the purpose of inducing favorable treatment.

Employees may accept meals, refreshments or entertainment in connection with business discussions, *provided*, that they are not excessive as to cost or frequency. It is the personal responsibility of every Employee to ensure that his/her acceptance of such meals, refreshments or entertainment is within prevailing Company Standards and could not reasonably be construed as an attempt by the offering party to secure favorable treatment or create an appearance of impropriety.

Employees may not accept gifts, including travel and accommodations, which have a retail or exchange value of $50.00 or more from an individual or firm doing or seeking to do business with the Company. Exceptions may be granted on an individual basis; however, Employees must immediately report the gift to their supervisor and the Ethics Officer and request a waiver of this rule.

In any circumstance where an Employee is offered meals, refreshments, entertainment or gifts and the offering may create an appearance of impropriety, regardless of the value thereof, the Employee should disclose the offering to his/her supervisor and the Ethics Officer in writing.

Except for loans by recognized banks and financial institutions which are available generally at market rates and terms, no Employee or member of his/her family may accept any loan, guarantee of loan or payment from an individual or firm doing or seeking to do business with Isolagen; nor is it permissible to accept any service, accommodation or travel of any value whatsoever, unless the primary purpose of such is the performance of the Company's business.

*Gifts or Payments to Foreign Officials*

Isolagen will scrupulously adhere to the letter and spirit of the Foreign Corrupt Practices Act, which prohibits, among other things, giving money or items of value to a foreign official or instrumentality for the purpose of influencing a foreign government. The Act further prohibits giving money or items of value to any person or firm, such as a consultant or marketing representative, when there is a reason to believe that it will be passed on to a foreign government official for this purpose. All questions concerning compliance with the Foreign Corrupt Practices Act should be referred to the Ethics Officer.

*Gifts or Payments in General*

- All approved expenditures for meals, refreshments and entertainment must be fully documented and recorded on the books of the Company in strict compliance with established policies and procedures.
- Employees are required to report to their supervisors any instance in which they are offered money, gifts which have retail or exchange value of $50.00 or more or anything else of value by a supplier or prospective supplier to Isolagen.
- Laws and regulations pertaining to entertainment, gifts and payments may be and are complicated. Questions regarding interpretations of specific policies should be submitted to the Ethics Officer.

***ANTITRUST***

The antitrust laws of the United States are calculated to promote free and open competition. It is incumbent upon Employees to seek guidance and instructions from supervisors, and if necessary, from the Ethics Officer whenever any questions relating to their compliance with those laws and regulations arise. All Employees are expected to conduct themselves in a manner designed to promote the Company's compliance with the antitrust laws, and no Employee shall discuss with any competitor: prices or terms of sale; division of territories or markets; allocation of customers; or boycotts of customers or suppliers.

***INTEGRITY OF COMPANY RECORDS***

*Financial Information and Records*

To ensure that public companies such as Isolagen disclose complete and accurate financial information in their periodic reports, federal securities law requires the Company's CEO and CFO to certify that: (i) they have reviewed each periodic report; (ii) based on their knowledge, there are no materially false statements or material omissions in the subject periodic report; (iii) the report fairly presents the issuer's financial condition and results of operations; (iv) the signing officers are responsible for establishing and maintaining effective internal controls and have evaluated the effectiveness of those controls within 90 days of the date of the report; (v) they have presented their



conclusions about the effectiveness of the controls in the subject report; (vi) they have disclosed control deficiencies and any fraud by management or Employees with a significant role in internal controls (regardless of materiality) to the auditors and the Audit Committee; and (vii) they have disclosed any material weaknesses in internal controls to the Company's auditors. In addition, all annual reports must include an internal control report concerning management's responsibility for establishing and assessing its internal control structure and procedures for financial reporting to which the Company's auditors must also attest and report. It is anticipated that additional requirements may be promulgated in the near future.

It is Company policy to comply with accepted accounting rules and controls at all times. All Company records must accurately reflect the transactions they record. In particular, this policy requires the following:

- No undisclosed or unrecorded fund or asset of the Company shall be established for any purpose;
- No false or misleading entries shall be made in the books or records of the Company for any reason and no Employee shall assist in any arrangement that results in any such entry;
- No payment or expenditure of the Company shall be approved without adequate supporting documentation or made with intention or understanding that any Party of such payment or expenditure is to be used, directly or indirectly, for any purpose other than that expressly described by the supporting documentation;
- Any Employee having information concerning any unrecorded fund or asset or any prohibited act shall promptly report such matter to the Ethics Officer;
- Medical claims of Employees contain confidential information. Such claims shall be treated in a manner to retain that confidentiality and in a manner consistent with Company policy and procedures; and

- The Company's internal and outside accountants must maintain all audit and review work product for five (5) years from the end of the applicable fiscal period.

In addition, every Employee should be aware that:

- It is a crime, punishable by imprisonment of up to ten (10) years, to knowingly and willfully violate Sarbanes-Oxley Act of 2002 provisions regarding retention of corporate audit records;

- It is a crime, punishable by imprisonment of up to twenty (20) years, to knowingly alter, destroy, conceal, etc. records or documents with the intent to impede, obstruct, or influence a federal government investigation or case filed in bankruptcy, or in relation to or contemplation of any such matter or case;

- It is a crime, punishable by imprisonment of up to twenty (20) years, to "corruptly" alter, destroy, mutilate, or conceal records or documents with the intent to impair their integrity or availability in an official proceeding; or to otherwise obstruct, influence, or impede a proceeding (or attempt to do so);

- It is a crime, punishable by imprisonment of up to ten (10) years, to knowingly, with the intent to retaliate, take any action harmful to a person for providing to a law enforcement officer any truthful information relating to the commission or possible commission of any federal offense; and

- You should contact the Ethics Officer should you have any question regarding the foregoing discussion.



*Personnel Records*

Personnel records are treated as confidential by the Company, unless otherwise required by law or permission to disclose their contents is given by an Employee. Notwithstanding the foregoing, the Company will confirm length of service and position held (and pay rate, when written permission is given by the Employee) when contacted by a prospective lender to an Employee or by a prospective employer after an Employee's separation from the Company.

*Information to Customers*

It is the Company policy to provide technical information which is as accurate as possible in order to properly guide our own Employees and customers in the sales and use of our products and services. No false or inaccurate data shall knowingly be recorded or used by any Employee. Any Employee having information concerning any such false data being recorded or used shall promptly report such a situation to the Ethics Officer.

*Computer Usage/Software Licensing*

It is the Company policy to restrict access to computer databases and electronic mail communications systems to authorized users for business and business-related purposes only. It is the Company policy to maintain compliance with software licensing requirements of our suppliers and vendors.

***POLITICAL CONTRIBUTIONS***

The Company may not make any remuneration of money or offer to do so directly or indirectly to any government official or politician in the United States or abroad for the purpose of influencing such official's or politician's actions. Our Employees are expected not to use Company funds or facilities or services for any political purpose in contravention of this policy.

This policy shall not apply to purely individual contributions by Employees. However, the use of Company funds to fund an Employee contribution, or the reimbursement of an Employee contribution is strictly prohibited.

***PROHIBITION AGAINST TRADING WHILE IN POSSESSION OF MATERIAL NON-PUBLIC INFORMATION***

*Confidential Information and Insider Trading*

Each Employee of the Company is forbidden from (i) utilizing non-public information regarding customers, suppliers and other business contacts for personal gain; and (ii) disclosing information regarding customers, suppliers and other business contacts acquired through the Company to persons not in the employ of the Company. All information obtained from a customer, supplier or other business contact in the ordinary course of business is regarded as confidential unless it is, beyond any doubt, widely and publicly known and is also clearly not detrimental information that might be embarrassing to the subject of the information. In addition, the Company forbids any Employee from trading, either personally or on behalf of others, on material non-public information ("Material Non-Public Information") or communicating Material Non-Public Information regarding the Company or any supplier, customer or other business contact of the Company to others in violation of the law. This sort of conduct is frequently referred to as "insider trading."

The Company's policy applies to every Employee and extends to activities within and outside their duties at the Company. Violation of this policy may result in disciplinary action, including but not limited to, termination; and any violation may constitute a crime. Furthermore, "insider trading" can result in the imposition of civil and criminal penalties under United States federal and state law. Every



Employee must read and retain a copy of this policy statement. Any questions regarding the Company's policy and procedures should be referred

to the Ethics Officer, whose name and location will be published and made available to Employees.

The term "insider trading" is not defined in the federal securities laws, but generally refers to the use of Material Non-Public Information for trading in securities (whether or not one is an "insider") or to the communication of Material Non-Public Information to others for their personal use.

While the law concerning insider trading is not static, it is generally understood that the law prohibits:

- trading by an insider, while in possession of Material Non-Public Information, or
- trading by a non-insider, while in possession of Material Non-Public Information, where the information either was disclosed to the non-insider in violation of an insider's duty to keep it confidential or was misappropriated, or
- communicating Material Non-Public Information to others.

The elements of insider trading and the penalties for such unlawful conduct are discussed below. If, after reviewing this policy statement, you have any questions, you should consult with the Ethics Officer.

*Insiders*

The concept of "insider" is broad. It includes Employees of the Company. In addition, a person can be a "temporary insider" if he/she enters into a special confidential relationship in the conduct of a company's affairs and as a result is given access to information solely for the Company's purposes. A temporary insider can include, among others, a company's attorneys, accountants, consultants, bank lending officers, vendors, customers, and the employees of such organizations. In addition, the company may become a temporary insider of another company with which it is negotiating. According to the United States Supreme Court, the company must expect the outsider to keep the disclosed non-public information confidential and the relationship must at least imply such a duty before the outsider will be considered an insider.

*Material Information*

Trading on inside information is not a basis for liability unless the information is material. "Material Information" generally is defined as information for which there is a substantial likelihood that a reasonable investor would consider it important in making his/her investment decisions, or information that is reasonably certain to have a substantial effect on the price of a company's securities. Information that Employees should consider material includes, but is not limited to:

- increases or decreases in dividends;
- declarations of stock splits and stock dividends;
- financial announcements including periodic results and forecasts, especially earnings releases and estimates of earnings;
- changes in previously disclosed financial information;
- mergers, acquisitions or takeovers;
- proposed issuances of securities;
- significant changes in operations or business trends;



- significant increases or declines in backlog orders or the gain or loss of a significant contract or customer;
- significant new products to be introduced;
- extraordinary borrowings;
- major litigation (civil or criminal);
- financial liquidity problems;
- significant changes in management;
- purchase or sale of substantial assets; and/or
- significant regulatory actions;

Material Information does not have to relate to the Company's business. For example, material information may include information contained in an as yet unpublished newspaper column which would affect the market price of various companies' securities. If the reporter disclosed the dates that reports on various companies would appear in *The Wall Street Journal* and whether those reports would be favorable or not in advance of publication, the reporter could be held criminally liable.

*Non-public Information*

Information is non-public until it has been effectively communicated to the marketplace. One must be able to point to some fact to show that the information is generally public. For example, information found in a report filed with the SEC, or appearing in *Dow Jones News*, *Reuters*

*Economic Services*, *The Wall Street Journal* or other publications of general circulation would be considered public.

Public dissemination usually contemplates some period of delay after release of the information to the press in order for outside investors to evaluate the release. A delay of three (3) full days should suffice for a simple announcement, such as a routine earnings announcement. A longer delay is appropriate when a complex transaction, such as a merger or reorganization, is involved.

Often there is Material Information within the Company that is not yet ripe for public disclosure by the Company itself. For example, during the early stages of discussion regarding a significant acquisition, the information about the discussion may be too tentative or premature to require, or even permit, public announcement by the Company. On the other hand, the information may be highly material in the sense that individuals with access to that information are themselves precluded from trading in the Company's stock. Whenever any doubt exists, the presumption should be against trading in the Company's stock by any insider with access to the information until approval has been sought through appropriate channels.

*Bases for Liability*

*Breach of Fiduciary Duty*

There is no general duty to disclose Material Information before trading on that Material Non-Public Information. However, if a fiduciary relationship exists between the parties to a transaction, and one of those parties has the right to expect that the other party will either disclose any Material Non-Public Information of which he/she is aware or refrain from trading, and fails to do so, the that party has breached his fiduciary duty to the other party.

Non-insiders may also be deemed to have fiduciary duties of insiders in certain instances. For example, if an attorney or an accountant enters into a confidential relationship with the Company through which he/she gains information, he/she may be deemed an insider or "tippee" if he/she personally benefits, directly or indirectly, from the disclosure. That non-insider may also be deemed to



owe a fiduciary duty to the Company's shareholders as a "tippee" if he/she is aware or should have been aware that he/she possesses confidential information from an insider (who has violated his fiduciary duty to the Company's shareholders) and the "tippee" personally benefits, directly or indirectly, from the disclosure.

In the "tippee" situation, a breach of duty occurs only if the insider personally benefits, directly or indirectly, from the disclosure. The benefit does not have to be pecuniary, but can be a gift, a reputational benefit that will translate into future earnings, or even evidence of a relationship that suggests an expectation of some benefit.

*Misappropriation*

Another basis for insider trading liability is the "misappropriation" theory, where liability is established when trading occurs on Material Non-Public Information that was stolen or misappropriated from any other person. For example, the U.S. Supreme Court held that a columnist defrauded *The Wall Street Journal* when he stole information which was to be used in an article and used it for trading in the securities markets prior to the article's publication. It should be noted that the misappropriation theory can be used to reach a variety of individuals not previously thought to be encompassed under the fiduciary duty theory. To the extent that an Employee obtains Material Non-Public Information about a supplier, customer or other business contact in the course of his employ by the Company and trades on it or provides that information to a third party who trades on it, the Employee may be deemed to have "misappropriated" the information.

*Penalties for Insider Trading*

Penalties for trading on or communicating Material Non-Public Information are severe, both for individuals involved in such unlawful conduct and their employers. A person can be subject to some or all of the penalties below even if he/she does not personally benefit from the violation. Penalties include civil injunctions; disgorgement of profits; jail sentences; fines for the person who committed the violation of up to three (3) times the profit gained or loss avoided, whether or not the person actually benefited; and fines for the employer or other controlling person of up to the greater of $1,000,000 or three (3) times the amount of the profit gained or loss avoided. In addition, any violation of this Code of Ethics can be expected to result in serious sanctions by the Company, including, without limitation, dismissal of the persons involved.

*Implementation Procedures*

The following procedures have been established to aid Employees in avoiding insider trading, and to aid the Company in preventing, detecting and imposing sanctions against insider trading. Every Employee of the Company must follow these procedures or risk serious sanctions, including dismissal, substantial personal liability and criminal penalties. If you have any questions about these procedures, you should consult the Ethics Officer.

*Identifying Inside Information*

Before trading for yourself or others in the securities of a company about which you may have potential inside information, ask yourself the following questions:

- Is the information material? Is this information that an investor would consider important in making his/her investment decisions? Is this information that would substantially affect the market price of the securities if generally disclosed?



- Is the information non-public? To whom has this information been provided? Has the information been effectively communicated to

the marketplace by being published in *Dow Jones News, Reuters Economic Services, The Wall Street Journal*or other publications of general circulation?

If, after consideration of the above, you believe that the information is material and non-public, or if you have questions as to whether the information is material and non-public, you should take the following steps:

- Report the matter immediately to the Ethics Officer.
- Do not purchase or sell the securities on behalf of yourself or others.
- Do not communicate the information inside or outside the Company, other than to the Ethics Officer.

After the Ethics Officer has reviewed the issue, you will be instructed to continue to refrain from trading and communicating the information, or you will be allowed to trade and communicate the information.

*Personal Securities Trading*

All officers and directors of the Company are required to obtain clearance from the Ethics Officer prior to effecting any securities transaction involving the securities of the Company in which they, their families (including the spouse, minor children and adults living in the same household as the Employee), or trusts of which they are trustees or in which they have a beneficial interest are parties. An Employee who believes he/she has or is uncertain whether information in his/her possession is material, non-public information should also obtain clearance from the Ethics Officer. The Ethics Officer will promptly notify the Employee of clearance or denial of clearance to trade. Notification of approval or denial to trade may be verbally given; however, it will be confirmed in writing within 72 hours of the verbal notification. Clearance of any particular trade by the Internal Compliance Officer will be based on his best judgment in reliance on the facts presented. Each Employee remains individually responsible for compliance with U.S. federal and state securities laws and the Code of Ethics.

*Restricting Access to Material Non-Public Information*

Information in your possession that you identify as material and non-public may not be communicated to anyone, including persons within the Company, except as provided above. In addition, care should be taken so that such information is secure. For example, files containing Material Non-Public Information should be sealed; access to paper and computer files containing Material Non-Public Information should be restricted; conversations in public places, such as restaurants, elevators and airplanes should be limited to information that is neither sensitive nor confidential; speaker phones should not be used if, as a result, the conversation may be heard by a party who does not have a "need to know."

If you become aware of a leak of Material Information, whether inadvertent or otherwise, you should report that fact immediately to the Ethics Officer or to the Chairman of the Audit Committee.

*Communications with Outsiders*

The Company typically communicates any disclosable Material Information with the press, its shareholders and the financial community through the issuance of press releases and the filing of periodic reports. All requests from outsiders for information regarding the general business or financial condition of the Company should be referred to one of the officers of the Company. Courts have even



treated the confirmation of information in some circumstances to constitute tipping. If you become aware of a rumor circulating about the Company, details concerning the rumor should be reported to the Ethics Officer as soon as possible so that a determination can be made whether it is necessary or advisable to make a general public announcement to dispel such rumor.

*Resolving Issues Concerning Insider Trading*

If, after consideration of the items set forth in this Code of Ethics, you have concerns as to whether information is material or non-public, or if there is any other unresolved question as to the applicability or interpretation of the foregoing procedures, or as to the propriety of any action, you must presume the information to be material and non-public and must discuss the matter with the Ethics Officer before trading or communicating the information to anyone.

***EXCEPTIONS TO THE CODE OF ETHICS***

The Ethics Officer may make exceptions on a case-by-case basis of this Code upon a determination that the conduct at issue involves a negligible opportunity for abuse or otherwise merits an exemption from the Standards set forth herein. All such exceptions must be received in writing by the person requesting the exemption before becoming effective.

***SUPERVISORY PROCEDURES***

The role of the Ethics Officer is critical to the implementation and maintenance of this Code of Ethics. Supervisory Procedures can be divided into two classifications: (i) prevention of violations of law; and (ii) the preservation of systems necessary to assure the integrity of the Company's financial reporting.

*Prevention of Violations of Law*

To prevent insider trading, the Ethics Officer should:

- provide, on a regular basis, a program to familiarize Employees with the Company's policy and procedures, including the furnishing of this Code of Ethics to all Employees and to each new Employee upon commencement of employment;
- answer questions regarding the Code of Ethics;

- resolve issues of whether information received by an Employee of the Company is material and non-public;
- review, with the assistance of the Company's legal counsel, on a regular basis and update as necessary the Code of Ethics;
- when it has been determined that an Employee of the Company has Material Non-Public Information, implement measures to prevent dissemination of such information, and if necessary, restrict Employees from trading the securities; and
- promptly review, and either approve or disapprove, in writing, each request of an Employee for clearance to trade in specified securities.

*Detection of Insider Trading*

To detect insider trading, the Ethics Officer should:

- review the trading activity reports and beneficial ownership disclosure, as filed with the SEC, filed by each officer and director;



- maintain regular communication with and be available to answer questions from Employees of the Company who are contemplating securities transactions; and
- coordinate the review of such reports with other appropriate officers or directors of the Company.

*Special Reports to Management*

Upon learning of a potential violation of the Code of Ethics, the Ethics Officer should promptly prepare a written report to management and the Audit Committee providing full details and recommendations for further action.

*Annual Reports to Management*

On an annual basis, the Ethics Officer should prepare a written report to the management of the Company and the Audit Committee setting forth the following:

- a summary of existing procedures to detect and prevent violations of the Code of Ethics;
- full details of any investigation, either internal or by a regulatory agency, of any suspected reporting impropriety, violation of this Code of Ethics or of any other Company standard or policy, or any violation of law, including insider trading; and the results of such investigation;
- an evaluation of the current procedures and any recommendations for improvement; and
- a description of the Company's continuing program to educate parties regarding insider trading, including the dates of such programs, since the last report to management and the Audit Committee.

***ACKNOWLEDGMENT***

We will expect every Employee, after he/she has read this Code of Ethics, to execute the attached Acknowledgment form affirming his/her knowledge and understanding of this Code of Ethics and affirming his/her responsibility as an Employee to promptly notify his/her immediate supervisor and the Ethics Officer if he/she has any questions or concerns regarding conduct that may raise concern that any of these policies have not been observed.

***CONFIDENTIALITY***

The Company will, to the fullest extent possible without contravening any law, regulation or statute, hold confidential the name of the any Employee reporting any event or conduct which he/she believes, in good faith, may raise concern that any policy described in the Company's Code of Ethics may not have been observed. In some circumstances; however, the Company may be required to furnish such information to law enforcement or governmental officials and counsel in order to address issued raised by such reports.

***ANNUAL QUESTIONNAIRES***

The Company shall prepare and distribute annually to each Employee, director, officer and business alliance partner, a Business Conduct Questionnaire and Certification, wherein each Employee shall certify as to his/her knowledge of circumstances, including actions taken, during the preceding fiscal year that had a bearing on the Code of Ethics.

Questionnaires shall be forwarded to the Company's legal counsel and will be considered privileged communications, and shall not be disclosed to any other Employee or person except as



determined by legal counsel or compelled by law. Copies of completed questionnaires are not to be retained in personnel files.

***ETHICS OFFICER***

Employees who discover violations of Company policies are encouraged to report the violations immediately to the Ethics Officer and to the Chairman of the Audit Committee. The Ethics Officer will be responsible for providing information about the Company's position on ethical issues, for responding to inquiries about Employee conduct, and for considering disciplinary action which may be taken against any persons found in violation of these Standards.

**PUBLICATION OF CONTACT INFORMATION**

The Ethics Officer shall prominently post on employee bulletins boards or in places designated for Company communications and other important information, the following information:

- The name and contact information for the Ethics Officer.
- The name and contact information for the Audit Committee Chairman
- The name and contact information for each member of the Audit committee.
- A sample questionnaire and report form substantially similar to the *Business Conduct Questionnaire and Annual Certification.*
- A copy of the Company's Code of Ethics.

In addition, contact information, a copy of the Code of Ethics and a sample questionnaire and report form substantially similar to the *Business Conduct Questionnaire and Annual Certification shall be posted on the Company's intranet.*

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**ACKNOWLEDGMENT**

***To: Isolagen, Inc. Ethics Officer***

I have read the Code of Ethics. I understand my responsibility to comply with the Code of Ethics and the process and consequences for dealing with violations thereof.

If I have any questions or concerns regarding conduct that may raise concern under this Code of Ethics, I will immediately follow one of the procedures suggested in this policy and will notify my immediate supervisor and Ethics Officer.

Signature

Print Your Name

Date

Job Title or Classification

Location



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**Isolagen, Inc.**
**CONFIDENTIAL**
***Business Conduct Questionnaire and Annual Certification***

The following questions pertain to Isolagen and its subsidiaries (collectively "Isolagen") for 2003. The Company will, to the fullest extent possible without contravening any law, regulation or statute, hold confidential the name of the any Employee reporting any event or conduct which

he/she believes, in good faith, may raise concern that any policy described in the Company's Code of Ethics may not have been observed.

| | | Yes* | No |
|---|---|---|---|
| 1. | Have you read Isolagen's Code of Ethics and are you adhering to the policies and standards set forth therein? | | |
| 2. | Have you or do you know of any other Employee who has offered to pay or otherwise compensate any federal, state, local or foreign government official or employee for services performed on behalf of Isolagen? | | |
| 3. | Have you or do you know of any person who has received anything having a value of over $50.00 from any person or company doing or seeking to do business with Isolagen? | | |
| 4. | Have you or do you know of any Employee who has supplied any services or confidential Company information to a competitor or supplier of Isolagen? | | |
| 5. | Do you have or do you know of any Employee who has any interest (other than ownership of publicly traded shares) in any entity with which Isolagen does business or which competes with Isolagen? Do any of your close relatives work for a customer or competitor of Isolagen? | | |
| 6. | Have or do you know of any Employee who has used Isolagen's assets, influence or information for personal purposes without adequately reimbursing Isolagen, and without making full disclosure of the same to your supervisor? | | |
| 7. | Have you or do you know of any other Employee who has made inaccurate, improper or misleading entries to documents Isolagen is required to maintain for or submit to any governmental agency or authority or any customer? | | |
| 8. | Have you or do you know of any Employee who has made inaccurate or misleading entries to Isolagen's records or failed to disclose properly any assets or liabilities of Isolagen? | | |
| 9. | Have you or do you know of any Employee who has failed to comply with any law or regulation applicable to Isolagen, including without limitation any environmental requirements? | | |
| 10. | Have you or do you know of any Employee who has made any domestic or foreign political contributions on behalf of Isolagen? (Personal contributions are excluded.) | | |
| 11. | Do you know of any Employee that has violated the Code of Ethics or any other Company policy or standard? | | |
| 12. | Do you know of any report, or other information that has been filed by Isolagen with the Securities and Exchange Commission, any stock exchange on which Isolagen's securities are listed or quoted, or distributed to any shareholders or prospective shareholders of Isolagen that contains any untrue statements of a material fact or omits to state a material fact necessary in order to make the statements made in such materials, in light of the circumstances under which such statements were made, not misleading? | | |
| 13. | Do you know of any financial statements, and other financial information included in any report, or other information that has been filed by Isolagen with the Securities and Exchange Commission, any stock exchange on which Isolagen's securities are listed or quoted, or distributed to any shareholders or prospective shareholders of Isolagen, that do not fairly present in all material respects the financial condition and results of operation of Isolagen as of and for the period presented in the materials? | | |
| 14. | Do you know of any significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of their evaluation, including any corrective actions regarding to significant deficiencies and material weaknesses? | | |

***If yes for questions 2-14, please explain on reverse side.**

Signature:

Name (please print):

Company/Subsidiary Division:

Position:

Phone Number:

*The completed form should be mailed to Isolagen, Inc., Company Ethics Office, 2500 Wilcrest, 5th Floor, Houston, TX 77042.*

Exhibit 14

ISOLAGEN, INC. CODE OF ETHICS
ACKNOWLEDGMENT
Isolagen, Inc. CONFIDENTIAL Business Conduct Questionnaire and Annual Certification

QuickLinks -- Click here to rapidly navigate through this document

**EXHIBIT 23.1**

**CONSENT OF INDEPENDENT ACCOUNTANTS**

We consent to the incorporation by reference in the Registration Statement on Form S-1/A (File No. 333-108769) of our report dated February 17, 2004 relating to the financial statements included in this Form 10-K.

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

Houston, Texas
March 29, 2004

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QuickLinks

EXHIBIT 23.1

CONSENT OF INDEPENDENT ACCOUNTANTS

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**Exhibit 31.1**

**Officer's Certification Pursuant to**
**Section 302 of the Sarbanes-Oxley Act of 202**

I, Michael Macaluso, Chief Executive Officer, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2003 of the registrant;

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

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

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

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

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

   c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

March 26, 2004

By: /s/ MICHAEL MACALUSO

*Chief Executive Officer*
*(Principal Executive Officer)*

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Exhibit 31.1

Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 202

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**Exhibit 31.2**

**Officer's Certification Pursuant to**
**Section 302 of the Sarbanes-Oxley Act of 202**

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

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2003 of the registrant;

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

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

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

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

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

   c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

March 26, 2004

By: /s/ JEFFREY W. TOMZ

*Chief Financial Officer*
*(Principal Financial Officer)*

QuickLinks

Exhibit 31.2

Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 202

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**Exhibit 32.1**

**CERTIFICATION PURSUANT TO**
**18 U.S.C. SECTION 1350,**
**AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Isolagen, Inc. (the "Company") on Form 10-K for the year ending December 31, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael Macaluso, Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C 78m or 78o(d)); and
- The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 26, 2004

By: /s/ Michael Macaluso

Michael Macaluso, CEO

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**Exhibit 32.2**

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Isolagen, Inc. (the "Company") on Form 10-K for the year ending December 31, 2002 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jeffrey W. Tomz, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C 78m or 78o(d)); and
- The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 26, 2004 By: /s/ JEFFREY W. TOMZ

Jeffrey W. Tomz, *CFO*

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Exhibit 32.2