ISOLAGEN INC
Form 424B4
June 10, 2004

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Filed pursuant to Rule 424(b)(4)
Registration No. 333-114952

7,000,000 Shares

Common Stock
$8.50 per share

Isolagen, Inc. is offering 7,000,000 shares. The common stock is listed on the American Stock Exchange under the symbol "ILE." On June 9, 2004, the last reported sale price of the common stock on the American Stock Exchange was $8.95 per share.

Investing in the common stock involves risks. See "Risk Factors" beginning on page 4.

	Per Share	Total
Price to the public	$ 8.50	$ 59,500,000
Underwriting discount	$ 0.51	$ 3,570,000
Proceeds to Isolagen	$ 7.99	$ 55,930,000

We and the selling stockholders identified in this prospectus have granted an over-allotment option to the underwriters. Under this option, the underwriters may elect to purchase a maximum of 1,050,000 additional shares (200,000 from us and 850,000 from the selling stockholders) within 30 days following the date of this prospectus to cover over-allotments.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

CIBC World Markets **Legg Mason Wood Walker**

Incorporated

Adams, Harkness & Hill, Inc.

The date of this prospectus is June 9, 2004.

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Prospectus Summary

This summary highlights information contained in other parts of this prospectus. Because it is a summary, it does not contain all of the information that you should consider before investing in the shares. You should read the entire prospectus carefully. The terms "we," "us," "our company" and "Isolagen" mean Isolagen, Inc. and its consolidated subsidiaries.

Our Company

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

We are developing our lead product candidate for the correction and reduction of the normal effects of aging, such as wrinkles and nasolabial folds. In March 2004, we announced positive results of our first Phase III clinical trial for our lead product candidate. We are planning to initiate two pivotal Phase III clinical trials for this product candidate during the third quarter of 2004. We expect to file a Biologics License Application for this product candidate during the first quarter of 2005. In late 2003, we began limited commercialization for our dermal product in the United Kingdom and Australia. We completed a Phase I clinical trial for our second product candidate for the treatment of periodontal disease in late 2003, and we are planning to initiate a Phase II clinical trial during the second quarter of 2004.

Our Target Market Opportunity

Our first two product candidates are directed at the aesthetic and dental markets. For the aesthetic market, we will target primarily dermatologists, plastic surgeons and cosmetic surgeons, of which there are approximately 23,000 in the United States. For the dental market, we will target dentists, of which there are approximately 149,000 in the United States. We believe that both of these markets are influenced by consumer awareness of the available therapies and their benefits that drive patients to practitioners to seek out treatment.

Aesthetic Market. According to the American Society for Aesthetic Plastic Surgery, nearly 8.3 million surgical and non-surgical cosmetic procedures were performed in 2003, up 20% from nearly 6.9 million in 2002. Consumer demand increased 22% in 2003 for non-surgical cosmetic procedures, exceeding more than 6.4 million procedures. Non-surgical procedures include injectable materials that are used to correct or reduce wrinkles and nasolabial folds. We believe growth in the aesthetic procedure market is driven by:

- aging of the "baby boomer" population, currently ages 40 to 58, representing over 27% of the U.S. population;
- increasing desire of many individuals to improve their appearance;
- impact of managed care and reimbursement policies on physician economics, which has motivated physicians to establish or expand the menu of elective, private-pay aesthetic procedures that they offer; and
- broadening base of the practitioners performing cosmetic procedures beyond dermatologists and plastic surgeons to non-traditional providers.

Dental Market. We believe there is a significant dental market opportunity for an effective therapy for regenerating tissue because a majority of the population will experience periodontal disease at some point in their lives.

Our Isolagen Process

Our proprietary Isolagen Process is an autologous cellular therapy designed to replenish deficiencies caused by the loss of fibroblast cells as a person ages. Fibroblast cells are found throughout the body and are responsible for producing collagen and elastin, which provide support structures for various tissues in the body, such as skin. As a person ages, he or she loses fibroblasts and the ability to produce and replace collagen and elastin leading to normal signs of aging, including both wrinkles and nasolabial folds. Our proprietary Isolagen Process takes the patient's cells from a small skin sample from which millions of fibroblast cells are extracted, allowed to multiply and injected into the patient. It takes approximately six weeks from obtaining the skin sample to produce the first injection. A total of three injections are administered to the patient at approximately two-week intervals. Our data indicates that following the injections, the new fibroblast cells lead to the production of collagen and elastin, which diminish the visible effects of aging. A patient may elect to cryogenically store his or her fibroblasts at our facilities to be used for future treatments.

Our Strategy

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

leveraging our expertise in autologous cellular therapies to expand into other applications;

optimizing our manufacturing processes to achieve cost reductions and scalability;

building a direct sales force;

expanding our international presence; and

capitalizing on strong direct to consumer response.

Corporate Information

Our principal executive offices are located at 2500 Wilcrest, 5th Floor, Houston, Texas 77042, and our telephone number is (713) 780-4754. Our web site address is *www.isolagen.com*. Information on our web site is not part of this prospectus.

Our trademarks include "Isolagen" for which we have a pending trademark registration in the United States, and "Isolagen, The Science of Natural Beauty", "Isolagen, The Science of Living Cells" and "Isolagen, Changing the Face of Time" for which we assert common law trademark rights. Other trademarks and trade names appearing in this prospectus are the property of the holder of such trademarks and trade names.

The Offering

Common stock offered by Isolagen	7,000,000 shares
Common stock to be outstanding after the offering	33,818,233 shares
Use of proceeds	We intend to use the net proceeds received by us in this offering to expand our manufacturing capabilities in the United States and Europe, to build our own direct sales force and fund U.S. product launch expenses, to fund research and development, including our two pivotal Phase III clinical trials for our lead product candidate and for general corporate purposes, including working capital. See "Use of Proceeds."
American Stock Exchange symbol	ILE

The number of shares of common stock to be outstanding after the offering is based on 26,818,233 shares outstanding as of June 9, 2004 and excludes as of June 9, 2004:

- 6,289,100 shares issuable upon exercise of outstanding options at a weighted average exercise price of $5.91 per share;
- 975,389 shares issuable upon exercise of outstanding warrants at a weighted average exercise price of $2.60 per share; and
- 506,900 shares issuable upon exercise of options available for future grant under our stock option plans.

Unless otherwise indicated, all information in this prospectus assumes no exercise of the over-allotment option granted to the underwriters.

Risk Factors

You should carefully consider the following factors and other information in this prospectus before deciding to invest in the shares.

Risks Related to Our Business and Industry

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

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

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

Commercialization of our Isolagen Process involves a high degree of risk and may take several years. Our product development efforts may fail for many reasons, including:

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

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

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

We are focused on product development and have not generated significant revenue from commercial sales of our products to date. We have incurred operating losses since our inception. Our revenues for the three months ended March 31, 2004 and for fiscal years 2003, 2002 and 2001 were $289,000, $446,000, $91,000 and $105,000, respectively. Our net loss for the three months ended March 31, 2004 and for fiscal years 2003, 2002 and 2001 was $4.9 million, $11.3 million, $5.4 million and $1.7 million, respectively. As of March 31, 2004, we had an accumulated deficit of $38.9 million.

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

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

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

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

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

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

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

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

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

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

necessary to achieve compliance.

Large-scale improvements in capacity and operating margins depend on the successful implementation of our ACE System that permits an automated harvesting process in a closed loop sterile environment. We anticipate that improved manufacturing practices as a result of our collaboration with Applikon Biotechnology will allow us to increase our capacity and to reduce many of our variable costs, including our labor costs. However, our ACE System is unproven, and we do not know whether we will be successful in automating the manufacturing process, validating the safety and effectiveness of these processes, obtaining the required scalability, achieving cost savings or obtaining FDA approval of these processes. In addition, the FDA, in its regulatory discretion, may

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

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

We began limited commercialization of our dermal product in the United Kingdom in late 2003. Our facilities in the United Kingdom were primarily designed to demonstrate the efficacy of our Isolagen Process, and have limited capacity. In light of increasing demand for our dermal product in the United Kingdom, we will be required to expend significant additional funds to increase the capacity of our U.K. operations, including the addition of personnel, introduction of systems enhancements, automation of our manufacturing process through the implementation of our ACE System and the establishment of new facilities. Our inability to timely expand our operations in the United Kingdom may limit our ability to maximize this market opportunity.

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

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

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

None of our facilities was designed or has the capacity to support the full-scale commercialization of our product candidates. Our existing facility in Houston, Texas was constructed to support our clinical trial efforts, and does not have the capacity to support commercialization of our Isolagen Process in the United States. Our manufacturing facilities in the United Kingdom and Australia were designed primarily to enable us to demonstrate the efficacy of our Isolagen Process, and to provide a platform for the future development of our manufacturing processes and our information and other support systems. Our U.K. facility is currently operating at capacity, and is unable to satisfy existing demand for our dermal product. While we are expanding our capacity at that facility, the limited size of that facility represents an inherent limitation of our capacity. The U.K. facility may not be able to meet the ongoing demand for our dermal product in the United Kingdom, even if our ACE System is effectively and timely implemented. We are in the process of planning the establishment of large-scale commercial production facilities in Europe and in the United States. If we encounter delays in establishing those facilities, the commercialization of our Isolagen Process will also be delayed. The failure to timely establish commercial manufacturing facilities in the United States and Europe may delay or prevent our future profitability.

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

Upon completion of this offering, we believe our cash resources will be sufficient to fund our

planned operations for at least 24 months. We are focused on research and development, are incurring losses from operations, have limited capital resources, and do not have access to a line of credit or other debt facility. We may need additional capital in the future. If we raise additional capital through the issuance of debt securities, the interests of our stockholders would be subordinated to the interests of our debt holders and any interest payments would reduce the amount of cash available to operate and grow our business. If we raise additional capital through the sale of equity securities, the ownership of our current stockholders would be diluted. Additionally, we do not know whether any financing, if obtained, will be adequate to meet our capital needs and to support our growth. If adequate capital cannot be obtained on satisfactory terms, we may terminate or delay regulatory approval of one or more of our product candidates, curtail or delay the implementation of our ACE System or delay the expansion of our sales and marketing capabilities. If we terminate or delay regulatory approval, curtail or delay the implementation of our ACE System or delay the expansion of our sales and marketing capabilities, our business may fail.

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

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

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

Prior to receiving approval to commercialize any of our product candidates, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA and other regulatory authorities in the United States and abroad, that our product candidates are both safe and effective. We will need to demonstrate our product candidates' efficacy and monitor their safety throughout the process. We have agreed to conduct two pivotal Phase III clinical trials related to our lead product candidate. If these trials or future clinical trials are unsuccessful, our business and reputation would be harmed and our stock price would be adversely affected.

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

resulting from our product candidates, may severely harm our business and reputation.

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

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

- the level of demand for our Isolagen Process and future products that we may develop;
- the timely and successful implementation of our ACE System;
- our ability to attract and retain personnel with the necessary strategic, technical and creative skills required for effective operations;
- the amount and timing of expenditures by practitioners and their patients;
- introduction of new technologies;
- product liability litigation;
- the amount and timing of capital expenditures and other costs relating to the expansion of our operations;
- government regulation and legal developments regarding our Isolagen Process in the United States and in the foreign countries in which we operate; and
- general economic conditions.

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

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

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

- FDA clinical trials and regulatory approvals;
- expansion of laboratory and manufacturing operations;
- research and development;

promotional and marketing activities;

brand development;

personnel costs; and

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

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

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

Even if we obtain regulatory approval for our product candidates, we will continue to be subject to extensive requirements by a number of foreign, national, state and local agencies. These

regulations will impact many aspects of our operations, including testing, research and development, manufacturing, safety, efficacy, labeling, storage, quality control, adverse event reporting, record keeping, approval, advertising and promotion of our future products. The FDA enforces post-marketing regulatory requirements, including the cGMP requirements, through periodic unannounced inspections. We do not know whether we will pass any future FDA inspections. Failure to pass an inspection could disrupt, delay or shut down our manfacturing operations. Failure to comply with applicable regulatory requirements could, among other things, result in:

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

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

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

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

If we become subject to any of the above requirements, it could be damaging to our reputation, and our business condition could be adversely affected.

Physicians may prescribe pharmaceutical or biologic products for uses that are not described in a product's labeling or differ from those tested by us and approved by the FDA. While such "off-label" uses are common and the FDA does not regulate physicians' choice of treatments, the FDA does restrict a manufacturer's communications on the subject of off-label use. Companies cannot promote FDA-approved pharmaceutical or

biologic products for off-label uses, but under certain limited circumstances they may disseminate to practitioners articles published in peer-reviewed journals. To the extent allowed by law, we intend to disseminate peer-reviewed articles on our future products to practitioners. If, however, our activities fail to comply with the FDA's regulations or guidelines, we may be subject to warnings from, or enforcement action by, the FDA.

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

In both the United States and a number of foreign jurisdictions, there have been legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our future products profitably. The FDA's policies may change and additional

government regulations may be enacted, which could prevent or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we might not be permitted to market our future products and our business could suffer.

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

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

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

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

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

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

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

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

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

- labeling requirements or limitations;
- market acceptance by practitioners and their patients;
- our ability to successfully automate our manufacturing process through implementation of our ACE System to allow us to more cost-effectively produce our

future products, thereby reducing the price at which we can offer our future products;

the effectiveness of our sales efforts and marketing activities; and

the success of competitive products.

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

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

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

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

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

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

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

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

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

If the ownership of our common stock continues to be highly concentrated, it may prevent you and other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause our stock price to decline.

Upon the completion of this offering, we expect our officers and directors will hold approximately 18.5% of our common stock. As such, they will

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

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

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

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

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

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

As of June 9, 2004, we had five issued U.S. patents, seven pending U.S. patent applications, 23 foreign patents and 19 pending foreign patent applications. If we fail to obtain or maintain these protections, we may not be able to prevent third parties from using our proprietary rights. We will be able to protect our proprietary rights from unauthorized use only to the extent that these rights are covered by valid and enforceable patents or are effectively maintained as trade secrets.

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

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

- the inventors of the inventions covered by each of our pending patent applications might not have been the first to make such inventions;
- because the information contained in patent applications is generally not publicly available, we might not have been the first to file patent applications for these inventions or similar technology;
- the future and pending applications we will file or have filed, or to which we will or do have exclusive rights, may not result in issued patents or may take longer than we expect to result in issued patents;
- the claims of any patents that are issued may not provide meaningful protection;

our issued patents may not provide a basis for commercially viable products or may not be valid or enforceable;

we might not be able to develop additional proprietary technologies that are patentable;

- the patents licensed or issued to us may not provide a competitive advantage;
- patents issued to other companies, universities or research institutions may harm our ability to do business;
- other companies, universities or research institutions may independently develop similar or alternative technologies or duplicate our technologies and commercialize discoveries that we attempt to patent;
- other companies, universities or research institutions may design around technologies we have licensed, patented or developed; and
- many of our patent claims are method, rather than composition of matter claims. Generally, composition of matter claims are easier to enforce and are more difficult to circumvent.

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

The rights to some of our patent applications were obtained in a purchase agreement with a third party. If this purchase agreement is found invalid or there are otherwise disputes regarding the invention and corresponding ownership rights in the invention, we may not be able to market future products covered by the license. Additionally, certain future and preexisting intellectual property rights are, or are expected to be, allocated to us in collaboration and development agreements with Applikon Biotechnology and the University of Texas Health Sciences Center at Houston. If the provisions of these agreements are found invalid or otherwise do not operate as we anticipate, there may be disputes as to inventorship and the corresponding rights in know-how and inventions resulting from the joint creation or use of intellectual property by us and our collaborators. We may not be able to use and claim proprietary rights to the technology resulting from these collaboration and cooperation agreements, which may adversely affect our business.

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

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

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

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

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

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

because they have substantially greater financial resources.

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

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

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

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

diversion of management's time and attention;

expenditure of large amounts of cash on legal fees, expenses and payment of damages;

decreased demand for our products or any of our future products and services; or

injury to our reputation.

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

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

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

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

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

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

Risks Related to the Offering

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

The market price of our common stock has experienced, and may continue to experience, significant volatility. During 2003 and the first quarter of 2004, the per share closing price of our common stock ranged from $4.10 to $11.79. The value of our common stock may decline regardless of our operating performance or prospects. Factors affecting our market price include:

- the success or failure of our product development efforts, especially those related to obtaining regulatory approvals domestically and internationally;
- the implementation of our ACE System;
- technological innovations developed by us or our competitors;
- variations in our operating results and the extent to which we achieve our key business targets;
- differences between our reported results and those expected by investors and securities analysts; and
- market reaction to any acquisitions or joint ventures announced by us or our competitors.

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

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

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

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

Our charter documents provide for staggered terms for the members of our Board of Directors. Our Board of Directors is divided into

three staggered classes, and each director serves a term of three years. At stockholders' meetings only those directors comprising one of the three classes will have completed their term and be subject to re-election or replacement.

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

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

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

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

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

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market after the closing of this offering, or as a result of the perception that these sales could occur. In addition, these factors could make it more difficult for us to raise funds through future offerings of common stock. There will be 33,818,233 shares of common stock outstanding immediately after this offering, based on the number of shares outstanding on June 9, 2004. All of the shares sold in this offering will be freely transferable without restriction or further registration under the Securities Act, except for any shares purchased by our executive officers, directors and principal stockholders. All shares held by our executive officers and directors are subject to lock-up agreements with the underwriters and will be eligible for sale in the public market 120 days from the date of this prospectus. In addition, some of our stockholders have entered into lock-up agreements with the underwriters covering 4,748,600 shares, providing that the shares cannot be sold for a period of 90 days from the date of this prospectus. The lock-up agreements are subject to customary exceptions and may be waived by CIBC World Markets Corp.

There is a limited public trading market for our common stock, which may limit your ability to sell shares of our common stock.

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

Investors in this offering will pay a much higher price than the book value of our common stock, and may suffer substantial future dilution upon the exercise of outstanding options and warrants.

If you purchase common stock in this offering, you will pay more for your shares than the amounts paid by existing stockholders for their shares. You will incur immediate and substantial dilution of $6.46 per share, representing the difference between our pro forma net tangible book value per share after giving effect to this offering and the offering price of $8.50. We have also issued options and warrants to purchase our common stock at prices significantly below the offering price. As these outstanding options or warrants are exercised, you will sustain further dilution.

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

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

Forward-Looking Statements

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

Common Stock Market Data

Since December 11, 2002, our common stock has been traded on the American Stock Exchange under the symbol "ILE." Prior to December 11, 2002, our common stock was quoted on the OTC Bulletin Board under the symbol "ISLG." The market for our common stock is limited and volatile. The following table sets forth the range of high and low bid quotations or high and low closing prices, as applicable, for our common stock for each of the quarterly periods indicated as reported by the OTC Bulletin Board or the American Stock Exchange. The prices for the OTC Bulletin Board reflect inter-dealer prices, without retail mark-up, mark-down or commissions.

	2004		2003		2002	
	High	Low	High	Low	High	Low
First Quarter	$ 11.79	$ 5.40	$ 5.55	$ 4.20	$ 7.25	$ 5.00
Second Quarter (through June 9, 2004)	12.04	8.40	7.25	4.10	6.95	2.90
Third Quarter			10.85	6.50	3.75	2.20
Fourth Quarter			9.03	5.15	5.75	3.00

On June 9, 2004, the closing price of our common stock on the American Stock Exchange was $8.95 per share. As of June 9, 2004, we had approximately 688 stockholders of record of our common stock.

Use of Proceeds

We estimate that the net proceeds from the sale of the shares of common stock we are offering will be approximately $55.4 million. If the underwriters fully exercise the over-allotment option, the net proceeds of the shares we sell will be approximately $57.0 million. "Net proceeds" is what we expect to receive after paying the underwriting discount and other expenses of the offering. We will not receive any proceeds from the sale of shares by the selling stockholders in the event that the over-allotment option is exercised.

Of the net proceeds that we will receive from this offering, we expect to use approximately:

$28.0 million to expand our manufacturing capabilities in the United States and Europe;

$10.0 million to build our own direct sales force and to fund U.S. product launch expenses; and

$6.0 million for research and development, including our two pivotal Phase III clinical trials for our lead product candidate.

We will use the balance of the net proceeds for general corporate purposes, including working capital. We may use a portion of our net proceeds to acquire complementary businesses, technologies, products or services. We currently have no agreements or commitments to complete any such transactions, however, and are not in negotiations to do so.

We have not yet finalized the amount of proceeds that we will use specifically for each of these purposes, and we may ultimately decide to use these proceeds for purposes other than those contemplated as of the date of this prospectus. The timing and amount of our actual expenditures will be based on many factors, including the timing of regulatory approval for our product candidates. Until we use the net proceeds of the offering, we will invest the funds in short-term, investment grade, interest-bearing securities.

Dividend Policy

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

Capitalization

The following table shows:

- our capitalization on March 31, 2004; and
- our capitalization on March 31, 2004, assuming the completion of the offering at a public offering price of $8.50 per share and the use of the net proceeds as described under "Use of Proceeds."

	As of March 31, 2004	
	Actual	As Adjusted
	(unaudited)	(unaudited)
Cash and cash equivalents	$ 13,087,936	$ 68,467,936
Stockholders' equity:		
Preferred stock; $0.001 par value; 5,000,000 shares authorized; no shares issued and outstanding, actual and as adjusted	$	$
Common stock; $0.001 par value; 50,000,000 shares authorized; 26,769,718 shares issued and outstanding, actual; 33,769,718 shares issued and outstanding, as adjusted	26,770	33,770
Additional paid-in capital	52,375,378	107,748,378
Other comprehensive income (foreign currency translation)	415,863	415,863
Accumulated deficit during development stage	(38,866,329)	(38,866,329)
Total stockholders' equity	$ 13,951,682	$ 69,331,682

The foregoing table excludes as of March 31, 2004:

- 6,334,100 shares issuable upon exercise of outstanding options at a weighted average exercise price of $5.89 per share;
- 1,039,785 shares issuable upon exercise of outstanding warrants at a weighted average exercise price of $2.59 per share; and
- 461,900 shares issuable upon exercise of options available for future grant under our stock option plans.

Dilution

Our net tangible book value on March 31, 2004 was approximately $13.4 million, or $0.50 per share. "Net tangible book value" is total assets minus the sum of liabilities and intangible assets. "Net tangible book value per share" is net tangible book value divided by the total number of shares outstanding.

After giving effect to the adjustments relating to the offering, our pro forma net tangible book value on March 31, 2004 would have been $68.8 million, or $2.04 per share. The adjustments made to determine pro forma net tangible book value per share are the following:

- an increase in total assets to reflect the net proceeds of the offering as described under "Use of Proceeds;" and
- the addition of the number of shares offered by this prospectus to the number of shares outstanding.

The following table illustrates the pro forma increase in net tangible book value of $1.54 per share and the dilution (the difference between the offering price per share and net tangible book value per share) to new investors:

Public offering price per share		$ 8.50
Net tangible book value per share as of March 31, 2004	$ 0.50	
Increase in net tangible book value per share attributable to the offering	$ 1.54	
Pro forma net tangible book value per share as of March 31, 2004 after giving effect to the offering		$ 2.04
Dilution per share to new investors in the offering		$ 6.46

The foregoing table excludes as of March 31, 2004:

- 6,334,100 shares issuable upon exercise of outstanding options at a weighted average exercise price of $5.89 per share;
- 1,039,785 shares issuable upon exercise of outstanding warrants at a weighted average exercise price of $2.59 per share; and
- 461,900 shares issuable upon exercise of options available for future grant under our stock option plans.

Business

Overview

We specialize in the development and commercialization of autologous cellular therapies for soft and hard tissue regeneration. Our product candidates use our proprietary Isolagen Process. Based on our accumulated experience through our retrospective study, clinical trials and treatment of patients in the United Kingdom, we believe that our Isolagen Process utilizes the patient's own cells to create safe and effective therapies to treat the underlying cause of the patient's condition. Autologous cellular therapy is the process whereby a patient's own cells are extracted, allowed to multiply and then injected into the patient.

We are developing our lead product candidate for the correction and reduction of the normal effects of aging, such as wrinkles and nasolabial folds. In March 2004, we announced positive results of our first Phase III clinical trial for our lead product candidate. We are planning to initiate two additional pivotal Phase III clinical trials for this product candidate during the third quarter of 2004. We expect to file a Biologics License Application, or BLA, for this product candidate during the first quarter of 2005. We completed a Phase I clinical trial for our second product candidate for the treatment of periodontal disease in late 2003, and we are planning to initiate a Phase II clinical trial during the second quarter of 2004. In late 2003, we began limited commercialization for our dermal product in the United Kingdom and Australia.

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

The Structure of Skin and Conditions that Affect Appearance

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

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

Our Target Market Opportunity

Aesthetic Market Opportunity

Aesthetic procedures have traditionally been performed by dermatologists, plastic surgeons and other cosmetic surgeons, of which there are approximately 23,000 in the United States, according to the American Society for Aesthetic Plastic Surgery, or ASAPS. According to the ASAPS, the total market for non-surgical cosmetic procedures was approximately $2.9 billion in 2003. We believe growth in the aesthetic procedure market is driven by:

- aging of the "baby boomer" population, currently ages 40 to 58, representing over 27% of the U.S. population;
- increasing desire of many individuals to improve their appearance;
- impact of managed care and reimbursement policies on physician economics, which has motivated physicians to establish or expand the menu of elective, private-pay aesthetic procedures that they offer; and
- broadening base of the practitioners performing cosmetic procedures beyond dermatologists and plastic surgeons to non-traditional providers.

Our lead product candidate is directed primarily at the aesthetic market. According to the ASAPS, nearly 8.3 million surgical and non-surgical cosmetic procedures were performed in 2003, up 20% from nearly 6.9 million in 2002. According to the ASAPS, consumer demand increased 22% in 2003 for non-surgical cosmetic procedures, exceeding more than 6.4 million procedures. We believe that the concept of non-surgical cosmetic procedures involving injectable materials has become more mainstream and accepted. According to the ASAPS, the following table shows the top five non-surgical cosmetic procedures performed in 2003:

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

Procedures among the 35 to 50 year old age group made up 47% of all non-surgical cosmetic procedures in 2003. The 51 to 64 year old age group made up 24% of all non-surgical cosmetic procedures in 2003, while the 19 to 34 year old age group made up 22% of the non-surgical cosmetic procedures. Botox injection was the most popular treatment among the 35 to 50 and 51 to 64 year old age groups.

Dental Market Opportunity

In addition to the aesthetic market, we believe there is an extensive dental market opportunity for an effective therapy for regenerating tissue because a majority of the population will experience periodontal disease at some point in their lives. According to the ADA, there were over 149,000 active privately practicing dentists in 2001.

Gum and bone erosion in the mouth increase with age. The single greatest cause of bone and tooth loss in the mouth is periodontal disease. Although modern dentistry's ability to conserve teeth has improved, the ability to preserve bone and soft tissue, or gum, remains a challenge. As the periodontal pockets deepen due to the presence of bacteria at the attachment of the gum to the tooth and/or jaw bone, the amount of bacteria trapped in these pockets increases, leading to inflammation and gum and

bone loss around the tooth. Therapeutic options that decrease the depth of the pockets make the patient's daily home care more effective and reduce the chance of further gum and bone loss.

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

Limitations of Existing Therapies

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

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

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

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

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

Our Solution

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

Natural mechanism of action. Our Isolagen Process produces a living cell therapy that is designed to replace the fibroblasts that have deteriorated over time as the patient ages. We believe that the fibroblasts created by our Isolagen Process and injected into the patient's dermis continue to multiply and lead to the production of collagen and elastin. These fibroblast cells are subject to the

normal physiological controls of tissue and, therefore, can potentially return the tissue to a more youthful appearance without over-correction or deformity.

Longer duration of effect. Fibroblast cells remain viable for many years and, therefore, the effects are likely to last longer. Some patients treated with our Isolagen Process have exhibited positive results for longer than one year. We believe our Isolagen Process will produce longer-lasting effects, and a permanency claim based on 12-month efficacy data is the subject of the extended portion of our planned pivotal Phase III clinical trials.

Less pain associated with the injection. We believe that patients experience less pain with our Isolagen Process because the injected material is less viscous and causes less irritation. A thinner needle is used, and anesthesia is generally not required for the injection.

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

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

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

Our Isolagen Process

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

Historically, autologous cell companies have been hampered by manufacturing technologies that use traditional methodology for culturing cells through the utilization of plastic flasks. This methodology is labor intensive, slow, involves many sterile interventions and is costly.

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

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

We have been collaborating with Applikon Biotechnology to patent the manufacturing system improvements beyond Applikon Biotechnology's existing patents. Our ACE System has been successful in the research setting, and we are now undertaking the design fabrication and qualification of the massed-produced single-use, disposable component. Our ACE System will then undergo validation testing prior to incorporation into the manufacturing process. Additionally, it may be necessary to obtain FDA clearance prior to incorporating our ACE System into our manufacturing process in the United States, which could delay its implementation.

Clinical Trials

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

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

Our Dermal Product Candidate

Phase III Clinical Trial. In July 2003, we commenced a Phase III clinical trial of our dermal product candidate pursuant to the IND for the treatment of wrinkles and scars. The trial was conducted at ten sites and included 158 patients in the "Intent To Treat" group. It was a double-blind clinical trial with 75% of the patients receiving the therapeutic dosage and the remaining 25% receiving a placebo. On March 3, 2004, we announced positive results of our four-month clinical endpoint. Of the evaluable population, 77% of treatment group patients were responders, whereas 36% of the placebo group were responders ($p<0.0001$). In this statistically significant result, response was determined by a change of two or more points on a 7-point photoguide scale four months following the first injection. A p-value is a statistical measure of the probability of drawing an erroneous conclusion from an experimental result. A p-value of less than or equal to 0.05 is generally considered to signify a statistically significant result, which means a result is unlikely to occur by chance. There were no serious adverse events related to our dermal product candidate observed in our study. There was some mild edema and bruising observed at the injection site in both the placebo and treatment groups, which resolved spontaneously. The FDA has expressed issues concerning the design of this study and stated that additional studies would be necessary to support BLA approval.

Planned Pivotal Phase III Clinical Trials. In view of the FDA's concerns with the completed Phase III clinical trial, we are currently finalizing the design of two pivotal Phase III clinical trials that we plan to commence during the third quarter of 2004. We had numerous communications throughout 2003 with the FDA with regard to study design. These communications included numerous submissions of data

and protocols, meeting requests and annual reports. We had face-to-face meetings in March, September and December 2003 with FDA staff in the Center for Biologics Evaluation and Research.

Following the recommendations of the FDA, we have simplified the study design and added some additional reports or studies. We established a clinical meaningfulness standard through validation using an FDA-recommended 6-point photoguide scale. Furthermore, we established the purity of the fibroblasts produced. The FDA requested that we demonstrate that greater than 99% of the cells were fibroblasts as part of an ongoing discussion with regard to purity testing. The data we submitted to the FDA showed that 99.6% of all cells in the study were positive for fibroblast antibody. We believe that the remaining study design issues were resolved largely from analysis of the results from the current Phase III clinical trial.

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

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

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

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

The study design for our first Phase III clinical trial was altered to include a 7-point scale with a two point shift to indicate efficacy and a desire to only include patients with lesions that were ranked as three or more. The 7-point scale was subsequently validated by comparison to the FDA-recommended 6-point photoguide used in related studies by other companies.

During discussions with the FDA regarding our SPA, the FDA recommended the use of the published and validated 6-point photoguide scale that had been used in previous clinical trials for approved

products in this category. As a result, our SPA submission did not include acne or facial scar patients, as these patients may not be adequately assessed using a 6-point photoguide scale.

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

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

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

Our Dental Product Candidate

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

Further clinical trials are planned and protocols have been prepared to assess the efficacy and safety of treatment of our dental product candidate for the treatment of the papilla. We are also preparing protocols for a clinical trial to assess the efficacy and safety of our dental product candidate for the treatment of deep periodontal pockets. These clinical trials will be traditional double blind, internal and placebo controlled studies and are designed to assess the therapeutic efficacy and safety of our dental product candidate.

Other Clinical Trials

We currently have an active IND for vocal cord injury. We are currently in discussions with the FDA regarding our Phase I clinical trial protocol, and we currently plan to initiate this trial during the second quarter of 2004. We are also exploring other opportunities for additional product candidates, including for the treatment of acne scars.

Our Strategy

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

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

Optimizing our manufacturing processes to achieve cost reductions and scalability. Through our collaboration with Applikon Biotechnology, we are developing our ACE System that will permit an automated cell growth and harvesting process in a closed loop sterile system. We expect the ACE System to yield significant cost reductions and allow us to implement a platform that enables scalable mass production.

Building a direct sales force. There are approximately 23,000 dermatologists, plastic surgeons and cosmetic surgeons in the United States. We plan to build our own direct sales force focused on calling on these physicians. We believe that by building our own direct sales force we will be able to maximize the value of our product candidates and provide the required focus to launch our future products successfully.

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

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

Sales and Marketing

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

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

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

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

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

Intellectual Property

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

As of June 9, 2004, we had five issued U.S. patents, seven pending U.S. patent applications, 23 issued foreign patents and 19 pending foreign patent applications. Our issued patents and patent applications primarily cover the method of using autologous cell fibroblasts for the repair-of-skin and soft tissue defects and the use of autologous fibroblast cells for tissue regeneration. We are in the process of pursuing several other patent applications.

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

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

patent claim may expire or remain in force for only a short period following commercialization, thereby reducing the advantage of the patent.

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

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

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

Competition

We compete with a variety of companies in the dermatology and plastic surgery markets, many of which offer substantially different treatments for similar problems. These include silicone injections, laser procedures, facial surgical procedures, such as facelifts and eyelid surgeries, fat injections, dermabrasion, collagen injections and Botulinum toxin injections. Indirect competition comes from facial care treatment products. Items catering to the growing demand for therapeutic skin care products include facial scrubs, anti-aging treatments, tonics, astringents and skin-restoration formulas.

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

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

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

Government Regulation

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

Domestic Regulation

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

FDA Approval Process

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

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

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

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

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

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

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

Phase II: The product is introduced into a limited patient population to:

- assess its efficacy in specific, targeted indications;
- assess dosage tolerance and optimal dosage; and
- identify possible adverse effects and safety risks.

Phase III: These are commonly referred to as pivotal studies. If a product is found to have an acceptable safety profile and to be potentially effective in Phase II clinical trials, new clinical trials will be initiated to further demonstrate clinical efficacy, optimal dosage and safety within an expanded and diverse patient population at geographically-dispersed clinical study sites.

If the FDA does ultimately approve the product, it may require post-marketing testing, including potentially expensive Phase IV studies, to monitor its safety and effectiveness.

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

The sponsor must submit to the FDA the results of the pre-clinical and clinical trials, together with, among other things, detailed information on the manufacturing and composition of the product, in the form of an NDA, or, in the case of a biologic, a BLA. The FDA has advised us it is regulating our Isolagen Process as a biologic. Therefore, we will be submitting BLAs to obtain approval of our product candidates. Once the submission has been accepted for filing, the FDA has 180 days to review the application and respond to the applicant. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved, but the FDA is not bound by the recommendation of an advisory committee.

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

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

Ongoing FDA Requirements

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

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

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

HIPAA Requirements

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

information collected in the course of conducting the research. As a result, unless they meet these HIPAA requirements, covered entities conducting clinical trials for us may not be able to share with us any results from clinical trials that include such health information.

International Regulation

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

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

Manufacturing

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

Our manufacturing process consists of a traditional cell culture process using sterile plastic flasks processed inside a sterile "biosafety cabinet." All manufacturing practices are strictly controlled under cGMP guidelines, all vendors are audited and all supplies are subject to quality control release criteria. We have a system in place for timely and effective corrective and preventive action to manage non-conformities reported by our customers or detected within our operations.

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

Through our collaboration with Applikon Biotechnology, we are developing our ACE System that permits an automated harvesting process in a closed loop sterile environment. Our ACE System will eliminate several of the steps and materials involved in our current system, will lead to significant cost reductions in both skilled labor and materials and will enable scalable mass production. We currently expect to introduce our ACE System for new patients in our United Kingdom facility in the fourth quarter of 2004.

Research and Development

In addition to our clinical development activities, our research and development activities include improving our manufacturing processes and reducing costs. Fibroblasts are a general support cell for the tissue and, in addition to their direct production of collagen and elastin, produce endocrine factors, which we believe may assist in the growth or repair of surrounding tissues, such as the epidermis. We believe this effect is responsible for some of the positive results that physicians have observed when treating patients with severe scarring. We continue to explore additional opportunities for our Isolagen Process for other applications, such as vocal cord injury, acne scarring, gastrointestinal and urological disorders and bone growth. We expense research and development costs as they are incurred. For the three months ended March 31, 2004 and for fiscal years 2003, 2002 and 2001, we incurred research and development expenses of $1.2 million, $3.3 million, $1.7 million and $0.9 million, respectively.

Employees

As of June 9, 2004, we employed 66 people on a full-time basis, including 38 in Houston, Texas, 20 in London, England, and eight in Sydney, Australia. We anticipate hiring additional employees in the areas of executive management, sales and marketing, quality assurance, manufacturing and research and development as the need arises. None of our employees are covered by a collective bargaining agreement, and we consider our relationship with our employees to be good. We may also employ consultants on an as needed basis to supplement existing staff.

Properties

Our principal executive offices are located in Houston, Texas. This facility occupies a total of approximately 11,200 square feet, including 7,300 square feet under a month-to-month lease that we may terminate at our option and 3,900 square feet under a lease that expires March 31, 2005. We are currently evaluating options to secure a larger facility for our manufacturing and research and development operations, and our principal executive offices.

We also maintain cellular laboratories in London, England and Sydney, Australia. Our London, England facility consists of approximately 9,400 square feet under a lease that expires in March 2010, but for which we have an option to cancel after March 24, 2005. Our Sydney, Australia facility consists of approximately 7,100 square feet under a lease that expires in November 2004, which we have an option to renew for an additional year. We are currently conducting feasibility studies for a new location for our European manufacturing operations.

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.

Management

The following table sets forth the names and ages of all of our directors and executive officers as of June 9, 2004. Our officers are appointed by, and serve at the pleasure of, the Board of Directors.

Name	Age	Title
Frank DeLape	50	Chairman of the Board of Directors
Michael Macaluso	52	Chief Executive Officer, President and Director
Jeffrey W. Tomz	32	Chief Financial Officer and Secretary
Olga Marko	61	Senior Vice President and Director of Research
Vaughan L. Clift, M.D.	43	Vice President of Operations
Nelson Haight	39	Controller
Steven Morrell	48	Director(1)
Henry Y.L. Toh	46	Director(1)
Ralph V. De Martino	49	Director(1)
Marshall G. Webb	61	Director

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

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

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

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

Jeffrey W. Tomz. Mr. Tomz was appointed Secretary and Treasurer in June 2001. In August 2001, Mr. Tomz resigned as Treasurer and was appointed Chief Financial Officer. Mr. Tomz is a Principal at Benchmark Equity Group, Inc. Mr. Tomz has served or is currently serving on the board of directors of three investee companies, as well as Trident III, L.L.C. and Trident II, L.L.C., which are private investment funds. Mr. Tomz was a Director of InfoHighway Communication Corp., a private communication company from September 1998 to September 2000. Prior to joining Benchmark in the fall of 1997, Mr. Tomz began his career as a certified public accountant with Arthur Andersen Worldwide.

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

Vaughan L. Clift, M.D. Dr. Clift was appointed Vice President of Operations in May 2002. He is in charge of the science aspects, regulatory affairs and manufacturing for all of our product candidates.

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

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

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

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

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

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

Principal and Selling Stockholders

As of June 9, 2004, 26,818,233 shares of our common stock were outstanding. The following table sets forth information known to us with respect to the beneficial ownership of our common stock as of that date and as adjusted to reflect the sale of common stock offered pursuant to this prospectus by:

- each stockholder known by us to own beneficially more than 5% of our common stock;
- each of our executive officers;
- each of our directors;
- all of our directors and executive officers as a group; and
- each selling stockholder.

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

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

	Shares beneficially owned prior to the offering		Shares to be sold in the offering(1)	Shares beneficially owned after the offering(2)	
Name and address of beneficial owner	**Number**	**Percent**		**Number**	**Percent**
Directors & Executive Officers					
Michael Macaluso(3)	2,875,734	10.3%		2,875,734	8.2%
Frank DeLape(4)	2,205,000	8.0	293,270	1,911,730	5.3
Olga Marko	1,050,000	3.9	227,258	822,742	2.3
Jeffrey W. Tomz(5)	323,600	1.2	24,587	299,013	*
Steven Morrell(6)	86,667	*		86,667	*
Ralph V. De Martino(7)	76,667	*		76,667	*
Vaughan L. Clift, M.D.(8)	70,000	*		70,000	*
Henry Y.L. Toh(9)	16,667	*		16,667	*

	Shares beneficially owned prior to the offering			Shares beneficially owned after the offering(2)	
Nelson Haight(10)	*			*	
Marshall G. Webb	15,000			15,000	
All current directors and executive officers as a group (10 persons)(11)	6,719,335	23.0	545,115	6,174,220	16.9

5% Stockholders					
Michael Avignon(12) #7 West River Crest Houston, Texas 77042	2,875,734	10.3		2,875,734	8.2
Buechel Family Ltd. Partnership(13) 76 Crest Drive So. Orange, New Jersey 07079	2,485,800	9.3		2,485,800	7.4
William K. Boss, Jr.	1,614,055	6.0	304,885	1,309,170	3.8

* Indicates ownership of less than 1%.

(1) The selling stockholders will only sell shares in the event the over-allotment option granted to the underwriters is exercised.

(2) The percentage of shares beneficially owned after the offering for the selling stockholders assumes the exercise in full of the over-allotment option granted to the underwriters.

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

(4) Includes 1,355,000 shares of common stock beneficially owned by Benchmark Equity Group, Inc., which is solely owned by Mr. DeLape, and includes options to purchase 850,000 shares of common stock held by Mr. DeLape. Benchmark Equity Group, Inc. is the selling stockholder in this offering. Does not include 736,666 shares of common stock beneficially held by Lighthouse Capital Insurance Company, a Cayman Islands unlimited licensed insurance company, which has issued a variable universal life insurance contract of which Mr. DeLape and his children are remote contingent beneficiaries. Mr. DeLape disclaims beneficial ownership of such shares held by Lighthouse and does not have voting or dispositive power with respect to such shares.

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

(6) Consists of options to purchase 86,667 shares of common stock.

(7) Consists of options to purchase 76,667 shares of common stock.

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

(9) Consists of options to purchase 16,667 shares of common stock.

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

(11) Includes options to purchase an aggregate of 2,425,001 shares of common stock.

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

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

Description of Capital Stock

The following description of our capital stock and provisions of our Certificate of Incorporation, as amended, and Bylaws is a summary. This description may not contain all of the information that is important to you. The following description is qualified in its entirety by reference to the provisions of our Certificate of Incorporation and Bylaws, copies of which are filed with the SEC.

Our authorized capital stock consists of 50,000,000 shares of common stock and 5,000,000 shares of preferred stock. As of June 9, 2004, there were outstanding:

26,818,233 shares of common stock;

6,289,100 shares issuable upon the exercise of options issued pursuant to our current stock option plans;

975,389 shares issuable upon the exercise of outstanding warrants; and

506,900 shares issuable upon the exercise of options available for future grant under our stock option plans.

Common Stock

Subject to preferences that may be applicable to any preferred stock outstanding at the time, the holders of our common stock are entitled to receive dividends out of legally available assets at such times and in such amounts as our Board of Directors may from time to time determine. Each stockholder is entitled to one vote for each share of common stock held on all matters submitted to a vote of stockholders. Cumulative voting for the election of directors is not authorized.

Our common stock is not subject to conversion or redemption and holders of our common stock are not entitled to preemptive rights. Upon the liquidation, dissolution or winding up of our company, the remaining assets legally available for distribution to stockholders, after payment of claims or creditors and payment of liquidation preferences, if any, on outstanding preferred stock, are distributable ratably among the holders of our common stock and any participating preferred stock outstanding at that time. Each outstanding share of common stock is fully paid and nonassessable.

Preferred Stock

Our Board of Directors has the authority, without action by our stockholders, to designate and issue preferred stock in one or more series. Our Board of Directors may also designate the rights, preferences and privileges of each series of preferred stock, any or all of which may be greater than the rights of the common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock on the rights of holders of the common stock until our Board of Directors determines the specific rights of the holders of the preferred stock. However, these effects might include: (a) restricting dividends on the common stock; (b) diluting the voting power of the common stock; (c) impairing the liquidation rights of the common stock; and (d) delaying or preventing a change in control of our company without further action by our stockholders.

As of the date of this prospectus, we have authorized two classes of preferred stock, Series A Convertible Preferred Stock and Series B Convertible Preferred Stock. These preferred shares were issued in 2003, but all outstanding shares have been converted into shares of common stock. No shares of Series A or Series B preferred stock are outstanding, and we do not intend to issue any shares of these series of preferred stock in the future.

Anti-Takeover Effects of Provisions of Delaware Law

Provisions of Delaware law and our Certificate of Incorporation, as amended, and Bylaws could make the acquisition of our company through a tender offer, a proxy contest or other means more difficult and could make the removal of incumbent officers and directors more difficult. We expect these provisions to discourage coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of our company to first negotiate with our Board of Directors. We believe that the benefits provided by our ability to negotiate with the proponent of an unfriendly or unsolicited proposal outweigh the disadvantages of discouraging these proposals. We believe the negotiation of an unfriendly or unsolicited proposal could result in an improvement of its terms.

Anti-Takeover Effects of Provisions of Our Charter Documents

Our Certificate of Incorporation, as amended, provides for our Board of Directors to be divided into three classes serving staggered terms. Approximately one-third of the Board of Directors will be elected each year. The provision for a classified board could prevent a party who acquires control of a majority of the outstanding voting stock from obtaining control of the Board of Directors until the second annual stockholders' meeting following the date the acquirer obtains the controlling stock interest. The classified board provision could discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company and could increase the likelihood that incumbent directors will retain their positions.

Our Bylaws do not permit stockholders to call a special meeting of stockholders. Our Bylaws provide that special meetings of the stockholders may be called only by a majority of the members of our Board of Directors, our Chairman of the Board of Directors, our Chief Executive Officer or our President. Our Bylaws require that all stockholder actions be taken by a vote of the stockholders at an annual or special meeting, and do not permit our stockholders to act by written consent without a meeting. Our Bylaws provide for an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to the Board of Directors. At an annual meeting, stockholders may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the Board of Directors. Stockholders may also consider a proposal or nomination by a person who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given to our Secretary timely written notice, in proper form, of his, her or its intention to bring that business before the meeting. The Bylaws do not give our Board of Directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting of the stockholders. However, our Bylaws may have the effect of precluding the conduct of business at a meeting if the proper procedures are not followed. These provisions may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.

Transfer Agent

The transfer agent for our common stock is American Stock Transfer & Trust Company located at 59 Maiden Lane, New York, New York 11038.

Underwriting

We and the selling stockholders have entered into an underwriting agreement with the underwriters named below. CIBC World Markets Corp., Legg Mason Wood Walker, Incorporated and Adams, Harkness & Hill, Inc. are acting as representatives of the underwriters.

The underwriting agreement provides for the purchase of a specific number of shares of common stock by each of the underwriters. The underwriters' obligations are several, which means that each underwriter is required to purchase a specified number of shares, but is not responsible for the commitment of any other underwriter to purchase shares. Subject to the terms and conditions of the underwriting agreement, each underwriter has severally agreed to purchase the number of shares set forth opposite its name below:

Underwriter	Number of Shares
CIBC World Markets Corp.	3,500,000
Legg Mason Wood Walker, Incorporated	2,450,000
Adams, Harkness & Hill, Inc.	1,050,000
Total	7,000,000

The underwriters have agreed to purchase all of the shares offered by this prospectus (other than those covered by the over-allotment option described below) if any are purchased. Under the underwriting agreement, if an underwriter defaults in its commitment to purchase shares, the commitments of non-defaulting underwriters may be increased or the underwriting agreement may be terminated, depending on the circumstances.

The shares should be ready for delivery on or about June 15, 2004 against payment in immediately available funds. The underwriters are offering the shares subject to various conditions and may reject all or part of any order. The representatives have advised us and the selling stockholders that the underwriters propose to offer the shares directly to the public at the public offering price that appears on the cover page of this prospectus. In addition, the representatives may offer some of the shares to other securities dealers at such price less a concession of $0.306 per share. The underwriters may also allow, and such dealers may reallow, a concession not in excess of $0.10 per share to other dealers. After the shares are released for sale to the public, the representatives may change the offering price and other selling terms at various times.

We and the selling stockholders have granted the underwriters an over-allotment option. This option, which is exercisable for up to 30 days after the date of this prospectus, permits the underwriters to purchase a maximum of 1,050,000 additional shares (200,000 from us and 850,000 from the selling stockholders) to cover over-allotments. If the underwriters exercise all or part of this option, they will purchase shares covered by the option at the public offering price that appears on the cover page of this prospectus, less the underwriting discount. If this option is exercised in full, the total price to the public will be $68.4 million, the total proceeds to us will be $57.5 million and the total proceeds to the selling stockholders will be $6.8 million. The underwriters have severally agreed that, to the extent the over-allotment option is exercised, they will each purchase a number of additional shares proportionate to the underwriter's initial amount reflected in the foregoing table.

The following table provides information regarding the amount of the discount to be paid to the underwriters by us and the selling stockholders:

	Per Share	Total Without Exercise of Over-Allotment Option	Total With Full Exercise of Over-Allotment Option
Isolagen	$ 0.51	$ 3,570,000	$ 3,672,000
Selling stockholders	0.51		433,500
Total		$ 3,570,000	$ 4,105,500

We estimate that our total expenses of the offering, excluding the underwriting discount, will be approximately $550,000.

We and the selling stockholders have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

All of our officers and directors have agreed to a 120-day "lock-up" with respect to all of their shares of common stock that they beneficially own, including securities that are convertible into or exchangeable or exercisable for shares. In addition, some of our stockholders have agreed to a 90-day lock-up with respect to 4,748,600 shares of common stock that they beneficially own. This means that, subject to certain exceptions, during the respective lock-up periods, we and such persons may not offer, sell, pledge or otherwise dispose of these shares without the prior written consent of CIBC World Markets Corp.

Rules of the SEC may limit the ability of the underwriters to bid for or purchase shares before the distribution of the shares is completed. However, the underwriters may engage in the following activities in accordance with the rules:

Stabilizing transactions. The representatives may make bids or purchases for the purpose of pegging, fixing or maintaining the price of the shares, so long as stabilizing bids do not exceed a specified maximum.

Over-allotments and syndicate covering transactions. The underwriters may sell more of our shares in connection with this offering than the number of shares they have committed to purchase. This over-allotment creates a short position for the underwriters. This short sales position may involve either "covered" short sales or "naked" short sales. Covered short sales are short sales made in an amount not greater than the underwriters' over-allotment option to purchase additional shares in this offering described above. The underwriters may close out any covered short position either by exercising their over-allotment option or by purchasing shares in the open market. To determine how they will close the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market, as compared to the price at which they may purchase shares through the over-allotment option. Naked short sales are short sales in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that, in the open market after pricing, there may be downward pressure on the price of the shares that could adversely affect investors who purchase shares in this offering.

Penalty bids. If the representatives purchase shares in the open market in a stabilizing transaction or syndicate covering transaction, they may reclaim a selling concession from the underwriters and selling group members who sold those shares as part of this offering.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales or to stabilize the market price of our common stock may have the effect of raising or maintaining the market price of our common stock or preventing or mitigating a decline in the market price of our common stock. As a result, the price of shares of our common stock may be higher than the price that might otherwise exist in the open market. The imposition of a penalty bid might also have an effect on the price of the shares if it discourages resales of shares.

Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of the shares. These transactions may occur on the American Stock Exchange or otherwise. If such transactions are commenced, they may be discontinued without notice at any time.

Foreign Securities Laws Restrictions

The United Kingdom

In the United Kingdom, the shares offered by this prospectus will only be available for purchase to a person who represents and agrees that:

- it has not offered or sold, and for up to six months following the consummation of this offering, will not offer or sell, any shares offered by this prospectus to persons in the United Kingdom except to persons whose ordinary activities involve them acquiring, holding, managing or disposing of investments (as principal or agent) for the purposes of their businesses or otherwise in circumstances which do not constitute an offer to the public in the United Kingdom for the purposes of the Public Offers of Securities Regulations 1995;

- it has complied and will comply with all applicable provisions of the Financial Services and Markets Act 2000, or the FSMA, in respect of anything done by it in relation to the shares offered by this prospectus in, from or otherwise involving the United Kingdom; and

- it has only communicated or caused to be communicated, and will only communicate or cause to be communicated, any invitation or inducement to engage in investment activity, within the meaning of Section 21 of the FSMA, received by it in connection with the shares offered by this prospectus in circumstances where Section 21(1) of the FSMA does not apply to our company or the selling stockholders, to persons who fall within the exemption to Section 21 of the FSMA set out in The Financial Services and Markets Act 2000 (Financial Promotion) Order 2001, or the Order, including to persons exempted under Article 19 (Investment Professionals) or Article 49(2)(a) to (d) (high net worth companies, unincorporated associations etc.) of the Order, or to persons to whom the invitation or inducement may otherwise lawfully be communicated or cause to be communicated.

The Netherlands

The shares offered by this prospectus may not be offered, sold, transferred or delivered in or from the Netherlands, directly or indirectly, as part of their initial distribution or at any time thereafter, and this prospectus may not be distributed or circulated, directly or indirectly, in or from the Netherlands, other than to individuals or legal entities which include, but are not limited to, banks, brokers, dealers, institutional investors and undertakings with a treasury department, who or which trade or invest in securities in the conduct of a business or profession.

Germany

The shares offered by this prospectus may be offered and sold in the Federal Republic of Germany only in accordance with the provisions of the Securities Sales Prospectus Act of the Federal Republic of Germany (*Wertpapier Verkaufsprospektgesetz*) and any other applicable German law. Consequently, in Germany, the shares offered by this prospectus will only be available to persons who by profession or trade or business buy or sell the shares offered by this prospectus for their own or a third party's account.

France

The shares offered by this prospectus may not be offered or sold, directly or indirectly, to the public in France. This prospectus has not been or will not be submitted to the clearance procedure of the *Autorité des Marchés Financiers*, or the AMF, and may not be released or distributed to the public in France. Investors in France may only purchase the shares offered by this prospectus for their own

account and in accordance with articles L. 411-1, L. 441-2 and L. 412-1 of the *Code Monétaire et Financier* and decree no. 98-880 dated October 1, 1998, provided they are "qualified investors" within the meaning of said decree. Each French investor must represent in writing that it is a qualified investor within the meaning of the aforesaid decree. Any resale, directly or indirectly, to the public of the shares offered by this prospectus may be effected only in compliance with the above mentioned regulations.

"Les actions offertes par ce document d'information ne peuvent pas être, directement ou indirectement, offertes ou vendues au public en France. Ce document d'information n'a pas été ou ne sera pas soumis au visa de l'Autorité des Marchés Financiers et ne peut être diffusé ou distribué au public en France. Les investisseurs en France ne peuvent acheter les actions offertes par ce document d'information que pour leur compte propre et conformément aux articles L. 411-1, L. 441-2 et L. 412-1 du Code Monétaire et Financier et du décret no 98-880 du 1er octobre 1998, sous réserve qu'ils soient des investisseurs qualifiés au sens du décret susvisé. Chaque investisseur doit déclarer par écrit qu'il est un investisseur qualifié au sens du décret susvisé. Toute revente, directe ou indirecte, des actions offertes par ce document d'information au public ne peut être effectuée que conformément à la réglementation susmentionnée."

Switzerland

The shares offered by this prospectus may be offered in Switzerland on the basis of a private placement, not as a public offering. The shares offered by this prospectus will neither be listed on the SWX Swiss Exchange nor are they subject to Swiss law. This prospectus therefore does not constitute a prospectus within the meaning of Art. 1156 of the Swiss Federal Code of Obligations or Arts. 32 et seq. of the Listing Rules of the SWX Swiss Exchange.

Legal Matters

The validity of the common stock offered will be passed upon for us by Dilworth Paxson LLP, Philadelphia, Pennsylvania. Ralph V. De Martino, one of our directors, is a partner in the firm of Dilworth Paxson LLP. Latham & Watkins LLP, Menlo Park, California, is counsel for the underwriters in connection with this offering.

Experts

Pannell Kerr Forster of Texas, P.C., independent auditors, have audited our financial statements included in our Annual Report on Form 10-K/A for the year ended December 31, 2003, as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements are incorporated by reference in reliance on Pannell Kerr Forster of Texas, P.C.'s report, given on their authority as experts in accounting and auditing.

Where You Can Find More Information

We have filed a registration statement on Form S-3 with the SEC in connection with this offering. We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy the registration statement and any other documents we have filed at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the Public Reference Room. Our SEC filings are also available to the public at the SEC's Internet site at *www.sec.gov*.

This prospectus is part of the registration statement and does not contain all of the information included in the registration statement. Whenever reference is made in this prospectus to any of our contracts or other documents, the reference may not be complete and, for a copy of the contract or document, you should refer to the exhibits that are a part of the registration statement.

The SEC allows us to "incorporate by reference" into this prospectus the information we file with it, which means that we can disclose important information to you by referring you to those documents. Information incorporated by reference is part of this prospectus. Later information filed with the SEC will update and supersede this information.

We incorporate by reference the documents listed below and any future filings made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, until this offering is completed:

- Annual Report on Form 10-K/A for the year ended December 31, 2003;
- Quarterly Report on Form 10-Q for the quarter ended March 31, 2004;
- Current Reports on Form 8-K dated February 3, 2004, February 24, 2004, March 3, 2004, April 23, 2004, April 28, 2004, May 12, 2004, May 24, 2004, and June 7, 2004;
- Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on April 28, 2004; and
- The description of our common stock contained in our registration statement on Form 8-A filed on December 10, 2002, and any amendment or report filed for the purpose of updating that description.

An updated description of our capital stock is included in this prospectus under "Description of Capital Stock."

You may request a copy of these filings, at no cost, by contacting us at:

Isolagen, Inc.
Attn: Corporate Secretary
2500 Wilcrest, 5th Floor
Houston, Texas 77042

Phone: (713) 780-4754

7,000,000 Shares

Common Stock

PROSPECTUS

June 9, 2004

CIBC World Markets

Legg Mason Wood Walker
Incorporated

Adams, Harkness & Hill, Inc.

You should rely only on the information contained in this prospectus. No dealer, salesperson or other person is authorized to give information that is not contained in this prospectus. This prospectus is not an offer to sell nor is it seeking an offer to buy these securities in any jurisdiction where the offer or sale is not permitted. The information contained in this prospectus is correct only as of the date of this prospectus, regardless of the time of the delivery of this prospectus or any sale of these securities.