INTERLEUKIN GENETICS INC
Form 10-K
April 26, 2005

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES AND EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2004

Commission File Number: 0-23413

INTERLEUKIN GENETICS, INC.

(Name of Registrant in its Charter)

Delaware	**94-3123681**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
135 Beaver Street, Waltham, MA	**02452**
(Address of principal executive offices)	(Zip Code)

Registrant s Telephone Number: **(781) 398-0700**

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

Common Stock, $0.001 par value per share	**Boston Stock Exchange**

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

Common Stock, $0.001 par value per share

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES x NO o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained in this form and will not be contained, to the best of the Registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K x.

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

The aggregate market value of the registrant s voting and non-voting common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common stock

was last sold as of the last business day of the registrant s most recently completed second fiscal quarter was $101,873,276.

As of April 19, 2005, there were 23,636,527 shares of the Registrant s Common Stock and 5,000,000 shares of the Registrant s Series A Preferred Stock, issued and outstanding.

Documents Incorporated By Reference

Portions of the Registrant s Definitive Proxy Statement for the 2005 Annual Meeting of Shareholders to be held on or about June 21, 2005, are incorporated by reference in Part III hereof.

Forward Looking Statements

This report on Form 10-K and the documents incorporated by reference within this document contain certain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act. Statements contained in this report that are not statements of historical fact may be deemed to be forward-looking statements. Words or phrases such as will likely result , expect , will continue , anticipate , estimate , intend , plan , project , outlook , or similar expressions a identify forward-looking statements. Forward-looking statements address or may address the following subjects:

- **The sufficiency of our current cash resources, together with additional research agreements, anticipated revenue from product launches and other arrangements to fund operations through mid-2006;**

- **Our expectation that we will receive at least $5.0 million in funding over the twenty-four month period ending March 2007 from an affiliate of Alticor under the terms of various research agreements with this affiliate;**

- **Our expectation that we will receive royalty payments and/or genetic risk assessment test processing revenue under the terms of a License Agreement and a Distribution Agreement with affiliates of Alticor;**

- **Our expectation that we may sign additional research agreements with affiliates of Alticor, or other third parties;**

- **Our expectation of the benefits that will result from the ongoing research programs that outside parties are conducting on our behalf;**

- **Any expectation we may have regarding the success of developing products, the timing of releasing products for sale or the success of these products when they are released;**

- **Any expectation we may have of attracting business partners to assist in developing, marketing or distribution of our products;**

- **Any expectation that certain healthcare related trends will emerge or continue that will support our business model;**

- **Our expectation that our total research and development costs will be between $4.0 million and $5.0 million for the year ended December 31, 2005;**

- **Our expectation that we might derive benefit from our patented intellectual property; and**

- **Our expectation that we will continue to experience losses until our genetic risk assessment testing revenue grows substantially from current levels.**

Actual results may vary materially from those expressed in forward-looking statements. Factors that could cause actual results to differ from expectations include but are not limited to; risks related to market acceptance of genetic risk assessment tests in general and our products in particular, risks related to technology and product obsolescence, delays in development of products, dependence on third parties, our ability to fund operations through mid-2006, competitive risks and those risks set forth within the section titled Certain Factors That May Affect Future Results of Operations or the Market for Our Common Stock beginning on page 19 within this report. We cannot be certain that our results will not be adversely affected by one or more of these factors or by other factors not currently anticipated. All information set forth in this Form 10-K is as of the date of this Form 10-K. Unless required by law we accept no responsibility to update this information.

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PART I

Item 1. *Business*

Overview

Interleukin Genetics, Inc. is a Delaware corporation. We are a personalized healthcare company focused on the role that genetically determined variation in the inflammatory response has on health and disease. Our mission is to develop tests and products that can help individuals improve and maintain their health through preventive measures. We hope to achieve our objective by developing:

- genetic tests;
- preventive products for those individuals at risk; and
- therapeutic products that are personalized based upon an individual s genetic makeup.

We hope to establish a leadership position in the personalized healthcare sector. We believe that by identifying individuals at risk for certain diseases and combining this knowledge with personalized interventions, we can help individuals improve their health outcomes. We have a growing portfolio of patents covering the influence of certain gene variations on risk for a number of common chronic diseases and conditions.

We believe that one of the great challenges confronting medicine today is to find the key to understanding why some people are more prone than others to developing serious chronic diseases and why some people respond to treatments for those diseases differently than others. Until doctors are able to understand the underlying causes for such variability, the practice of medicine will remain largely constrained to the current approach of prescribing therapies based on broad, sweeping recommendations in which very different individuals receive the same treatment. This approach to medicine is quite impersonal and often ineffective.

Until now, scientific study of chronic diseases has largely focused on identifying factors that cause a disease. Common examples of such factors include cholesterol in the case of heart disease, bacteria of the mouth in the case of periodontal disease and reduced estrogen levels in the case of osteoporosis. However, the mere presence of these initiating factors does not necessarily mean a person will develop a disease. For example, everyone with a cholesterol level considered high does not develop heart disease, nor does everyone with a normal cholesterol level avoid heart disease. Rather, the common diseases as we know them only develop when our bodies respond to the initiating factors in a certain way. We believe that personalized health profiles should replace the impersonal reliance on generalized markers of health status.

In March 2003, we entered into a broad strategic alliance with several affiliates of the Alticor Inc. family of companies to develop and market personalized nutritional and skin care products. For the purpose of clarity, in this document we will refer to Alticor and all of its wholly-owned subsidiaries, including Access Business Group, Pyxis Innovations and Quixtar as Alticor . The alliance utilizes our intellectual property and expertise in genomics to develop personalized consumer products. Alticor has a long history of manufacturing and distributing high quality nutritional supplements and skin care products to a worldwide market.

We are devoting most of our resources to the support of the strategic collaboration with Alticor which includes the development of our genetic risk assessment tests to be sold in combination with Alticor s products. A portion of our resources is also devoted to the development of a new product for the periodontal market. Thus far, our revenue has consisted primarily of research payments from Alticor and minimal royalties from our periodontitis genetic risk assessment test known as PST®. We expect to continue incurring losses as we continue to develop our new tests and products.

The tremendous expansion of our understanding of the human genome will change the face of healthcare, including approaches to prevention and treatment of diseases. The ability to obtain detailed knowledge of an individual s genetic information, the recent developments in the understanding of inflammation, and an aging baby boomer generation have converged to create an opportunity for us to leverage our core technology into a new approach in healthcare called personalized wellness .

Inflammation

One of the many benefits of the Human Genome Project is our new understanding of the role of single nucleotide polymorphisms (SNPs). Once used as a tool to help scientists decipher the human genome, SNP analysis now is the principal instrument used to dig much more deeply into the relevance of genetic variations for the benefit of human health. SNPs have been used to establish correlation between the presence or absence and risk or susceptibility to certain disease conditions. A variation in a common SNP may cause a gene to make a variant protein leading to a discernible physiological impact. We have focused on the SNP variations associated with inflammation and have conducted clinical studies involving over 20,000 individuals. Working with the University of Sheffield (Sheffield) in the United Kingdom, we have identified the function of several SNP variations that exert important influences on the body s inflammatory response.

Inflammation is the overt expression of the body s protective mechanism in response to a challenge. Over the last dozen years, understanding of the role of inflammation in several diseases has increased. It is now accepted that many chronic inflammatory diseases begin with a challenge to the tissues of the body and that the inflammatory response system of an individual mediates the clinical manifestation of the disease. The diagram below reflects some of the diseases that are thought to be significantly influenced by inflammation. It is now known that SNP variations in the genes that influence the inflammatory process can, in fact, predict a person s risk/trajectory of a disease or a person s response to certain medications.

Inflammation is the first organized response to any injurious challenge to the body, such as a bacterial infection. It is a well-defined process that involves the migration and activation of leukocytes from the

blood to the site of challenge. The objective of inflammation is to localize and destroy the deleterious agent. If the deleterious agent cannot be cleared, the inflammation becomes chronic.

There are classic inflammatory diseases, such as rheumatoid arthritis, but in recent years inflammation has been found to underlie several major diseases. For example, it is now known that inflammation is a major component of the process that leads to acute heart attacks.

If an individual has a strong inflammatory response, he may be more successful in clearing a bacterial infection than an individual with a less robust response. However, an individual with a strong response may be at increased risk for a more severe course in one or more of the chronic diseases of mid to later life, such as cardiovascular disease, osteoporosis, and Alzheimer s disease.

Core Technology

Our intellectual property is highly focused on the discoveries that link genetic variation in key inflammation genes to risk for disease. Since the IL-1 and TNFα genes appear to be two of the strongest control points for the development and severity of inflammation, we have focused our efforts on them.

We have patents issued on single SNPs and SNP patterns in the IL-1 gene cluster as they relate to use for identifying individuals on the rapid path to chronic disease complications. We believe these patents are controlling relative to IL-1 SNP patterns that would be used for genetic risk assessment tests. We also have issued claims and filed applications that focus on the use of IL-1 and TNFα SNPs to screen for nutritional compounds that block inflammatory mechanisms in individuals with certain genetic patterns.

Although the biology of inflammation is complex, among the first genes activated with any injurious challenge are the genes for IL-1 and TNFα. These chemicals then activate multiple biochemical cascades that lead to the cellular and molecular mechanisms that constitute inflammation. In the early 1990 s we developed innovative computer modeling approaches to explore how complex biological systems were regulated. This led to the issuance of several patents. Using computer models, and clinical and laboratory data, we determined that IL-1 and TNFα were at critical biological leverage points, and we initiated research programs to determine if variations in expression of IL-1 and TNFα were clinically important. Our work in this area was sufficiently early to allow us to acquire a patent portfolio with broad coverage for the use of variations in IL-1 genes for predictive medicine, selection of appropriate therapeutics, and development of preventive and therapeutic agents.

In the early 1990 s, at the same time that we were beginning to focus on the importance of IL-1, Dr. Gordon Duff in the United Kingdom identified the first SNPs in the IL-1 genes, and he and other investigators demonstrated that individuals with some of those variations produced higher levels of IL-1.

In 1993, we initiated research collaborations with Dr. Duff, and in 1994, we initiated a joint venture agreement with him and Sheffield to investigate and patent the clinical use of variations in the genes that control inflammation.

Groups of IL-1 SNPs are often inherited together as patterns called haplotypes. We have a patent issued on haplotypes in the IL-1 gene cluster and their biological and clinical significance.

Studies by us and others have now shown that individuals who have certain IL-1 gene variations or patterns of variations:

- tend to have increased levels of IL-1; and
- tend to have increased levels of other inflammatory mediators that are downstream of IL-1.

Individuals with a particular IL-1 genotype have significantly higher levels of IL-1 and other inflammatory mediators. Individuals with another specific genotype pattern tend to have lower levels of inflammatory mediators. It is also important to note that the IL-1 gene variations, on which we are

focused, are highly prevalent in the population, with 8-10% of the Caucasian population being homozygous (i.e., the individual has two copies of the variant) for the less frequent variant.

We have laboratory and human research systems for screening drug and nutrient compounds for their differential effects on people with different genetic variations. Patent applications have been filed on this technology. These systems are also used for discovering biomarkers , i.e., biological chemicals that are indicative of a disease process. The goals of our Functional Genetics screening systems and biomarker programs are as follows:

- create IL-1 genotype/haplotype specific human cell lines for high throughput screening of nutritional products designed for the modulation of the inflammatory response; and

- identify novel and proprietary biomarkers that allow one to monitor nutrient effects on the inflammatory response in individuals with certain genetic patterns.

Genetics of weight gain and loss

We have recently expanded our genetics intellectual property to include gene variations, or genotypes, that regulate one important mechanism involved in fat metabolism. When an individual consumes more calories than they burn, the excess energy is stored in fat cells as lipid droplets. One of the key chemicals that regulates the mobilization of fat from the lipid droplet to be burned as energy is called perilipin. Investigators at Tufts University Medical School and Tufts Human Nutrition and Research Center have identified variations in the perilipin gene that appear to regulate fat metabolism and body weight. Studies have been completed on several thousand individuals that show that women with one specific perilipin genotype weigh an average of 22 pounds more than women with another perilipin genotype. The first paper on these findings was published in 2004 in *Clinical Genetics* by Qi, Corella, Greenberg, Ordovas, and co-workers entitled: Genetic variation at the perilipin (PLIN) locus is associated with obesity-related phenotypes in White women. We have licensed all rights to the use of this genetic test for weight management and for the use of this genetic information to develop nutritional products to facilitate weight management in individuals who have certain perilipin gene variations. Additional studies are in progress.

Biomarker discovery and development systems

In addition to determining which gene variations assess which individuals may be more likely to develop earlier and more severe disease, we are discovering the specific SNPs that actually control the biology to cause the disease differences. These functional SNPs guide the identification of novel biomarkers for monitoring an individual s disease status before the individual develops symptoms of disease or to monitor response to preventive or therapeutic agents to control the disease development. In addition, the functional SNPs provide targets for refining drug and nutrient benefits on a specific individual, also known as pharmacogenetics or nutrigenetics .

In the screening systems described above, we are working to identify which biomarkers are influenced by the differences in IL-1 functional SNPs. This information will be used to then screen nutritional and drug compounds that have the potential to modify the response to health challenges in people with a specific genetic variation.

Business Strategy

We are in the business of personalized healthcare. We are currently developing tests and plan to develop products that can help individuals improve and maintain their health through preventive measures. As highlighted in the diagram below, we plan to develop the following types of products:

- genetic risk assessment tests;

- preventive nutritional products (foods and nutritionals developed to prevent disease onset); and

- personalized therapeutics that treat an individual with existing disease and use genetic information to expedite drug development and to target the drug use to individuals most likely to respond favorably.

We will use our intellectual property and expertise to develop products or acquire additional intellectual property that can be leveraged, through collaboration with partners, to address unmet market needs.

Product Development Approach

As reflected in the diagram below, our current commercial strategy is to partner with companies with formulation and manufacturing capabilities and those that have sales and marketing capabilities to distribute our products. We currently have no plans to develop our own sales force. The first of these strategic partnerships is the partnership we have with Alticor. The details of this partnership are described within the section titled Strategic Alliances and Collaborations beginning on page 14.

Critical Components to Our Commercialization Strategy

Our revenue model consists of: 1) charging a fee for processing a genetic risk assessment test and generating a personalized risk assessment report; and 2) receiving a royalty from sales of products developed with a partner, or profit sharing from product sales. Furthermore, we plan to collaborate with other companies in research and development. In these collaborations, we expect to receive a certain

amount of research funding from the partner covering labor, material, overhead and a small amount of profit.

Products

Product Available for Sale

Our first genetic risk assessment test, PST®, identifies patients at risk for rapid progression of periodontitis. Periodontitis is a bacterially induced chronic inflammation that destroys the collagen fibers and bone that surround and support the teeth. Untreated, periodontitis will eventually result in tooth loss. Individuals who test positive for this genotype will normally be placed on a more frequent recall program with their dental provider, and would be candidates for more aggressive treatment with available therapeutics.

PST® was the result of the discovery of an association between specific IL-1 SNPs and severe periodontal disease. IL-1 is a cytokine protein that is known to play a role in inflammation and the expression of periodontal disease. Patients with this specific genotype have been found to progress more rapidly towards severe periodontal disease. It has also been determined that cells with this genotype produce as much as four times more IL-1 in response to the same bacterial challenge. Prevention or therapeutic intervention aimed at reducing the bacterial challenge should decrease the stimulus for IL-1 production and could thereby protect the patient against the potentially destructive effects of this genotype. Based on clinical trials we have conducted, we estimate that approximately 30% of the Caucasian population will test positive for this genotype.

We developed PST® under the terms of a project agreement with Sheffield. In November 1997, a patent related to the detection of genetic predisposition to periodontal disease was issued to us. We initiated commercial sales of PST® in October 1997 and the revenue derived from it to date has been minimal. We are currently marketing PST®, through various distributors in the U.S. and Europe. We are currently modifying PST® and planning to replace it with a new product that could be marketed together with a preventive nutritional product for periodontal disease.

Products in Development

We plan to develop three categories of products:

1. Genetic Risk Assessment Tests those that combine a genetic test with other disease-specific risk factors and produce a disease-specific personalized risk assessment. The information gathered from the genetic test and other sources is processed through a proprietary disease-specific algorithm to produce a personalized report. These products will be combined with a complementary product or service that provides a preventive or therapeutic solution to the problem. A strategic partner may provide these complementary products and services. Revenue from these products will be in the form of a processing fee charged to the strategic partner together with a minimal royalty from the complementary product sales.

2. Preventive Nutritional Products foods or nutritional products that are developed under a medical food regulatory pathway to assist in the therapy and management of a specific disease. These products will be sold through a strategic alliance with a distribution partner directly to physicians and medical professionals. Revenue from these products will either be a royalty on product sales or a profit sharing resulting from product sales.

3. Personalized Therapeutics - compounds effective in the treatment of persons with a specific genetic variation that determines their response to the drug. These compounds may come from several sources, including, (i) off-patent drugs that can be re-patented as a treatment for a person who has a specific genotype disease, (ii) drugs that were discontinued during development but

shown to be safe in humans which might gain approval if we were able to identify the specific patients for whom they will work, and (iii) drugs being developed, or recently launched for a specific indication that could also be developed for a different disease. Revenue from these products will consist of a processing fee for the test and royalties and milestone payments from product sales.

As of December 31, 2004, the following products were in our development pipeline:

Genetic Risk Assessment Tests

Cardiovascular Products (CUG-001, CJG-001, CKG-001)

The causes and mechanisms of atherosclerotic cardiovascular disease (CVD) are complex and not completely understood. Consequently, prediction, diagnosis and treatment of coronary artery disease has focused on the development of a set of risk factors that help to identify those individuals who are most at risk. Medical treatment and nutritional counseling focuses on modulation of any recognized risk factors that can be modified. The traditional CVD risk factors, such as high cholesterol, diabetes and smoking, account for slightly over half of first CVD events, such as heart attack. When this fact is considered together with the enormous cost to the healthcare system of treating all high-risk individuals with cholesterol lowering prescription drugs to prevent CVD, it is easy to understand why there is great interest in developing new tests to stratify individuals risk. Likewise, there is already a bewildering array of products confronting consumers who wish to enhance their own cardiovascular health through non-prescription dietary and nutritional approaches. We believe the rapid explosion in knowledge about variation in the human genome holds great promise for providing the scientific basis for tests that can help the healthcare practitioner and consumer better understand individual risk and make more informed decisions among medical and nutritional products.

Chronic inflammation is now a well-recognized risk factor in the development of CVD and for subsequent heart attacks. We have conducted studies that demonstrate certain variations (SNPs) in the IL-1 genes contribute to a pro-inflammatory state. One pattern of IL-1 SNPs leads to increased levels of inflammation and an increased risk of an acute myocardial infarction (heart attack). A second pattern of IL-1 SNPs leads to qualitative differences in inflammation and is associated with an increased risk of clogged heart arteries that produce pain on exercise (angina). Since the IL-1 SNPs that an individual is born with do not change, they may be used to predict risk for specific types of heart disease and to guide preventive therapies.

We are developing this product to be marketed with one of Alticor s personalized nutritional products. The development of the genetic test is nearly complete, while the nutritional product is in late-stage development. Versions of this product are being developed for other regions outside of North America.

Osteoporosis Products (OUG-001, OJG-001, OKG-001)

Osteoporosis, the most common age-related bone disease, results in a decrease in the strength of the bone that leaves the affected individual more susceptible to fractures. According to the National Institute of Health, 10 million Americans suffer from the disease and another 34 million have low bone mass, placing them at increased risk for the disease. Although osteoporosis occurs in both men and women, it begins earlier and progresses more rapidly in women after menopause. The consequences of osteoporosis can be both physical and financial. Hip and vertebral fractures, which are commonly associated with osteoporosis, have a profound impact on quality of life. The National Institute of Health estimated that, as of 2003, direct financial expenditures (hospitals and nursing homes) for osteoporosis and related fractures are estimated to be $14 billion annually.

We have conducted several research projects with major osteoporosis centers. Results of these studies have indicated that a number of small variations in the IL-1 gene cluster, referred to as polymorphisms, are associated with a more rapid rate of bone loss and an increased risk of vertebral fracture in post-menopausal Caucasian women. A genetic predisposition test could identify women at elevated risk for developing osteoporosis-related vertebral fracture early in the course of the disease and allow these women and their physicians to practice preventive medicine. This would enable nutritional or therapeutic intervention or recommendations for changes in lifestyle or diet at an early stage, so that bone loss and fractures are minimized or prevented.

This product will combine the IL-1 SNPs with other SNPs in other genes known to be associated with bone loss to form a genetic panel. Once the development of the test panel is completed, we will begin the development of the algorithm that will incorporate other risk factors to generate a personalized risk assessment.

We are developing this product to be marketed with one of Alticor s personalized nutritional products. Versions of this product are also being developed for other regions outside of North America.

Weight Management Product (WUG-001, WJG-001)

According to the 1999-2003 National Health and Nutrition Examination Survey (NHANES), an estimated 65% of adults in the U.S. are overweight (Body Mass Index > 25). Overweight and obese individuals are at increased risk for many diseases including heart disease, type II diabetes, and some types of cancer. This product is in Clinical Phase of development. The objective is to identify individuals with specific genetic variations that affect how people gain and maintain weight. Another version of this product is being developed for a country outside of North America.

Preventive Nutritional Product

Periodontal Disease (PUN-001)

This product is in Early Research Phase of development. It consists of nutritional ingredients that will be formulated to be efficacious as part of the therapy and management of periodontal disease. We expect this product to be co-developed with a marketing partner with a presence in the dental market and with a manufacturing partner. The product is designed for patients who currently have severe periodontal disease or who have mild disease plus one of the risk factors for severe disease, including smoking, diabetes, or are positive for a genetic test for periodontal disease.

Personalized Therapeutic Products

Endometriosis (EUT-001)

This product is also in Early Research Phase of development. We considered multiple potential inflammatory disease targets and chose to do preliminary studies in endometriosis. We are doing a pre-clinical study in which we will be implanting genotype-specific human endometrial tissues into mice and treating them with various anti-inflammatory compounds. This study will lead us to the selection of the appropriate therapeutic compound to advance to the next development phase.

Product Development and Commercialization Phases

Early Research

A product is in Early Research Phase when it is just a concept being investigated in our research laboratory or with an academic partner. The experiments being conducted are usually *in vitro* using our genotype-specific cell lines. The experiments may also be *in vivo* using our Human Test System at Boston

University or the University of Arkansas. The results of these investigative experiments will determine whether or not the product proceeds to the next phase.

Clinical Development

As an internal procedural standard, we conduct three categories of clinical trials in conjunction with our genetic risk assessment tests. The first trial is called a proof of concept trial, used to prove a laboratory finding. The results of this trial are utilized to support the initial patent application and therefore the trial needs to be completed before the patent application can be filed. The second trial is a confirmatory trial. The purpose of the confirmatory trial is to independently confirm the results of the proof of concept trial. The third trial relates to clinical utility. The clinical utility trial is conducted to learn what is the most effective utilization of the test in actual clinical practice.

Product Development

Following confirmatory studies, additional trials are completed on larger populations to help develop broad scientific evidence supporting the clinical utility of each of our tests. Such additional trials not only strengthen the support for each test s known use (e.g., detecting genetic susceptibility) but also lead to additional practical uses of the genetic risk assessment tests (e.g., use of the genetic risk assessment tests to determine a patient s responsiveness to a given drug).

During this phase, the algorithm, for risk assessment products, is also being developed for testing in the clinical environment. Also during this phase, a business development effort gets underway to find a marketing and distribution partner and preliminary market research is launched.

Commercialization

At this phase, a partner is in place for the marketing and distribution of the product. We usually develop a scientific credibility program to obtain the support of thought-leaders in the disease area. The educational programs are put in place and training begins. In some instances, there may already be a firm order in place for a minimum number of genetic risk assessment tests.

During this phase, a brand name is developed for the product and, if necessary, a pilot launch of the product takes place to test receptivity and market adoption. A product can still be dropped at this phase if the pilot launch fails to meet expectations.

Product Pipeline Summary

The table below summarizes the current stage of development of the products described above.

We expect the market launch of our cardiovascular risk assessment test to occur in the first quarter of 2006. However, we have no guarantee that the complementary product from our partner will be successfully developed by that time or that the test and the nutritional product will be adopted by the target population when introduced to the market.

We have spent $4.1 million, $3.5 million and $3.1 million on research and development during the years ended December 31, 2004, 2003 and 2002, respectively. We expect to spend between $4.0 million and $5.0 million in 2005. These research and development expenses include research funded by Alticor.

Laboratory Testing Procedure

Each of our genetic risk assessment tests requires consumers, dentists or physicians to follow a specific protocol. To conduct a genetic risk assessment test, the doctor, dentist or consumer collects cells from inside the cheek on a brush and submits it to our laboratory. Our clinical laboratory then performs the test following our specific protocol and informs the dentist/physician or consumer of the results.

During 2004, we completed the construction of our state-of-the-art genetic testing laboratory (for which we will shortly seek approval under the Clinical Laboratory Improvement Act of 1988 (CLIA)) to process all the test samples resulting from the expected product launches. The regulatory requirements associated with a clinical laboratory are addressed under the section titled Government Regulation beginning on page 18. The capacity of the laboratory is approximately 1,000,000 tests per year with a full complement of equipment and personnel. We plan to partner with a number of reference laboratories to provide backup support should we receive samples beyond our capacity.

Marketing and Distribution Strategy

We will market and distribute our products through strategic partnerships. The type of sales and marketing partner will differ based on the type of products.

Genetic Risk Assessment Tests

Our marketing partner for these products will likely be a consumer product company with nutritional products that can mitigate the risk assessed by our tests. The nutritional products are likely to be personalized (based on the individual s genetics). Alticor is one such partner. We expect the market launch of our cardiovascular risk assessment test, the first of our tests to be distributed in Alticor s multi-level marketing channel, to occur in the first quarter of 2006.

Another type of marketing partner for these products could be a specialty health/wellness company with a large membership of individuals motivated to maintain wellness. These companies could be regionally or nationally located.

Preventive Nutritional Products

Our sales and marketing partner for these products will most likely either be a consumer or a pharmaceutical product company with a sales force that call on medical/dental professionals. Although the sales representatives may detail the medical/dental professionals, access to the product by patients may or may not require a prescription. The partner is likely to have national or worldwide distribution capabilities.

Personalized Therapeutic Products

Our sales and marketing partner for these products will likely be a pharmaceutical company that is a late entry in a particular disease market and is seeking a product with a differentiating feature. The partner is likely to be progressive in genomics technology and have appreciation for the value of personalized medicine.

Reimbursement

The availability and levels of reimbursement by governmental and other third-party payers affect the market for any healthcare service. These third-party payers continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for medical products and services. We believe that the extent of third-party payer reimbursement will heavily influence physicians and dentists decisions to recommend genetic risk assessment tests, as well as patients elections to pursue testing.

We expect consumers to pay out-of-pocket for their personalized risk reports. Further, our distribution agreement with Alticor entered into in early 2004 calls for us to invoice Alticor directly for the processed tests and, therefore we will not be subject to third-party reimbursement. We have some products under development that may require third-party reimbursement. To the extent that some of our products are sold through the medical channel, our ability to successfully commercialize these products will depend on obtaining adequate reimbursement from third-party payers.

Strategic Alliances and Collaborations

Our strategy is to develop products for research and clinical use and commercialize such products through strategic alliances. We have followed a strategy of working with strategic partners at the fundamental discovery stage in product development and in sales and marketing. This strategy has given us access to discoveries while reducing up-front research expenses and will give us access to markets without committing to the high costs of selling and advertising.

Alticor

In March 2003, we entered into a broad strategic alliance with Alticor to develop and market novel nutritional and skin care products. The alliance utilizes our intellectual property and expertise in genomics to develop personalized consumer products. Alticor has a long history of manufacturing and distributing high quality nutritional supplements and skin care products to a worldwide market through the multi-level marketing channel.

The alliance has included an equity investment, multi-year research and development agreements, a licensing agreement with royalties on marketed products, the deferment of outstanding loan repayment and the refinancing of bridge financing obligations. The financial elements of this alliance are described in greater detail in the section titled Liquidity and Capital Resources beginning on page 32.

In broad terms, we expect that this alliance will open our research and development products to our partner s proven marketing and distribution channels. We believe that the benefits derived from nutritional products that are being developed by Alticor will be greatly enhanced by applying our deeper understanding of the underlying human genetics. Further, Alticor and we share a belief that the future of personalized nutritional supplementation and skin care will be based on an individual s genetic makeup. This alliance will focus on developing genetic risk assessment tests to determine a genetic profile of an individual and developing nutritional supplements and skin care products that will benefit individuals of that genetic profile.

University of Sheffield

We have followed a strategy of working with partners at the fundamental discovery stage. This strategy has given us access to discoveries while reducing up-front research expenses. Since 1994, we have had an alliance with Sheffield. Under this alliance, Sheffield has conducted fundamental discovery and genetic analysis, and we have focused on product development, including clinical trials, and the commercialization of these discoveries.

In 1999, we entered into a new arrangement with Sheffield and its investigators replacing the research and development agreement that had been in place with Sheffield since 1996. Pursuant to that arrangement, we issued an aggregate of 475,000 shares of our common stock to Sheffield and certain of its investigators in exchange for the relinquishment by Sheffield of its interests under certain previous agreements with us. In addition, that agreement required us to issue to Sheffield and certain of its investigators options to purchase an aggregate of 50,000 shares of stock at the current market price each June 30th during the period of time the arrangement was in place. Sheffield was entitled to additional options to purchase 10,000 shares of stock at the current market price each June 30th for each patent that was filed on our behalf during the previous twelve months. The agreements with Sheffield and certain of its investigators expired in June 2004. We renegotiated the agreement with a Sheffield investigator to include a retainer and travel expenses but included no stock options through September 30, 2005 with an annual automatic renewal unless sooner terminated.

Other Academic Research Collaborations

In addition to our collaborations with Sheffield, we have active research collaborations at the following academic institutions:

Tufts University

We have licensed genetic technology from Tufts University related to the control of fat metabolism, body weight, and metabolic syndrome. We have active research agreements with Tufts that are focused on

the genetics of body weight and on the development of products that alter fat metabolism and body weight. These studies are under the direction of Drs. Jose Ordovas and Andrew Greenberg at Tufts.

Mayo Clinic

We previously funded and conducted a clinical study of genetics and cardiovascular disease at the Mayo Clinic. Although the clinical phase of this project is completed, further research on the clinical data and on the patients DNA continues in collaboration with Dr. Peter Berger who was the principal investigator at Mayo but is now Head of Interventional Cardiology at Duke University.

University of California in San Francisco (UCSF)

We have studies with UCSF in late stages that are focused on the genetics of osteoporosis and the genetics of cardiovascular disease.

These studies are under the direction of Drs. Stephen Cummings and Katherine Stone.

Boston University

We have funded research at Boston University Medical Center to determine the influence of IL-1 gene variations on biochemical factors involved in various inflammatory diseases that are the targets for drug development by multiple companies. This information will be used to develop pharmacogenetic tests.

University of Arkansas

In March 2002, we entered into a collaboration with the University of Arkansas for Medical Sciences College of Medicine to study how genetic variations in inflammatory genes influenced risk for Alzheimer s Disease and to identify potential drug targets for that disorder. The collaboration is ongoing. In addition, we have recently completed studies at the University of Arkansas on the influence of genetic variations on muscle function with aging and in response to exercise.

PST® Commercial Partnerships

Hain Diagnostika/ADS GmbH and Laboral International

In December 2000, we entered into an exclusive seven-year license agreement with Hain Diagnostika/ADS GmbH (Hain) for the marketing, distribution and processing of PST® in all countries outside of North America and Japan. In May 2003, we amended the agreement with Hain to a non-exclusive license limited to the European Territory. Since then we added Laboral International as a non-exclusive PST® distributor in Europe. Revenue from Hain and Laboral International was minimal in 2004 and 2003.

Kimball Genetics, Inc.

In September 2000, we entered into a 5-year agreement with Kimball Genetics, Inc. to process PST® tests and market the product in the United States on a non-exclusive basis. Since December 2001, Kimball has been our sole marketing partner within the United States. We receive a royalty from Kimball for every PST® test processed. Revenue from Kimball was minimal in 2004 and 2003.

Intellectual Property

Our commercial success may depend at least in part on our ability to obtain appropriate patent protection on our drug discovery and diagnostic products and methods. We currently own exclusive rights in twenty issued U.S. patents, which have expiration dates between 2015 and 2020, and have twenty

additional U.S. patent applications pending, which are based on novel genes or novel associations between particular gene sequences and certain inflammatory diseases, and disorders. Of the twenty issued patents, sixteen relate to genetic tests for periodontal disease, osteoporosis, asthma, coronary artery disease, sepsis and disease associated with IL-1 inflammatory haplotypes, three relate to BioFusion, our biologic modeling software, and one relates to a transgenic mouse model.

We have been granted a number of corresponding foreign patents and have a number of foreign counterparts of our U.S. patents and patent applications pending.

We have received trademark protection for PST®, our periodontal genetic risk assessment test. Our proprietary technology is subject to numerous risks, which we discuss in Certain Factors That May Affect Future Results of Operations or the Market for Our Common Stock beginning on page 19 of this report.

Competition

The competition in the field of Personalized Health is not well defined due to lack of an established market and customer base. The concept is new and requires consumers to do things differently, hence it is a disruptive technology . Adoption of such technologies typically requires substantial market development and customer prospecting. There are a few companies offering predisposition tests and product recommendations but we believe they neither have the intellectual property nor the scientific credibility required to provide leadership or present a real competitive obstacle to us. We intend to lead the Personalized Health sector with products that meet a specific market need in a targeted segment so as to facilitate adoption of the technology.

There are a number of companies involved in identifying and commercializing genetic markers in the form of a genetic test; however, the companies differ in product end points and target customers. The companies in the industry break down into four sectors, including, 1) Predictive Medicine Companies, 2) SNP Discovery Companies, 3) Personalized Health Companies, and 4) Technology Platform Companies.

Our potential competitors in the United States and abroad are numerous and include, among others, major pharmaceutical and diagnostic companies, specialized biotechnology firms, universities and other research institutions. Many of our potential competitors have considerably greater financial, technical, marketing and other resources than we have, which may allow these competitors to discover important genes or successfully commercialize these discoveries before us. If we do not discover disease-predisposing genes, characterize their functions, develop genetic tests and related information services based on such discoveries, obtain regulatory and other approvals, and launch these services or products before competitors, we could be adversely affected. Additionally, some of our competitors receive data and funding from government agencies. To the extent our competitors receive data and funding from those agencies at no cost to them, they may have a competitive advantage over us.

In the case of newly introduced products requiring change of behavior (such as genetic risk assessment tests), multiple competitors may accelerate market acceptance and penetration through increasing awareness. Moreover, two different genetic risk assessment tests for the same disease may in fact test or measure different components, and thus, actually be complementary when given in parallel as an overall assessment of risk, rather than being competitive with each other.

Furthermore, the primary focus of most companies in the field is performing gene-identification research for pharmaceutical companies for therapeutic purposes, with genetic risk assessment testing being a secondary goal. In contrast, our primary business focus is developing and commercializing genetic risk assessment tests for common diseases and forward-integrating these tests with additional products and services. We anticipate only an ancillary drug discovery program, if any.

Government Regulation

The sampling of blood, saliva or cheek scrapings from patients and subsequent analysis in a central clinical laboratory does not, at the present time, require Federal Drug Administration (FDA) or regulatory authority approval inside the U.S. for either the sampling procedure or the analysis itself. The samples are collected using standard materials previously approved as medical devices, such as sterile lancets and swabs. The testing procedure itself is performed in one or more registered, certified clinical laboratories under CLIA, administered by the Health Care Financing Administration. The federal regulations governing approval of the laboratory facilities and applicable state and local regulations governing the operation of clinical laboratories would also apply to the laboratories performing tests for us. Changes in such regulatory schemes could require advance regulatory approval of genetic risk assessment tests sometime in the future and could have a material adverse effect on our business. In addition, certain billing practices require that we, or a subsidiary, be licensed and regulated under CLIA.

In addition, while our main focus is on genetic risk assessment testing, we may, in the future, endeavor to partner with pharmaceutical companies in the area of drug development. Any drug products developed by us or our future collaborative partners, prior to marketing in the United States, would be required to undergo an extensive regulatory approval process by the FDA. The regulatory process, which includes preclinical testing and clinical trials of each therapeutic product in order to establish its safety and efficacy, can take many years and requires the expenditure of substantial resources. Data obtained from preclinical and clinical activities are susceptible to varying interpretations which could delay, limit or prevent regulatory agency approval. In addition, delays or rejections may be encountered during the period of therapeutic development, including delays during the period of review of any application. Delays in obtaining regulatory approvals could adversely affect the marketing of any therapeutics developed by us or our collaborative partners, impose costly procedures upon us and our collaborative partners activities, diminish any competitive advantages that we and our collaborative partners may attain and adversely affect our ability to receive royalties.

Once regulatory approval of a product is granted, the approval may impose limitations on the indicated uses for which it may be marketed. Further, even if such regulatory approval is obtained, a marketed product and its manufacturer are subject to continuing review. The discovery of previously unknown problems with a product or manufacturer may result in restrictions on such product or manufacturer. Such restriction could include withdrawal of the product from the market.

Other Information

Our executive offices are located at 135 Beaver Street, Waltham, Massachusetts 02452, and our telephone number is 781/398-0700. We were incorporated in Texas in 1986 and we re-incorporated in Delaware in March 2000. We maintain a website at www.ilgenetics.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to such reports are available to you free of charge through the Investor Relations Section of our website as soon as practicable after such materials have been electronically filed with, or furnished to, the Securities and Exchange Commission. The information contained on our website is not incorporated by reference into this Form 10-K. We have included our website address only as an inactive textual reference and do not intend it to be an active link to our website.

Employees

As of April 19, 2005, we had eighteen full-time and part-time employees. Of our employees, ten were engaged primarily in the research, development and commercialization of tests and eight were engaged primarily in administrative or managerial activities. Our employees are not covered by a collective bargaining agreement, and we consider our relations with our employees to be good.

Certain Factors That May Affect Future Results of Operations or the Market for Our Common Stock

We have a history of operating losses and expect these losses to continue in the future.

We have experienced significant operating losses since our inception and expect these losses to continue for some time. We incurred losses from operations of $5.1 million in 2002, $5.9 million in 2003 and $6.7 million in 2004. As of December 31, 2004, our accumulated deficit was $54.6 million. Our losses result primarily from research and development, general and administrative expenses. We have not generated significant revenue from product sales, and we do not know if we will ever generate sufficient revenue from product sales to cover our operating expenses. We will need to generate significant revenue to continue our research and development programs and achieve profitability. We cannot predict when, if ever, we will achieve profitability.

The market for genetic risk assessment tests is unproven.

The market for genetic risk assessment tests is at an early stage of development and may not continue to grow. The general scientific community, including us, has only a limited understanding of the role of genes in predicting disease. When we identify a gene or genetic marker that may predict disease, we conduct clinical trials to confirm the initial scientific discovery and to establish the scientific discovery s clinical utility in the marketplace. The results of these clinical trials could limit or delay our ability to bring the test to market, reduce the test s acceptance by our customers or cause us to cancel the program, any of which limit or delay sales and cause additional losses. The only genetic risk assessment test we currently market is PST®, and it has produced only minimal revenue to date. The marketplace may never accept our products, and we may never be able to sell our products at a profit. We may not complete development of or commercialize our other genetic risk assessment tests.

The success of our genetic risk assessment tests will depend upon their acceptance as medically useful and cost-effective by patients, physicians, dentists, other members of the medical and dental community and by third-party payers, such as insurance companies and the government. We can achieve broad market acceptance only with substantial education about the benefits and limitations of genetic risk assessment tests. Our tests may not gain market acceptance on a timely basis, if at all. If patients, dentists and physicians do not accept our tests, or take a longer time to accept them than we anticipate, then it will reduce our anticipated sales, resulting in additional losses.

The market for personalized healthcare is unproven.

The competition in the field of Personalized Health is not well defined due to a lack of an established market and customer base. The concept is new and requires consumers to do things differently, hence may be considered a disruptive technology . Adoption of such technology requires substantial market development and customer prospecting. There are a few companies offering predisposition tests or health risk assessments and product recommendations based upon these assessments. Activities in these areas remain small and the overall market is unproven. While both Alticor and we have done some initial market research regarding the marketability of these products, there can be no assurance that these products will be successful upon launch or that they can be sold at sufficient margins to make them profitable to our partners or us. If customers do not accept our tests, or take a longer time to accept them than we anticipate, then it will reduce our anticipated sales, resulting in additional losses.

We rely heavily on third parties to perform sales, marketing and distribution functions on our behalf, which could limit our efforts to successfully market products.

We have limited experience and capabilities with respect to distributing, marketing and selling genetic risk assessment tests. We have relied and plan to continue to rely significantly on sales, marketing and distribution arrangements with third parties, over which we have limited influence. If these third parties do

not successfully market our products, it will reduce our anticipated sales and increase our losses. If we are unable to negotiate acceptable marketing and distribution agreements with future third parties, or if in the future we elect to perform sales, marketing and distribution functions ourselves, we will incur significant costs and face a number of additional risks, including the need to recruit experienced marketing and sales personnel. In March 2003, we entered into a strategic alliance with Alticor. As part of this alliance, Alticor will conduct sales, marketing and distribution functions on our behalf. In February 2004, we received a purchase order from Alticor for a firm minimum order of genetic risk assessment tests to be delivered during the first year of product launch. While Alticor has far more experience and success in marketing, selling and distributing products than we do, we could become very dependent upon their success and their failure to successfully market our products could reduce our anticipated sales and increase our losses.

If we fail to obtain additional capital, or obtain it on unfavorable terms, then we may have to end our research and development programs and other operations.

We anticipate that our current and anticipated financial resources are adequate to maintain our current and planned operations through mid-2006. If we are not generating sufficient cash or cannot raise additional capital prior to that date, we will be unable to fund our business operations and will be required to seek other strategic alternatives.

Our future capital needs depend on many factors. We will need capital for the commercial launch of additional genetic tests, continued research and development efforts, obtaining and protecting patents and administrative expenses. Additional financing may not be available when needed, or, if available, it may not be available on favorable terms. If we cannot obtain additional funding on acceptable terms when needed, we may have to discontinue operations, or, at a minimum, curtail one or more of our research and development programs.

Because a single shareholder has a controlling percentage of our voting power, other stockholders voting power is limited.

As of December 31, 2004, a single stockholder owned, or had rights to own approximately 57.7% of our outstanding common stock. Accordingly, this stockholder will be able to determine the outcome of stockholder votes, including votes concerning the election of directors, the adoption or amendment of provisions in our Certificate of Incorporation or By-Laws and the approval of certain mergers and other significant corporate transactions, including a sale of substantially all of our assets. This stockholder may make decisions that are adverse to other stockholders or warrantholders interests. This ownership concentration may also adversely affect the market price of our common stock. Three of our four directors are individuals chosen by this single stockholder. These directors might pursue policies in the interest of this single stockholder to the detriment of our other stockholders.

The Series A Preferred Stock has certain rights which are senior to common shareholder rights and this may reduce the value of the common stock.

The Series A Preferred Stock, which was issued to Alticor in March 2003, accrues dividends at the rate of 8% of the original purchase price per year, payable only when, as and if declared by the Board of Directors and are non-cumulative. If we declare a distribution, with certain exceptions, payable in securities of other persons, evidences of indebtedness issued by us or other persons, assets (excluding cash dividends) or options or rights to purchase any such securities or evidences of indebtedness, then, in each such case the holders of the Series A Preferred Stock shall be entitled to a proportionate share of any such distribution as though the holders of the Series A Preferred Stock were the holders of the number of shares of our common stock into which their respective shares of Series A Preferred Stock are convertible as of the record date fixed for the determination of the holders of our common stock entitled to receive such distribution.

In the event of any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, the holders of the Series A Preferred Stock shall be entitled to receive, prior and in preference to any distribution of any of our assets or surplus funds to the holders of our common stock by reason of their ownership thereof, the amount of two times the then-effective purchase price per share, as adjusted for any stock dividends, combinations or splits with respect to such shares, plus all declared but unpaid dividends on such share for each share of Series A Preferred Stock then held by them. After receiving this amount, the holders of the Series A Preferred Stock shall participate on an as-converted basis with the holders of common stock in any of our remaining assets.

The preferential treatment accorded the Series A Preferred Stock might reduce the value of the common stock.

If we are unsuccessful in establishing additional strategic alliances, our ability to develop and market products and services will be damaged.

Entering into strategic alliances for the development and commercialization of products and services based on our discoveries is an important element of our business strategy. We anticipate entering into additional collaborative arrangements with Alticor and other parties in the future. We face significant competition in seeking appropriate collaborators. In addition, these alliance arrangements are complex to negotiate and time-consuming to document. If we fail to maintain existing alliances or establish additional strategic alliances or other alternative arrangements, then our ability to develop and market products and services will be damaged. In addition, the terms of any future strategic alliances may be unfavorable to us or these strategic alliances may be unsuccessful.

If we fail to obtain an adequate level of reimbursement for our products or services by third-party payers, then our products and services will not be commercially viable.

The availability and levels of reimbursement by governmental and other third-party payers affect the market for any healthcare service. These third-party payers continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for medical products and services. To the extent that our products are sold through the medical channel, our ability to successfully commercialize our existing genetic risk assessment test and others that we may develop depends on obtaining adequate reimbursement from third-party payers. The extent of third-party payer reimbursement will likely heavily influence physicians and dentists decisions to recommend genetic risk assessment tests, as well as patients elections to pursue testing. If reimbursement is unavailable or limited in scope or amount, then we cannot sell our products and services profitably. In particular, third-party payers tend to deny reimbursement for services which they determine to be investigational in nature or which are not considered reasonable and necessary for diagnosis or treatment. To date, few third-party payers have agreed to reimburse patients for genetic risk assessment tests, and we do not know if third-party payers will, in the future, provide full reimbursement coverage for these genetic tests. If third-party payers do not provide adequate reimbursement coverage, then individuals may choose to directly pay for the test. If both third-party payers and individuals are unwilling to pay for the tests, then the number of tests we can sell will be significantly decreased, resulting in reduced revenue and additional losses.

If we fail to obtain patent protection for our products and preserve our trade secrets, then competitors may develop competing products and services, which will decrease our sales and market share.

Our success will partly depend on our ability to obtain patent protection, in the United States and in other countries, for our products and services. In addition, our success will also depend upon our ability to preserve our trade secrets and to operate without infringing upon the proprietary rights of third parties.

We own exclusive rights in twenty issued U.S. patents and have a number of additional U.S. patent applications pending. We have also been granted a number of corresponding foreign patents and have a

number of foreign counterparts of our U.S patents and patent applications pending. Our patent positions, and those of other pharmaceutical and biotechnology companies, are generally uncertain and involve complex legal, scientific and factual questions. Our ability to develop and commercialize products and services depends on our ability to:

- Obtain patents;
- Obtain licenses to the proprietary rights of others;
- Prevent others from infringing on our proprietary rights; and
- Protect trade secrets.

Our pending patent applications may not result in issued patents or any issued patents may never afford meaningful protection for our technology or products. Further, others may develop competing products, which avoid legally infringing upon, or conflicting with, our patents. In addition, competitors may challenge any patents issued to us, and these patents may subsequently be narrowed, invalidated or circumvented.

We also rely on trade secrets and proprietary know-how that we seek to protect, in part, by confidentiality agreements. The third parties we contract with may breach these agreements, and we might not have adequate remedies for any breach. Additionally, our competitors may discover or independently develop our trade secrets.

Third parties may own or control patents or patent applications and require us to seek licenses, which could increase our costs or prevent us from developing or marketing our products or services.

We may not have rights under patents or patent applications that are related to our current or proposed products. Third parties may own or control these patents and patent applications in the United States and abroad. Therefore, in some cases, to develop or sell any proposed products or services, with patent rights controlled by third parties, our collaborators or we may seek, or may be required to seek, licenses under third-party patents and patent applications. If this occurs, we will pay license fees or royalties or both to the licensor. If licenses are not available to us on acceptable terms, our collaborators or we may be prohibited from developing or selling our products or services.

If third parties believe our products or services infringe upon their patents, they could bring legal proceedings against us seeking damages or seeking to enjoin us from testing, manufacturing or marketing our products or services. Any litigation could result in substantial expenses to us and significant diversion of attention by our technical and management personnel. Even if we prevail, the time, cost and diversion of resources of patent litigation would likely damage our business. If the other parties in any patent litigation brought against us are successful, in addition to any liability for damages, we may have to cease the infringing activity or obtain a license.

Technological changes may cause our products and services to become obsolete.

Our competitors may develop risk assessment tests that are more effective than our technologies or that make our technologies obsolete. Innovations in the treatment of the diseases in which we have products or product candidates could make our products obsolete. These innovations could prevent us from selling, and significantly reduce or eliminate the markets for, our products.

We may be prohibited from fully using our net operating loss carryforwards, which could affect our financial performance.

As a result of the losses incurred since inception, we have not recorded a federal income tax provision and have recorded a valuation allowance against all future tax benefits. As of December 31, 2004, we had

net operating loss carryforwards of approximately $39.5 million for federal and state income tax purposes, expiring in varying amounts through the year 2024. We also had a research tax credit of approximately $761,000 at December 31, 2004 that expires in varying amounts through the year 2024. Our ability to use these net operating loss and credit carryforwards is subject to restrictions contained in the Internal Revenue Code which provide for limitations on our utilization of our net operating loss and credit carryforwards following a greater than 50% ownership change during the prescribed testing period. We have experienced two such ownership changes. One change arose in March 2003 and the other was in June 1999. As a result, all of our net operating loss carryforwards will be limited in utilization. The annual limitation may result in the expiration of the carryforwards prior to utilization. In addition, in order to realize the future tax benefits of our net operating loss and tax credit carryforwards, we must generate taxable income, of which there is no assurance.

We are subject to intense competition from other companies, which may damage our business.

Our industry is highly competitive. Our competitors in the United States and abroad are numerous and include major pharmaceutical and diagnostic companies, specialized biotechnology firms, universities and other research institutions, including those receiving funding from the Human Genome Project. Many of our competitors have considerably greater financial resources, research and development staffs, facilities, technical personnel, marketing and other resources than we do. Furthermore, many of these competitors are more experienced than we are in discovering, commercializing and marketing products. These greater resources may allow our competitors to discover important genes or genetic markers before we do. If we do not discover disease predisposing genes and commercialize these discoveries before our competitors, then our ability to generate sales and revenue will be reduced or eliminated, and could make our products obsolete. We expect competition to intensify in our industry as technical advances are made and become more widely known.

We are subject to government regulation which may significantly increase our costs and delay introduction of future products.

The sale, performance or analyses of our genetic tests do not currently require FDA or other federal regulatory authority approval. Changes in existing regulations could require advance regulatory approval of genetic risk assessment tests, resulting in a substantial curtailment or even prohibition of our activities without regulatory approval. If our genetic tests ever require regulatory approval, on either a state or federal level, then the costs of introduction will increase and marketing and sales of products may be significantly delayed. We anticipate that the testing procedure itself will be performed primarily in our own genetic testing laboratory which will need to be certified under the auspices of the Clinical Laboratory Improvement Act of 1988 (CLIA), administered by the Health Care Financing Administration. We anticipate there will also be additional state and local regulations governing the operation of this laboratory. A delay in receiving CLIA certification or any applicable state or local certification would reduce our revenue and increase our net losses.

We may be subject to product liability claims that are costly to defend and that could limit our ability to use some technologies in the future.

The design, development, manufacture and use of our genetic risk assessment tests involve an inherent risk of product liability claims and associated adverse publicity. Producers of medical products face substantial liability for damages in the event of product failure or allegations that the product caused harm. We currently maintain product liability insurance, but it is expensive and difficult to obtain, may not be available in the future on economically acceptable terms and may not be adequate to fully protect us against all claims. We may become subject to product liability claims that, even if they are without merit, could result in significant legal defense costs. We could be held liable for damages in excess of the limits of our insurance coverage, and any claim or resulting product recall could create significant adverse publicity.

Ethical, legal and social issues related to genetic testing may reduce demand for our products.

Genetic testing has raised issues regarding the appropriate utilization and the confidentiality of information provided by genetic testing. Genetic tests for assessing a person s likelihood of developing a chronic disease have focused public attention on the need to protect the privacy of genetic assessment medical information. For example, concerns have been expressed that insurance carriers and employers may use these tests to discriminate on the basis of genetic information, resulting in barriers to the acceptance of genetic tests by consumers. This could lead to governmental authorities prohibiting genetic testing or calling for limits on or regulating the use of genetic testing, particularly for diseases for which there is no known cure. Any of these scenarios would decrease demand for our products and result in substantial losses.

Our failure to timely assess and report on the effectiveness of our internal control over financial reporting in accordance with U.S. federal securities laws and the resulting disclaimer from our independent registered public accounting firm may expose us to regulatory sanctions and cause a loss of investor confidence in our internal controls, and adversely affect the trading price of our shares.

As of December 31, 2003, we were not an accelerated filer (as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended) and, therefore, did not expect to be required to comply with Section 404 of the Sarbanes-Oxley Act of 2002 until the fiscal year ending December 31, 2005. However, because our public common float exceeded $75 million on June 30, 2004, we became obligated to comply with Section 404 for the fiscal year ended December 31, 2004. Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting as of our most recent fiscal year end and a report by our independent registered public accounting firm of their opinions on our assessment. Management has selected the framework set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its *Internal Control-Integrated Framework*. Management did not complete its work related to the year ended December 31, 2004. Because of this, Grant Thornton LLP was unable to, and did not, express an opinion on management s assessment of its internal control over financial reporting for our fiscal year ended December 31, 2004. Our failure to timely implement an evaluation framework and complete our assessment of our internal control over financial reporting, identify and remediate any material weaknesses that may exist, and our auditors inability to provide an opinion on management s assessment, could expose us to regulatory sanctions or cause a loss of investor confidence in our internal controls, and in turn might adversely affect the market price of our common stock.

Our dependence on key executives and scientists could adversely impact the development and management of our business.

Our success substantially depends on the ability, experience and performance of our senior management and other key personnel. If we lose one or more of the members of our senior management or other key employees, it could damage our development programs and our business. In addition, our success depends on our ability to continue to hire, train, retain and motivate skilled managerial and scientific personnel. The pool of personnel with the skill that we require is limited. Competition to hire from this limited pool is intense. We compete with numerous pharmaceutical and healthcare companies, as well as universities and nonprofit research organizations in the highly competitive Boston, Massachusetts s business area. Loss of the services of Dr. Philip R. Reilly, our Chief Executive Officer, Dr. Kenneth Kornman, our President and Chief Scientific Officer, or Mr. Fenel M. Eloi, our Chief Operating Officer and Chief Financial Officer, could delay our research and development programs or otherwise damage our business. In March 2003, we entered into employment agreements with three-year terms with Dr. Reilly, Dr. Kornman and Mr. Eloi. Each of these employees can terminate his employment upon 30 days notice. We do not maintain key man life insurance on any of our personnel.

In a circumstance in which Alticor enters a business in competition with our own, our Directors might have a conflict of interest.

In conjunction with our strategic alliance with Alticor, we have agreed to certain terms for allocating opportunities as permitted under Section 122(17) of the Delaware General Corporation Law. This agreement, as set forth in the Purchase Agreement, regulates and defines the conduct of certain of our affairs as they may involve Alticor as our majority stockholder and its affiliates, and the powers, rights, duties and liabilities of us and our officers and directors in connection with corporate opportunities.

Except under certain circumstances, Alticor and its affiliates have the right to engage in the same or similar activities or lines of business or have an interest in the same classes or categories of corporate opportunities as we do. If Alticor or one of our directors appointed by Alticor, and its affiliates acquire knowledge of a potential transaction or matter that may be a corporate opportunity for both Alticor and its affiliates and us, to the fullest extent permitted by law, Alticor and its affiliates will not have a duty to inform us about the corporate opportunity or be liable to us or to you for breach of any fiduciary duty as a stockholder of ours for not informing us of the corporate opportunity, keeping it for its own account, or referring it to another person.

Additionally, except under limited circumstances, if an officer or employee of Alticor who is also one of our directors is offered a corporate opportunity, such opportunity shall not belong to us. In addition, we agreed that such director will have satisfied his duties to us and not be liable to us or to you in connection with such opportunity.

The terms of this agreement will terminate on the date that no person who is a director, officer or employee of ours is also a director, officer, or employee of Alticor or an affiliate.

We do not expect to pay dividends for the foreseeable future and you should not expect to receive any funds without selling your shares of common stock, which you may only be able to do at a loss.

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. Therefore, you should not expect to receive any funds without selling your shares, which you may only be able to do at a loss.

Item 2. *Properties*

Our offices and laboratories are located at 135 Beaver Street. In February 2004, we entered into a new lease expanding our space to approximately 19,000 square feet and extended the term of the lease through March 2009.

Item 3. *Legal Proceedings*

We are not currently a party to any material legal proceedings and management is not aware of any contemplated proceedings by any governmental authority against us.

Item 4. *Submission of Matters to a Vote of Security Holders*

No matters were submitted to a vote of security holders during the fourth quarter of the year ended December 31, 2004.

PART II

Item 5. ***Market for Registrant s Common Equity and Related Stockholder Matters and Issuer Purchases of Equity Securities***

Market Information

Our common stock began trading on The Nasdaq SmallCap Market on November 26, 1997 under the symbol MSSI and on the Boston Stock Exchange under the symbol MSI. In August 1999, our common stock symbol changed to ILGN on the Nasdaq SmallCap Market and ILG on the Boston Stock Exchange. On December 10, 2002, our common stock was delisted from the Nasdaq SmallCap Market and began trading on the OTC Bulletin Board under the symbol ILGN.OB . The common stock currently trades on the OTC Bulletin Board and the Boston Stock Exchange. Prior to November 1997, there was no established trading market for the common stock. The following table sets forth, for the periods indicated, the high and low sales prices for the common stock, as reported by the OTC Bulletin Board.

	High	Low
2004:		
First Quarter	$ 5.00	$ 3.75
Second Quarter	$ 5.01	$ 4.05
Third Quarter	$ 4.93	$ 2.76
Fourth Quarter	$ 4.59	$ 2.70

	High	Low
2003:		
First Quarter	$ 1.73	$ 0.48
Second Quarter	$ 3.34	$ 1.70
Third Quarter	$ 3.27	$ 2.10
Fourth Quarter	$ 5.13	$ 3.10

Stockholders

As of April 19, 2005, there were approximately 119 stockholders of record and according to our estimates, 2,100 beneficial owners of our common stock.

Dividends

We have not declared any dividends to date and do not plan to declare any dividends on our common stock in the foreseeable future.

Sale of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

Item 6. *Selected Financial Data*

The following table sets forth our financial data as of and for each of the five years ended December 31, 2004. The selected financial data as of and for each of the five years ended December 31, 2004 has been derived from our financial statements. Our financial statements and the related reports as of December 31, 2004 and 2003 and for the years ended December 31, 2004, 2003 and 2002 are included elsewhere in this Annual Report on Form 10-K. The information below should be read in conjunction with the financial statements and Management s Discussion and Analysis of Financial Condition and Results of Operations included in Item 7.

	Year Ended December 31,				
	2004	**2003(1)**	**2002**	**2001**	**2000**
Statement of Operations Data:					
Revenue	$ 34,671	$ 54,105	$ 289,908	$ 202,942	$ 256,387
Cost of revenue	351	20,658	484	48,674	183,833
Gross profit	34,320	33,447	289,424	154,268	72,554
Operating Expenses:					
Research and development	4,078,316	3,457,861	3,082,484	2,686,621	2,167,409
Selling, general and administrative	2,658,037	2,443,219	2,333,314	2,244,274	3,093,379
Total operating expenses	6,736,353	5,901,080	5,415,798	4,930,895	5,260,788
Loss from operations	(6,702,033)	(5,867,633)	(5,126,374)	(4,776,627)	(5,188,234)
Other income (expense):					
Interest income	58,115	48,535	26,784	263,435	280,298
Interest expense	(140,410)	(144,804)	(71,894)	(9,818)	(22,514)
Amortization of note discount	(461,874)	(595,014)	(150,082)		
Other income (expense)		2	15,447	304	(48,377)
Net loss	$ (7,246,202)	$ (6,558,914)	$ (5,306,119)	$ (4,522,706)	$ (4,978,827)
Accretion of convertible preferred stock discount		(8,094,727)			
Net loss attributable to common stockholders	$ (7,246,202)	$ (14,653,641)	$ (5,306,119)	$ (4,522,706)	$ (4,978,827)
Basic and diluted net loss per common share	$ (0.31)	$ (0.63)	$ (0.24)	$ (0.21)	$ (0.27)
Weighted average common shares outstanding	23,482,642	23,193,195	21,713,432	21,049,437	18,315,320

	As of December 31,				
	2004	**2003(1)**	**2002**	**2001**	**2000**
Selected Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 4,528,425	$ 4,759,453	$ 733,848	$ 3,922,736	$ 5,390,601
Working capital	$ 3,276,072	$ 4,216,466	$ (279,029)	$ 3,270,667	$ 4,457,828
Total assets	$ 6,185,501	$ 5,340,604	$ 1,249,779	$ 4,393,126	$ 5,694,511
Long term debt and capital lease obligations, less current portion	$ 1,212,691	$ 765,129	$ 1,518,322	$ 11,091	$ 46,989
Stockholders equity (deficit)	$ 3,527,507	$ 3,912,371	$ (1,384,560)	$ 3,550,548	$ 4,493,805

(1) As restated, see Note 2 to the consolidated financial statements included in Item 8.

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

General Overview

We are in the business of personalized health. We are developing tests and products that can help individuals improve and maintain their health through preventive measures. We plan to develop the following types of products: 1) genetic risk assessment products, 2) preventive nutritional products (foods and nutritionals developed to prevent disease onset), and 3) personalized therapeutics that treat an individual with existing disease and use genetic information to expedite drug development and to target the drug use to individuals most likely to respond favorably. We will use our intellectual property and expertise to develop products or acquire additional intellectual property that can be leveraged, through collaboration with partners, to address unmet market needs. We are currently developing a number of genetic risk assessment tests to be distributed by Alticor in their multi-level marketing channel, the first of which the market launch is expected to occur in the first quarter of 2006.

Our current commercial strategy is to partner with companies that have sales and marketing capabilities and products or services that complement our own products. We currently have no plans to develop our own sales force; we plan to rely on our strategic partners to promote and distribute our products. The first of these strategic partnerships is the partnership we have with Alticor and its affiliates. The details of this affiliation are described within the section titled Strategic Alliance and Collaborations beginning on page 14.

Our revenue model consists of : 1) charging a fee for processing a genetic risk assessment test and generating a personalized risk assessment report; and 2) receiving a royalty from sales of products developed with a partner, or profit sharing from product sales. Furthermore, we plan to collaborate with other companies in research and development. In these collaborations, we expect to receive a certain amount of research funding from the partner covering labor, material, overhead and a small amount of profit. Our first such collaboration is with Alticor for the development of personalized nutritional and skincare products.

In March 2003, we entered into a broad strategic alliance with several affiliates of Alticor to develop and market personalized nutritional and skin care products. The alliance utilizes our intellectual property and expertise in genomics to develop personalized consumer products. Alticor has a long history of manufacturing and distributing high quality nutritional supplements and skin care products to a worldwide market through the multi-level marketing channel.

We are devoting most of our resources to the support of the strategic collaboration with Alticor which includes the development of our genetic risk assessment tests to be sold in combination with Alticor s products. A portion of our resources is also devoted to the development of a new product for the periodontal market. Our funding has consisted primarily of research payments from Alticor and trivial royalties from PST®. Additionally, we expect to continue incurring losses as we continue to develop our new tests and products.

The alliance has included an equity investment, multi-year research and development agreements, a licensing agreement with royalties on marketed products, the deferment of outstanding loan repayment and the refinancing of bridge financing obligations. The financial elements of this alliance are described in greater detail in the section titled Liquidity and Capital Resources beginning on page 32.

Sufficiency of working capital remains our greatest challenge. The amount of cash generated from research collaborations with Alticor is not adequate to fund our operations, thus, resulting in an annual cash burn. The situation is, however, improving as discussed in the Liquidity and Capital Resources section beginning on page 32. Our current cash resources, together with additional research agreements, anticipated revenue from product launches, and other arrangements are adequate to fund operations through mid-2006.

Critical Accounting Policies

Our significant accounting policies are described in Note 3 to the consolidated financial statements included in this report. We believe our most critical accounting policies are in the areas of our strategic alliance with Alticor, stock-based compensation and income taxes. We do not include the value of stock options issued to employees or our Directors as an expense. Had we expensed our stock-based compensation using the Black-Scholes option-pricing model described below, our losses would have increased $875,000 in 2004 (or $0.04 per common share), $1,145,000 in 2003 (or $0.05 per common share) and $752,000 in 2002 (or $0.04 per common share).

Strategic alliance with Alticor:

We account for our strategic alliance with Alticor in accordance with Emerging Issues Task Force (EITF) No. 01-1, *Accounting for Convertible Instruments Granted or Issued to a Nonemployee for Goods or Services or a Combination of Goods or Services and Cash* (EITF No. 01-1). Under EITF No. 01-1, the proceeds received from Alticor in connection with the March 5, 2003 transaction must first be allocated to the fair value of the convertible instruments issued. As of March 5, 2003, the fair value of the convertible instruments issued was $23.7 million; therefore any proceeds received from Alticor in connection with the March 5, 2003 transaction, up to $23.7 million, will be recorded as equity.

Stock-based compensation:

We account for our stock-based compensation plans under Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB No. 25). Under APB No. 25, no stock-based compensation is reflected in net income, as all options granted under the plans had an exercise price equal to the market value of the underlying common stock on the date of grant and the related number of shares granted is fixed at that point in time. The following table illustrates the effect on net loss and loss per common share if we had applied the fair value recognitions provisions of Statement of Financial Standard (SFAS) No. 123, *Accounting for Stock-Based Compensation*, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation-Transition and Disclosure*, issued in December 2002. The stock compensation expense in the below table recognizes the expense over the vesting period of the stock options.

	Years Ended December 31,		
	2004	**2003 (As Restated)**	**2002**
Net loss attributable to common stockholders:			
As reported	$ (7,246,202)	$ (14,653,641)	$ (5,306,119)
Stock-based employee compensation expense	874,847	1,145,079	752,134
Pro forma	$ (8,121,049)	$ (15,798,720)	$ (6,058,253)
Basic and diluted net loss per common share:			
As reported	$ (0.31)	$ (0.63)	$ (0.24)
Pro forma	$ (0.35)	$ (0.68)	$ (0.28)

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model with the weighted-average assumptions listed in the table below for a stock that does not pay dividends.

	Years Ended December 31,					
	2004		2003		2002	
Risk-free interest rate	4.00	%	4.00	%	4.00	%
Expected life	7 years		7 years		7 years	
Expected volatility	80	%	80	%	100	%

The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options. Our employee stock options have characteristics significantly different from those of traded options such as extremely limited transferability and, in most cases, vesting restrictions. In addition, the assumptions used in option valuation models (see above) are based upon historical averages that may not predict future results, particularly the expected stock price volatility of the underlying stock. Because changes in these input assumptions can materially affect the fair value estimate, in management s opinion, existing valuation models do not provide a reliable, single measure of the fair value of our employee stock options.

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123 (Revised 2004) Share-Based Payment (SFAS No. 123R). SFAS No. 123R addresses all forms of share-based payment (SBP) awards, including shares issued under employee stock purchase plans, stock options, restricted stock and stock appreciation rights. SFAS No. 123R will require us to expense SBP awards with compensation cost for SBP transactions measured at fair value. The FASB originally stated a preference for a lattice model because it believed that a lattice model more fully captures the unique characteristics of employee stock options in the estimate of fair value, as compared to the Black-Scholes model which we currently use for our footnote disclosure. The FASB decided to remove its explicit preference for a lattice model and not require a single valuation methodology. SFAS No. 123R requires us to adopt the new accounting provisions beginning in 2006. We currently account for our stock-based compensation plans in accordance with APB No 25. Therefore, the adoption of this statement is likely to have a material effect on our consolidated financial results.

Income taxes:

The preparation of our consolidated financial statements requires us to estimate our income taxes in each of the jurisdictions in which we operate, including those outside the United States, which may be subject to certain risks that ordinarily would not be expected in the United States. The income tax accounting process involves estimating our actual current exposure together with assessing temporary differences resulting from differing treatment of items, such as deferred revenue, for tax and accounting purposes. These differences result in the recognition of deferred tax assets and liabilities. We must then record a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized.

Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against deferred tax assets. We have recorded a full valuation allowance against our deferred tax assets of $15.2 million as of December 31, 2004, due to uncertainties related to our ability to utilize these assets. The valuation allowance is based on our estimates of taxable income by jurisdiction in which we operate and the period over which our deferred tax assets will be recoverable. In the event that actual results differ from these estimates or we adjust these estimates in future periods we may need to adjust our valuation allowance which could materially impact our financial position and results of operations.

Results of Operations

Comparison of Year Ended December 31, 2004 to Year Ended December 31, 2003

Revenue for the year ended December 31, 2004 was $35,000 compared to $54,000 for the year ended December 31, 2003, a decrease of $19,000 or 36%. Royalties on PST® sales were $18,000 (1,719 tests) and $21,000 (1,803 tests) for 2004 and 2003, respectively. Both years include licensing revenue of $16,000. Revenue of $17,000 associated with a one-time funded study was included for the year ended December 31, 2003.

Research and development expenses were $4.1 million for the year ended December 31, 2004 compared to $3.5 million for the year ended December 31, 2003, an increase of $620,000 or 18%.

Funded research and development expenses were $2.7 million for the year ended December 31, 2004 compared to $1.4 million for the year ended December 31, 2003, an increase of $1.3 million or 89%. In March 2003, we entered into a research agreement with Alticor to develop genetic tests and software to assess personalized risk and develop and use screening technologies to validate the effectiveness of the nutrigenomic consumables Alticor is developing. Additionally, we will play a key role in enhancing and maintaining scientific credibility in academic and medical communities. After our initial focus in developing products for the United States and Canada, we expect that we will expand our focus to include developing nutrigenomic products for sale overseas and developing products in the United States and overseas in other area of wellness and skin care. Research and development expenses associated with this agreement were $1.9 million and $1.4 million for the years ended December 31, 2004 and 2003, respectively. In June 2004, we entered into another research agreement with Alticor to conduct research into the development of a test to identify individuals with specific genetic variations that affect how people gain and maintain weight. Research and development expenses associated with this agreement were $673,000 for the year ended December 31, 2004. In addition, during 2004 and 2003, we conducted genotyping tests for Alticor for research purposes. The costs associated with these tests were $90,000 for the year ended December 31, 2004 and $52,000 for the same period in 2003.

Unfunded research and development expenses were $1.4 million for the year ended December 31, 2004 compared to $2.0 million for the year ended December 31, 2003, a decrease of $645,000 or 32%. The decrease in unfunded research and development expenses reflects a re-allocation of internal resources from internally funded projects to the funded research projects. This decrease was partially offset by expenses associated with developing our clinical genetic testing laboratory.

Selling, general and administrative expenses were $2.7 million for the year ended December 31, 2004 compared to $2.4 million for the prior year, an increase of $215,000 or 9%. This increase is primarily the result of adding the appropriate infrastructure in our efforts to develop other markets for our products.

Interest income was $58,000 for the year ended December 31, 2004 compared to $49,000 for 2003. Interest expense of $140,000 was incurred during the year ended December 31, 2004, compared to $145,000 in 2003. The decrease is primarily due to the lower interest rate as a result of the refinancing transaction with Alticor completed in July 2003 offset by a slight increase in the Bank s prime rate over the two periods.

We recorded amortization of note discount of $462,000 for the year ended December 31, 2004 in comparison to $595,000 in 2003. Of the $462,000 expense in 2004, $311,000 is due to the amortization of the $1.5 million of discount resulting from the beneficial conversion feature of the convertible debt issued in March 2003 and $151,000 is due to the amortization of the $732,000 of discount associated with the below market stated interest rate on the same debt. Of the $545,000 expense in 2003, $259,000 is due to the amortization of the $1.5 million of discount resulting from the beneficial conversion feature of the convertible debt issued in March 2003, $126,000 is due to the amortization of the $732,000 of discount associated with the below market stated interest rate on the same debt and $210,000 is due to the

amortization of the value of the warrants issued in connection with certain promissory notes in August 2002, which were retired in July 2003.

Comparison of Year Ended December 31, 2003 to Year Ended December 31, 2002

Revenue for the year ended December 31, 2003 was $54,000 compared to $290,000 for the year ended December 31, 2002, a decrease of $236,000 or 81%. Royalties on PST® sales were $21,000 (1,803 tests) and $27,000 (1,704 tests) for 2003 and 2002, respectively. Licensing revenue was $16,000 and $13,000 for 2003 and 2002, respectively. Revenue of $17,000 associated with a one-time funded study was included for the year ended December 31, 2003. Revenue for the year ended December 31, 2002, included a one-time fee of $250,000 from Pyxis Innovations, Inc.

Research and development expenses were $3.5 million for the year ended December 31, 2003 compared to $3.1 million for the year ended December 31, 2002, an increase of $370,000 or 12%.

Funded research and development expenses were $1.4 million for the year ended December 31, 2003. There were no funded research and development expenses in 2002. In March 2003, we entered into a research agreement with Alticor to develop genetic tests and software to assess personalized risk and develop and use screening technologies to validate the effectiveness of the nutrigenomic consumables Alticor is developing. Additionally, we will play a key role in enhancing and maintaining scientific credibility in academic and medical communities. After our initial focus in developing products for the United States and Canada, we expect that we will expand our focus to include developing nutrigenomic products for sale overseas and developing products in the United States and overseas in other area of wellness and skin care. Research and development expenses associated with this agreement were $1.4 million for the year ended December 31, 2003. In addition, during 2003, we conducted genotyping tests for Alticor for research purposes. The costs associated with these tests were $52,000.

Unfunded research and development expenses were $2.0 million for the year ended December 31, 2003 compared to $3.1 million for the year ended December 31, 2002, a decrease of $1.1 million or 34%. The decrease in unfunded research and development expenses reflects a re-allocation of internal resources from internally funded projects to the funded research projects.

Selling, general and administrative expenses were $2.4 million for the year ended December 31, 2003 compared to $2.3 million for the year ended December 31, 2002, an increase of $110,000 or 5%.

Interest income during 2003 was $49,000 compared to $27,000 during 2002, an increase of $22,000 or 81%. This increase was due to the higher cash balances we held during 2003, resulting from the sale of equity to Alticor. Interest expense of $145,000 was incurred during the year ended December 31, 2003, compared to $72,000 during 2002. This increase was due to interest expense related to our long-term debt to Alticor and the term promissory notes sold in August 2002, which were refinanced by Alticor in 2003.

We recorded amortization of note discount of $595,000 for the year ended December 31, 2003 in comparison to $150,000 in 2002. Of the $595,000 expense in 2003, $259,000 is due to the amortization of the $1.5 million of discount resulting from the beneficial conversion feature of the convertible debt issued in March 2003, $126,000 is due to the amortization of the $732,000 of discount associated with the below market stated interest rate on the same debt and $210,000 is due to the amortization of the value of the warrants issued in connection with certain promissory notes in August 2002 which were retired in July 2003. The $150,000 expense in 2002 was solely due to the amortization of the value of the warrants.

Liquidity and Capital Resources

Cash is one of the key financial performance indicators for us. As of December 31, 2004, we had cash and cash equivalents of $4.5 million. Net cash used in operating activities was $5.9 million during the years ended December 31, 2004 and 2003. Cash was used primarily to fund operations.

Investing activities used cash of $1.1 million in 2004 and $123,000 in 2003. During 2004 cash was used to purchase fixed assets and to fund the development of intellectual property. Specifically, we completed the construction of our clinical genetic testing laboratory to process the tests from our product launches.

Financing activities provided cash of $6.8 million for the year ended December 31, 2004 compared to $10.1 million for the year ended December 31, 2003. During 2004, we received $6.2 million from our strategic alliance with Alticor and $707,000 from the exercise of stock options and stock purchases through the employee stock purchase plan. During 2003, we received $9.4 million from our strategic alliance with Alticor. We also received $1.1 million in proceeds from the issuance of notes payable, $595,000 of which was used to repay an outstanding bridge loan including accrued interest.

We currently do not have any commitments for any material capital expenditures. Our obligations at December 31, 2004 for capital lease payments totaled $18,000. These capital lease obligations mature through March 2006 at various interest rates.

A summary of our contractual obligations as of December 31, 2004 is included in the table below:

	Payments Due By Period				
Contractual Obligations	**Total**	**Less than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 Years**
Long-Term Debt Obligations	$ 2,595,336	$	$	$ 2,595,336	$
Capital Lease Obligations	18,076	15,059	3,017		
Operating Lease Obligations	1,870,131	443,436	880,440	546,255	
TOTAL	$ 4,483,543	$ 458,495	$ 883,457	$ 3,141,591	$

In March 2003, we entered into a broad strategic alliance with several affiliates of the Alticor, Inc. family of companies to develop and market personalized nutritional and skin care products. As part of the strategic alliance, we entered into a research agreement (Research Agreement I) with Alticor, governing the terms of developing and validating nutrigenomic and dermagenomic tests and products. Alticor provided us with $5.0 million during the twenty-four months ending March 2005, to conduct certain research projects.

In June 2004, we entered into a research agreement (Research Agreement II) with Alticor, valued at $2.2 million, as amended, to conduct research into the development of a test to identify individuals with specific genetic variations that affect how people gain and maintain weight. During the first phase of the agreement, we received $1.4 million in research funding over a period of six months beginning on July 1, 2004. If Alticor determines, in its sole discretion, that it has a reasonable likelihood of commercializing weight management nutritional products, we will be eligible to receive, during the second phase of the agreement, an additional $820,000 in funding over a six-month period.

In March 2005, we entered into an agreement with Alticor to expand the research being performed under Research Agreement I (Research Agreement III) to provide additional funding of $2.7 million over the two years beginning April 1, 2005. Also in March 2005, we entered into an additional research agreement (Research Agreement IV) with Alticor for exploratory research valued at $2.3 million over a two-year period commencing April 1, 2005. These research agreements are expected to provide us with a total of $5.0 million during the two-year period ending March 2007.

In addition, in April 2005, Alticor paid us, upon achieving a certain milestone, $2.0 million as an advance payment for genetic risk assessment tests to be processed under the terms of the Distribution Agreement. Further, Alticor agreed to extend the drawdown period of the $1.5 million working capital credit line through 2007.

We believe our current cash resources, together with additional research agreements, anticipated revenue from product launches, and other arrangements are adequate to fund operations through mid-2006.

Item 7A. ***Quantitative and Qualitative Disclosure about Market Risk***

As of December 31, 2004, the only financial instruments we carried were cash and cash equivalents. We believe the market risk arising from holding these financial instruments is immaterial.

Some of our sales and some of our costs occur outside the United States and are transacted in foreign currencies. Accordingly, we are subject to exposure from adverse movements in foreign currency exchange rates. At this time we do not believe this risk is material and we do not currently use derivative financial instruments to manage foreign currency fluctuation risk. However, if foreign sales increase and the risk of foreign currency exchange rate fluctuation increases, we may in the future consider utilizing derivative instruments to mitigate these risks.

Item 8. ***Financial Statements and Supplementary Data***

The Consolidated Financial Statements of the Company, together with the Independent Auditors Reports, see the Index to Financial Statements on page F-1 of this report.

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

None.

Item 9A. ***Controls and Procedures***

(a) *Evaluation of Disclosure Controls and Procedures.* Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Annual Report on Form 10-K, have concluded that, based on such evaluation, our disclosure controls and procedures were adequate and effective to ensure that material information relating to us, including our consolidated subsidiaries, was made known to them by others within those entities, particularly during the period in which this Annual Report on Form 10-K was being prepared.

In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

(b) *Changes in Internal Controls.* There were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control that occurred during our last fiscal quarter, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management s Report of Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended, as a process designed by, or under the supervision of, the company s principal executive and principal financial officers and effected by the company s board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

The company s internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As of December 31, 2003, the company was not an accelerated filer (as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended) and, therefore, did not expect to be required to comply with Section 404 of the Sarbanes-Oxley Act of 2002 until the fiscal year ending December 31, 2005. However, because the company s public common float exceeded $75 million on June 30, 2004, it became obligated to comply with Section 404 for the fiscal year ended December 31, 2004.

Management endeavored to assess the effectiveness of the company s internal control over financial reporting as of December 31, 2004. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its *Internal Control-Integrated Framework*. Management did not complete its work as of December 31, 2004. Management continued its efforts and in March 2005, retained consultants to assist in its assessment of internal control over financial reporting. Although substantial progress has been made as of March 31, 2005, management was unable to complete its assessment as of that date. Management recognizes the need to address compliance with Section 404, and expects to do so during 2005. As a result, the company s independent registered public accounting firm, Grant Thornton LLP, has issued a disclaimer opinion included in Item 8 of this Form 10-K.

The disclaimer opinion issued by the independent auditors identifies a material weakness in the company s internal control over financial reporting. A material weakness is a significant deficiency, or combination of significant deficiencies, that results in more than a remote likelihood that a material misstatement of the financial statements will not be prevented or detected.

Based on management s work to date, it acknowledges the above mentioned weakness in the design control related to lack of segregation of duties. This is due to the small number of employees within the financial and administrative functions of the company. However, management believes that its extensive oversight mitigates the risks associated with such lack of segregation. Management will continue to evaluate the employees involved and the control procedures in place to determine whether the potential benefits of adding employees to clearly segregate duties justifies the expense associated with such increases.

Item 9B. ***Other Information***

Not applicable.

PART III

Item 10. ***Directors and Executive Officers of the Registrant***

Information required under this Item will be contained in our Proxy Statement for the 2005 Annual Meeting, which is incorporated herein by reference under the sections entitled Management, Compliance with 16(a) of the Securities Exchange Act of 1934, and Code of Conduct and Ethics .

Item 11. ***Executive Compensation***

Information required under this Item will be contained in our Proxy Statement for the 2005 Annual Meeting, which is incorporated herein by reference under the section entitled Executive Compensation .

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

Information required under this Item will be contained in our Proxy Statement for the 2005 Annual Meeting, which is incorporated herein by reference under sections entitled Security Ownership of Certain Beneficial Owners and Management and Equity Compensation Plan Information .

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

Information required under this Item will be contained in our Proxy Statement for the 2005 Annual Meeting, which is incorporated herein by reference under the section entitled Certain Relationships and Related Transactions .

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

Information required under this Item will be contained in our Proxy Statement for the 2005 Annual Meeting, which is incorporated herein by reference under the section entitled Ratification of Appointment of Independent Public Accountants .

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

(a) Documents Filed as Part of Report

1. Financial Statements:

The Consolidated Financial Statements of the Company and the related report of the Company s independent registered public accounting firm thereon have been filed under Item 8 hereof.

2. Financial Statement Schedules:

The information required by this item is not applicable.

3. Exhibits:

The exhibits listed below are filed as part of or incorporated by reference in this report. Where such filing is incorporated by reference to a previously filed document, such document is identified in parentheses.

Exhibit No.	**Identification of Exhibit**
3.1	Articles of Incorporation of the Company, as amended (incorporated herein by reference to Exhibit 3.1 of the Company s Quarterly Report on Form 10-Q filed August 14, 2000)
3.2	Bylaws of the Company, as adopted on June 5, 2000 (incorporated herein by reference to Exhibit 3.2 of the Company s Quarterly Report on Form 10-Q filed August 14, 2000)
3.3	Certificate of Designations, Preferences and Rights of Series A Preferred Stock (incorporated herein by reference to Exhibit 3.1 of the Company s Current Report filed on Form 8-K on March 5, 2003)
3.4	Certificate of Amendment to Certificate of Incorporation, as filed with the Delaware Secretary of State on August 5, 2003 (incorporated herein by reference to Exhibit 3.1 of the Company s Quarterly Report on Form 10-Q filed on November 12, 2003)
4.1	Form of Stock Certificate representing Common Stock, $0.001 par value, of the Company (incorporated herein by reference to Exhibit 4.1 of the Company s Quarterly Report on Form 10-Q filed August 14, 2000)
10.1@	Interleukin Genetics, Inc. 1996 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.17 of the Company s Registration Statement No. 333-37441 on Form SB-2 filed October 8, 1997)
10.2@	Amendment to the Interleukin Genetics, Inc. 1996 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.18 of the Company s Registration Statement No. 333 37441 on Form SB-2 filed October 8, 1997)
10.3@	Form of Stock Option Agreement (incorporated herein by reference to Exhibit 10.19 of the Company s Registration Statement No. 333-37441 on Form SB-2 filed October 8, 1997)
10.4@	Stock Option Exercise Agreement (incorporated herein by reference to Exhibit 10.20 of the Company s Registration Statement No. 333-37441 on Form SB-2 filed October 8, 1997)
10.5@	Non-Qualified Stock Option Agreement dated June 1, 1999, between the Company and Philip R. Reilly (incorporated herein by reference to Exhibit 10.2 of the Company s Quarterly Report on Form 10-QSB filed August 16, 1999)
10.6+	Research and Technology Transfer Agreement dated effective July 1, 1999, between the Company and the University of Sheffield (incorporated herein by reference to Exhibit 10.1 of the Company s Quarterly Report on Form 10-QSB filed November 15, 1999)

10.7+	Research Support Agreement dated effective July 1, 1999, between the Company and the University of Sheffield (incorporated herein by reference to Exhibit 10.2 of the Company s Quarterly Report on Form 10-QSB filed November 15, 1999)
10.8+	Consulting Agreement dated effective July 1, 1999, between the Company and Gordon Duff, PhD, FRCP (incorporated herein by reference to Exhibit 10.3 of the Company s Quarterly Report on Form 10-QSB filed November 15, 1999)
10.9@	Non-Qualified Stock Option Agreement dated November 30, 1999 between the Company and Philip R. Reilly (incorporated herein by reference to Exhibit 4.5 of the Company s Registration Statement No. 333-32538 on Form S-8 filed March 15, 2000)
10.10@	Employment Agreement dated December 1, 1999 between the Company and Kenneth S. Kornman. (incorporated herein by reference to Exhibit 10.25 of the Company s Annual Report on Form 10-K filed April 15, 2000)
10.11@	Employment Agreement dated April 1, 2000 between the Company and Philip R. Reilly. (incorporated herein by reference to Exhibit 10.26 of the Company s Annual Report on Form 10-K filed on April 15, 2000)
10.12@	2000 Employee Stock Compensation Plan for the Company (incorporated herein by reference to Exhibit 10.3 of the Company s Quarterly Report on Form 10-Q filed August 14, 2000)
10.13@	Form of Nonqualified Stock Option Grant (incorporated herein by reference to Exhibit 10.4 of the Company s Quarterly Report on Form 10-Q filed August 14, 2000)
10.14@	Form of Incentive Stock Option Grant (incorporated herein by reference to Exhibit 10.5 of the Company s Quarterly Report on Form 10-Q filed August 14, 2000)
10.15@	Employment Agreement dated June 18, 2000 between the Company and Fenel Eloi (incorporated herein by reference to Exhibit 10.6 of the Company s Quarterly Report on Form 10-Q filed August 14, 2000)
10.16	Note Purchase Agreement between the Company and Pyxis Innovations, Inc. dated October 22, 2002 (incorporated herein by reference to Exhibit 10.1 of the Company s Current Report on Form 8-K filed on October 28, 2002)
10.17	Security Agreement between the Company and Pyxis Innovations, Inc dated October 22, 2002 (incorporated herein by reference to Exhibit 10.2 of the Company s Current Report on Form 8-K filed on October 28, 2002)
10.18	Form of Common Stock Purchase Warrant (incorporated herein by reference to Exhibit 10.3 of the Company s Quarterly Report on Form 10-Q filed on November 7, 2002)
10.19	Registration Rights Agreement dated August 9, 2002 (incorporated herein by reference to Exhibit 10.4 of the Company s Quarterly Report on Form 10-Q filed on November 7, 2002)
10.20	Stock Purchase Agreement between the Company and Pyxis Innovations, Inc dated March 5, 2003 (incorporated herein by reference to Exhibit 10.1 of the Company s Current Report on Form 8-K filed on March 5, 2003)
10.21	Amendment No. 3 to Note Purchase Agreement between the Company and Pyxis Innovations, Inc, dated March 5, 2003 (incorporated herein by reference to Exhibit 10.2 of the Company s Current Report on Form 8-K filed on March 5, 2003)
10.22	Amendment No. 2 to the Security Agreement between the Company and Pyxis Innovations, Inc., dated March 5, 2003 (incorporated herein by reference to Exhibit 10.3 of the Company s Current Report on Form 8-K filed on March 5, 2003)

10.23	Form of Amended and Restated Promissory Note (incorporated herein by reference to Exhibit 10.4 of the Company s Current Report on Form 8-K filed on March 5, 2003)
10.24	Amendment No. 2 to Note Purchase Agreement between the Company and Pyxis Innovations, Inc. (incorporated herein by reference to Exhibit 10.5 of the Company s Current Report on Form 8-K filed on March 5, 2003)
10.25+	Research Agreement between the Company and Access Business Group dated March 5, 2003 (incorporated herein by reference to Exhibit 10.6 of the Company s Current Report on Form 8-K filed on March 5, 2003)
10.26+	Exclusive License Agreement between the Company and Access Business Group dated March 5, 2003 (incorporated herein by reference to Exhibit 10.7 of the Company s Current Report on Form 8-K filed on March 5, 2003)
10.27	Registration Rights Agreement between the Company and Pyxis Innovations, Inc. dated March 5, 2003 (incorporated herein by reference to Exhibit 10.8 of the Company s Current Report on Form 8-K filed on March 5, 2003)
10.28@	Amendment No. 1 to the Employment Agreement with Philip R. Reilly (incorporated herein by reference to Exhibit 10.9 of the Company s Current Report on Form 8-K filed on March 5, 2003)
10.29@	Amendment to the Employment Agreement with Fenel Eloi (incorporated herein by reference to Exhibit 10.10 of the Company s Current Report on Form 8-K filed on March 5, 2003)
10.30@	Amendment to the Employment Agreement with Kenneth Kornman (incorporated herein by reference to Exhibit 10.11 of the Company s Current Report on Form 8-K filed on March 5, 2003)
10.31@	Form of Director s Indemnity Agreement dated March 5, 2003 (incorporated herein by reference to Exhibit 10.13 of the Company s Current Report on Form 8-K filed on March 5, 2003)
10.32@	Amendment 2 to the Employment Agreement with Fenel M. Eloi, dated December 11, 2003 (incorporated herein by reference to Exhibit 10.43 of the Company s Annual Report on Form 10-K filed on March 29, 2004)
10.33	Commercial Lease Agreement between the Company and Clematis LLC dated February 13, 2004 (incorporated herein by reference to Exhibit 10.44 of the Company s Annual Report on Form 10-K filed on March 29, 2004)
10.34+	Distribution Agreement with the Company and Access Business Group International LLC, dated February 26, 2004 (incorporated herein by reference to Exhibit 10.45 of the Company s Annual Report on Form 10-K filed on March 29, 2004)
10.35+	Research Agreement by and between the Company and Access Business Group LLC dated June 17, 2004 (incorporated by reference to Exhibit 10.1 of the Company s Quarterly Report on Form 10-Q filed on August 10, 2004)
10.36	Interleukin Genetics, Inc. 2004 Employee, Director and Consultant Stock Plan (incorporated by reference to Exhibit 99.1 of the Company s Registration Statement No. 333-118551 on Form S-8 filed on August 25, 2004)
10.37+	Amendment #1 to Research Agreement by and between the Company and Access Business Group LLC dated June 17, 2004 (incorporated by reference to Exhibit 10.1 of the Company s Quarterly Report on Form 10-Q filed on November 3, 2004)

10.38*++	Research Agreement by and between the Company and Access Business Group LLC dated March 5, 2005
10.39*++	Research Agreement by and between the Company and Access Business Group LLC dated March 5, 2005
10.40*	First Amendment to Distribution Agreement with the Company and Access Business Group International LLC, dated February 28, 2005
10.41*	Second Amendment to Stock Purchase Agreement between the Company and Pyxis Innovations, Inc dated February 28, 2005
21.1*	Subsidiaries of the Company
23.1*	Consent of Grant Thornton LLP
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002
32*	Certification pursuant to Section 906 of Sarbanes-Oxley Act of 2002

* Filed herewith.

+ The Securities and Exchange Commission with respect to certain portions of this exhibit has previously granted confidential treatment. Omitted portions have been filed separately with the Securities and Exchange Commission.

++ Confidential treatment requested as to certain portions of the document, which portions have been omitted and filed separately with the Securities and Exchange Commission.

@ Management contract or compensatory plan, contract or arrangement

SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INTERLEUKIN GENETICS, INC.
By: /s/ FENEL M. ELOI
Fenel M. Eloi
Chief Operating Officer, Chief Financial Officer, Secretary and Treasurer

Date: April 25, 2005

In accordance with the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the date indicated.

Signatures	Title	Date Signed
/s/ PHILIP R. REILLY Philip R. Reilly	Chairman of the Board of Directors and Chief Executive Officer (Principal Executive Officer)	April 25, 2005
/s/ FENEL M. ELOI Fenel M. Eloi	Chief Financial Officer, Secretary & Treasurer (Principal Financial and Accounting officer)	April 25, 2005
/s/ GEORGE CALVERT George Calvert	Director	April 25, 2005
/s/ THOMAS R. CURRAN, JR. Thomas R. Curran, Jr.	Director	April 25, 2005
/s/ WILLIAM J. VIVEEN, JR. William J. Viveen, Jr.	Director	April 25, 2005

INTERLEUKIN GENETICS, INC. AND SUBSIDIARY
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Interleukin Genetics, Inc.

We have audited the accompanying consolidated balance sheets of Interleukin Genetics, Inc. (the Company) (a Delaware corporation), as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders equity (deficit) and comprehensive loss, and cash flows for each of the years in the three year period ended December 31, 2004. These consolidated financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Interleukin Genetics, Inc. as of December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the years in the three year period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2, the accompanying fiscal 2003 consolidated financial statements have been restated.

We were also engaged to audit, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company s internal control over financial reporting as of December 31, 2004, based on the criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Since management was unable to complete its assessment on internal control over financial reporting as of December 31, 2004, and therefore we were unable to apply other procedures to satisfy ourselves as to the effectiveness of the Company s internal control over financial reporting, the scope of our work was not sufficient to enable us to express, and we did not express, an opinion either on management s assessment or on the effectiveness of the Company s internal control over financial reporting in our report dated April 22, 2005.

/s/ GRANT THORNTON LLP

Boston, Massachusetts
April 22, 2005

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Interleukin Genetics, Inc.

We were engaged to audit management s assessment included in the accompanying Management Report of Internal Control Over Financial Reporting that Interleukin Genetics, Inc. maintained effective internal control over financial reporting as of December 31, 2004 based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting.

Management did not complete their evaluation of design effectiveness of internal control as of December 31, 2004. Based on the limited procedures we performed we noted what we believe to be a material weakness relating to limited segregation of duties. A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. We have identified the following material weakness that has not been identified as a material weakness in management s assessment: the Company does not maintain an appropriate segregation of duties for the functions of initiating, authorizing, recording, and reconciling transactions. This material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2004 financial statements, and this report does not affect our report dated April 22, 2005 on those financial statements.

A Company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A Company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Since management was unable to complete its assessment on internal control over financial reporting and we were unable to apply other procedures to satisfy ourselves as to the effectiveness of the Company s internal control over financial reporting, the scope of our work was not sufficient to enable us to express, and we do not express, an opinion either on management s assessment or on the effectiveness of the Company s internal control over financial reporting.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Interleukin Genetics, Inc. as of December 31, 2004 and 2003 and the related consolidated statements of operations, stockholders equity (deficit) and comprehensive loss, and cash flows for each of the years in the three year period ended December 31, 2004 and our report dated April 22, 2005 expressed an unqualified opinion.

/s/ GRANT THORNTON LLP

Boston, Massachusetts
April 22, 2005

INTERLEUKIN GENETICS, INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS

	December 31, 2004	2003 (As Restated)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,528,425	$ 4,759,453
Accounts receivable, net of allowance for doubtful accounts of $0 in 2004 and 2003	10,131	